FOR IMMEDIATE RELEASE

Clinical Data Management Leaders Reveal Underlying Challenges Impacting Trial Timelines

Faster time to finalize protocol design and upfront planning to manage data outside the eCRF are keys to more efficient trials

New study also highlights need to transform clinical data management practices to enable risk-based approaches

BOSTON and PLEASANTON, CA — June 21, 2018 — At the upcoming DIA 2018 Annual Meeting, Tufts Center for the Study of Drug Development (CSDD) will preview its study findings on the root causes for delays and inefficiencies impacting trial timelines. As a follow-up to the *2017 eClinical Landscape Study*, sponsored by Veeva Systems (NYSE:VEEV), Tufts CSDD spoke with more than 40 data management executives about the top challenges and opportunities in clinical data management. Findings indicate there is a significant opportunity to transform data management practices for greater agility and to accelerate adoption of risk-based approaches.

Protocol changes, amendments, and uncertainty in finalizing the protocol design cause upfront delays that have a negative downstream impact on key data management activities. Clinical leaders indicate that improving processes for early consensus and leveraging modern, agile systems that better adapt to protocol changes can significantly streamline execution and speed timelines.

Executives also expressed concerns with the ability to manage data beyond eCRF. They believe having a steady stream of comprehensive and clean data throughout the trial, much of it prioritized through risk-based approaches, will assist in faster decision-making and shorter overall cycle times.

“Protocol design is taking longer to finalize and undergoing more iterations, creating challenges in data management and overall trial efficiency,” said Ken Getz, research associate professor and director at the Tufts Center for the Study of Drug Development. “Also, data volume supporting clinical endpoints is rapidly increasing. More data comes from sources other than eCRF and lab data, creating substantial integration and coordination difficulties for data management.”

“There is tremendous opportunity to address the limitations of traditional data collection to accelerate clinical trial timelines,” said Henry Levy, chief strategy officer at Veeva. “As the number of data sources continues to rise, data management teams will have a greater need to see all their clinical data, at all times. Veeva’s vision is to help organizations seamlessly bring their data together throughout the course of a trial and make the transition to risk-based trials where data is collected and analyzed for a current, holistic view of the patient.”

Join Veeva and Tufts CSDD at the DIA 2018 Annual Meeting for more details on the study results and their implications. Don’t miss their session on Tuesday, June 26, at 1:10 p.m. in theater #2 of the exhibit hall. Richard Young, vice president of Veeva Vault EDC, will also share Veeva’s vision for the future of clinical data management. Learn more at veeva.com/DIA2018.

Additional Information
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About the Tufts Center for the Study of Drug Development
The Tufts Center for the Study of Drug Development at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide

range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues. For more information, visit csdd.tufts.edu.

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