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Sum-up of workshop conducted in UK 6 April 2017

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Third party vendor management – Pharma Sponsor's Perspective. Who's responsibility should it be?

Rikke Winther (Lundbeck)

Moving from a traditional unit-based outsourcing model to a fixed price model where third party vendors are contracted and managed by the clinical CRO, who is also fully liable for subcontractors.

- Prerequisites for success
- Challenges with change orders
- CRO's mitigation of risk
- Important of trust and clear lines of communication.

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Considerations in managing third party risk through the contracting process

Hannah Curtis (CMS Cameron McKenna LLP)

Management of third party suppliers through prime vendor CROs creates opportunities to better utilise study budgets and manage the risks associated with the delivery of clinical studies.

- Responsibilities, clearly identified service levels, insurance, liabilities and indemnities as well as governing law and mechanisms for dispute resolution.
- Contractual mechanisms for management of third party vendors, specific goods and services to be provided, dependencies, audit requirements and how to report on progress to Sponsor.

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CRO Vendor Management Approach

John Murray (INC Research)

The pharma/biotech industry faces a dilemma. With shrinking resources they are looking to outsource more and more activities to CROs, including the management of specialist services provided by third party vendors. And yet the majority of sponsors still have concerns on the ability of CROs to provide this service.

- Means of addressing this challenge through Clinical Vendor Management Group and subject-matter experts
- Discussions

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Third Party - Dealing with Sponsors and CROs

Scott Ohanesian (Quick Stat)

Third party vendors are being asked to do more. Sponsors are looking to reduce the number of organisations they manage, reduce liability commitments and leverage cost benefits of volume that third party vendors can negotiate (economies of scale). Often the sponsor requires the vendor to integrate different resources that include their own and those of other suppliers. Management during the study can involve providing tracking data and coordinating discussions.

- Different case stories were presented and discussed

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What does ICH GCP (R2) mean for the management of Sponsor/CRO relationships and what do we have to prove?

Geoff Taylor (Eisai)

With the introduction of ICH GCP (R2) the question arises as to what it means to the industry as a whole and sponsor-CRO relationships.

- Key point is the adoption of appropriate quality management systems using a logical risk-based and continual-improvement approach. Overall approach is a multifactorial assessment of the likelihood of errors and deciding on the possible impact of these errors.
- Perhaps the biggest change seems to be the transfer of responsibilities where any trial related duty or function that is transferred to and assumed by a CRO should be specified in writing.

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Interactive session

Teams were directed to consider risks, challenges and benefits associated with three different contracting models.

- The overall conclusion was that all three approaches offered benefits and challenges.
- The consensus was that the approach should be tailored to each individual study.
- Discussions focused on using the best expertise available to make appropriate decisions on third party service providers through open considerations between the sponsor and the CRO.

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How does the contract help/hinder the successful delivery of a project

John Faulkes (PPMLD)

How can the contract itself help and/or hinder delivery of a successful project?

- How sponsors can ensure the performance of third party vendors without getting involved in micro-management?
- Useful motivational factors and tactics to engage service providers and how they can be captured in the contract.
- Case studies of how differences between the sponsor's expectations, the scope of services and the contract can result in dissatisfaction for all parties. This was followed by suggestions on how such failing may be avoided.

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