Third Party Contracting – A CRO Perspective

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April 27, 2017

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Discussion Topics

1. Engaging a CRO
2. The Various Approaches & CRO Considerations
3. Case Study
4. Open Discussion

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1

• Utilizing a CRO for Third Party Contracting & Management

Why

- Client Convenience / Single Payee
- Leverage CRO global footprint
- Previously negotiated contracting terms and established relationships with vendors.
- CRO, as SME, can flag unreasonable risk.

When

- Early, often, and as identified.

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2 • CRO Manages Vendor

Request Received –
Client requests CRO to manage Vendor.

Process Established –
Client holds the contract with the Vendor.

Vendor Selection –
CRO can offer a list of frequently used vendors.

Management –
CRO manages Vendor during the course of the study.

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2 • CRO Contracts with & Manages Vendor

Request Received –

Client requests CRO to contract and manage Vendor.

Vendor Selection –

CRO offers a list of vendors for Client Consideration.

Process Established –

CRO will hold the contract with the Vendor

Contract Engagement –

CRO negotiates and executes agreement with Vendor.

Management –

CRO manages Vendor during the course of the study.

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3 • Case Study: Risk-Averse Drug Depot

Study Drug - Manufacturing, Labelling

- Early Determination
- Highest Risk
- Risk of Loss to IP
- Client Indemnification

Customs - Importer of Record

- Indemnification for Valuation
- Significant Risk
- Country Mix Critical

Distribution

- Material-Based Risk
- IP indemnification
- Risk of Loss

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4 • Open Discussion

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