

Align Clinical CRO Publishes New Operational Data Exchange Standard for Life Sciences Industry Input

Industry group's first technology standard to make it easier for sponsors and CROs to share information during clinical trials

BARCELONA, Spain — 15 January 2019 — Align Clinical CRO, a life sciences industry standards group that includes eight leading contract research organizations (CROs) and Veeva Systems (NYSE:VEEV), today announced its first technology standard is available for industry review and input. The new operational data exchange standard aims to facilitate seamless information sharing during clinical trials and give sponsors greater visibility into study execution when working with CROs.

Cross-functional domain experts developed the standard to improve the exchange of information between sponsors and CROs during phase II and phase III clinical trials. The standard supports operational data related to milestones and metrics for areas such as general trial information, study start-up, patient enrollment, and data management. The operational data exchange standard also provides technical considerations when developing APIs for clinical trial systems.

Align Clinical CRO is dedicated to creating open technology standards, with input from across the industry, that make it easier for sponsors and CROs to work together during trials. The group is now soliciting public review and feedback on its operational data exchange standard through March 15, 2019 at AlignClinicalCRO.org. Once industry input is received, Align Clinical CRO will make the final standard available in spring 2019.

As drug innovation has increased across the industry so has outsourcing to CROs as a way for sponsors to run trials faster and improve operational efficiency. By 2020, sponsors are expected to outsource 72% of clinical trials to CROs.¹ Pre-competitive industry standards can help bring more consistency to trial management and improve sponsor visibility into trial processes.

"Open technology standards can transform clinical trials to be more productive, reduce operational costs, and speed execution across the industry," said Henry Levy, president of Align Clinical CRO. "Align Clinical CRO is committed to improving CRO collaboration with life sciences companies and reducing the time and effort in product development."

To learn about the Align Clinical CRO mission and stay up-to-date on the standards in development, visit AlignClinicalCRO.org.

About Align Clinical CRO

Align Clinical CRO is an industry standards group founded by Veeva Systems and the world's largest CROs. The group is dedicated to creating open technology standards that improve trial execution and collaboration with life sciences companies, making it easier for sponsors and CROs to work together during clinical trials. For more information, visit www.AlignClinicalCRO.org.

###

Contact:

Kiran May Veeva Systems +44-796-643-2912 kiran.may@veeva.com

¹ Research and Markets: The New 2015 Trends of Global Clinical Development Outsourcing Market (January 2015)