

Does a Sponsor Clinical Trial Reporting System fit into a Sponsor/CRO alliance?

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Agenda

- A Sponsor position
 - ◆ How we do it
- The Benefits
- Conclusion

Sponsor Position

How we do it!





Outsourced Model

- Outsource majority of 'hands-on' work
 - ◆ Approx 80%+ of work done by CRO's
- Internal staff
 - ◆ Provide subject matter expertise to project team
 - ◆ Manage work and timelines
 - ◆ Provide oversight of CRO
 - ◆ Liaison between Project Team and CRO
 - ◆ Agree and Provide specifications to CRO

- Have several 'Preferred Providers'
- Mix of Western and 'Low-Cost', as well as a Regional Unit (Shanghai)
- Use about 450 FTE's at these pCRO's
 - ◆ Large volume of studies
 - ◆ Large variety of work

- pCRO use
 - ◆ Our systems
 - ◆ Our processes
 - ◆ Our reporting standards (Based on CDISC)

- Master Service Agreements
 - ◆ Facilitate quick start up & flexibility

- Responsible for training their own staff
 - ◆ ‘Train the trainer’

- Standards in place
 - ◆ Case Report Forms
 - ◆ Database Modules
 - ◆ Algorithms
 - ◆ Presentations (Tables, Listings & Figures)
 - ◆ Documents

- Reporting System
 - ◆ Generic Software

The Benefits

The model brings



- As priorities change:
 - ◆ Can re-allocate CRO resources quickly
 - No scope/contractual issues
 - ◆ Can move work between suppliers
- Can use a mix of suppliers on a given piece of work
- Communication between parties not an issue

- Minimise set-up activities
 - ◆ No contracts - MSA
 - ◆ No “out of scope” discussions
 - Time & materials
 - ◆ Staff pool trained in system/standards
 - Look for staff to be assigned to support our projects for medium term

■ Integration of systems/processes

◆ Upstream activities

- Databasing
- Standards/Algorithms

◆ Downstream activities

- Writing
- Document Management
- Submission compilation
- Regulatory Response

■ Broad Team access

- ◆ Emphasis on ongoing monitoring of data as it is collected
 - Easy access to this by all personnel – internal & external
- ◆ May use several suppliers on a given study
 - Share across different aspects of work – ongoing monitoring, interim & final reporting, DSMB, RMC, etc
- ◆ All internal and multiple external suppliers can all have same access

- Standardisation of Algorithms and tables/listings/figures
 - ◆ Consistent algorithms applied across studies and projects
 - Given the same specifications 2 programmers can often yield different results

- Cross study work
 - ◆ Facilitated in terms of easy access and standards
 - ◆ Regulatory Response work facilitated by standardisation and “knowledge-base”

■ Long Term Audit Trail

- ◆ Different processes used across studies means risk that ‘knowledge’ will be held by individuals and/or a pCRO – need to avoid this

■ Regulatory Inspection

- ◆ Same processes used for all studies facilitates ability to keep everything fit and ready for an inspection
- ◆ Working with 100’s studies, 100’s of staff – need “standards” to keep track of these
- ◆ Efficiency
 - Small inefficiencies multiplied across 100’s studies have serious impact on resources and costs

Conclusion

One model does not fit all situations...



- But, in large scale outsourcing model, this model brings/allows:
 - ◆ Flexibility of resources
 - ◆ Quick (Instant?) project initiation
 - ◆ Integration with other functions/groups
 - ◆ Easy Access to materials
 - ◆ Facilitates use of standards and cross-study work
 - ◆ Sharing of programming code
 - ◆ Long term management of large volumes of studies

- So, the use of the Sponsor system and processes definitely speeds up and facilitates the reporting process (for us)
- Dependant on strong relationship between Sponsor & pCRO's