Roundtable:
External Ethics and Compliance Perspective 2 - Third Parties - CROs

Moderator: Dave O'Shaughnessy, VP Compliance, Quintiles

Panel Members:

Dr. Douglas Peddicord, PhD
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A Great Opportunity to Discuss Third Party Views and Challenges

- CROs provide very diverse services to sponsors/healthcare companies
  - Basic research, all aspects of clinical research and the associated regulatory requirements, laboratory/analytical work, submissions/registrations of products, support for marketing, market access, medical communication and educations, sales forces etc.
- CRO have extensive experience of working in regulated environments (GxP etc.)
  - Dealing directly with government agencies and their expectations (in regulatory interactions, regulatory inspections) etc.
  - Alongside and/or on behalf of sponsors
- Sponsor / CRO Strategic partnerships, preferred provider models have increased
- Challenge of creating an effective ethics and compliance interface
  - Strategically, operationally, and governance
- Opportunity to explore some aspects today

Given the importance of third parties to pharma/healthcare companies, this session aims to provide an opportunity for the audience to hear directly from ACRO on:

- Sharing views and perspectives on the importance of ethics and compliance
- Providing some views/feedback on how sponsor/customer expectations are received / impact CROs
- Exploring any ideas on how this may continue to improve
- Giving the audience an opportunity to think about how best to engage third parties/CROs as they meet / execute their compliance oversight obligations / responsibilities

For third parties / CROs – do you fully understand the interfaces, relationships and dependencies?

Audience invited to explore the following topics with the panel:

- Transparency & Data Privacy
- Third Parties – R&D, GxP, ABAC, FMV, Disclosure
- R&D – Commercial Interface – Medical Affairs, Medical Governance
- Global /Regional / Local Challenges – post-marketing surveillance, late phase studies