

Crucial Data Solutions Names Dr. Leigh J. Mack Chief Medical Officer Amid Industry Al Shift

RENO, NV, UNITED STATES, July 17, 2025 /EINPresswire.com/ -- Crucial Data Solutions (CDS), provider of the industry's only end-to-end eClinical platform available as a native mobile app, today announced that Leigh J. Mack, MD, PhD has rejoined the



company as Chief Medical Officer. Dr. Mack, who previously served in this role from 2017 to 2021, brings renewed focus to aligning artificial intelligence (AI) with the future of regulatory compliance and clinical trial execution.

A recognized leader in clinical research and healthcare automation, Dr. Mack returns at a pivotal time for the industry. In 2025, the U.S. Food and Drug Administration (FDA) initiated a full-scale rollout of internal generative AI tools, accelerating scientific review processes for Investigational New Drug (IND) applications. This signals a turning point in how data will be reviewed, verified, and submitted, creating urgent demand for interoperable, AI-ready software.

"As regulators evolve, so must the platforms that serve them," said Dr. Mack. "In 2025, FDA started using AI to evaluate and review components of new drug applications and parts of clinical trial documents. Today, CDS is ready to support this shift with a seamless, validated clinical trial platform that captures, verifies, and transmits data to AI systems while maintaining full regulatory compliance and data integrity. Regulatory has gone AI—are you ready? At CDS, we are."

Dr. Mack became a boarded fellow in clinical research (Academy of Physicians in Clinical Research [APCR]) and a Certified Principal Investigator in 2016. He has decades of experience integrating advanced automation, including robotic process automation (RPA), task mining, and large language models into clinical trial ecosystems. His innovations have enabled sponsors and CROs to accelerate patient identification, optimize operational efficiency, and improve data quality across global studies.

As Chief Medical Officer, Dr. Mack will oversee clinical strategy and regulatory innovation across the TrialKit platform, which offers fully integrated capabilities from eConsent and EDC to virtual

visits, ePRO, and AI-enabled reporting and analysis. His deep understanding of FDA and EMA frameworks positions CDS to help research teams not only meet, but lead, the new standards in AI-assisted evidence generation.

"With Leigh's leadership, we're reaffirming our commitment to building software that is not only modern and mobile, but also future-ready," said Paul Grady, Chief Executive Officer of CDS. "TrialKit continues to be the platform that scales with our customers, offering the configurability, interoperability, and compliance needed for today's most demanding clinical trials. As Al reshapes regulatory review and data workflows, CDS is proud to be at the forefront of this evolution."

For more information about Crucial Data Solutions and the TrialKit platform, visit <u>www.crucialdatasolutions.com</u>.

About Crucial Data Solutions

Founded in 2010, Crucial Data Solutions (CDS) is the provider of TrialKit, the most innovative eClinical platform on the market. Trusted by sponsors, CROs, and research institutions worldwide, TrialKit supports the end-to-end management of clinical trials and non-interventional studies. CDS is committed to making advanced data collection and management solutions accessible to all, combining affordability, scalability, and cutting-edge technology to meet the evolving needs of the life sciences industry.

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