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## Leading CROs Form New Industry Standards Group to Improve Collaboration with Sponsors

*Align Clinical CRO to create open technology standards that make it easier for life sciences companies and CROs to work together during clinical trials*

**NEW YORK — March 27, 2018** — Six leading contract research organizations (CROs) and [Veeva Systems](#) (NYSE:VEEV) today introduced [Align Clinical CRO](#), a new industry standards group dedicated to making it easier for sponsors and CROs to work together during clinical trials. Founding members, with input across the industry, plan to help create open technology standards intended to improve trial execution and collaboration with life sciences companies.

For the first time, leading CROs, including [ICON plc](#), [Medpace](#), [Pharmaceutical Product Development, LLC \(PPD\)](#), [PRA Health Sciences](#), [Syneos Health](#), and [UBC](#) are coming together to develop open technology standards to transform clinical trial operations across the entire industry to speed product development.

“There is tremendous potential to enhance clinical trial execution with common technology standards that benefit the entire industry,” said Henry Levy, president of Align Clinical CRO. “The assembly of Align Clinical CRO represents an important industry collaboration to improve the trial process and how the industry works together to accelerate drug development.”

Align Clinical CRO will create open technology standards intended to help increase sponsor and CRO productivity, reduce operational costs, and run trials faster. The group’s first standard is anticipated to be an Operational Data Exchange standard to facilitate seamless information sharing between sponsors and CROs. This is expected to include the definition of a technical standard for data to be exchanged between a sponsor and a CRO relating to the operational execution of a trial, including key metrics and milestone information.

CROs play an integral role in supporting drug development, with clinical outsourcing expected to increase to 50% by 2020.<sup>1</sup> As sponsors run a growing number of trials with multiple CROs, developing pre-competitive industry standards will help bring more consistency to trial management and address the complexity of trial oversight to make drug development processes more efficient.

Align Clinical CRO will post its Operational Data Exchange standard for public review and input later this year, which will also be reviewed and considered as part of the adoption of proposed standards. Visit [AlignClinicalCRO.org](#) to learn about the group’s mission and stay up-to-date on the standards in development.

### What Align Clinical CRO Members Are Saying:

“Leading experts are coming together in Align Clinical CRO to streamline how data is shared between CROs and sponsors during trials,” said Thomas O’Leary, chief information officer at ICON plc. “We look forward to contributing to the group and creating standards that drive greater speed and productivity across the industry.”

“Align Clinical CRO will play an important role in helping the industry accelerate innovation and get new treatments to patients faster,” said Mark Roseman, senior vice president of clinical operations at Medpace. “We are excited to join forces with like-minded CROs that want to move the industry forward and make clinical trial execution more efficient.”

“This is the first time CROs are coming together to make this commitment to transform clinical trials across our industry and we are excited to be part of this effort,” said Michael Brooks, executive vice

<sup>1</sup> CRO Industry Primer: A 2016 Credit Suisse Research Analysis, June 2016

president of product registration at PRA Health Sciences. “This shows our mutual commitment to make the drug development process more efficient and to help bring needed therapies to market more quickly.”

“Align Clinical CRO will help speed the timeline for gaining new therapy approvals for patients,” said Rachel Stahler, chief information officer at Syneos Health. “By creating a vehicle for CROs to collaborate and share actionable insight with sponsors, we can improve operational delivery and streamline the increasingly complex trial process.”

“UBC is excited to join Align Clinical CRO,” said Brett Huselton, senior vice president of commercial strategy for product and opportunity development at UBC. “We are committed to developing open technology standards that benefit the entire industry and make clinical trial processes more efficient.”

#### **Additional Information**

Connect with Align Clinical CRO on LinkedIn: [linkedin.com/company/align-clinical-cro](https://www.linkedin.com/company/align-clinical-cro)

Follow @AlignCRO on Twitter: [twitter.com/AlignCRO](https://twitter.com/AlignCRO)

#### **About Align Clinical CRO**

Align Clinical CRO is an industry standards group founded by Veeva Systems and the world’s largest CROs, including ICON plc, Medpace, Pharmaceutical Product Development LLC (PPD), PRA Health Sciences, Syneos Health, and UBC. 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](http://www.alignclinicalcro.org).

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#### **Contact:**

Lisa Barbadora  
Barbadora Ink  
610-420-3413  
[lbarbadora@barbadoraink.com](mailto:lbarbadora@barbadoraink.com)