



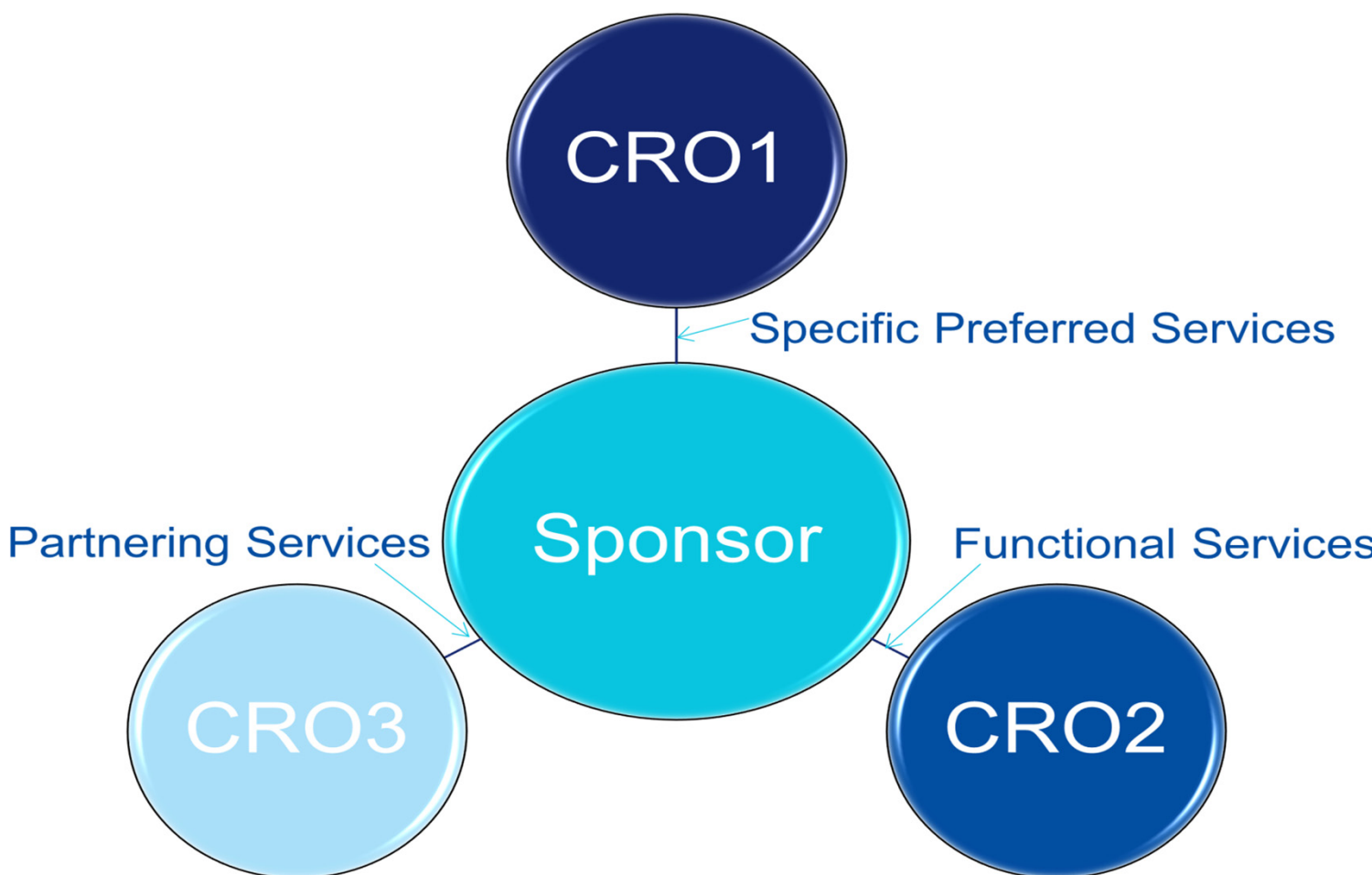
Roadmap for Managing Multiple CRO Vendors

Veena Nataraj MS Shire, Karin LaPann MS Shire

INTRODUCTION

Sponsor companies are focused on bringing innovative therapies to the market as they strive for competitive advantage. To achieve this there is a need to streamline processes, and to further lower the R&D costs by using Clinical Research Organization (CRO)s to share risks and rewards. When working with CROs, the strength of the relationship established between the two organizations is critical for successful outcomes. For Sponsor companies, governance and oversight is critical to success. Similarly for CROs clear communication including resourcing needs is important for a smooth working relationship. The CROs support clinical studies or Therapeutic Area programs in a variety of ways, from functional services to long term partnerships. Often, cooperative agreements can be adjusted to the needs of the Sponsor, bringing together people and tools from both organizations. The below identifies methodologies and proposed solutions for ensuring positive outcomes, for Sponsors, and ultimately, for patients.

TYPES OF RELATIONSHIPS



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

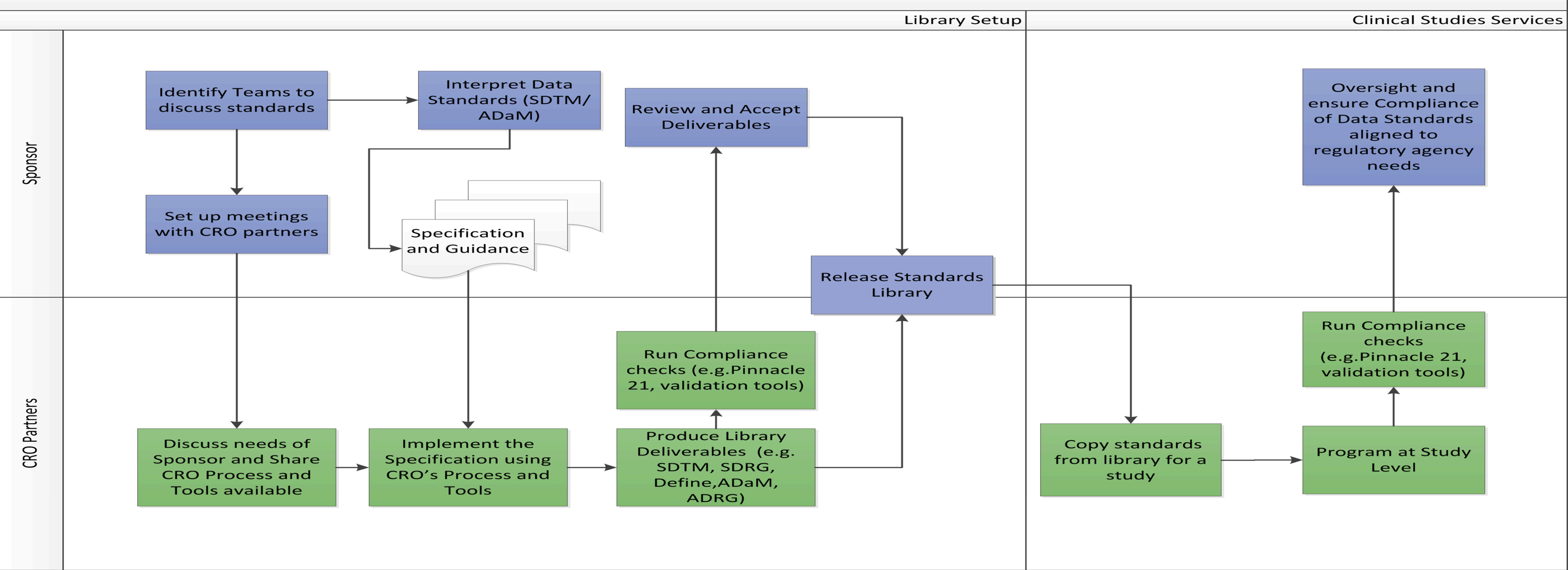
Problems	Solutions
No consistent and repeatable decision making framework for use in Clinical Studies	Establish a management framework for Standards Governance that oversees the development and use of Data Standards used by internal teams and CROs
<ul style="list-style-type: none">Lack of version control for documents causing multiple people receiving different informationThe CDISC Implementation Guides defines generic standards for global use and needs documentation for sponsor interpretation	<ul style="list-style-type: none">Use technology solutions (e.g. SharePoint) as a collaboration platform to share documents and meeting minutesProvide metadata documentation to the CRO for a consistent implementation of standards across Clinical study teams.Conduct team meetings at the standards level and provide mutually acceptable solutions by working through advantages or constraints of the CRO tools and processes
Ensure CROs follow established guidance and best practices	Develop templates based on the readily available documents: <ul style="list-style-type: none">CDISC End to End Implementation and User Guides<ul style="list-style-type: none">CDASH, SDTM, ADaM, Define XML, TA User GuidesPhUSE Templates and best practices<ul style="list-style-type: none">nSDRG for SENDcSDRG for SDTMADRG for ADaMStudy Data Standardization PlanWhite Papers (Visit Numbering and Screening)FDA/PMDA Documents<ul style="list-style-type: none">Technical Conformance GuideData Standards Catalog
Ensure CRO deliverables meet Sponsor expectations	<ul style="list-style-type: none">Develop tools to evaluate compliance to established standardsProvide training to CRO and internal teams on expected standards through e-learnings

FUTURE

Investment of tools and processes for a combined solution

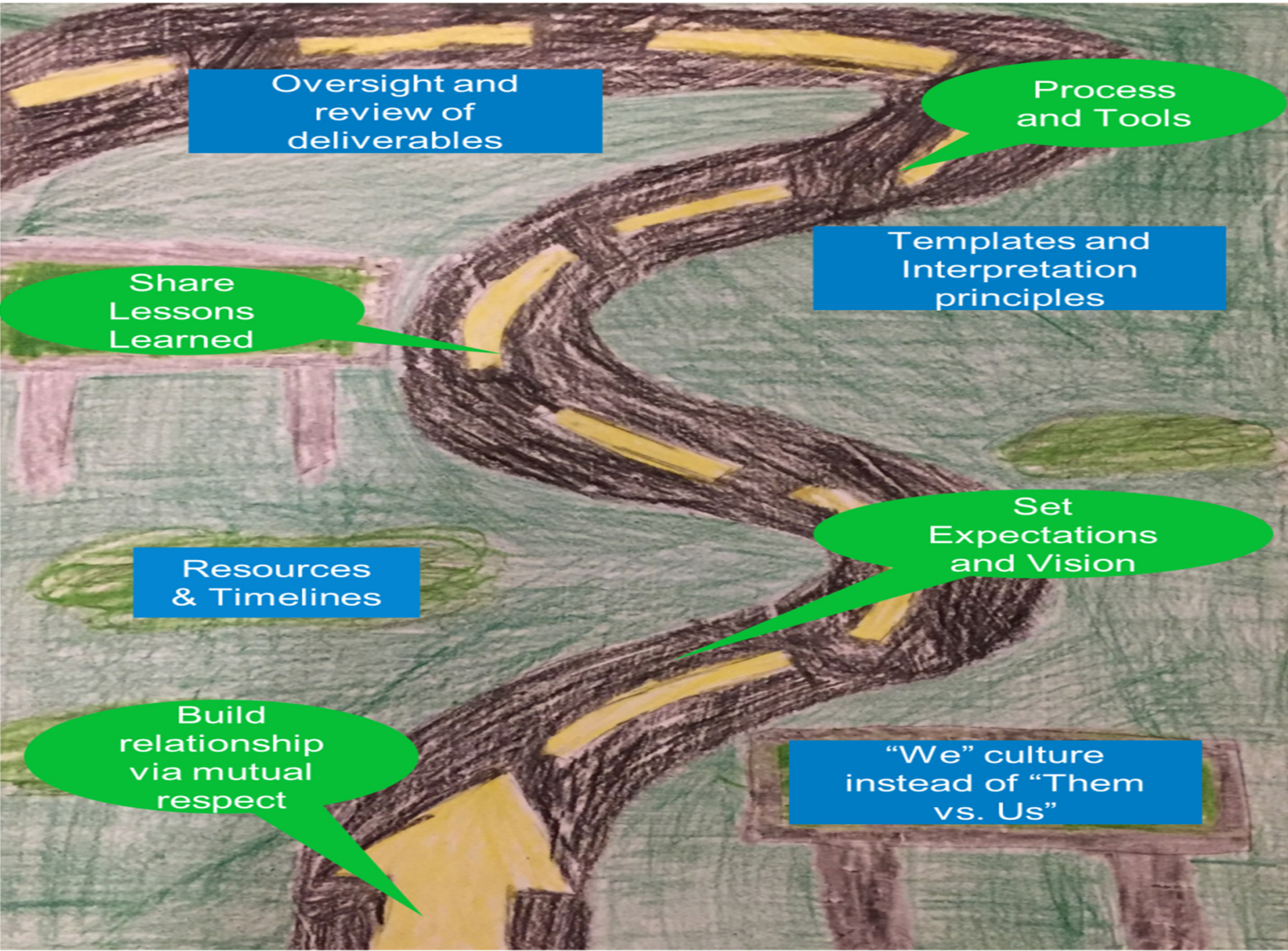
Budget considerations impact the decisions (e.g., who will pay for the tools, will it be a co-investment or whether to build or buy the tools)

Information Flow between Sponsor and CRO Partners



CONCLUSION:

Managing CROs 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. This poster highlights solutions for common pain points to remove roadblocks for a successful partnership.



For additional information please contact:

Veena Nataraj
Clinical Standards
Shire
vnataraj@shire.com
781-482-0906

Karin LaPann
Clinical Standards
Shire
klapann0@shire.com
781-266-3968