Decoding eClinical Trends

Data and Insights on eConsent, IRT, eCOA, and AI

SUVODA®

su•vo•da

[su-vo-dah] noun

Derived from Sanskrit - the ancient root language of Sinhalese, the native tongue of our co-founder and CEO – Suvoda loosely translates to **"the dawn of well-being."**

From the beginning, we envisioned building a company with a deep sense of purpose: to help **you uncover scientific breakthroughs that deliver life-sustaining therapies to patients in urgent need, so they have healthier tomorrows.**

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Section 1

Technology evolutions in clinical trials

The last five years have seen particular growth as our industry leverages advancements in technology to serve patients, sites, and sponsors, especially in complex clinical trials with significant requirements and little room for error. Data from representative surveys and focus group discussions, as well as informal sources like LinkedIn and webinar polls, shows that patients, sites, and sponsors are largely ready for new technologies to improve clinical trial processes and advance patient health and well-being.

Drawing on these representative and informal data, this report aims to provide sponsors and CROs with a guide to selected trends in clinical trial technology adoption and to share insight on what peer organizations are thinking. We hope it provides a useful tool to understand our industry from a new perspective and navigate critical decisions that impact clinical trials.

Section 2

eConsent: Growing adoption readiness

Paving the way for greater patient understanding

Informed consent is the cornerstone of clinical trials, ensuring patients comprehend the specifics and implications of their trial participation. Traditional consent forms, often comprised of highly technical content, may hinder patient understanding and potentially lead to premature trial exit.

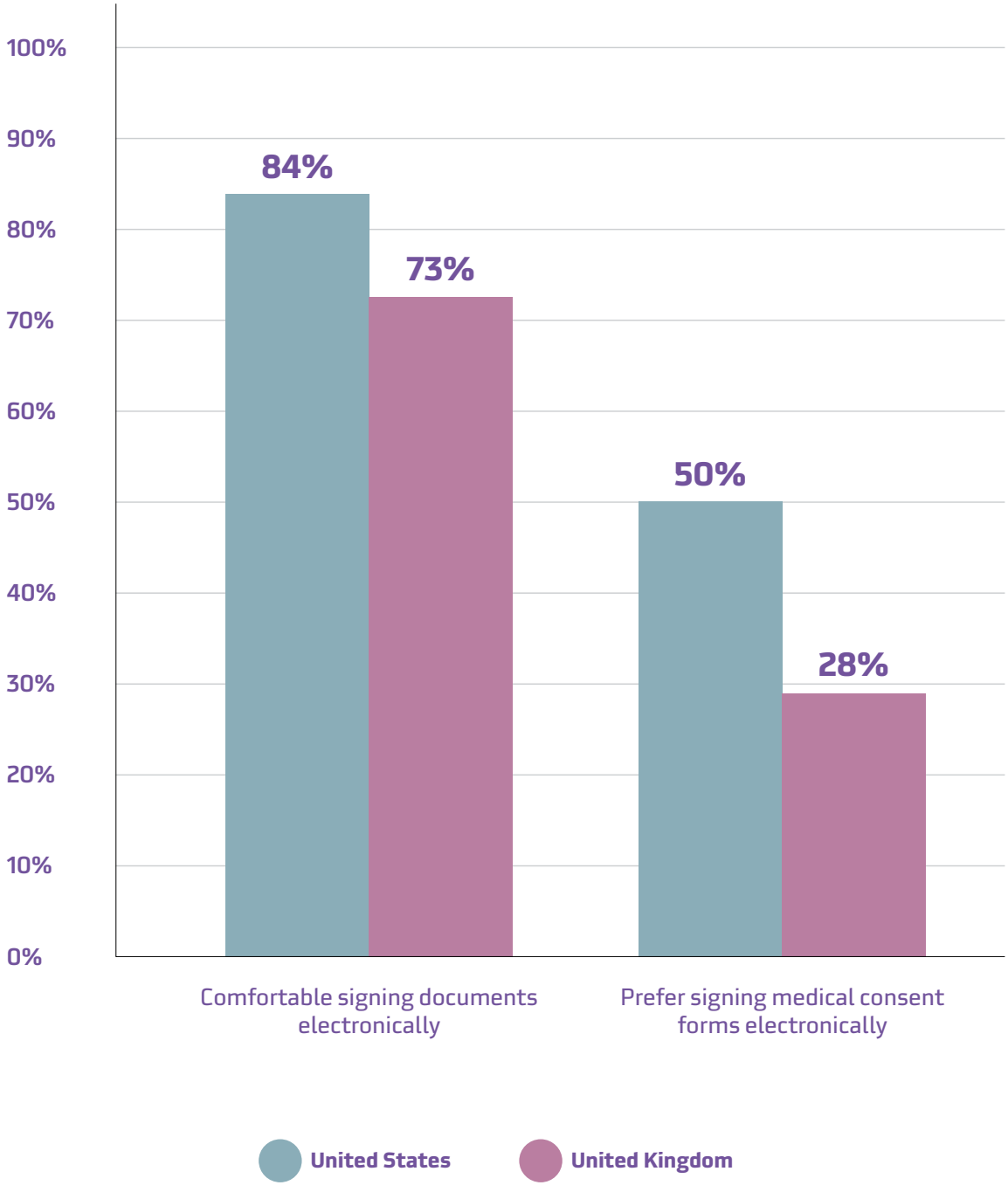
Digitizing consent can support better patient comprehension and engagement. Cohen et al report in the Journal of Medical Internet Research that eConsent can offer a more accessible and user-friendly option for patients, with higher satisfaction compared to paper-based methods.[1]

Notably, many patients, sites, and sponsors appear ready to use eConsent. In a survey of the general population, Suvoda found that overall, a large majority of people in the US and the UK are comfortable signing documents electronically. Half of US respondents indicated that they prefer electronic signature over paper for medical consent forms, as did a significant minority of UK respondents.[2]

[1] Edwin Cohen et al., "Comparative Effectiveness of Econsent: Systematic Review," Journal of Medical Internet Research 25 (September 1, 2023), https://doi.org/10.2196/43883

[2] "Survey from Suvoda Shows Comfort with Electronic Signatures Is on the Rise, yet Healthcare Consent Still Lags," Suvoda, April, 2023, https://www.suvoda.com/insights/all-news/survey-shows-comfort-with-electronic-signatures

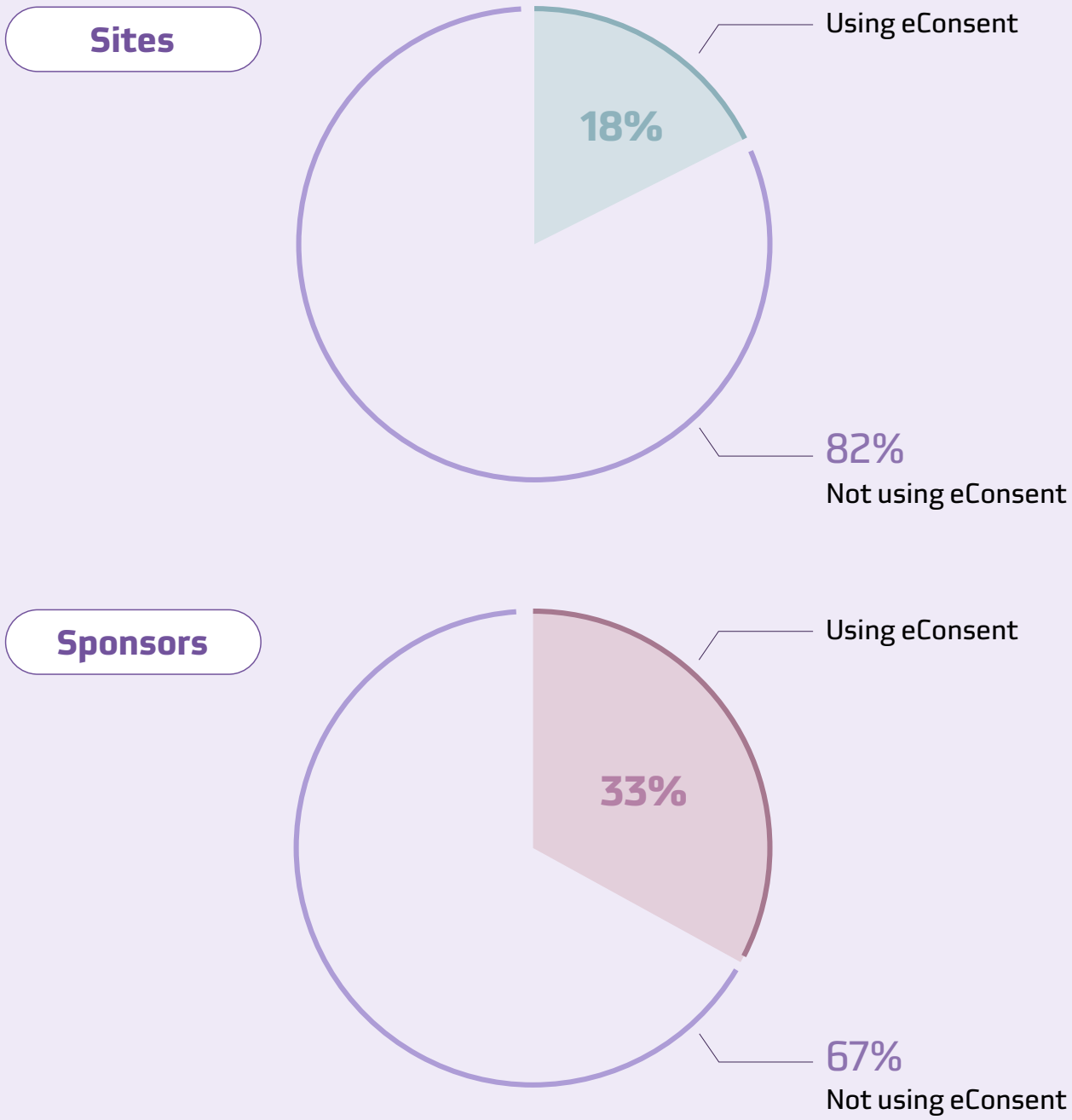
Patient comfort and preference with electronic signatures



Source: Suvoda. "Survey From Suvoda Shows Comfort with Electronic Signatures Is on the Rise, Yet Healthcare Consent Still Lags." April, 2023.

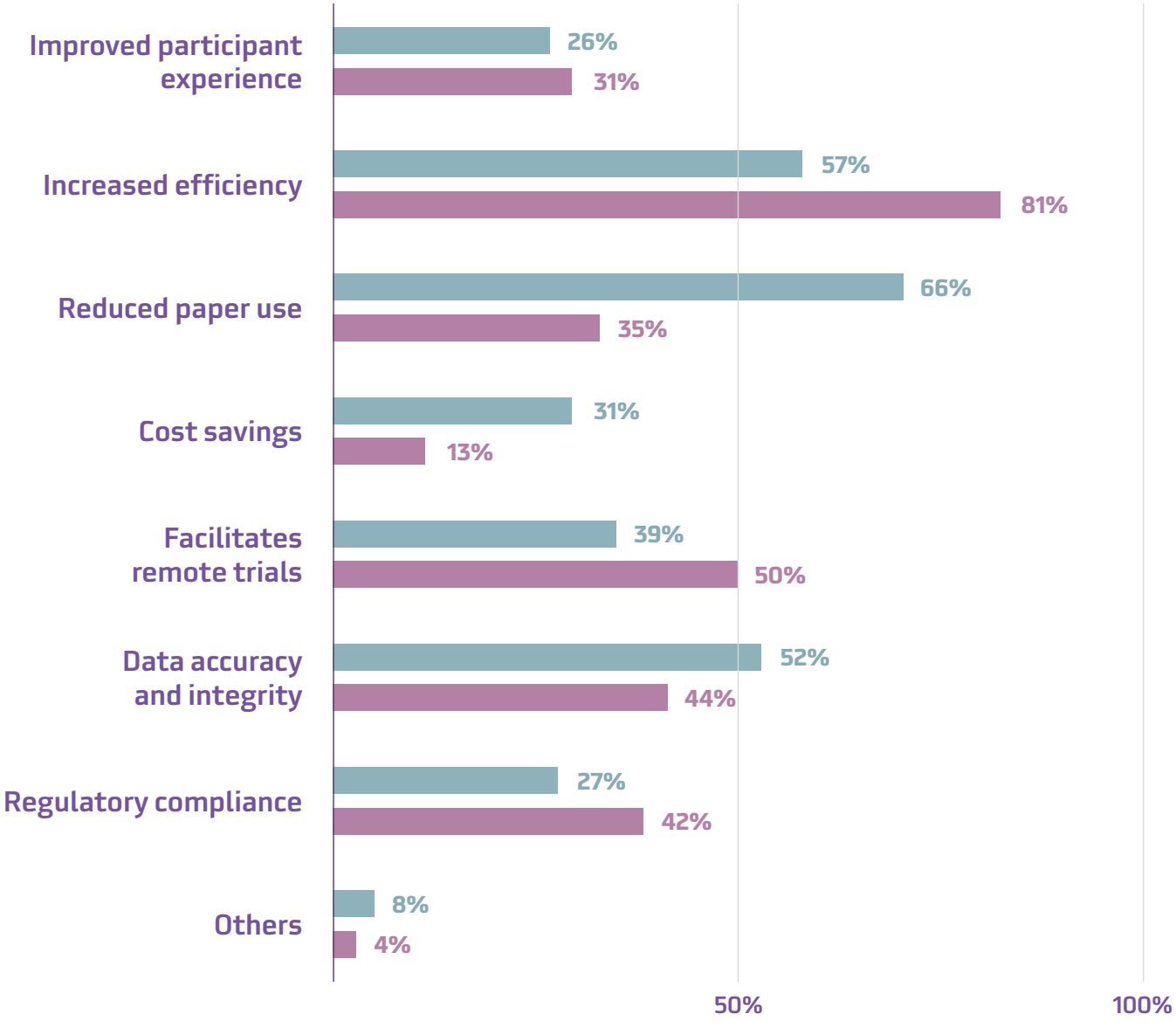
In another Suvoda eConsent survey of sites and sponsors, we found that although a lack of eConsent adoption exists across sites and sponsors, many do see benefits to its use.

Percentage of sites and sponsors using eConsent



Source: Suvoda. "eConsent Market Survey" October, 2023.

Perceived benefits of eConsent among sponsors and sites

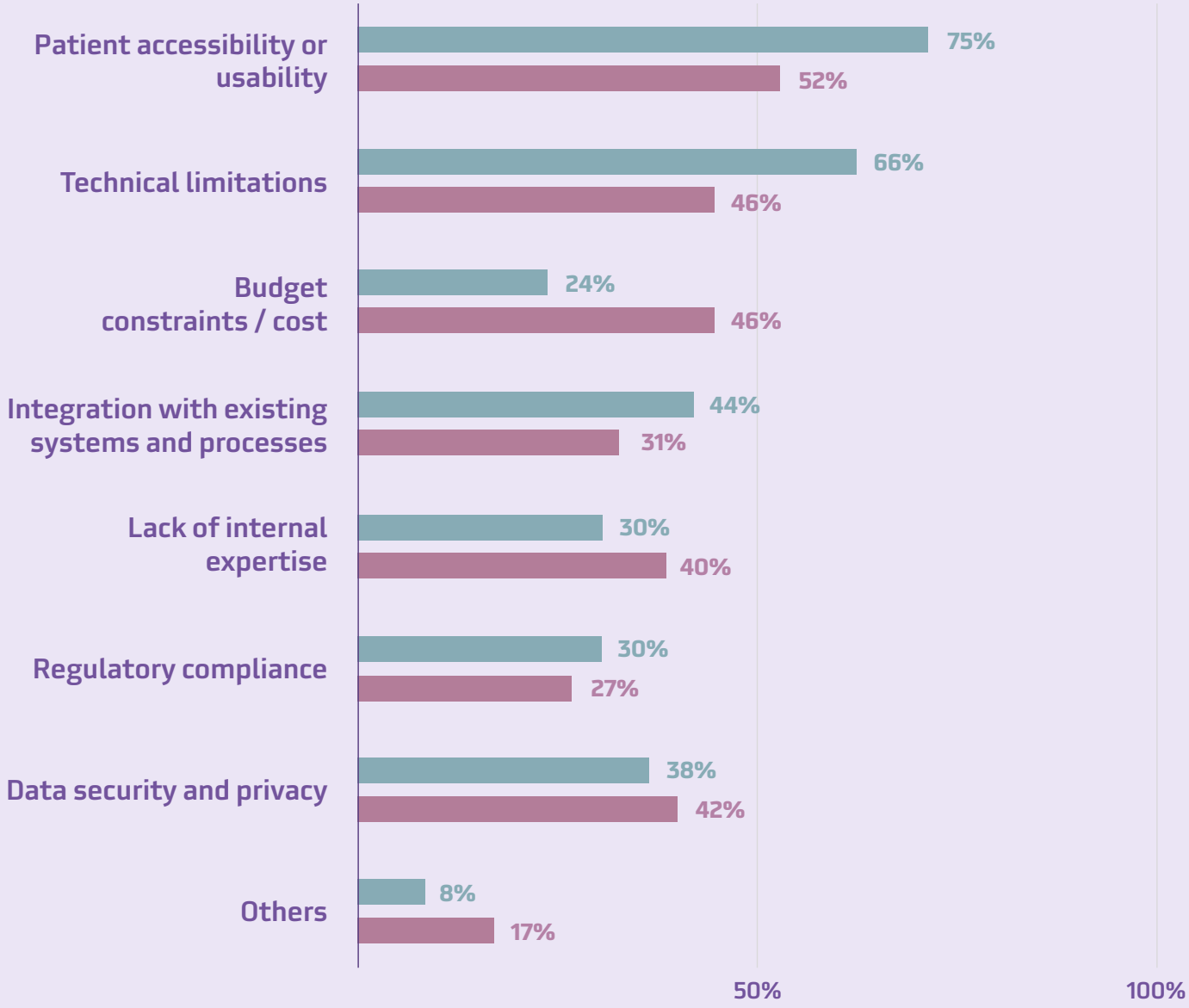


Percentage of site and sponsor respondents who selected each characteristic as a top 3 benefit of adopting an eConsent solution for clinical trials.

Source: Suvoda. "eConsent Market Survey" October, 2023.

Barriers to eConsent adoption vary. Many sponsors and sites are concerned about usability issues for patients themselves, despite patients' digital literacy and comfort with electronic signatures.

Perceived barriers to eConsent among sponsors and sites



Percentage of site and sponsor respondents who selected each characteristic as a top 3 concern of adopting an eConsent solution for clinical trials.

Source: Suvoda. "eConsent Market Survey" October, 2023.

An important goal of eConsent is to demystify the consent process in clinical trials, and with near universal tech literacy and increasingly user-friendly tools, it is poised to fulfill that promise. By streamlining consent forms and using clear explanations, eConsent may provide an important step towards enhancing patient comprehension, fostering a more inclusive and patient-centric future in clinical research.

Section 3

IRT: Driving supply and cost optimization

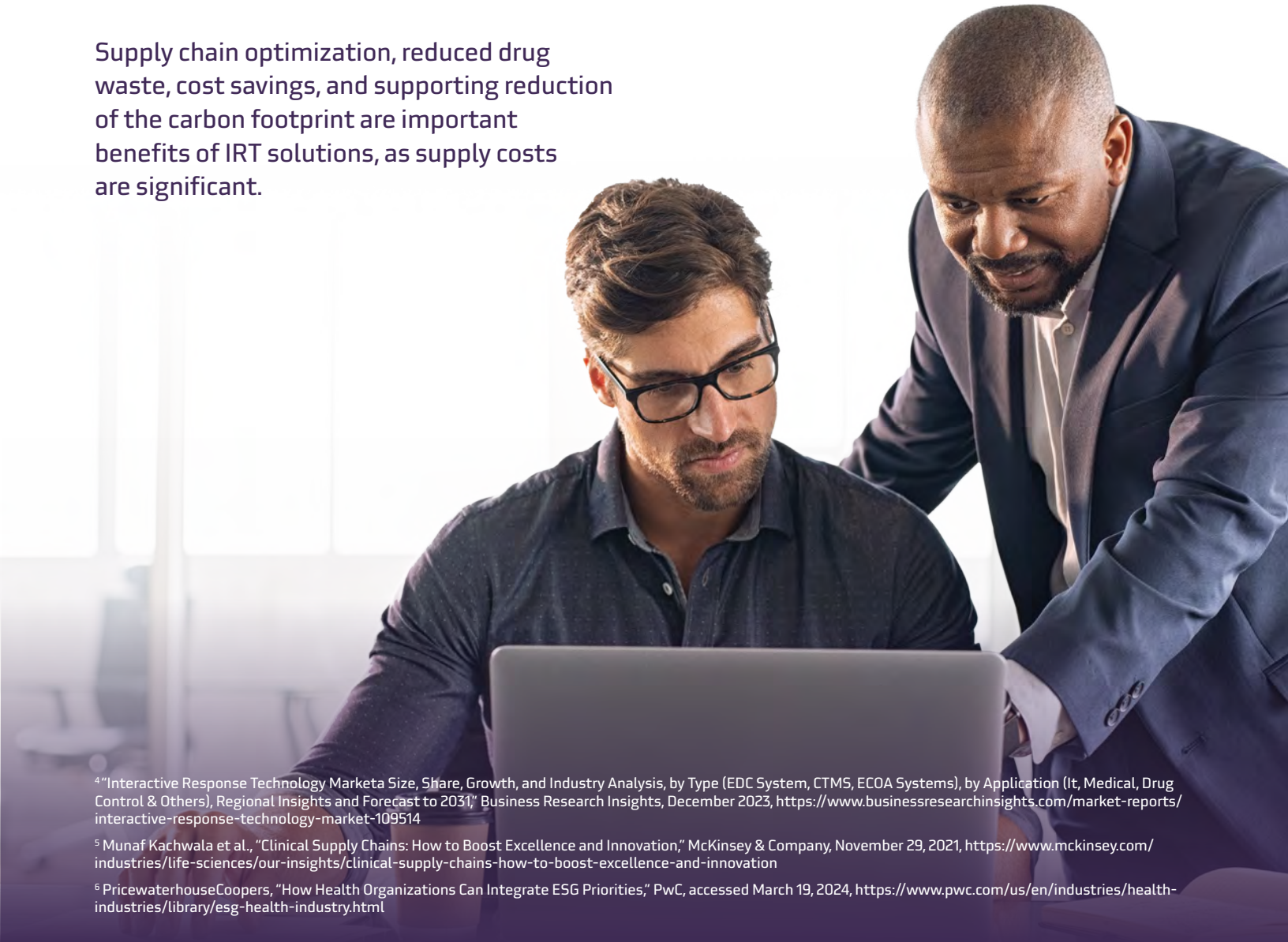
Improving efficiency in clinical supplies management

In clinical trials, it is critical to ensure that each patient receives the correct medication at the right time and place.

IRT is an important solution to help sponsors manage drug supply efficiently. Although IRT solutions have been part of the clinical trial landscape for some time, their use in clinical trials is still growing.[4]

Supply chain optimization, reduced drug waste, cost savings, and supporting reduction of the carbon footprint are important benefits of IRT solutions, as supply costs are significant.

One McKinsey study found that IRT solutions can optimize clinical trial supply chains to reduce waste and associated costs by an estimated 15-20%.[5] This can be a critical tool to meet industry needs, as 94% of life sciences executives said improving supply chain was a top priority in 2021.[6]



[4] "Interactive Response Technology Marketa Size, Share, Growth, and Industry Analysis, by Type (EDC System, CTMS, ECOA Systems), by Application (It, Medical, Drug Control & Others), Regional Insights and Forecast to 2031," Business Research Insights, December 2023, https://www.businessresearchinsights.com/market-reports/interactive-response-technology-market-109514

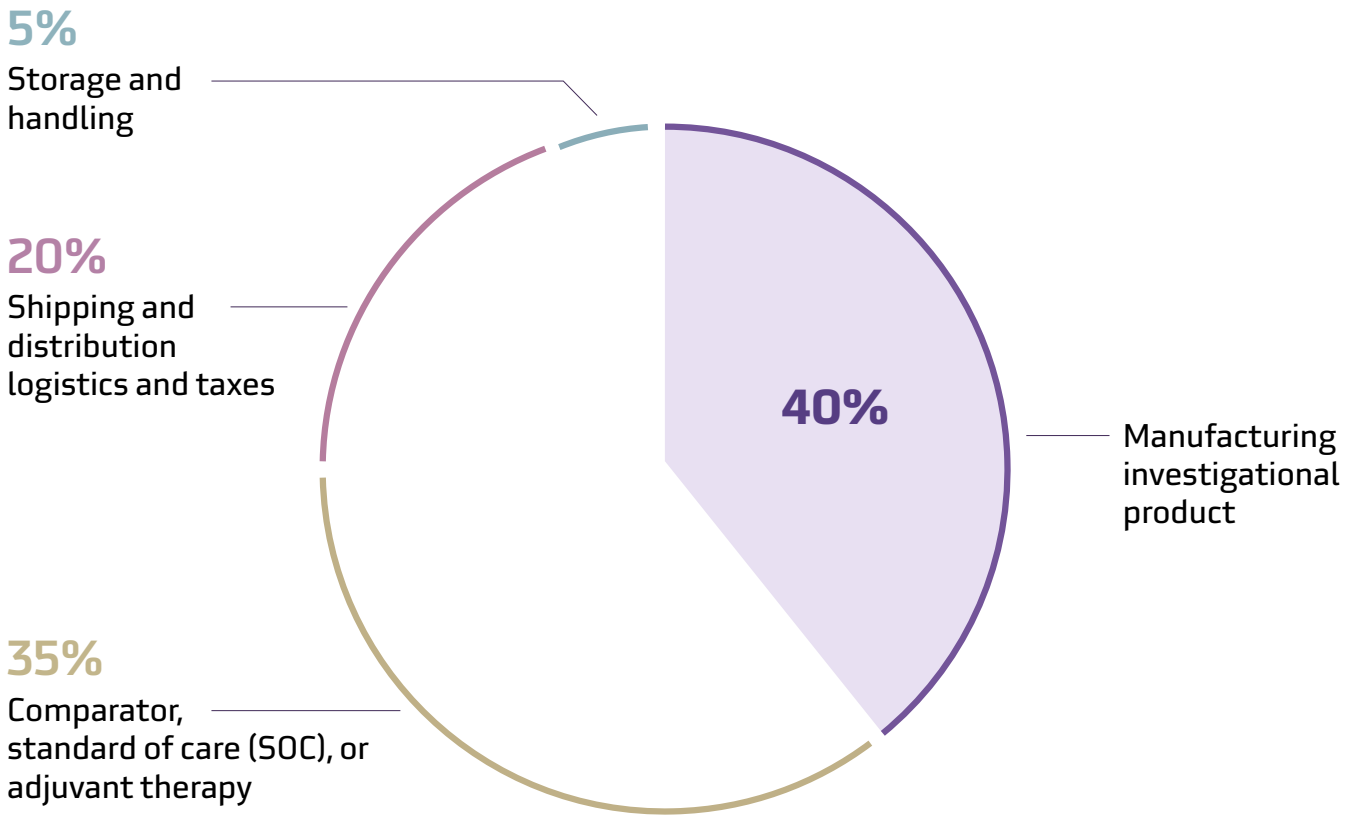
[5] Munaf Kachwala et al., "Clinical Supply Chains: How to Boost Excellence and Innovation," McKinsey & Company, November 29, 2021, https://www.mckinsey.com/industries/life-sciences/our-insights/clinical-supply-chains-how-to-boost-excellence-and-innovation

[6] PricewaterhouseCoopers, "How Health Organizations Can Integrate ESG Priorities," PwC, accessed March 19, 2024, https://www.pwc.com/us/en/industries/health-industries/library/esg-health-industry.html

As an example, the median waste level for investigational medicinal product (IMP) kits in the above McKinsey study was at 50%,[7] a clear opportunity for improvement. A recent Suvoda webinar poll bolsters these findings; 75% of participants named costs of manufacturing investigational products and sourcing costs for comparators, standard of care, and adjuvant therapies as the major cost drivers in their clinical trial supply.[8]

Major cost drivers in clinical supply

Webinar participants were asked:
What are the biggest clinical supply costs in your trial?



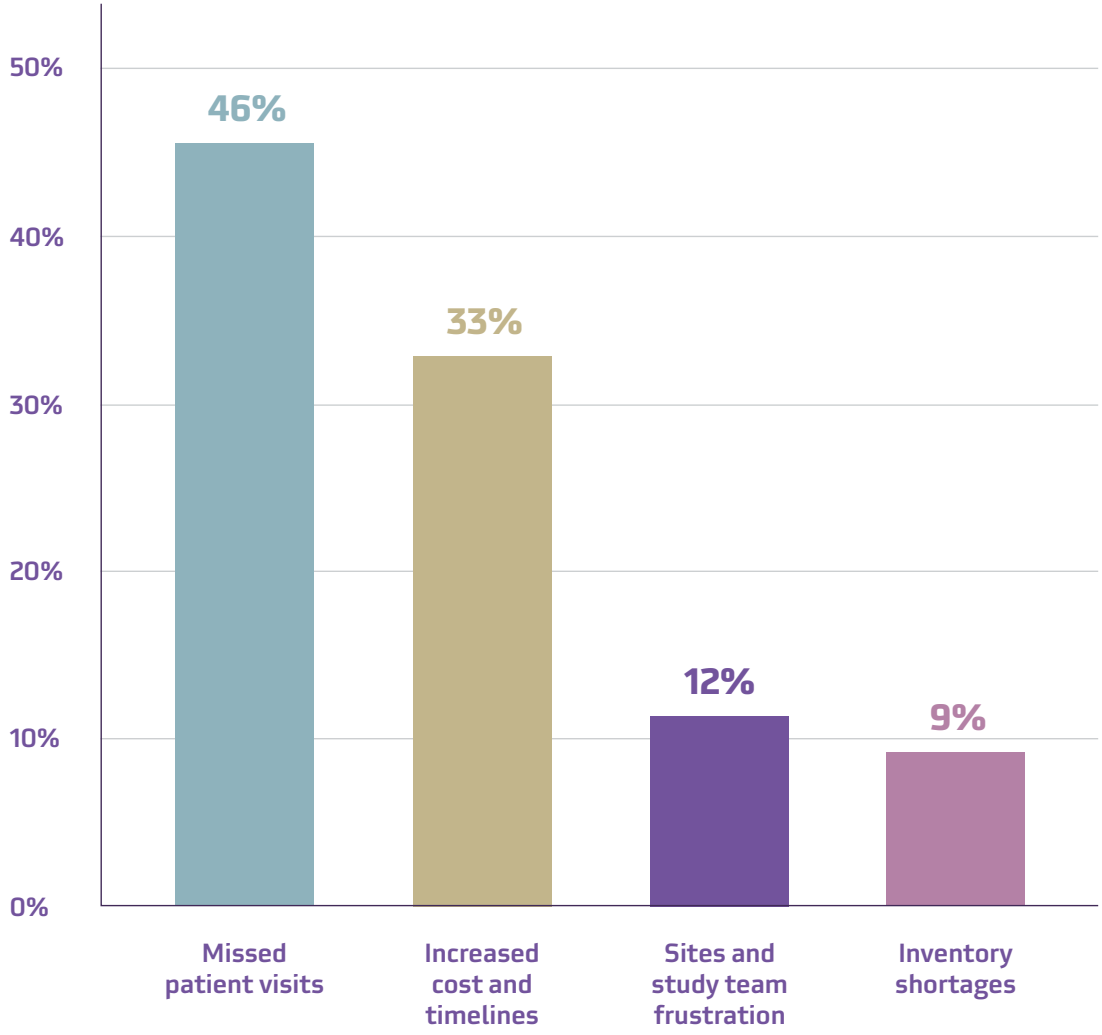
Source: Suvoda. "Major Cost Drivers of Clinical Supply." October, 2023.

[7] Munaf Kachwala et al., "Clinical Supply Chains: How to Boost Excellence and Innovation," McKinsey & Company, November 29, 2021, https://www.mckinsey.com/industries/life-sciences/our-insights/clinical-supply-chains-how-to-boost-excellence-and-innovation

[8] "Major Cost Drivers of Clinical Supply," Suvoda, October 2023, https://www.suvoda.com/insights/blog/major-cost-drivers-of-clinical-supply

Problems in clinical supply chains create challenges for patients, sites, and sponsors. A LinkedIn poll showed that the majority of the Suvoda community consider missed patient visits to be the greatest challenge for clinical trials when supply is disrupted. As one respondent said, "Missed patient visits = missed data points."

Implications for clinical trials when supply is disrupted



IRT systems are an important tool to address challenges of drug supply, reducing drug waste, and driving cost efficiency. Optimized supply chains help patients, giving the best chance for drugs to reach patients on time.

Source: Suvoda. "What are the greatest challenges for trials when clinical supply is disrupted?" March, 2024.

Section 4

eCOA adoption predicted to rise

Enhancing ease of outcome reporting and data accuracy

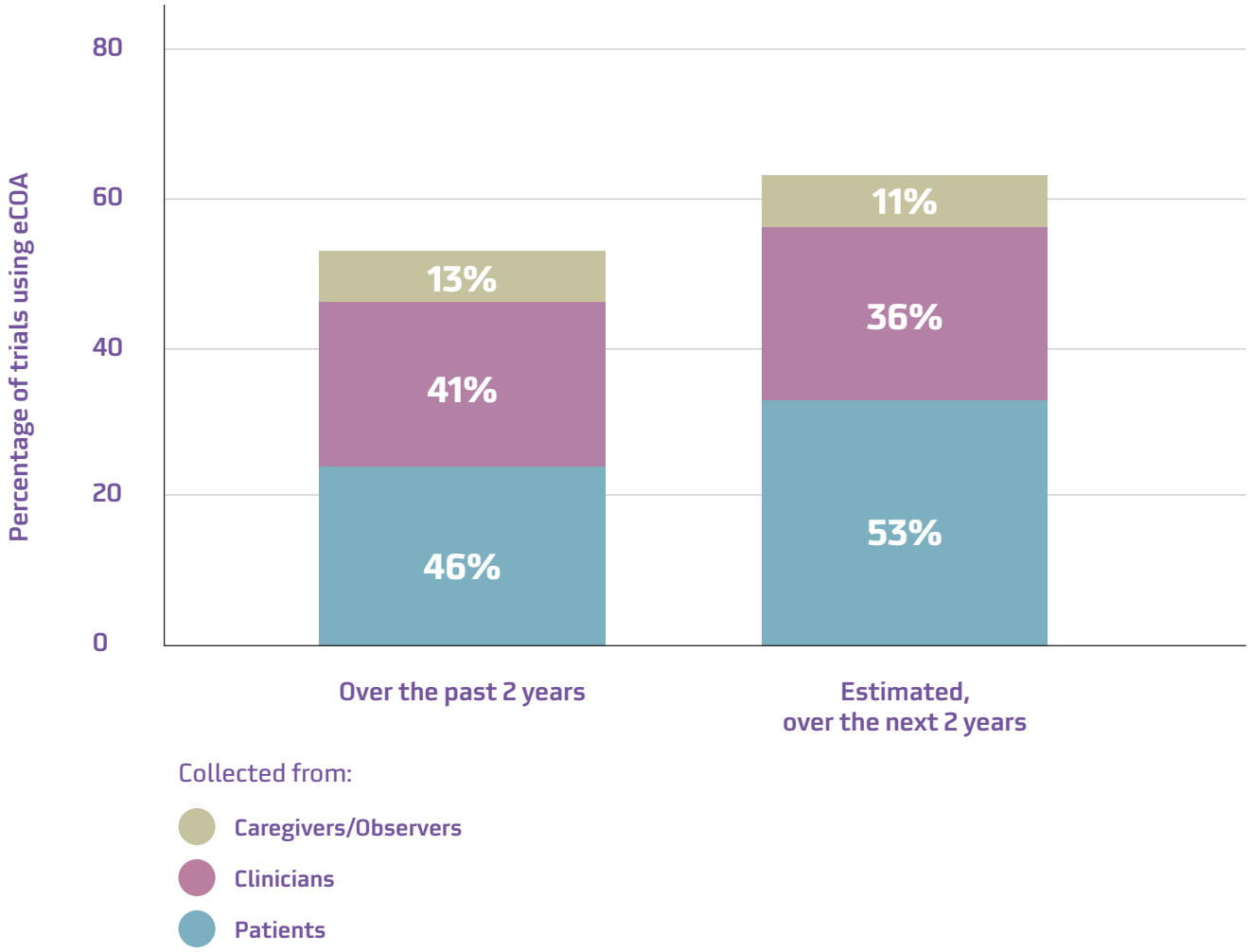
As the clinical trial industry has adopted electronic clinical outcomes assessment (eCOA) methods over the last 20 years, we have been able to improve patient questionnaire compliance, to minimize transcription errors between paper and electronic systems, and to reduce time spent inputting data and aligning across paper and electronic platforms.[9] eCOA is now firmly embedded within the clinical trial landscape, with sponsors reporting in the Industry Standard Research (ISR) that they have used eCOA in 53% of their trials over the last two years, and plan to use eCOA in 64% of trials over the next two years.[10]

Within this growth, there is a noticeable shift toward prioritizing patient-reported outcomes (PROs). Sponsors expect ePROs to make up 53% of the COAs collected in the next two years, compared to 45% over the last two years, which emphasizes an increasing value placed on patients' voice and experience.

[9] "What Is Electronic Clinical Outcomes Assessment (ECOA) for Clinical Trials?," Suvoda, November 20, 2023, https://www.suvoda.com/insights/blog/electronic-clinical-outcomes-assessment-ecoa

[10] eCOA/ePRO Benchmarking and Market Dynamics (5th Ed.) (ISR Reports, September 27, 2023), https://research.isrreports.com/reportaction/2023-ecoa-epro-benchmarking-market-dynamics/Marketing

Use of eCOA in current and future trials



Source: Industry Standard Research. "eCOA/ePRO Benchmarking and Market Dynamics (5th Ed.)." September, 2023.

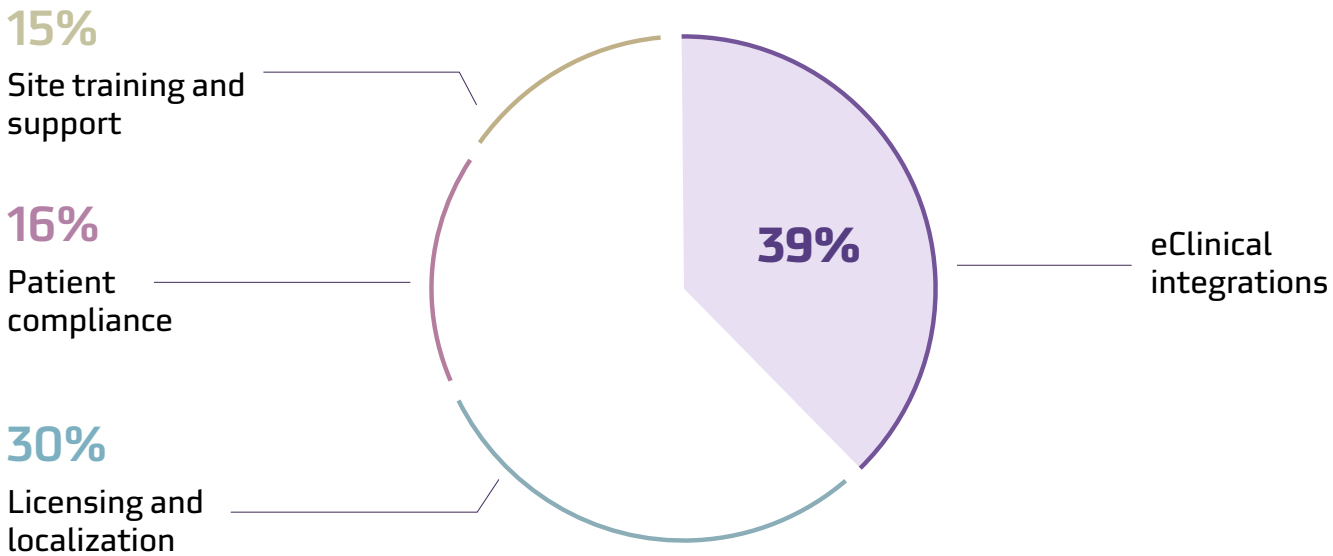
Although eCOA is widely adopted, it is also a technology tool that can cause frustrations during implementation. In conversations with sponsors, we have heard that traditional eCOA solutions can be challenging due to issues with build and deployment, implementation, and usability.

Common challenges in eCOA implementations

Build and Deployment	• Licensing and localization • Lack of questionnaire reusability • Overall deployment speed and quality
Implementation	• Assessment management • Manual data management • Global device logistics • Integration with other eClinical technologies
Usability	• Site and patient user experience • Global user support (quality responsiveness, accessibility)

Specifically, integrations are an issue that often comes up for sponsors. In a Suvoda LinkedIn poll, 39% of respondents said eClinical integrations are their biggest challenge in eCOA implementations.

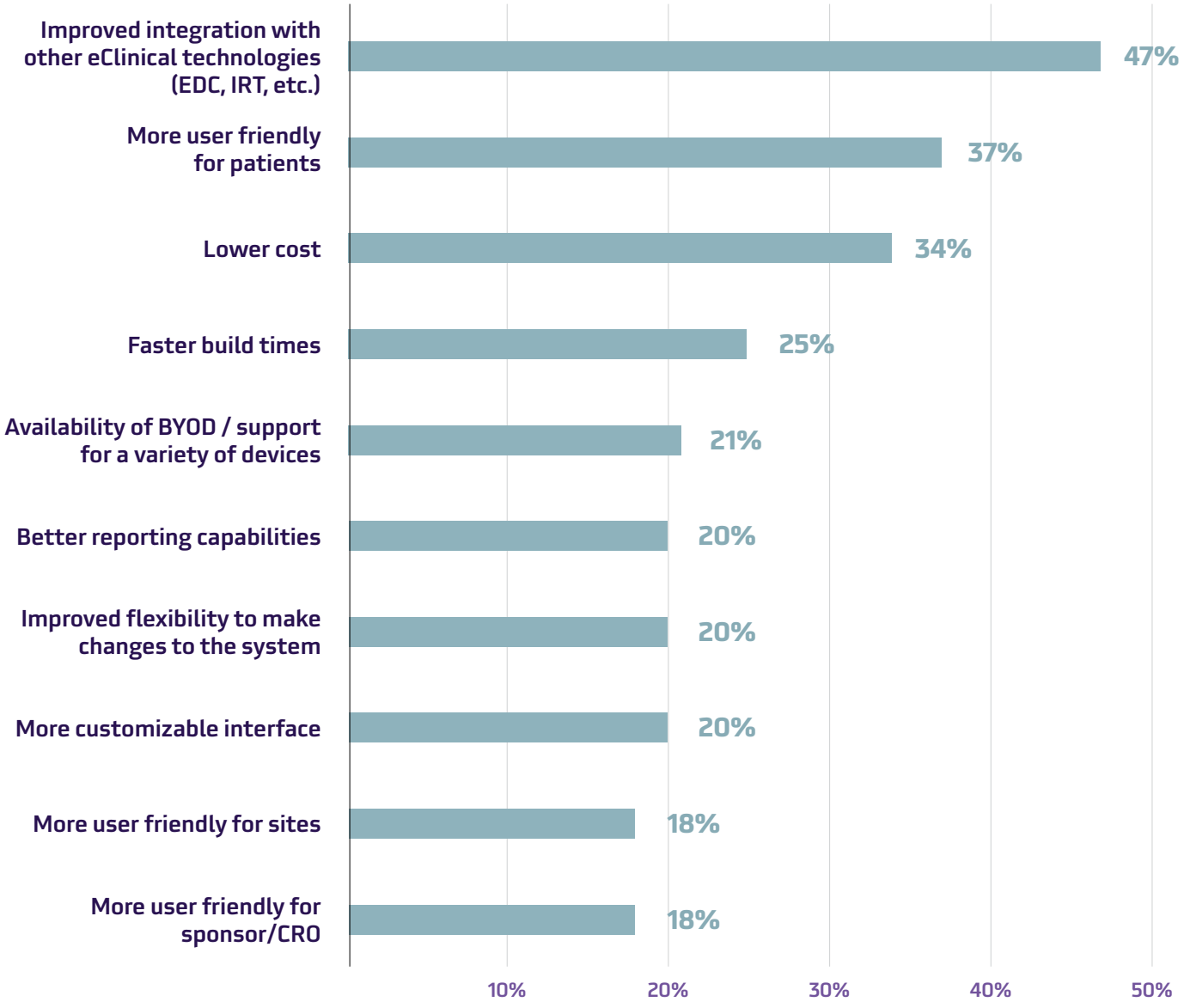
Greatest challenges in eCOA implementations



Source: Suvoda. "What Are the Biggest Challenges in eCOA Implementations?" February, 2024.

ISR's research found similar trends, with 47% of sponsors identifying improved integrations with eClinical technologies as an area for traditional eCOA improvement.[11]

Areas for desired eCOA improvements



Source: Industry Standard Research. "eCOA/ePRO Benchmarking and Market Dynamics (5th Ed.)." September, 2023.

[11] eCOA/ePRO Benchmarking and Market Dynamics (5th Ed.) (ISR Reports, September 27, 2023), https://research.isrreports.com/reportaction/2023-ecoa-epro-benchmarking-market-dynamics/Marketing

Notably, 37% of sponsors identified patient usability as another opportunity for improvement in eCOA solutions.[12] RWS Life Sciences, an expert in usability testing, identifies several characteristics of eCOA solutions that drive patient usability, including the user experience, design, and device.[13]

A framework for patient usability of eCOA solutions

User Experience

- Ability to navigate between screens
- Ability to change answers as needed
- Clear beginning and end of the questionnaire

Design

- Font and color choices
- Size and function of the answer button

Device

- Touchscreen accuracy
- Touchscreen responsiveness

Source: Suvoda. "RWS Life Sciences Certification Validates That Suvoda eCOA Is Intuitive and Easy to Use." November, 2023.

eCOA has been and will continue to be an important tool within the clinical trial industry. As we continue to develop powerful, unified, and easy to use solutions, we can strengthen data accuracy and drive increasing effectiveness in clinical outcome assessments collection. Just as important, this can improve the patient experience during trials while maintaining data integrity, leading to enhanced clinical trial efficiency and reliability.

[12] eCOA/ePRO Benchmarking and Market Dynamics (5th Ed.) (ISR Reports, September 27, 2023), https://research.isrreports.com/reportaction/2023-ecoa-epro-benchmarking-market-dynamics/Marketing

[13] "Suvoda ECOA Earns High Marks in Patient Usability Study," Suvoda, November, 2023, https://www.suvoda.com/insights/all-news/suvoda-ecoa-earns-high-marks-in-patient-usability-study

Section 5

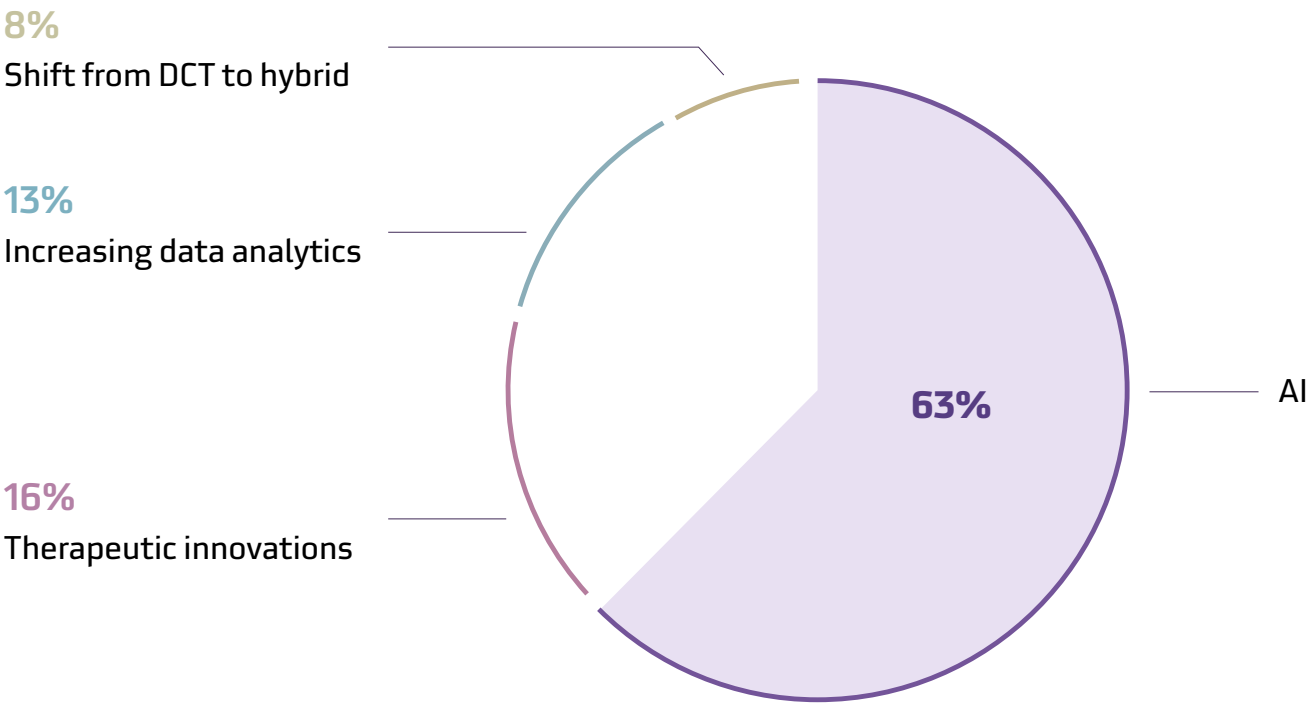
Cautious optimism about AI to drive clinical trial efficiency

Augmenting clinical trial processes with AI

Artificial intelligence (AI) was the dominant technology story of 2023. It appears likely that AI will continue to become increasingly important in clinical trials in 2024 and beyond.

Many clinical trial professionals expect AI to be a predominant influence in the coming year. A recent Suvoda LinkedIn poll showed that 63% of participants anticipate AI to emerge as the leading trend shaping clinical trials in 2024.

4 Key Trends Shaping Clinical Trials in 2024



Source: Suvoda. "What Do You Expect Will Be the Biggest Trend Impacting Clinical Trials in 2024?" December, 2023.

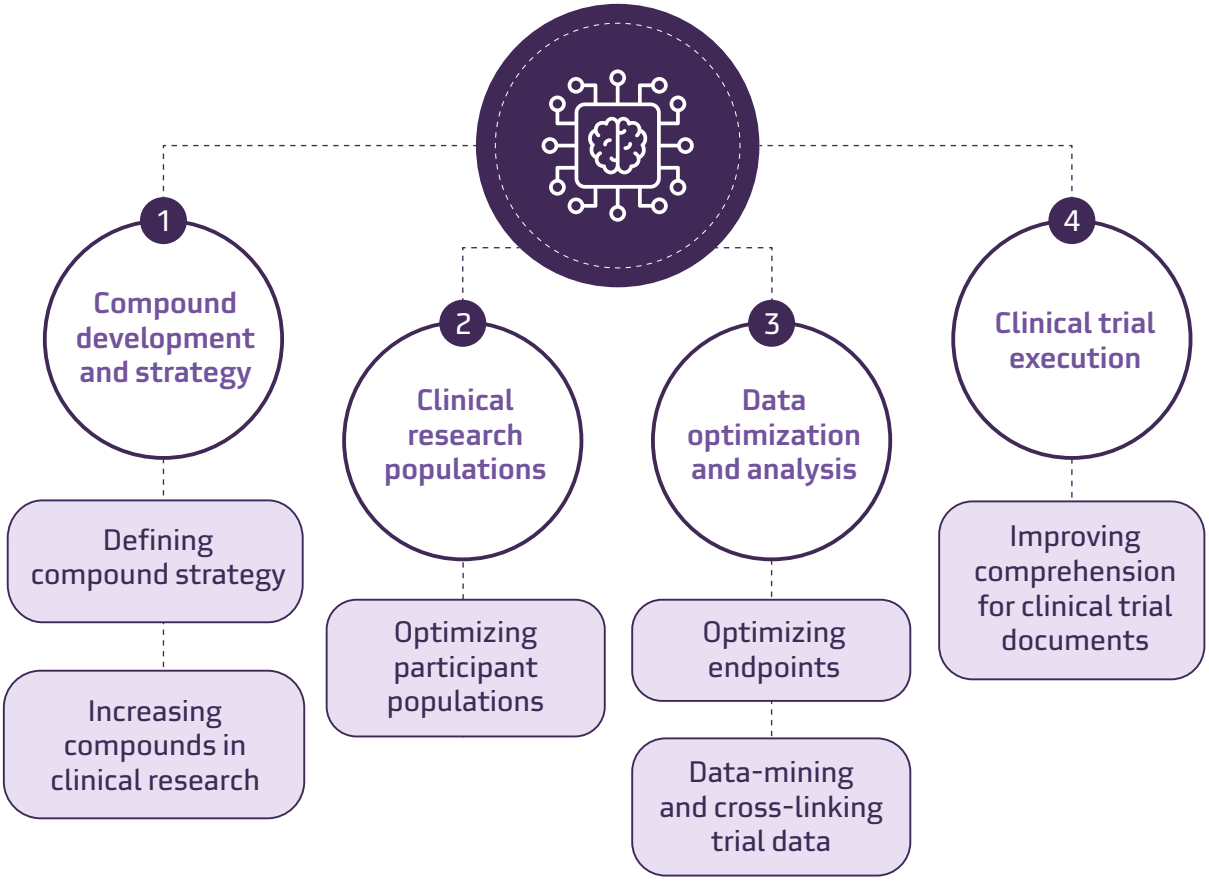
There are many potential applications for AI in clinical research, and much has been written about them.[14] Suvoda has distilled the many opportunities into a framework that categorizes AI applications around compound development and strategy, clinical research populations, data optimization and analysis, and clinical trial execution.

In clinical trial execution, for example, we are already seeing substantial improvements. Notably, at a large community cancer center, AI-enhanced recruitment reduced screening time for 90 patients across three trials from 110 to just 24 minutes.[15]

[14] Anagnostopoulos, Chris, David Champagne, Alex Devereson, Thomas Devenyns, and Heikki Tarkkila. "How Artificial Intelligence Can Power Clinical Development." McKinsey & Company, November 22, 2023. https://www.mckinsey.com/industries/life-sciences/our-insights/how-artificial-intelligence-can-power-clinical-development

[15] J. Thaddeus Beck et al., "Artificial Intelligence Tool for Optimizing Eligibility Screening for Clinical Trials in a Large Community Cancer Center," JCO Clinical Cancer Informatics, no. 4 (November 2020): 50–59, https://doi.org/10.1200/cci.19.00079

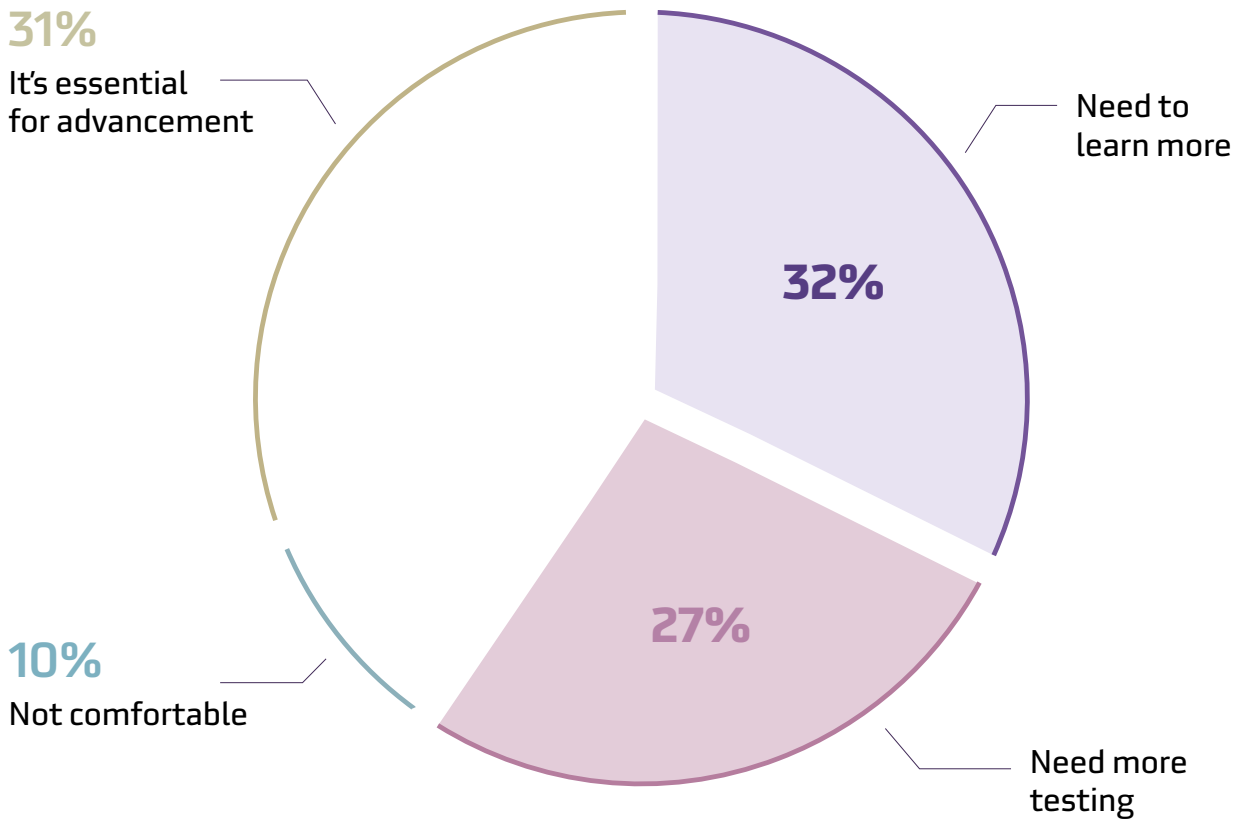
Framework: Potential applications of AI in clinical research



Source: LinkedIn. "34 Big Ideas That Will Change Our World in 2024." December, 2023., McKinsey & Company. "How Artificial Intelligence Can Power Clinical Development." November, 2023.

Within the clear enthusiasm for AI applications in clinical trials, many professionals see a need for a measured and practical approach to AI implementation. For example, in another LinkedIn poll, while nearly one-third of respondents considered AI as essential to clinical trial advancement, roughly 60% wanted to learn more or felt AI needed more testing.

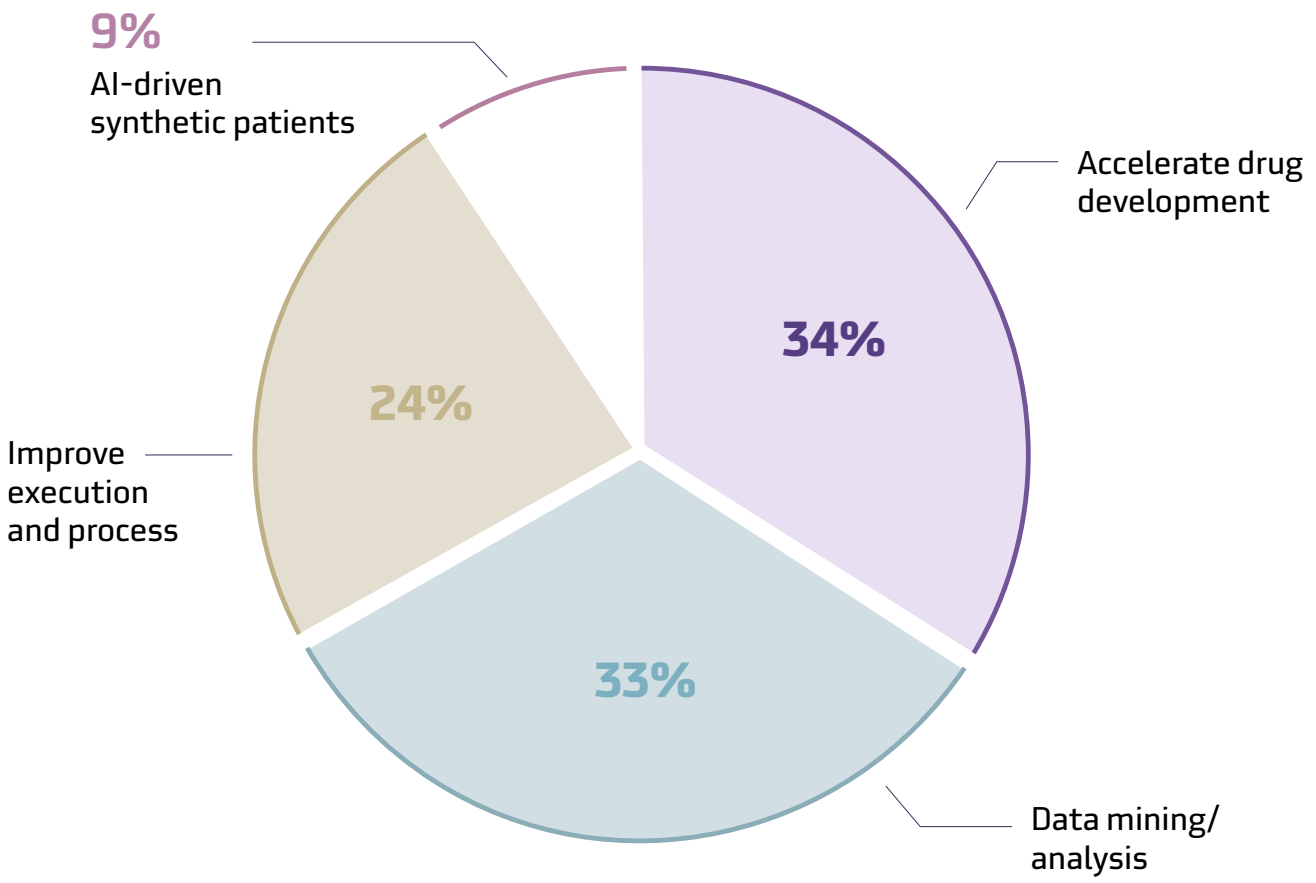
Comfort with AI use in clinical trials



Source: Suvoda. "How Comfortable Are You with AI Being Used in Clinical Trials?" September, 2023.

Responding to another poll, trial professionals identified practical AI applications as the biggest immediate impact of AI in clinical trials. Although ideas like AI-driven synthetic patients are exciting possibilities to push toward in the future, more pragmatic uses were what poll respondents identified as significant at the present.

Biggest impacts of AI in clinical trials



Source: Suvoda. "What Do You Think Will Be the Biggest Impact of AI in Clinical Trials?" January, 2024.

Together, these data suggest that industry stakeholders see a need to take small steps to apply this new advancement ethically, safely, and to the benefit of patients and trials. There is optimism toward leveraging AI technology for clinical trial efficiencies and insights. With thoughtful, step-wise implementation, AI can become a critical tool in shaping the future of healthcare innovations.

Section 6

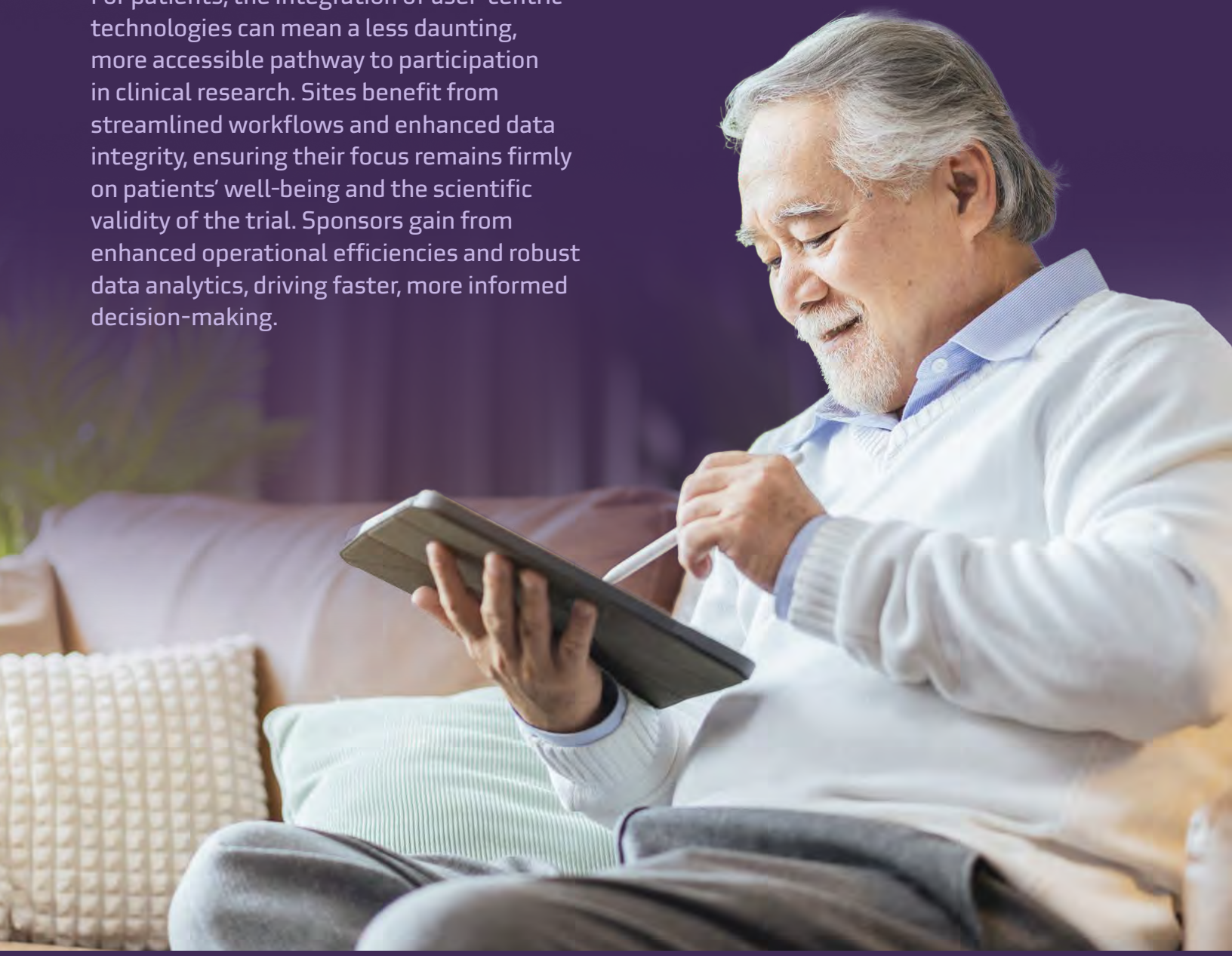
The future of clinical trials

The dawn of a new era in clinical research

As technologies continue to be embedded into various processes throughout clinical trials, it appears we are approaching a new era in medical research. Innovations are enhancing and redefining clinical trials to make research processes more efficient, patient-friendly, and data-driven.

For patients, the integration of user-centric technologies can mean a less daunting, more accessible pathway to participation in clinical research. Sites benefit from streamlined workflows and enhanced data integrity, ensuring their focus remains firmly on patients' well-being and the scientific validity of the trial. Sponsors gain from enhanced operational efficiencies and robust data analytics, driving faster, more informed decision-making.

A new experience for all parties involved in clinical trials has started to take shape, empowered by technology. As clinical trials sponsors, sites, and vendors continue to innovate and adopt these advancements, we are collectively paving the way for quicker, safer, and more effective treatments.

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