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Clinical Trial Site Technology

2021 State of the Industry Report

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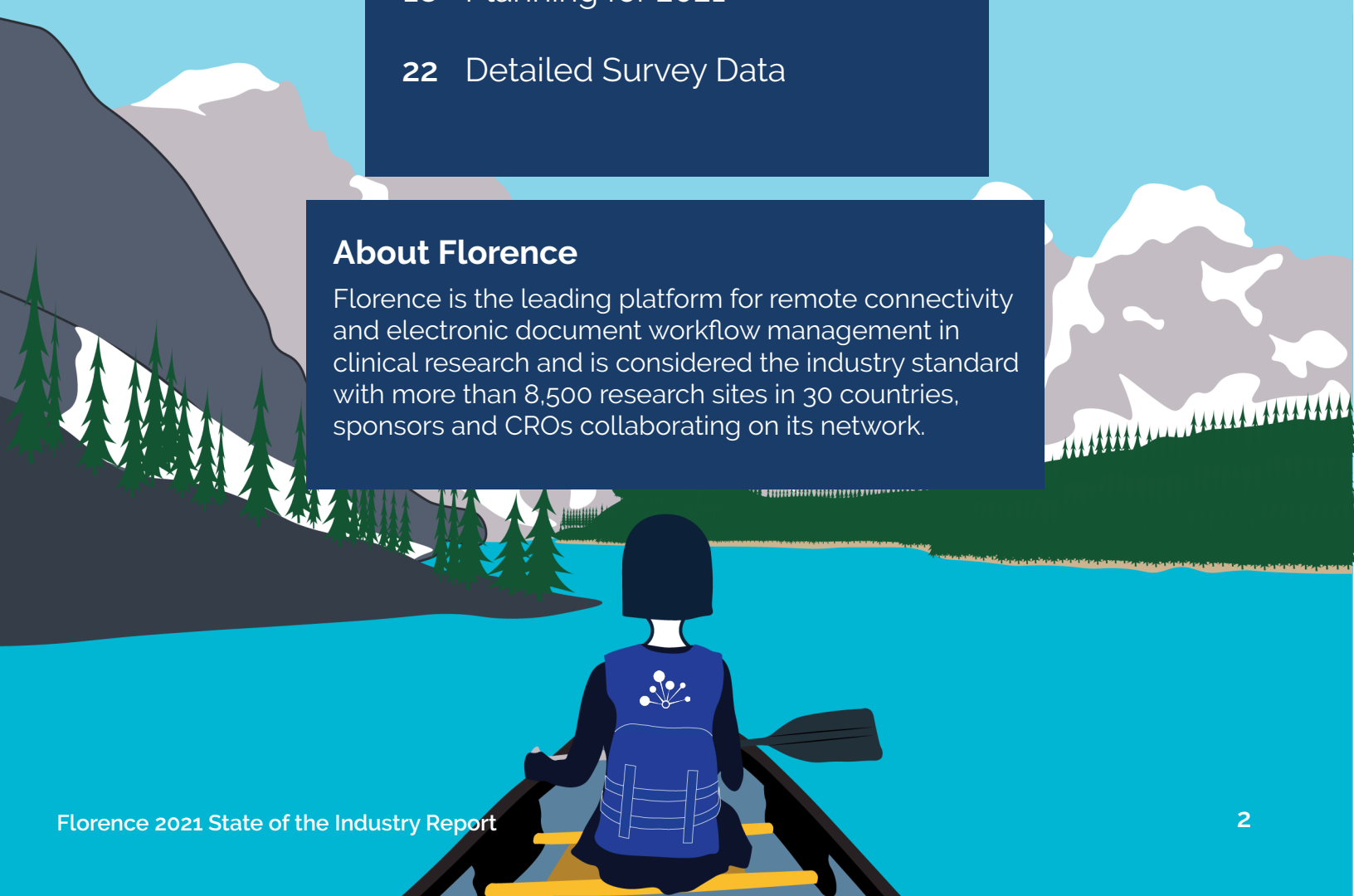

About Florence

Florence is the leading platform for remote connectivity and electronic document workflow management in clinical research and is considered the industry standard with more than 8,500 research sites in 30 countries, sponsors and CROs collaborating on its network.

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Why Read this Report?

COVID-19 disrupted clinical trial operations in 2020 and mandated that leaders mitigate physical site access challenges with technology.

Leaders should do three things as they prepare their strategic plans for 2021:

- Reflect on 2020 and analyze how COVID-19 exposed inefficient clinical operations processes.
- Understand the clinical operations technology trends that are concrete enough to begin investing in 2021.
- Recognize the risks to be identified and mitigated in 2021.
- Prepare yourself for changes coming to the clinical operations landscape over the next three or more years.

This report provides insights from more than 200 respondents to the Florence Industry State of the Industry Survey, from dozens of stakeholders who are members of the Florence Executive Advisory Board, and more than 8,500 study sites and more than 8,000 sponsors using Florence.

To speak with a Florence technology expert, please send us an email at FlorenceTeam@Florencehc.com.

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2020 Key Insight

Remote Collaboration Required

In the 2020 State of the Industry survey conducted in December 2019, remote site access for monitoring, source data review, and collaboration was considered necessary yet was not a top priority.

The December 2019 survey showed that only 18% of respondents claimed remote monitoring accounted for 50% or more of their monitoring visits. 58% predicted remote monitoring would account for 50% or more of monitoring visits by 2022.

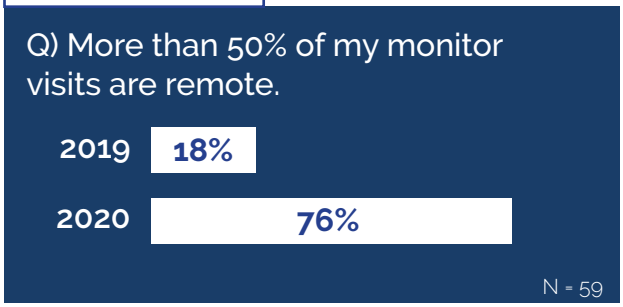
Moreover, less than 6% of respondents considered remote site access their top priority in 2020.

After the disruption of COVID-19, the continuation of clinical operations requires remote monitoring, remote data review, and remote site access.

In this year's survey, 76% of sponsors conduct most or all monitoring remotely, which is 420% more than in 2019. 83% of sponsors and 80% of sites anticipate most monitoring will be remote by 2023.

Data suggest that the rapid growth of remote site access is mainly a result of continuing clinical operations during COVID-19. However, this trend will continue as sites and sponsors begin to realize the value of this investment.

Data Point



The data also indicate that site-owned remote site access solutions have continued to grow.

This trend stems from the need to standardize processes and systems across a study site. Technology such as Florence eHub facilitates the transition to a site-based system by integrating existing workflows remotely.

The vendor's obligation to support the study sites' adoption and success became prominent in 2020. Sponsors rely on proven site-based systems because of the need to deploy technology rapidly to study sites for critical studies. Florence offers sponsors more than 95% acceptance of remote monitoring technology in 2020.

Watch Stories of How Sites and Sponsors Quickly Adjusted to COVID-19 Disruptions.

FlorenceStories.com

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Five Key 2020 Observations

1 COVID-19 Boosted Technology Investment

47% of study sites and 36% of sponsors increased their technology investments in 2020 to minimize disruptions from COVID. Major investments focused on remote connectivity and access technology.

2 Pivot to Remote Connectivity Exposed Broken Clin Op Processes

64% of sponsors report that they exchange documents with sites via Email or a non-purpose built document vault platform, significantly delaying studies and introducing compliance risks.

3 Enabling Remote Work for Clin Ops Teams Now Key Motivator

71% of sponsors and 64% of sites indicate that the ability to work remotely is a critical factor in making technology investments.

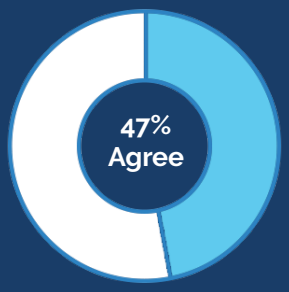
4 Sponsors Bet Big on Remote Access Technology to Address COVID-19 Disruptions

Among others, Pfizer invested heavily in site-based eISF platforms, and 76% of sponsors now conduct monitoring visits primarily remotely as opposed to 18% in 2019.

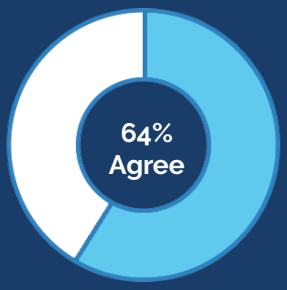
5 Sponsors Eliminate Paper from Clinical Operations Processes

87% of sponsors now report eliminating paper processes internally and at their study sites as a primary reason for technology investments.

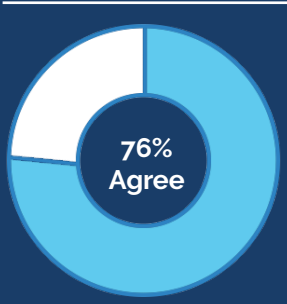
Industry Pulse



We increased technology investment due to COVID.



Email is our primary exchange tool for sensitive data.



Monitor visits are mostly conducted remotely.

**Florence 2021 State of the Industry Survey N=75*

"Florence's platform is helping us to respond to the changing environment due to COVID-19 and further progress COVID-19 research with the capability to perform remote monitoring where approved by regulatory authorities and ethics committees,"

Rob Goodwin
Vice President and Head of the Operations Center of Excellence in Global Product Development
Pfizer

Read the Complete Guide to eISF and Remote Site Access

Download Here

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2021 Key Theme

Vendors Become Partners

To avoid disruptions caused by COVID-19, clinical operations leaders discovered that they needed to quickly fix broken processes to maintain existing protocols and initiate new ones in 2020.

Established vendors started revamping their offerings to fill these gaps, and new firms entered the market.

Clinical operation leaders in 2021 will need to identify which of these technologies will succeed long-term and which will disappear.

To predict which technologies will continue to transform clinical operations, leaders need to shift their focus from solving short-term challenges to focusing on the long-term return on investment and success chances.

Sites and sponsors should turn to their vendors as more than just software providers to succeed in the future, and they should expect them to become their partners in the clinical trial life cycle.

Vendors as partners means many leaders will need to learn a new skill in 2021: Vendor Management.

For long-term success, leaders must ask the following questions when investing in technology in 2021:

1. Does the tech provider have proven site adoption?
2. Does the tech provider guarantee and support site success?
3. Will this technology be scalable across all protocols and all global sites?
4. Will this technology integrate with existing systems and processes?
5. Can this technology serve as the foundation for future platform services?

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Five 2021 Projections

The survey data indicates five key trends will emerge across clinical operations in 2021.

Sponsors and Sites will make Big Investments in Remote Access

83% of sponsors and 80% of sites expect they will perform most or all monitoring remotely in three years. To achieve this goal, sponsors and sites are investing more in eISF platforms at sites in 2021.

Sites will Strengthen Return on Investment Cases for Technology

Budget concerns prevent 68% of sites from investing in technology. Sites will evaluate the return on investment to secure budgets and petition sponsors to reimburse them as technology becomes crucial for operations.

Sites will add Workflows to Purpose-built eISF Foundation

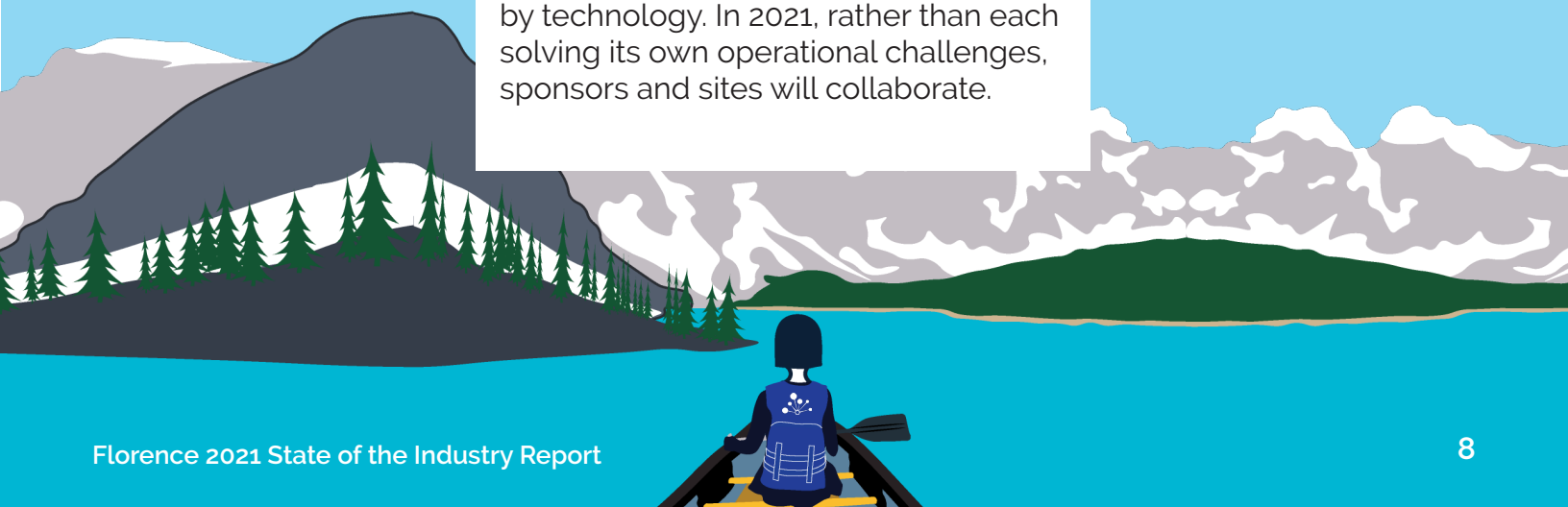
By the end of 2021, 65% of sites will have a purpose-built eISF platform in place and will begin layering advanced workflow solutions such as eConsent (47%), eSource (37%), and Feasibility (32%), on top of this integrated infrastructure.

Sponsors will Expect and Harness Site-based Systems

90% of sites say investing in technology will increase their chances of being selected for a study. As sites build their own infrastructure, sponsors will learn to expect capabilities and use existing infrastructure.

Sponsors and Sites will Collaborate on Solutions

The next three years will see sponsors and sites experiencing similar primary clinical operations processes affected by technology. In 2021, rather than each solving its own operational challenges, sponsors and sites will collaborate.



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Minimizing 2021 Risk Exposure

1 Sites Reject Hastily Deployed Remote Access Technology

30% of sponsors cite "long-term site adoption" as a primary concern with technology implementation. In 2021, the sites that agreed to sponsor mandated remote access will evaluate it as part of their long-term technology strategy.

To ensure long-term adoption and success, sponsors must ensure their technology vendor focuses on solving site workflow challenges.

2 Regulatory Agencies Dive Deep in Technology Exposing Compliance Gaps

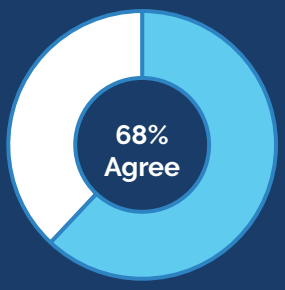
As part of the COVID-19 global health emergency, the FDA introduced updated guidance for conducting clinical trials in 2020. As clinical operations return to some standard level in 2021, regulatory agencies will prioritize new technologies that facilitate data sharing regionally and internationally.

Sponsors and sites need to ensure their technology solutions comply with regulatory agency guidance and international privacy laws like GDPR and CCPA.

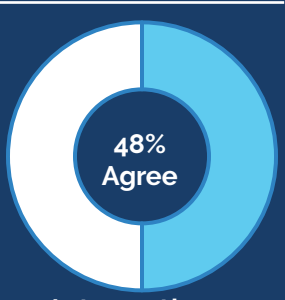
The primary risk exposure is the sites failure to maintain ownership and control of documents and data. Sponsors must pay attention to the permission controls enacted by remote site access technology.

Industry Pulse

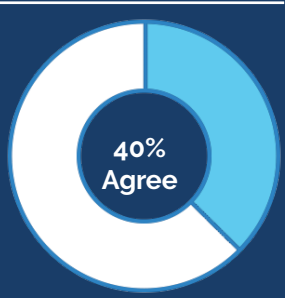
Primary Concerns of Technology Adoption at Study Sites



Budget and Costs



Integrations



Transitions

Florence 2021 State of the Industry Survey N=75

Read the FDA Guidance for Remote Monitoring

Download Here

Dr. Christina Brennan
Vice President Clinical Research
Northwell Health

"Collaborating in real-time on a single document management platform helps us tackle study tasks faster and keep research on track."

Look inside the Florence eISF platform, Florence eBinders.

Inside Tour

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On the Horizon: 2023+

Sites and Sponsors Collaborate

Before the coronavirus pandemic, leading organizations in clinical research had been gradually developing a technology plan.

These agendas have catapulted forward due to the pandemic.

This acceleration challenges the industry by shortening lengthy vendor evaluation processes, disrupting existing cross-functional workflows, and requiring swift and meticulous compliance and regulatory rework.

Yet, there are opportunities for organizations that face this change head-on: avoiding costly study delays, supporting patient participation in critical chronic disease studies, increasing study oversight and compliance adherence, and more.

All stakeholders anticipate technology will have a greater impact than expected on all core aspects of clinical trial life cycles over the next three years..

In the next three years we expect technology to:

1. Connect all clinical trial stakeholders for seamless information sharing.
2. Optimize integrations to facilitate the usage of new technology within a standardized ecosystem.
3. Automate study start-up processes through task automation.
4. Strengthen compliance by automating tracking, alerts, and readiness indicators..
5. Improve patient safety by providing real-time alerts and protocol information.
6. Automate the source to EDC connection to reduce repetitive tasks and accelerate data analysis.
7. Reduce site-selection dropouts by providing deeper visibility into site selection processes.
8. Increase the patient experience by augmenting the study site with direct-to-patient technology.

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Four 2023+ Predictions

The survey data indicates five key trends will emerge across clinical operations in 2021.

Sites Remain Central but are Augmented with Direct to Patient

Trials that are decentralized and hybrid continue to make headlines, but it is crucial to understand that these technologies augment the site-based experience.

For sites to capitalize on these advances, they require technology that allows for integrating these solutions into their workflows.

Platforms Built on eISF Foundations Rise in Prominence

80% of sponsors and sites expect consenting, study start-up, recruitment, source data collection, and monitoring to be mostly accomplished with technology by 2023.

To succeed in this transition, sites must invest in centralized solutions that can scale across protocols and add advanced workflow modules to existing eISF infrastructure.

Integrations Power Direct Source Capture, Exchange, and Analysis

90% of sponsors and 62% of sites believe patient source data collection will be mostly automated by 2023. 30% of sites said automation of the EMR to EDC is their top priority in 2021.

Sites and sponsors need to integrate a single point solution across multiple sources (EMR, eSource, Paper Source, Wearables) to enable this future.

Sponsors Access All Site Data Through Single Point Access

35% of sites state sponsors access their site through a site-owned solution, changing the paradigm from sites learning sponsor systems to sponsors learning site systems.

To prevent the risk of system failure, the sponsor must invest in hub technology that connects the varying systems at the study site and serves as a single point of access.

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2023+ Rise of an Electronic Hub

Remote access to study sites currently requires sponsors to log into dozens of different platforms across hundreds of study sites (eISF, CTMS, EMR/EHR, eConsent, eSource).

Similarly, sites must log into dozens of sponsor portals (EDC, eTMF, RBM) to manage their studies.

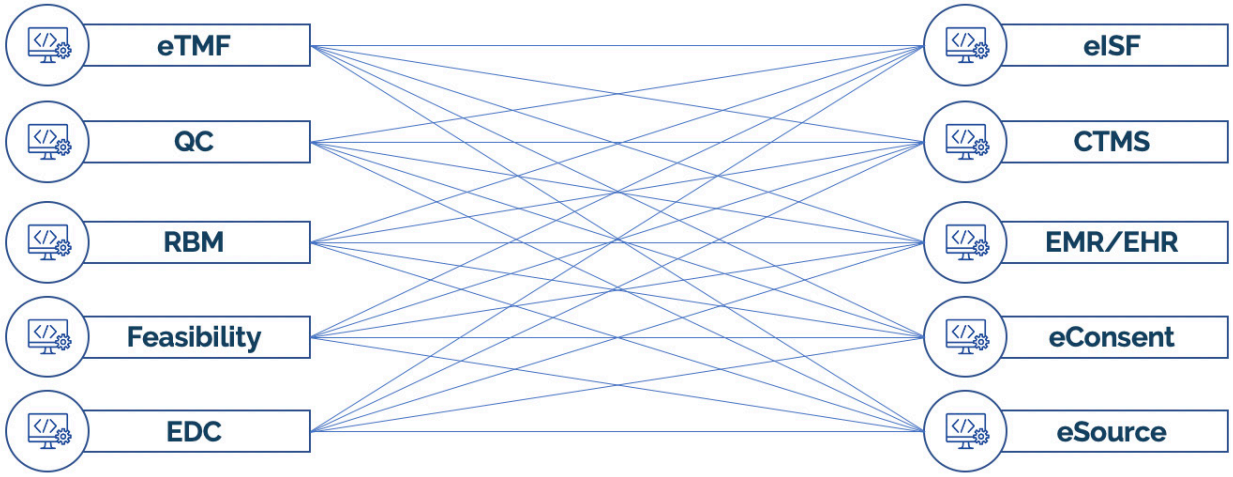
Data indicates the study site and the sponsor will standardize the integration of an electronic hub, or eHub, within three years to eliminate this disjointed ecosystem.

The eHub integrated with the study site's existing systems will provide a single access point for any sponsor/CRO.

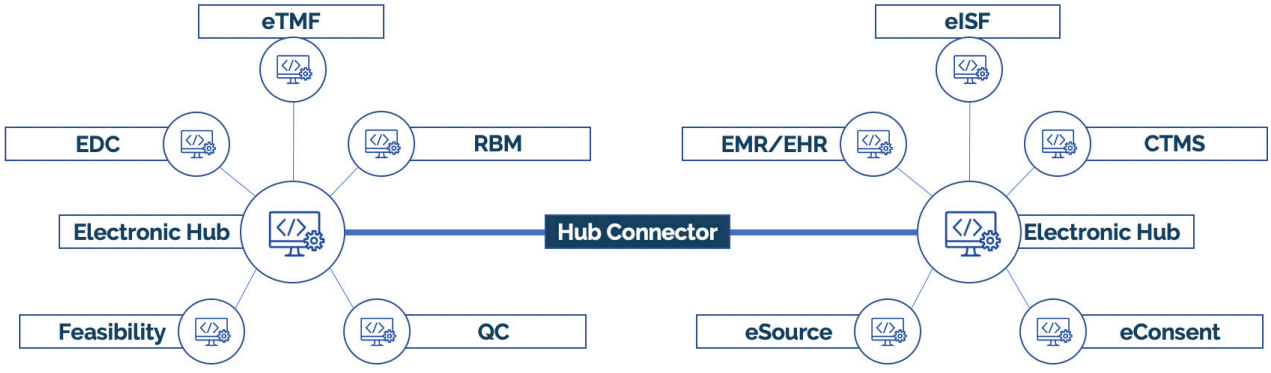
The Sponsor/CRO's eHub will integrate with any site's eHub to seamlessly exchange information via a single connection point.

Interoperability will be a key factor in this transformation over the next three years, requiring sites and sponsors to select technologies that provide integration.

Today, access requires access to multiple systems.



In the future, access is through a single integrated eHub connection.



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Insights on Key Technology Platform Adoption

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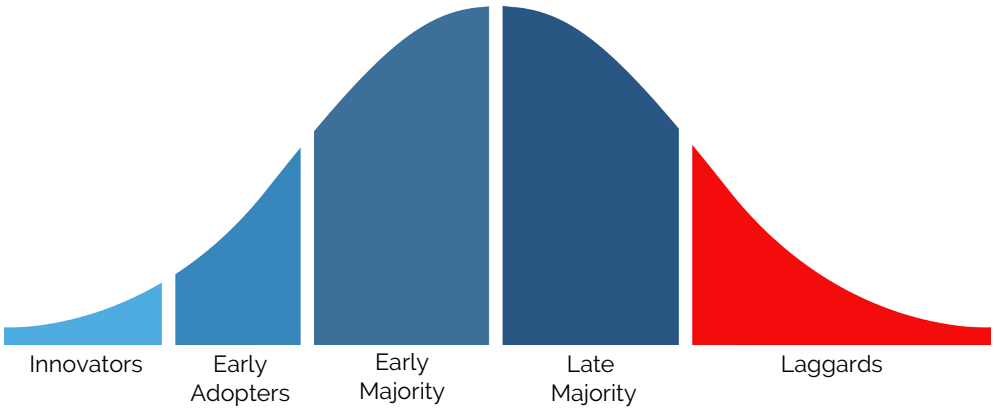
Key Technology Adoption in 2021 Among Clinical Research Sites

Our annual survey of clinical research sites revealed four significant technologies that are important to leadership teams.

While many technology platforms are in discussion, these are the four that emerged as essential for preparing your organization for technology transformation.

Technology Adoption Lifecycle

The most effective way of displaying technology adoption is by placing it on the technology adoption lifecycle curve. This curve indicates where a technology is in its maturity, and how highly you should be prioritizing it to remain relevant.



Innovators are risk-takers who have the resources and desire to try new things, even if they fail.

Early adopters are selective about which technologies they start using. They are considered the "one to check in with" for new information.

Early majority take their time before adopting a new idea; they are willing to embrace new technology as long as they understand how it fits.

Late majority adopt in reaction to peer pressure, emerging norms, or economic necessity.

Laggards are traditional and make decisions based on past experiences. Laggards run the risk of becoming impossible to do business with as they maintain antiquated systems and processes.

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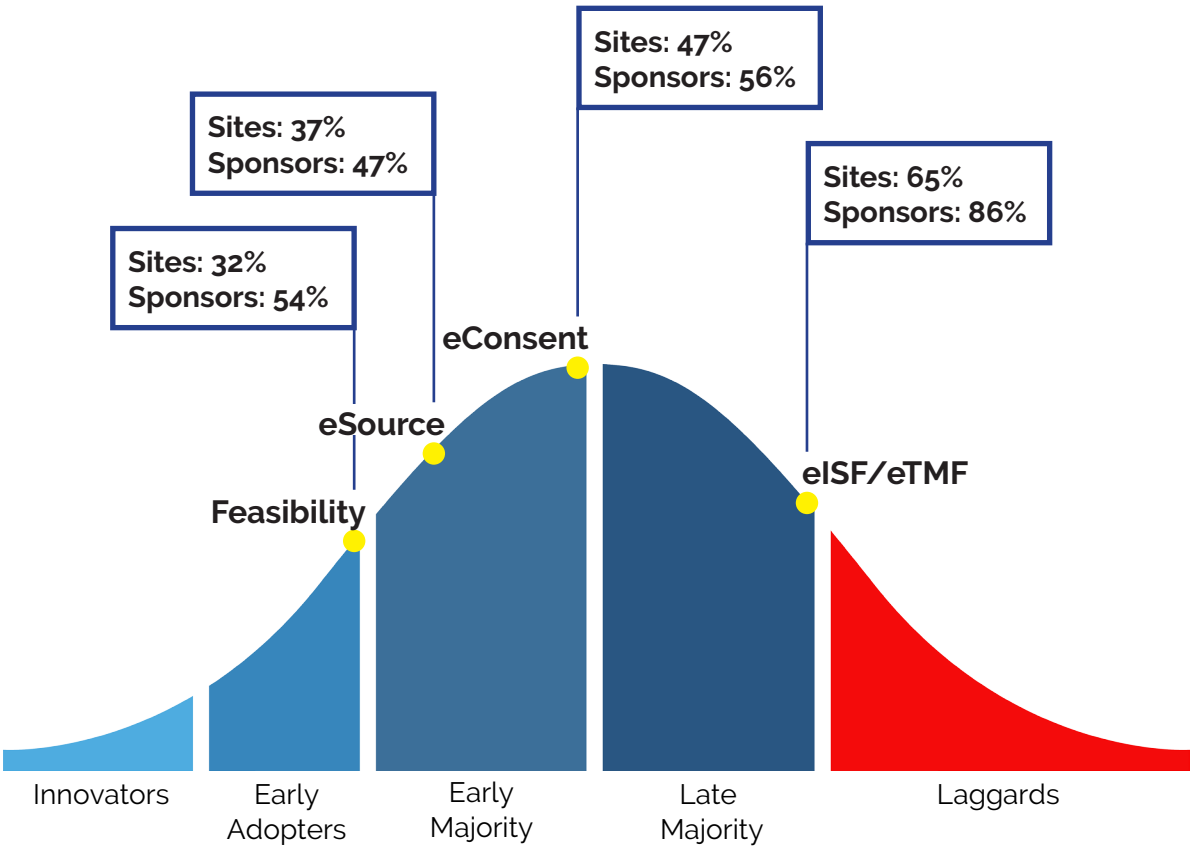
2021 Technology Adoption Lifecycle

eISF/eTMF: The eISF (Electronic Investigator Site File) and eTMF (Electronic Trial Master File) will achieve "late majority" adoption status in 2021. Without an effective document management system, it will become increasingly difficult for organizations to operate clinical trials and interact with other stakeholders.

eConsent: In 2021, the number of sites and sponsors indicating they will be using eConsent reaches 47% and 56%, respectively, compared to an average of 28% in 2020.

eSource: In the year 2021, eSource will pass into the early majority phase of adoption. 37% of sites and 47% of sponsors will have an eSource solution in place, compared to an average of 21% in 2020.

Site Feasability: Early-adopter status is achieved by feasibility and selection tools in 2021, with 32% of clinical trial sites adopting them and 54% of sponsors.



Ryan Jones
CEO and Co-Founder
Florence Healthcare

"The next couple of years will see a lot of changes in clinical operations. We are fortunate to have a customer network of 8,500 study sites and many of the leading sponsors and CROs in over 30 countries providing us with direct feedback on how to create research solutions."

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Planning for 2021

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2021 Site Action Plan

Add these elements to your 2021 strategic plan.

Eliminate Paper Based Systems and Workflows

Your site must be entirely digital from start to finish to participate in the next generation of clinical trial technology.

If you are still using paper for any workflows, plan to invest in core technology to eliminate it by 2021.

Make Remote Access to Documents a Priority

Remote access to your regulatory, consent, and source documents will remain a requirement in 2021 and beyond.

Investigate and prepare budgets for eISF, eSource, and eConsent as part of a strategic plan.

Present your Technology and Technology Plans to Sponsors

Sponsors are willing to reimburse sites for their technology costs as part of study costs.

Develop a return on investment analysis with your vendor to drive sponsor adoption and buy-in for your software solutions.

Focus on Ability to Integrate when Selecting Solutions

Integration is an essential characteristic of all technology solutions. As more options become available to streamline your processes, you will need a unified ecosystem to eliminate repetitive tasks.

The vendor should verify integration capabilities with existing and future systems.

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2021 Sponsor Action Plan

Add these elements to your 2021 strategic plan.

Focus on Solving Site Workflow Challenges First

Until you address your study site's workflow problems, you will not solve your remote site access challenges.

When deploying new technologies for remote access, invest in site-specific technologies and partner with vendors who understand the site experience.

Partner with a Vendor who will Drive Site Adoption and Success

The success of your remote site access strategy will depend on you and your vendors equally.

Partner with vendors that have a proven track record of driving site adoption and success. The vendor should guarantee 95%+ site adoption.

Gain a Deep Understanding of Site-based Technology

As sites invest more in technology, it is essential that sponsors know the types of available solutions and how they can harness them to minimize disruptions in site workflows.

Partner with a site-first vendor with a platform of solutions currently used by study sites to better understand the ecosystem.

Turn-on Single Point Access to the Study Sites via Integrated Hub

The sponsor has historically deployed a wide range of solutions to access and collect data at the study site.

It will be necessary to install a single point of access, or hub, in the study site in 2021 and beyond. The hub will interact with regulatory, source, and consent platforms.

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Next Steps

Sites

Centralize your operations on an eISF with Florence eBinders.

Join 8,500 study sites in 30 countries who partner with Florence to streamline their workflows on the eISF.

Florencehc.com/eBinders
info@florencehc.com

Sponsors and CROs

Get remote access to your study sites for eISF monitoring and source data review.

Florence eHub connects you directly to your study sites. Currently managing more than 2 Million monitoring actions every month across our network of 8,500 study sites in 30 countries.

Florencehc.com/eHub
info@florencehc.com

Sponsors and CROs

Power your operations with an Electronic Trial Master File connected to your study sites.

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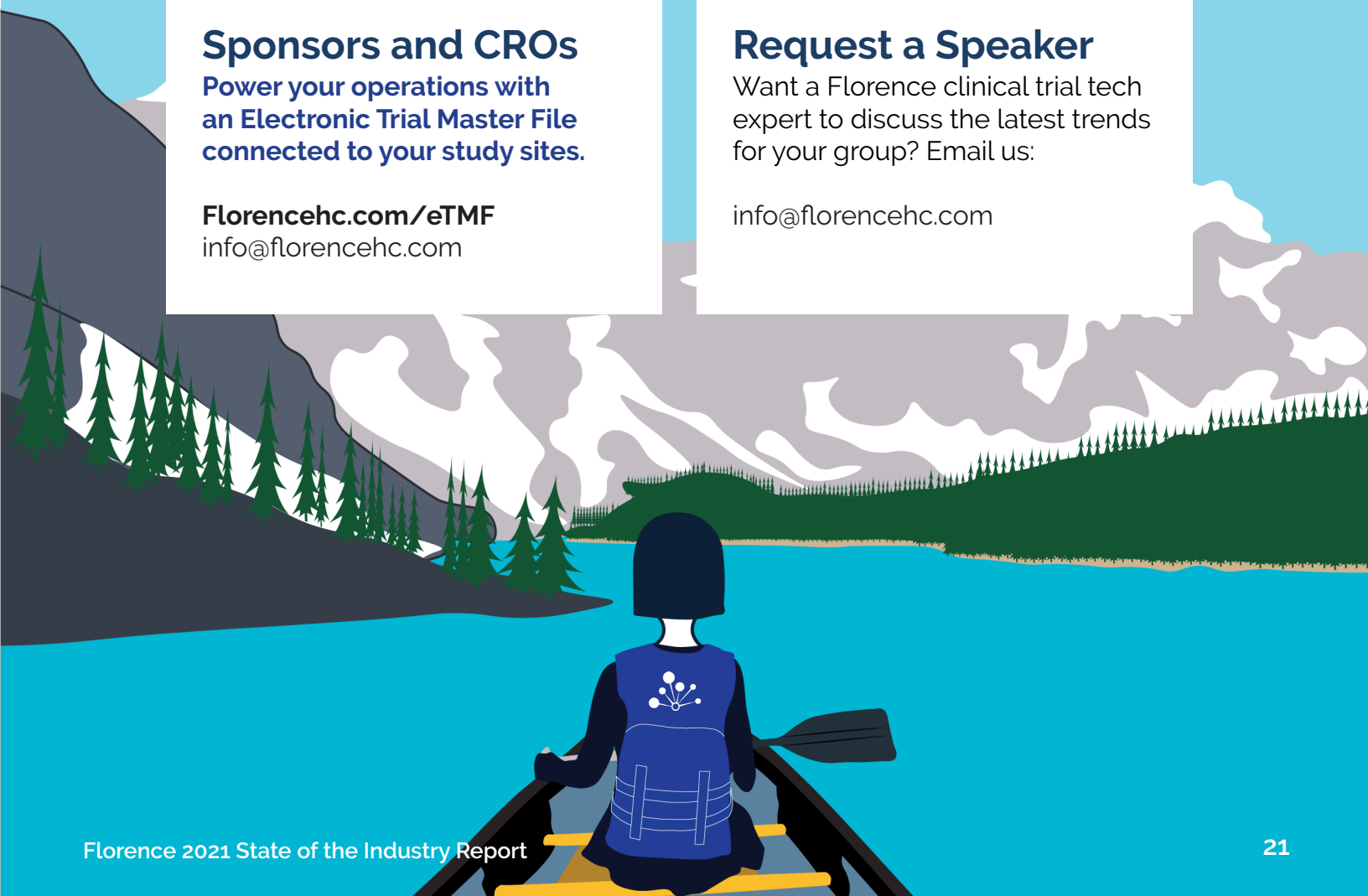
Request a Speaker

Want a Florence clinical trial tech expert to discuss the latest trends for your group? Email us:

info@florencehc.com



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Inside the 2021 State of the Industry Report Survey

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Respondent and Survey Information

The 2021 State of the Industry Report survey was conducted in December 2020.

Industry Segment (N 241)	
CRO	17%
Academic Medical Center	15%
Independent Site	15%
Pharma	12%
Hospital/ Health System	9%
Biotech	8%
Cancer Center	5%
Site Network	4%
Medical Device	3%
Other	12%

Seniority (N 240)	
Experienced	38%
Director	23%
Manager	17%
C-Level	11%
Vice President	10%

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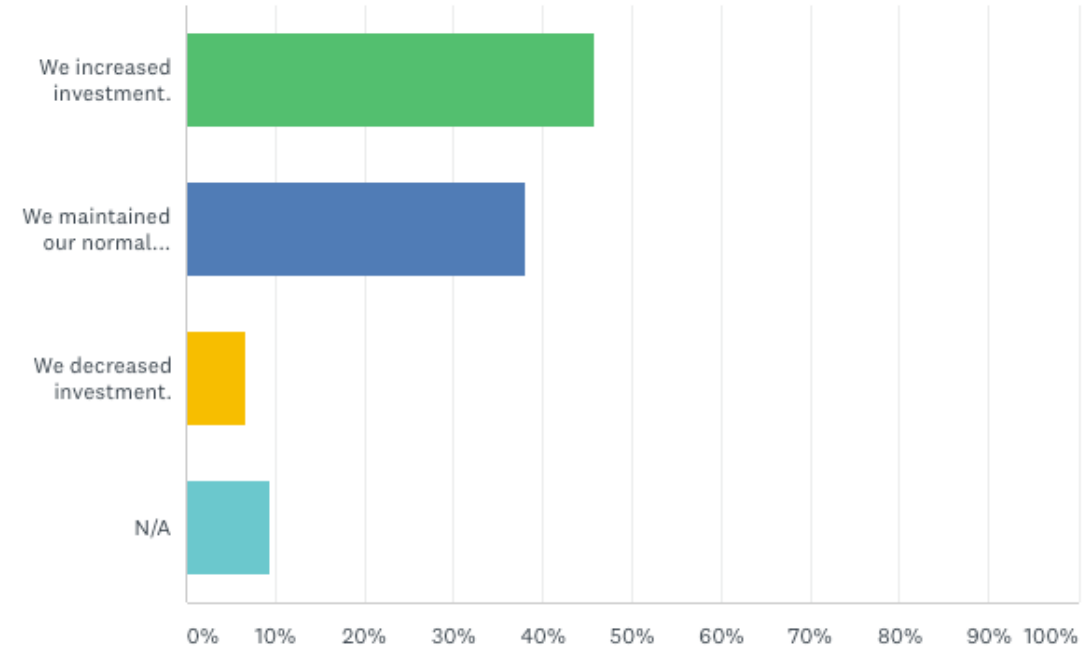
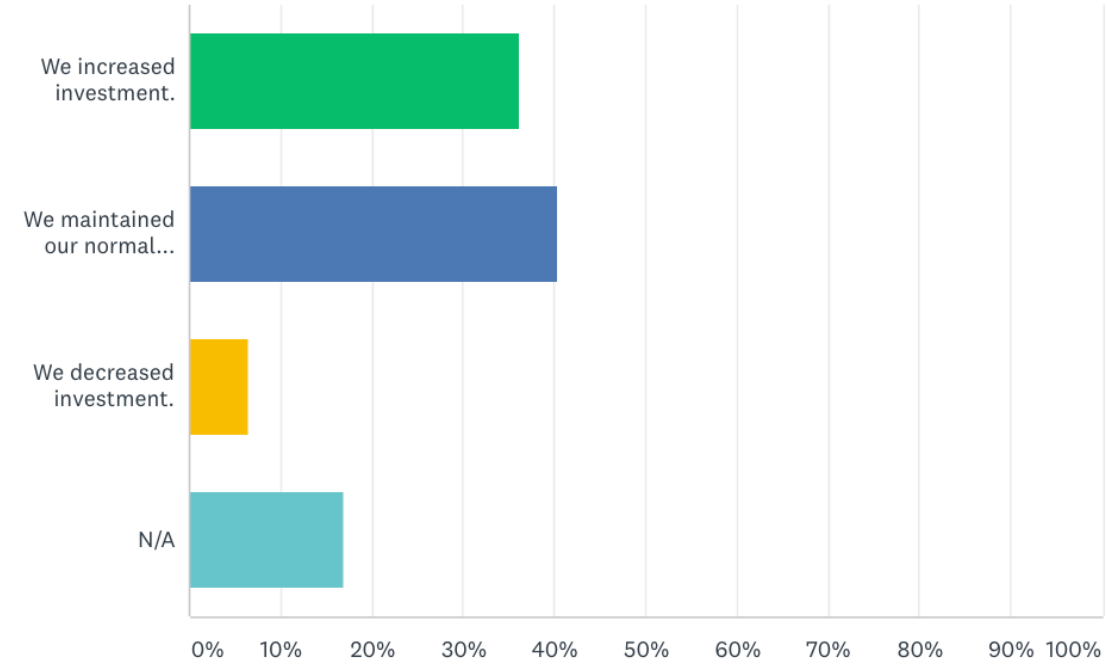
How has COVID changed the way your organization is investing in clinical operations technology?

Site Respondents (N 118)



Sponsor Respondents (N 94)



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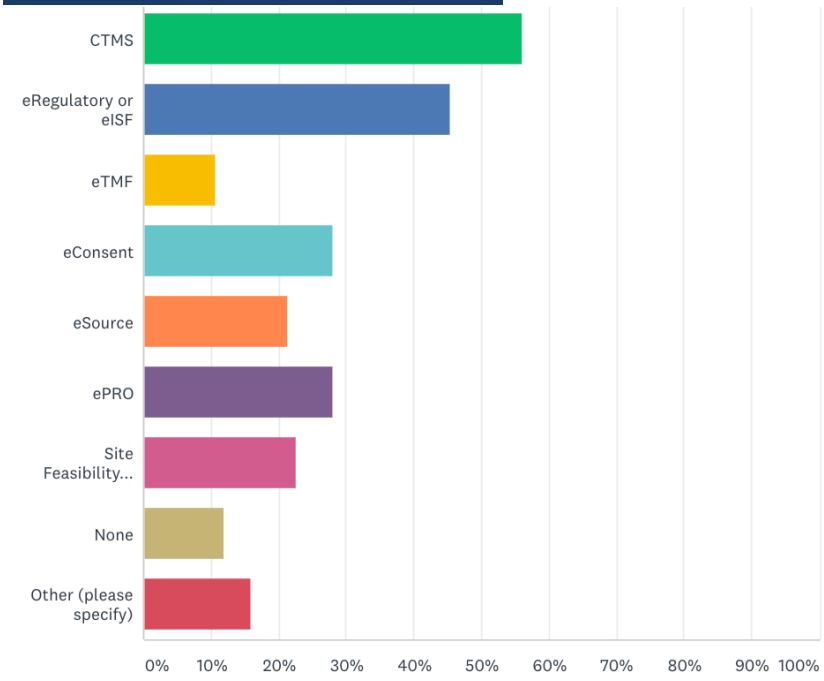
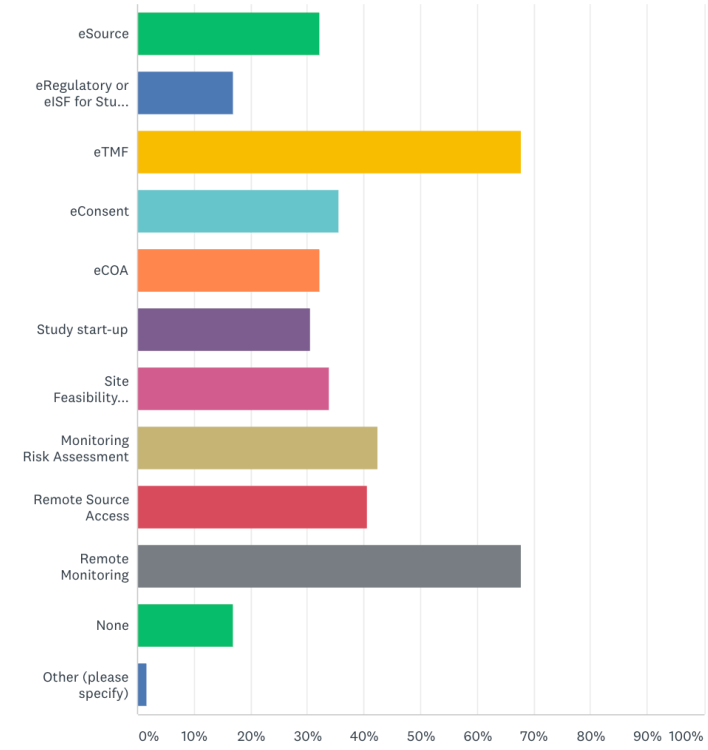
What eClinical solutions does your organization use today? Check all that apply.

Site Respondents (N 75)



Sponsor Respondents (N 59)



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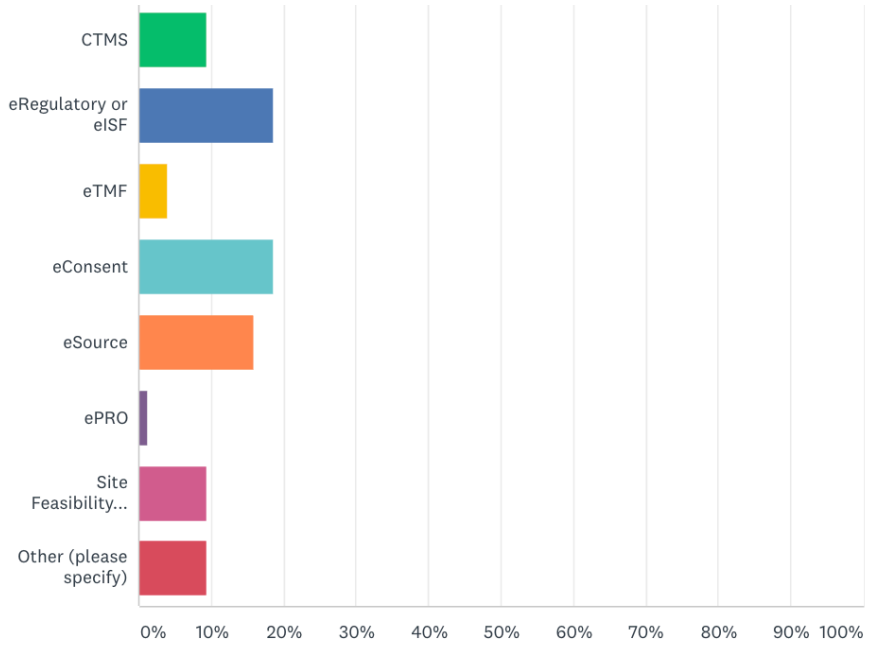
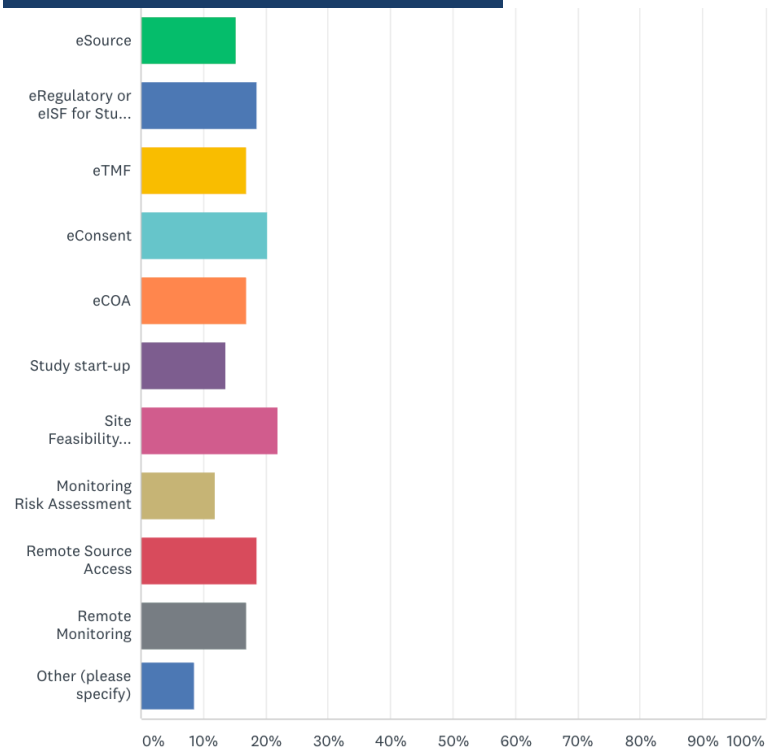
What eClinical solutions does your organization plan to purchase in the next 12 months? Check all that apply.

Site Respondents (N 75)



Sponsor Respondents (N 59)



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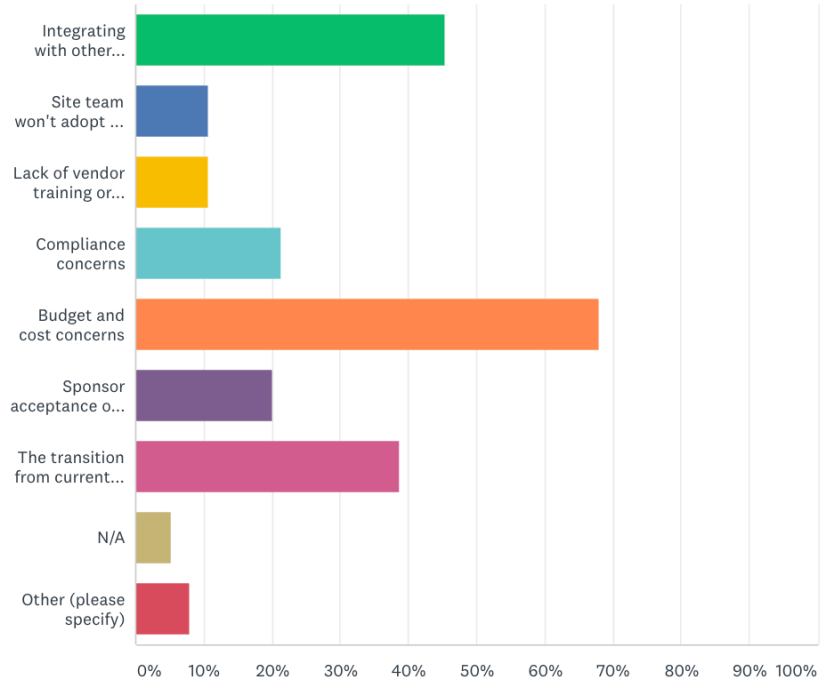
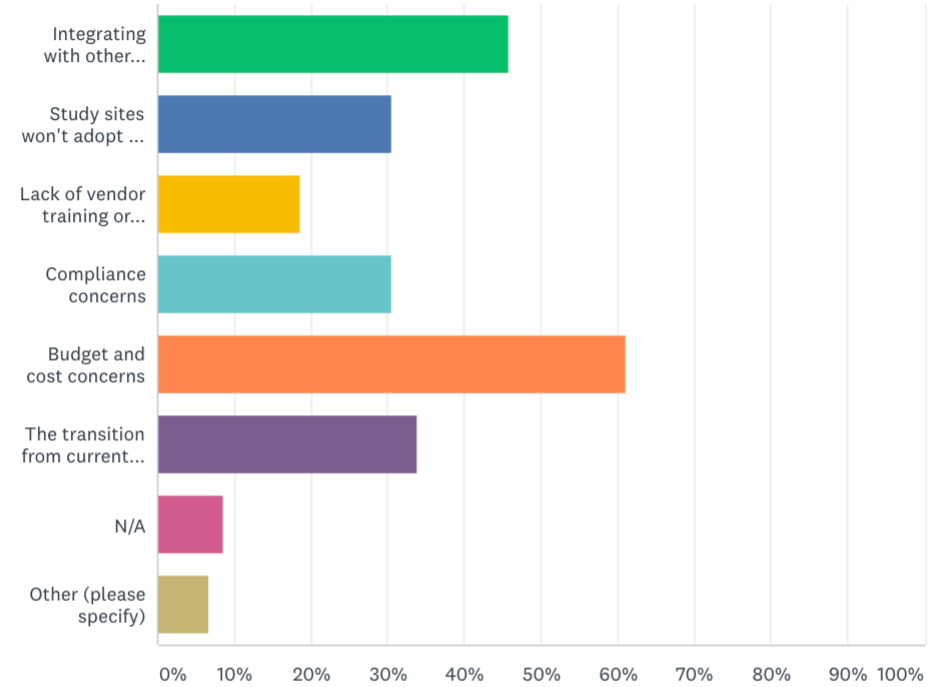
What are your biggest barriers to investing in technology? Check all that apply.

Site Respondents (N 75)



Sponsor Respondents (N 59)



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If you could solve one of these challenges in 2021, which would it be?

Site Respondents (N 75)

Advanced Patient/Subject Matching Integrated with EMR	10.67%
Direct EMR to EDC Connectivity for Automated Data Entry	29.33%
Training and Credential Tracking of Study Staff	13.33%
Consenting of Subjects	8.00%
Remote Monitoring and Document Access and QC Workflows for Sponsors/CROs	12.00%
Remote Source Access Workflows for Monitor Needs	6.67%
Automated Regulatory and Study Startup Workflows	20.00%

Sponsor Respondents (N 59)

Advanced Patient/Subject Matching	6.78%
Faster Source Document Collection for AE's, Safety Events, etc.	6.78%
Evolving Strategic Approach to SDR/SDV	11.86%
Remote Monitoring, Document Access and QC (for accuracy and completeness)	27.12%
Automated Regulatory and Study Startup Documentation	15.25%
TMF Completeness	6.78%
Site Selection	8.47%
Site Responsiveness to Data Entry and Monitoring Needs for Database Lock Timelines	6.78%
Site Adoption of Technology Solutions	10.17%

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What is the primary way your organization exchanges documents with sponsors/sites?

Site Respondents (N 75)

Site-Owned eClinical Platform (eBinders, etc.)	34.67%
Sponsor Provided Upload Portal	25.33%
Digital File Share Platform (i.e. Dropbox, Sharepoint)	9.33%
Email	28.00%
Paper Shipments/Mail	2.67%

Sponsor Respondents (N 59)

Site-Owned eClinical Platform (eBinders, etc.)	0.00%
Sponsor/CRO Provided Upload Portal	35.59%
Digital File Share Platform (i.e. Dropbox, Sharepoint)	22.03%
Email	38.98%
Paper Shipments/Mail	3.39%

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During COVID, what is the primary way your organization enables Source Data Verification (SDV)?

Site Respondents (N 75)

Encrypted Digital Capture from Source Application Direct to Site-Owned eISF Platform (eBinders, etc.)	16.00%
Print from Source Application, Scan and Upload to Sponsor-Provided Portal	25.33%
Direct EMR/EHR Access to Monitors	41.33%
Email or Fax	6.67%
Paper Shipments/Mail	2.67%
N/A	8.00%

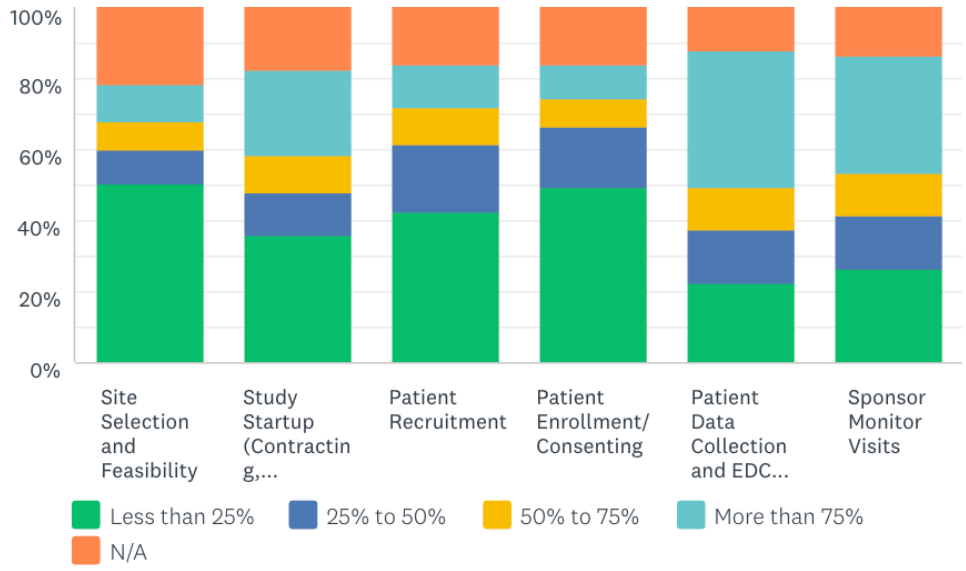
Sponsor Respondents (N 59)

Monitor Access and Workflows Within Site-Owned eISF Platform (eBinders, etc.)	11.86%
Study Sites Upload to Sponsor/CRO-Provided Portal	25.42%
Direct EMR/EHR Access for our Monitors	30.51%
Email or Fax	10.17%
Paper Shipments/Mail	5.08%
N/A	16.95%

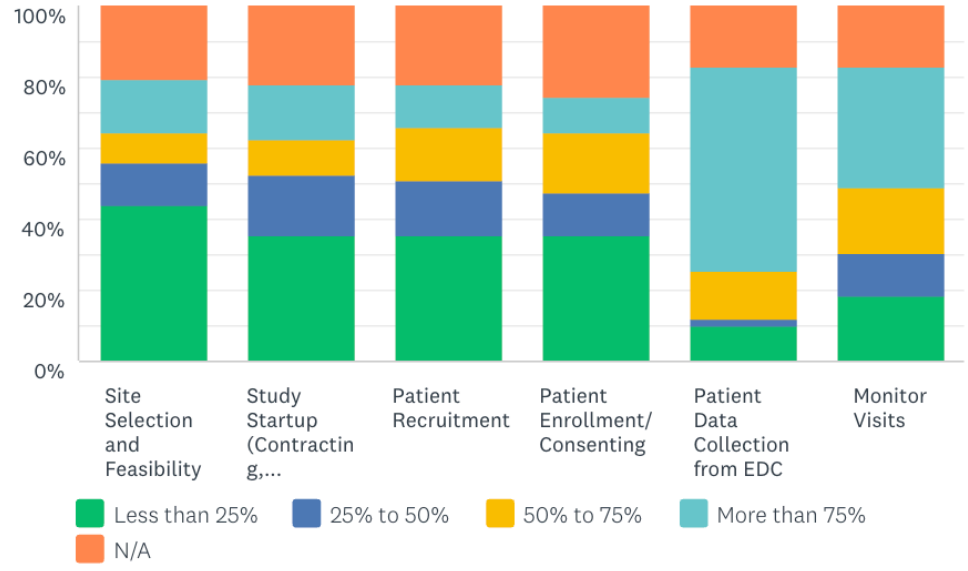
Florence

At your organization, what percentage of these tasks is supported by eClinical solutions today?

Site Respondents (N 75)



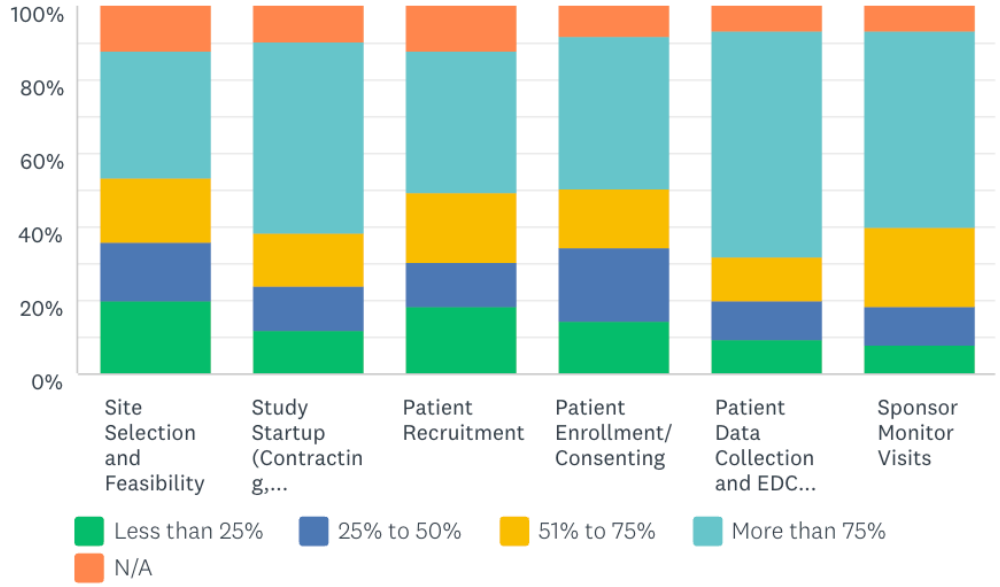
Sponsor Respondents (N 59)



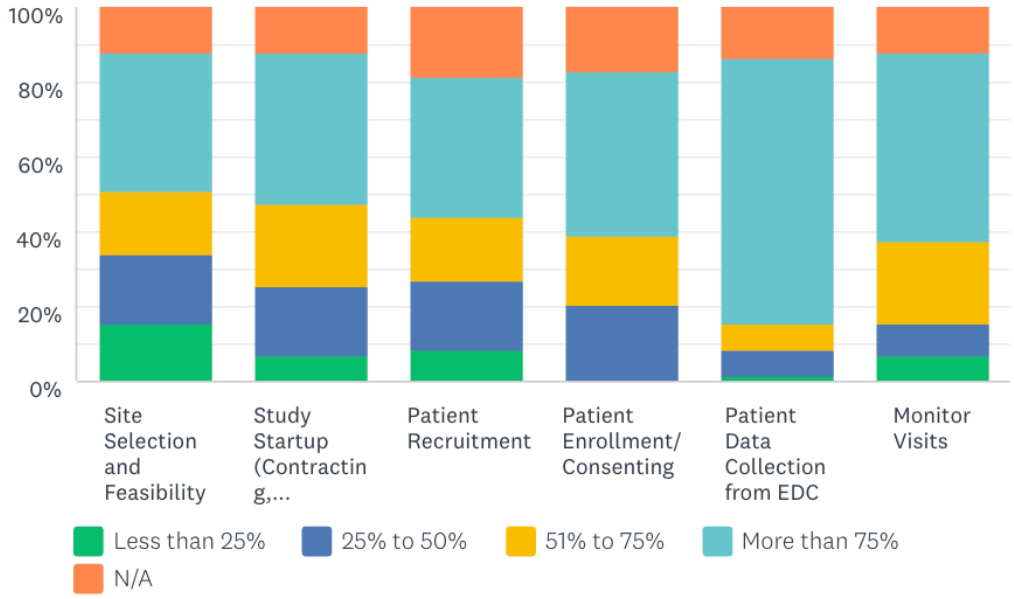
Florence

At your organization, what percentage of these tasks do you expect will be supported by eClinical solutions in three years?

Site Respondents (N 75)



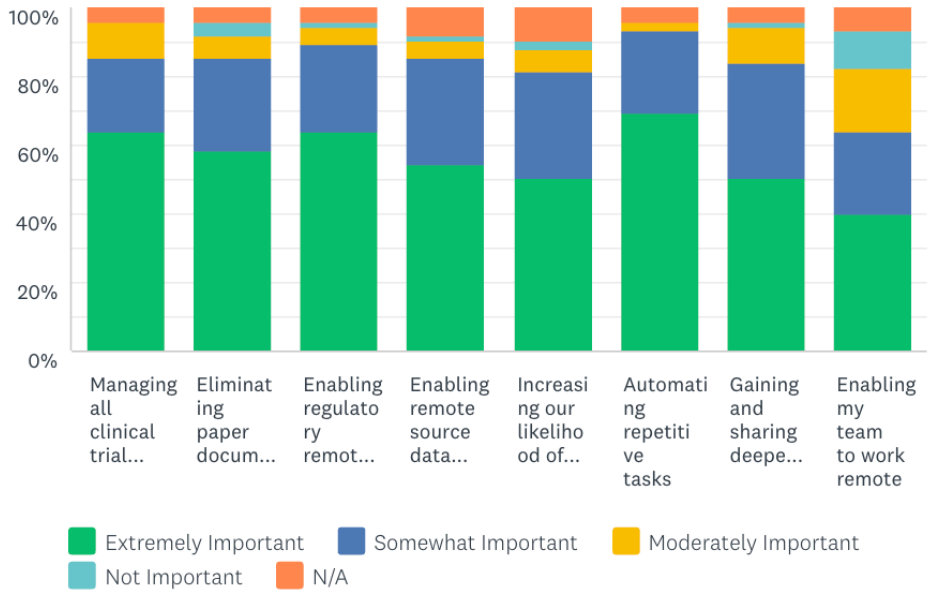
Sponsor Respondents (N 59)



Florence

How important are these factors to your organization when selecting and investing in eClinical solutions?

Site Respondents (N 75)



Sponsor Respondents (N 59)