

Will Interest in Artificial Intelligence (Finally) Drive Greater Vendor and Tech Consolidation in the Clinical Trial Space?

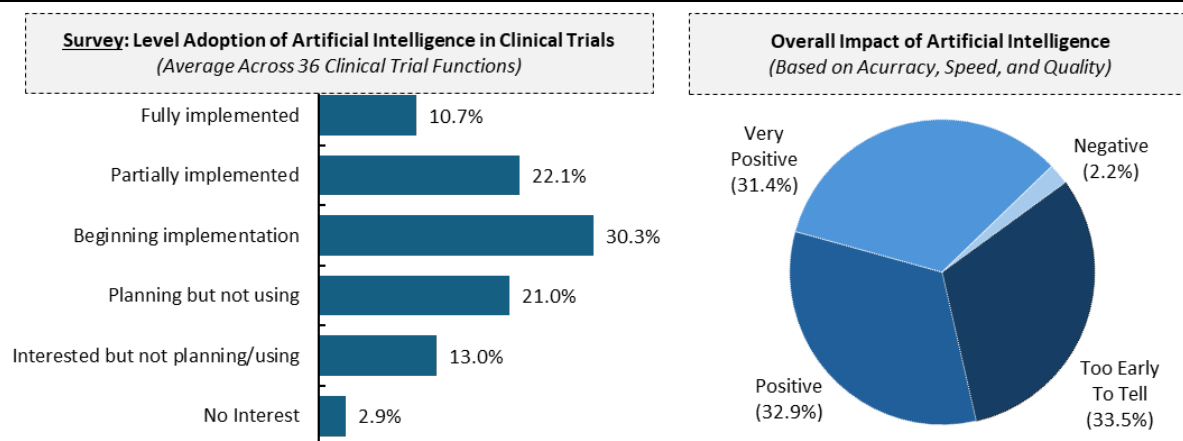
Key Thoughts and Insights Coming Out of the 2025 SCOPE Summit

The Bourne Partners team attended the 2025 Summit for Clinical Ops Executives (SCOPE) in Florida last week to meet with software vendors, site operators, and biopharma executives to get “boots-on-the-ground” visibility to software adoption trends in the clinical trial space. We believe that there is a consensus understanding that integrated software/technology platforms generate a number of benefits for their users, including accelerated clinical trial timelines, enhanced data quality, scale efficiencies, and volume-based pricing. This, in turn, should lead to opportunities for greater consolidation among “point” software/tech-enabled service solution vendors.

In our view, **the adoption of integrated technology platforms could be accelerated in the coming years by competitive pressures to adopt artificial intelligence (AI)**. AI requires access to large quantities of quality and reliable data. With integrated technology platforms, data can be captured and updated in one place, improving data quality and reliability and creating a single source of truth across all clinical trial activities. Also, integrated platforms reduce the risk of lost and erroneous data that can occur due to double-data entry and the interfacing of disparate software applications. *For more discussion, see our recent deep-dive market research reports on clinical trial software technologies ([Link](#); January 22, 2025) and on clinical trial site networks ([Link](#); September 12, 2024).*

Interest in clinical trial software technologies appears to be increasing with over 4,000 attendees at this year’s SCOPE Summit in Orlando, Florida. This was up from just over 3,500 in 2024 and 3,300 in 2023. *By far*, the top topic of conversation at SCOPE was artificial intelligence (AI) -- followed by the potential impact of the second President Trump administration and the increasing market influence of clinical trial site networks. We think that the rising interest in AI for clinical trials has a number of derivative implications, including (among others) the need to eliminate “data silos” caused by the adoption of disparate “point” software solutions.

Figure 1: Adoption of AI is Still Limited, But Early Feedback is Broadly Positive (Survey Data)



Source: Presentation by the Tufts Center for the Study of Drug Development at the SCOPE Summit (February 5, 2025)

1) Thoughts on the Current State of Artificial Intelligence in Clinical Trials

Feedback at SCOPE confirmed that artificial intelligence (AI) for clinical trials is very much in its early days. Based on our conversations with sponsors, CROs, site networks, and software vendors, the general perception is that AI has only achieved about ~10% of its expected potential, to date, in clinical trials. This aligns with survey data presented at SCOPE by the *Tufts Center for the Study of Drug Development* (Tufts CSDD). The Tufts CSDD surveyed 302 executives at biopharma sponsors and CROs on their level of AI adoption across 36 different clinical trial activities. The majority of survey respondents reported that their AI adoption was still in either the planning stage or in implementation. On average, only 10.7% of activities were reported to be “fully implemented” on AI. Unsurprisingly, this percentage skewed higher among larger sponsors and CROs (as measured by the number of active clinical trials at the respondent organization) and higher for more complex therapeutic areas (with oncology having the highest rate of AI usage). Also, for those having fully or partially implemented AI, early feedback was very positive with an average time savings reported to be 18%. Refer to Figure 1 on the prior page.

Figure 2: AI Use Cases Have Tended to Gravitate Around Document Generation

Survey Question: In Which Areas Are YOU Experienced When it Comes to AI at Your Organization?

Top Responses	Number	Percent
Literature Reviews	80	24.5%
Content Development for Educational Materials	60	19.9%
Protocol Design -- Writing	56	18.5%
Patient Narratives	51	16.9%
Data Analysis -- Imaging Data	39	12.9%
Regulatory Submissions	39	12.9%
Identification of Diverse Populations	36	11.9%
Consent Form Development	35	11.6%
Endpoint Analysis	35	11.6%
Data Analysis -- "Omics" Data Such as Proteomic Data, Metabolomic Data, Etc.	34	11.3%
Protocol Design -- RWD in Inform Endpoints	34	11.3%
Protocol Design -- RWD in Inform Eligibility Criteria	34	11.3%

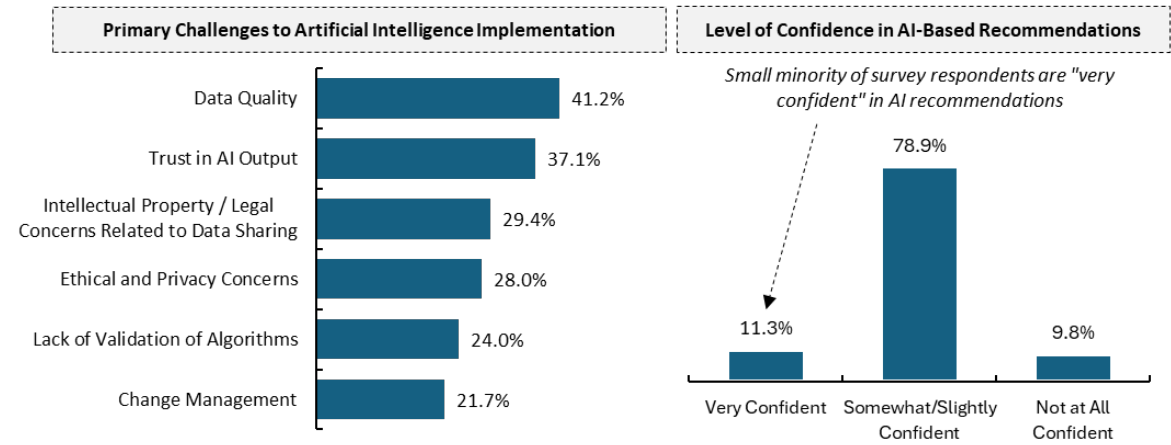
Source: Presentation by the Tufts Center for the Study of Drug Development at the SCOPE Summit (February 5, 2025)

A number of panel discussions at the SCOPE Summit highlighted use cases for AI. Early use cases for AI seem to be focused on lower risk administrative “scut” work with limited ethical considerations or impact on patient safety. Over time, however, users hope to funnel experience (and financial savings) gained here into more clinical and patient-facing activities. Specifically, use cases seem to be mainly centered on document generation -- e.g., literature reviews, content development for educational materials, protocol design (writing), and regulatory submissions. To a lesser degree, we heard use cases in image and data analysis, site monitoring, and patient recruitment. This includes detecting data anomalies in site performance as part of risk-based quality monitoring (RBQM) programs. RBQM is an important component of the just released ICH E6 (R3) guidelines, so we expect an increasing focus here in the coming years. Using AI, sponsors report being able to generate monitoring reports in 80% less time coupled with the ability to generate follow up letters to investigators at the push of a button. Also, in some cases, AI has significantly helped with clinical research associate (CRA) job satisfaction with one large pharma company highlighting that CRA turnover declined from 35% annually (pre-AI) to less than 2% (post-AI). Refer to Figure 2.

The top challenge that we heard related to AI adoption was data access and quality. One first step towards improving data access and quality, in our view, is an optimization of the underlying information technology architecture. This includes the adoption of more integrated software/technology platforms. Also, several panel discussions highlighted a lack of trust in the AI output as another major barrier to AI adoption. There is no benefit

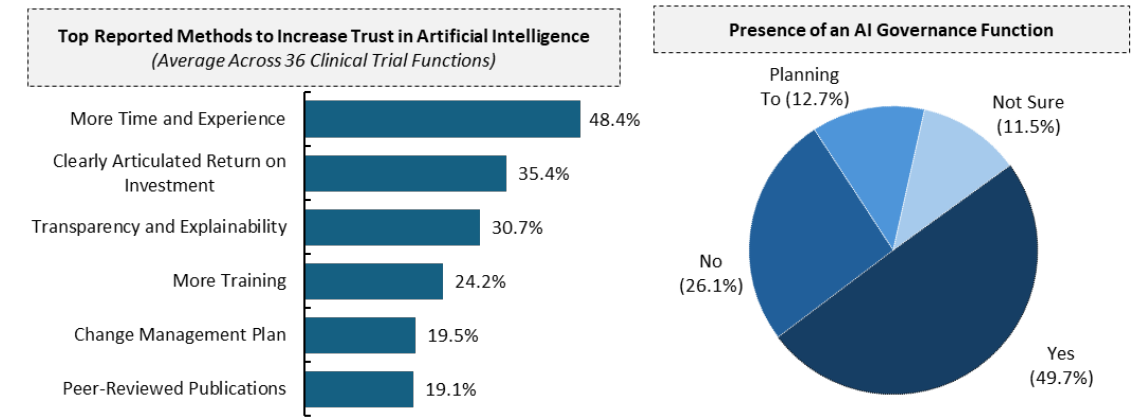
from AI software that is not used. And, in situations when the software output is not trusted, employees often feel the need to manually check the recommendations, which undermines the rationale for adoption. The best solution here is simply time and experience using the software. Having governance structures in place can also help to build trust in an AI software application. Notably, only about half of the sponsors and CROs we spoke with at SCOPE had formal AI governance structures in place to prioritize and vet AI applications, and a number of those who did were not confident in its effectiveness. So, there appears to be considerable work for the industry here to bolster trust. Refer to Figures 3 and 4.

Figure 3: Poor Data Quality Leading to Low Confidence in AI-Based Recommendations



Source: Presentation by the Tufts Center for the Study of Drug Development at the SCOPE Summit (February 5, 2025)

Figure 4: Trust in and Governance of AI Applications

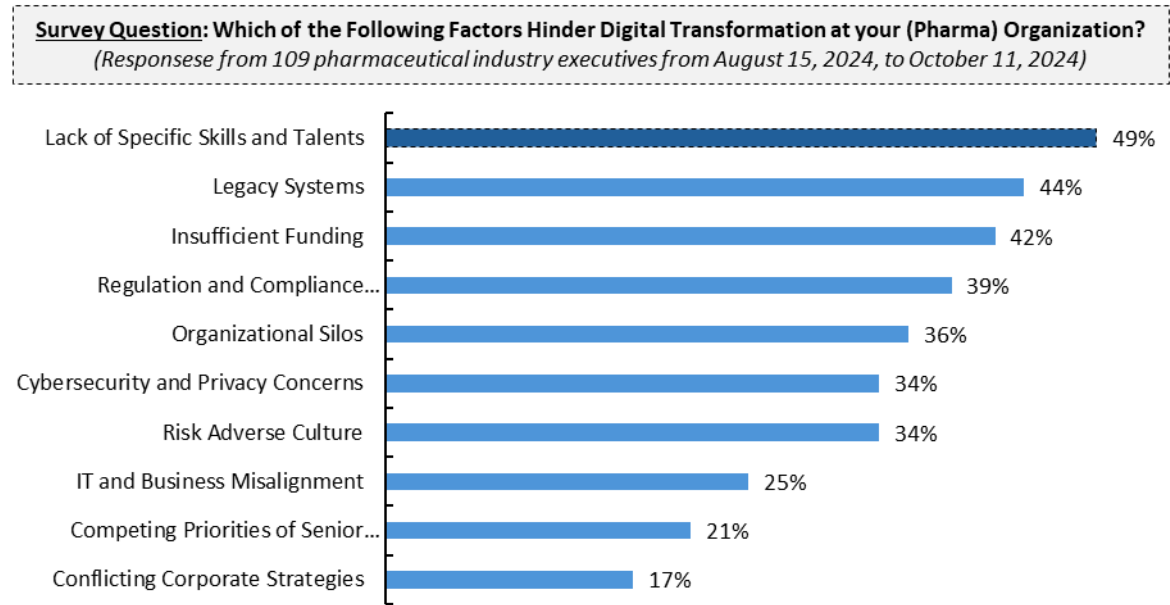


Source: Presentation by the Tufts Center for the Study of Drug Development at the SCOPE Summit (February 5, 2025)

Finally, we continue to hear complaints about shortages of technical staff, e.g., data scientists, engineers, and developers, etc. Essentially, the rapid pace of innovation, including advances in generative AI, has outstripped the ability of pharma company training programs to keep up -- creating a growing "skills gap." In fact, the "lack of specific skills and talents" was identified as the top barrier to digital transformation efforts in the pharma industry by 49% of respondents in a recent GlobalData survey. Over the last five years, many pharma companies have turned to outsourcing for all or part of their information technology functions, including governance, change management,

implementation, and application maintenance. We expect this shift to “shared services” to continue for the foreseeable future. Refer to Figure 5.

Figure 5: Shortages of Information Technology Staff Could Hamper AI Adoption



Source: GlobalData (“Digital Transformation and Emerging Technologies in the Healthcare Industry” (November 2024)

2) Thoughts on the Future Success of Artificial Intelligence Software in Clinical Trials

We have received a lot of questions on what makes one particular artificial intelligence (AI) software application successful (versus another). Virtually all the biopharma presenters at the SCOPE Summit spoke of an immense organizational-wide interest in AI adoption. There is a consensus that the availability (and use) of AI in clinical trials will become ubiquitous at some point. Yet, outcomes generated by AI can vary. Stories of AI software failing to live up to its original expectations have become commonplace across all healthcare. Our conversations at the SCOPE Summit surfaced three factors that differentiate AI solutions from each other -- 1) access to quality (proprietary) data, 2) ongoing supervision on the front and back end of AI-enabled workflows, and 3) change management.

- *Access to Quality (Proprietary) Data.* In a future environment of full AI adoption, companies will compete based on their ability to access unique and curated data sources. Curating data is often over half of the total cost of an AI strategy, in our opinion. The quality of the output of AI is only as good as the input data. Clinical research involves a wide range of non-relatable data sources, e.g., medical record data, billing/claims data, socio-demographic data, script and specialty pharma data, genetic data, and health equity data, among many others. Also, much of the most valuable information in healthcare is unstructured in nature in the form of physician notes. Finally, there is a need to maintain compliance with privacy regulations. All of this results in healthcare data being difficult to work with. As one vendor at the Summitt told us: “In the Land of AI, data is king.”
- *Ongoing Supervision.* Because AI is trained on historical data, the value of its insights and recommendations can deteriorate over time as environmental circumstances change. Human subject matter experts are almost always needed to train and track the performance of algorithms in partnership with data scientists. Essentially, humans

are needed to provide the necessary context to information being fed to the AI algorithms. This is an ongoing iterative process that requires commitment by both the vendor and the customer.

- **Change Management.** AI software needs to be actually trusted and used in order to be disruptive to existing workflows. Organizational resistance to AI (e.g., fear of change), particularly among employees, was a constant topic of discussion. As such, we think the support of advisory services from the vendor, although expensive, can be very helpful to optimize the implementation process and to rethink workflows in new ways. One does not want to automate existing bad practices. *As Henry Ford once said: "If I had asked my customers what they wanted, they would have said a faster horse."*

It is important to note that all three of these factors of success involve the coupling of AI with a human being. While there may be limited scenarios in which AI software can truly function autonomously, a constant theme at the SCOPE Summit was that AI should be seen as an enhancement of what a human can do (not a replacement). For instance, for document generation, the AI software can create "first drafts," perform consistency checks, and flag any regulatory issues. The human partner then would need to provide context and tailor language for nuance and compliance. Similarly, AI software can provide preliminary data analyses for humans to subsequently customize. Also, for site and patient monitoring, the AI software can detect subtle anomalies in data in real-time for humans to investigate and take the next step. Finally, AI can help screen for high performing investigator sites and predict enrollment patterns. Humans can evaluate ethical issues and intervene to address site challenges.

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