Webinar Q&A

Managing Risk and Oversight in Decentralized Clinical Trials Using Industry Standards

Recorded October 30, 2019

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Hosted by:
ExL Events

Questions submitted by audience participants.
Responses provided by Dennis Salotti.

Q1) Are you able to share any names of sponsors who are leading the way with adoption of these technologies?

We maintain anonymity concerning specific company affiliations. However, many companies that are progressive in their adoption of these technologies often share their experiences at conferences and meetings. ExL's Virtual Clinical Trials Conference is one such example. Others are organized by eyeforpharma, CBI/Knect365, The Conference Forum (DPharm), and Cambridge Healthtech Institute.

Q2) Are there any valid statistics on ROI using decentralized trials that you know of?

I have not seen this presented at the industry level but rather in presentation of specific case studies by sponsors and solutions providers. As these are specific and typically individual contexts, I would not consider them universally extrapolatable or reproducible. Further experience is needed before valid ROI statistics for DCTs are well understood.

Q3) Do you see organizations just using decentralized trials when they aren't ready because the industry is moving that way?

I see organizations exploring DCT approaches as one of many potential solutions to address the perennial challenges faced by the industry, most notable, clinical trial participation, and engagement. Our research suggests firms are conservative in how they implement DCTs and are not yet implementing DCT tools and approaches at a scale that has the opportunity to drive transformative change. I do think there may be an element of 'pack mentality,' however, I do not think it is the driving force behind interest in DCTs – I think this stems more from pressures to recruit and retain trial participants and the negative implications of failing to do so.

Q4) Are there standards/compliance measures (Operational and QA) for sponsor oversight of CRO quality during clinical trials?

Yes, the Avoca Quality Consortium provides a framework for CRO oversight and a quality metrics framework that fits within that overall quality oversight framework. AQC Member companies have access to these resources in the AQC Knowledge Center.

Q5) Have you noticed an increase in clinical trials in the dietary supplement space?

We do not monitor the dietary supplement space, so I cannot comment on that. Clinicaltrials.gov may be a resource to look at to analyze the US trials for trends related to your question.