

Roadmap for Managing Multiple CRO Vendors

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27 April 2017



Managing Multiple CRO Partners

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- Methodology to establish and implement CDISC standards
- Solutions to ensure a successful partnership
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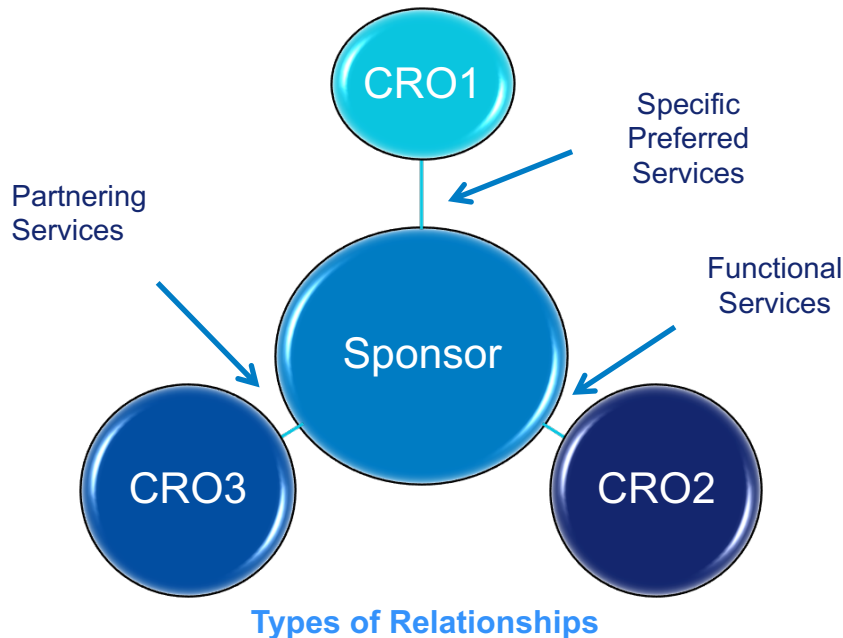
Join me for a tour!



Introduction



Sponsor - focused on bringing innovative therapies to the market



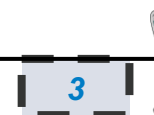
- Share the risks and success
- Governance and oversight is critical to success
- Cooperative agreements brings together people and tools from both organizations.

Methodology

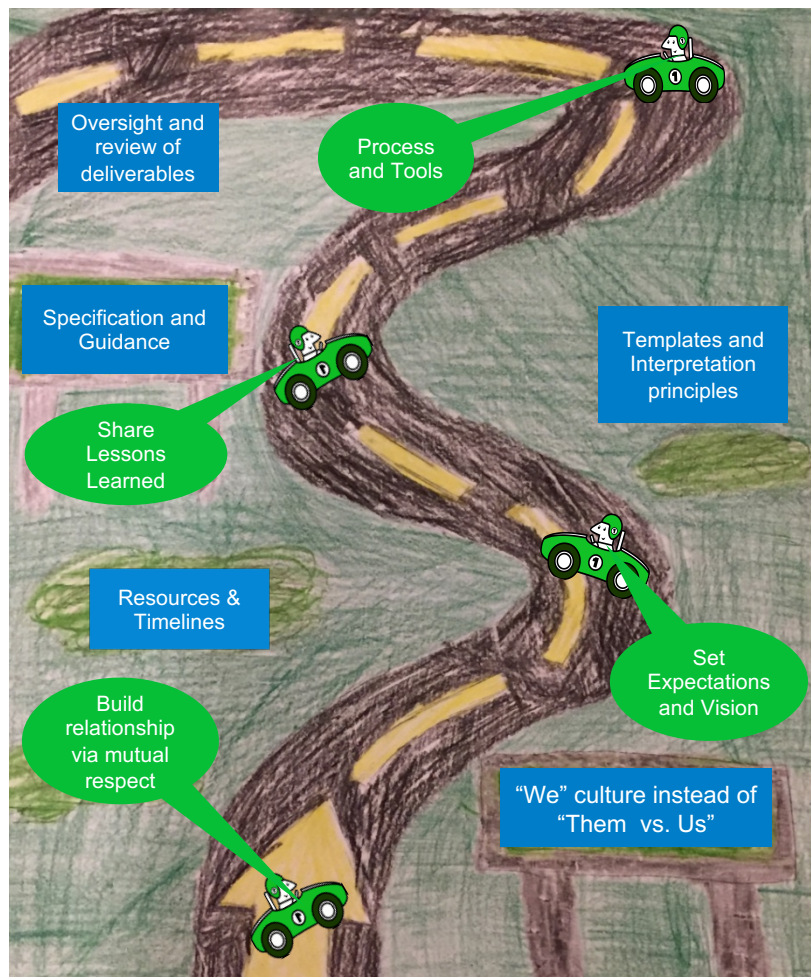
1. Establish behavior driven culture to create atmosphere of trust and open communication	a) Work as “WE” instead of “them vs us”
	b) Identify teams with combined membership from both organizations to complement each other
	c) Clearly define roles and responsibilities
	d) Set clear expectations on milestones and deliverables
2. Create a Standards Roadmap with long and short term goals	a) Discuss and provide CDISC standards interpretation
	b) Implement Sponsor Standards Library at CRO and release after UAT
	c) Share in the evaluation and implementation of CRO Processes and Tools
3. Share knowledge across organizations	a) Oversee to ensure compliance of Data Standards are aligned to regulatory agency needs
	b) Share experiences of using standards during study implementation
	c) Conduct lessons learned after each standard implementation

Proposed Solutions

Problems	Solutions
Problem 1. Issues identified before pre-clinical studies for a combined solution that establishes a guidance framework for Clinical Studies.	a) Collaborate with other functional areas of both organization to identify existing tools and make them available. a) Establish a management framework for Standards Governance that oversees the development and use of standards. b) Train both Sponsor and CRO teams on expected standards through e-learnings, CDISC trainings and communicating on standards at regular intervals. c) Develop tools that evaluate compliance to established standards and that ensure oversight by collecting, reviewing metrics at regular intervals.
Problem 2. Communication issues across the organization for implementation of sponsor standard Specification	a) Use technology solutions (e.g. SharePoint) as collaboration. b) Provide metadata documentation to the CRO for a consistent implementation of standards across Clinical study teams. c) Conduct team meetings at the standards level with the CRO and provide mutually acceptable solutions.



Conclusion



Managing CRO partnerships is an art critical to a successful relationship, and requires a balanced approach of adjusting to CRO processes while ensuring sponsor-interpreted standards are followed.

This relationship is stronger if the rules of engagement include mutual respect and using a “WE” mentality.

We have highlighted several solutions to remove roadblocks for a successful partnership.



Resources

Acknowledgements:

- I would first thank Diane Piper for her encouragement, Karin LaPann for her contribution to this presentation and related articles and Shire Team members for taking the time to review and provide suggestions

Related Articles:

- Other related articles includes
 - CSS 2017 PhUSE Conference Poster - http://www.phusewiki.org/docs/2017_CSS_US/PP13_Final.pdf
 - PharmaSUG 2017 ePoster (coming soon in May 2017!)

For questions, please contact:

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Proposed Solutions

Problem 1.

No consistent and repeatable decision making framework for use in Clinical Studies.

a) Establish a management framework for Standards Governance that oversees the development and use of Data Standards used by internal teams and CROs.

Problem 2.

Communication issues across the organization for implementation of sponsor standard Specification

Use both technology and business process solutions:

a) Use technology solutions (e.g. SharePoint) as collaboration.

b) Provide metadata documentation to the CRO for a consistent implementation of standards across Clinical study teams.

c) Conduct team meetings at the standards level with the CRO and provide mutually acceptable solutions.

Proposed Solutions

Problem 3. Ensure CROs follow established guidance and best practices .	a) Use industry available standards that can be readily used for Sponsor templates and make them available for study team use. (includes CDISC standards for CDASH, SDTM, ADaM, Derfine.xml, PhUSE templates such as SDRG, ADRG, FDA standards for studies.
	b) Train both Sponsor and CRO teams on expected standards through e-learning, CDISC trainings and communicating on standards at regular intervals.
	c) Develop tools that evaluate compliance to established standards and that ensure oversight by collecting, reviewing metrics at regular intervals.
Problem 4. Investment of tools and processes for a combined solution that shares success and mitigates risks	a) Collaborate with other functional areas of both organization to identify existing tools.
	b) Discuss and agree on who will pay for the tools, will it be a co-investment, or whether to build or buy the tools.