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2025 SCOPE Conference Emphasizes AI and Better Technologies to Improve Patient Outcomes

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The 2025 SCOPE Conference (Summit for Clinical Ops Executives), held last week in Orlando, FL, brought together more than 4,500 industry leaders, innovators, and experts in the clinical operations field. With an agenda covering a wide array of topics, including clinical trial planning and management, patient recruitment and retention, data management, and regulatory compliance, the conference highlighted the industry's collective focus on improving patient outcomes by leveraging cutting-edge technology. While these new technologies will undoubtably shape the sector, they will also have ever-evolving legal ramifications — meaning industry participants must also prioritize legal compliance and risk mitigation strategies.

AI Integration Into Clinical Trials. Predictably, the dominant theme from the conference was the integration of artificial intelligence (AI) into various aspects of the clinical trial life cycle. While most attendees and presenters could agree on the immediate use of AI as an efficiency tool for formerly tedious jobs such as data analysis and aggregation, there were a few mold-breaking use cases on display. Among these breakthrough generative AI use cases were companies developing tools targeted at materials generation, trial design and optimization, patient selection and site engagement, and pre-clinical trial analyses.

EHR to EDC Integration. Another focus of the conference was the unification of the industry through improved integration of electronic health records (EHR) and electronic data capture (EDC) systems. Integration efforts aim to streamline data flow, reduce redundancies, and enhance the accuracy and efficiency of clinical trials. The integration of EHR to EDC was emphasized as a critical step toward creating a more cohesive and efficient clinical trial ecosystem.

Wearable Technology and Patient Platforms. Lastly, there was a strong emphasis on wearable technology and providing patients with easier clinical trial engagement, in order to obtain more detailed patient data (to subsequently feed into AI analysis tools) and achieving better retention outcomes. The post-COVID "work-from-home mindset" was identified as a critical factor in providing patients with more flexible tools to engage in clinical trials.

Our Legal Takeaways. As organizations continue to integrate AI and other new technologies into their daily operations, there will continue to be new legal developments to consider. Here's what we recommend:

1. *Stay Informed on Regulatory Changes***.** As AI use cases and capabilities continue to evolve, legislation is continually shifting in response. State laws can vary across jurisdictions and governmental agencies are regularly issuing new guidance and policies with respect to AI use. Organizations should be prepared to and expect to regularly pivot their operations and procedures as new laws and guidance are enforced.

2. *Implement and Monitor Data Privacy and Security Measures.* With the rise of new technologies, data privacy and security are more important than ever. In addition to conducting regular audits, policies and procedures should be regularly updated for compliance with current laws and regulations, such as the significant proposed amendments to the Security Rule under HIPAA that were recently published by the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).
3. *Develop and Follow Responsible AI Guidelines.* Responsible AI use should become a central focus of an organization's operations, and operational guidelines should be regularly updated to align with emerging best practices and ethical standards. This includes measures that account for AI's accuracy limitations and potential bias that can create significant risk exposure for an organization.

The increased automation that will come from new technologies will allow the industry to break down old processes and move more efficiently through the clinical trial process and identify positive outcomes that previously could have flown under the radar. This inevitably means more therapies, devices, and tools to help ease patient suffering. However, this rapid advancement also necessitates organizations to take a vigilant approach to their legal compliance and risk mitigation strategies.

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