



## Turning Sponsor/CRO Relationships into Partnerships for Success

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Source: <http://www.clinicaltrialsarena.com/archive/>

# THE PARTNERSHIP PROBLEM

Resourcing  
issues

Performance  
problems

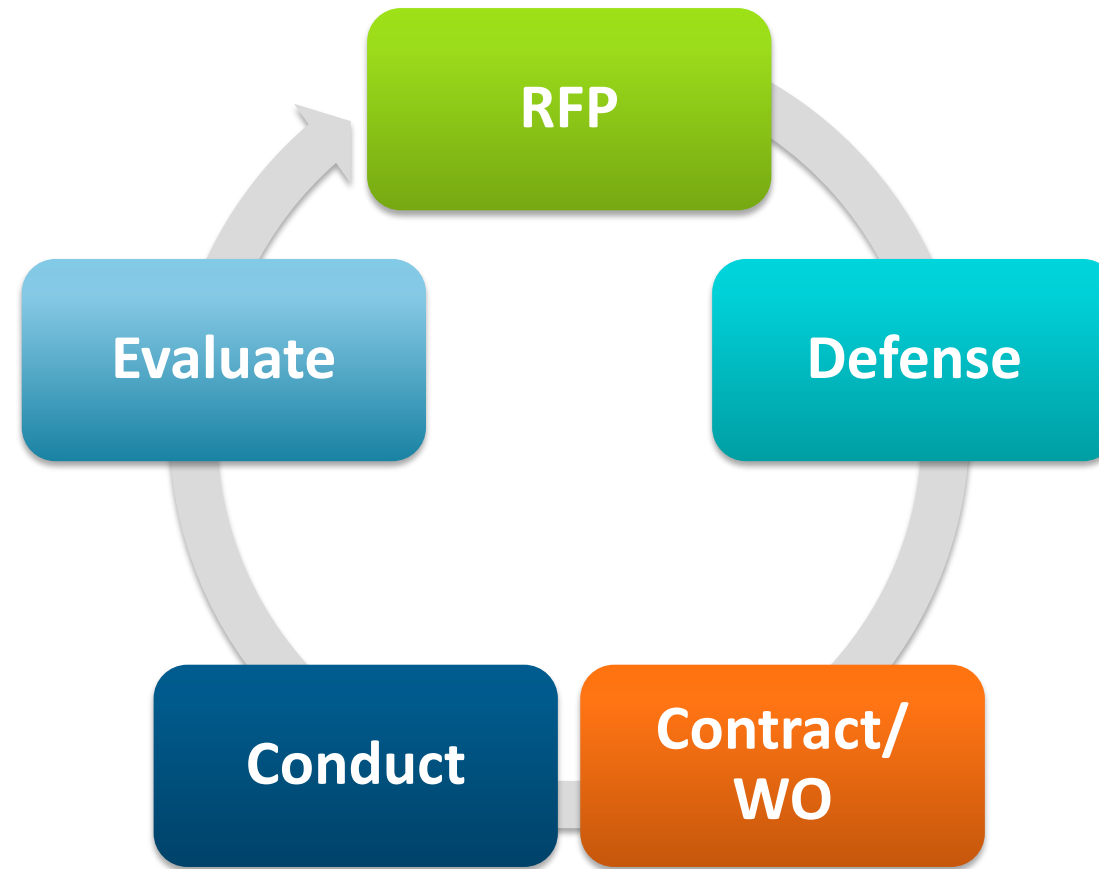
Missed  
timelines

Dissatisfied!

Mistrust  
or fear



# THE RFP PROCESS IS TRANSACTIONAL AND TIME-CONSUMING



# LOOP OF DOOM

*“We can’t stop behaving  
like a vendor until you  
stop treating us like one”*



“We can’t stop treating  
you like a vendor until you  
stop behaving like one”

# CASE FOR STRATEGIC PARTNERSHIP

*Expand our thinking beyond the  
transactional*



# CHALLENGES OF PARTNERSHIPS BETWEEN SPONSOR AND CRO

Fundamentally different business models

Risk asymmetry

Each party may have multiple strategic partnerships, creating competition

Supplier complacency

Opportunistic behavior by either party

Unrealistic expectations

- ✓ That either side will repeatedly sacrifice its own interests for the good of its partner
- ✓ That everything will be perfect from now on

# CHARACTERISTICS OF PARTNERSHIPS

- ✓ More than “full-service model”
- ✓ Includes “soft” factors,
  - ✓ High degree of mutual trust and respect
- ✓ A “formal” business arrangement codified in written agreements with metrics
  - ✓ Also includes attitudes, mindset, and behaviors of individuals at the “partner” companies.
- ✓ Sponsor treats individuals at the CRO as extended team members.
- ✓ When (not if) problems occur, both sides sit down to engage in root-cause diagnosis and correction.



# MISALIGNMENT OF GOALS & OBJECTIVES BETWEEN SPONSOR AND CRO AND POOR INFORMATION SHARING



# DIFFERENT FROM A TRANSACTIONAL SERVICE RELATIONSHIP

Needs to last long enough to motivate investment (of time, effort, and/or capital) by partners

- ✓ drive continuous improvement and innovation

Close integration of planning and operations between partners

- ✓ Information sharing
- ✓ extensive integration of processes
- ✓ coordinated decision-making

Significant investment in joint planning to minimize or mitigate risks to both sides

Define how each side will benefit, and what each sides needs to commit and and invest to ensure success

# STRATEGIC PARTNERSHIPS REQUIRE

High degree of **TRUST**  
between partners

Tolerance for failure

Individual and organizational competencies for managing differences between partners, and for **managing inevitable disagreement and conflict.**

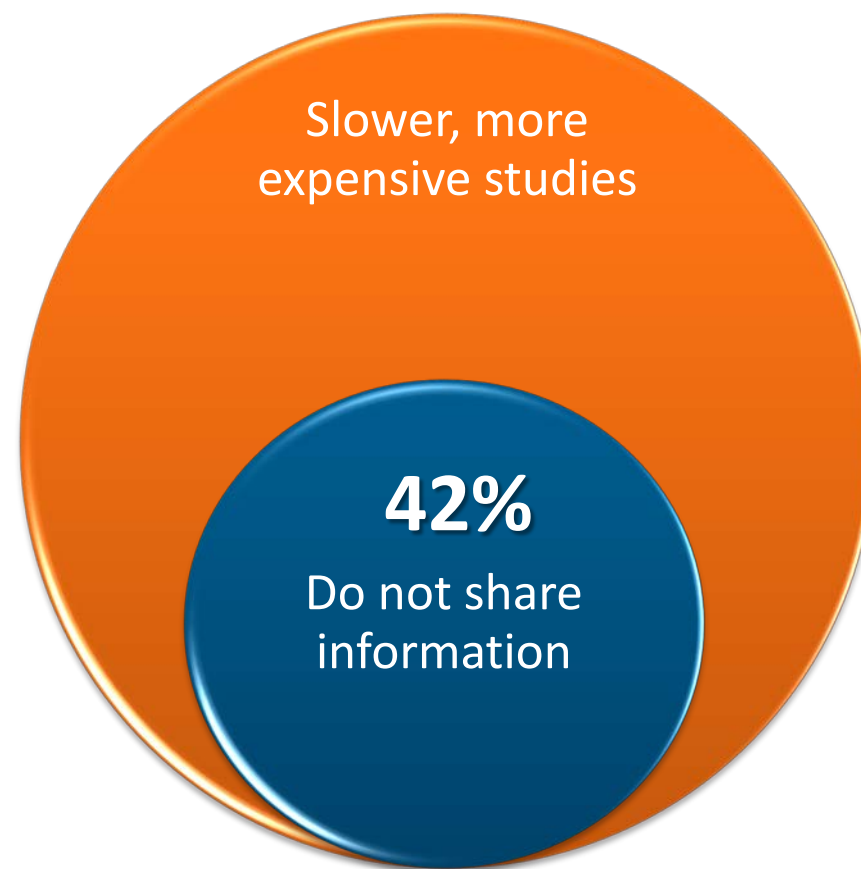
**Robust governance structures and mechanisms across multiple functions and levels**

- ✓ Building and maintaining alignment within each organization may be greater than doing so with the partner.

**Agreement language that recognizes maximization of long-term value over short-term gains**

- ✓ CROs view guaranteed revenue streams in exchange for long-term commitments (resourcing) more positively than penalty language

## AMONG SPONSORS WHO REPORT...



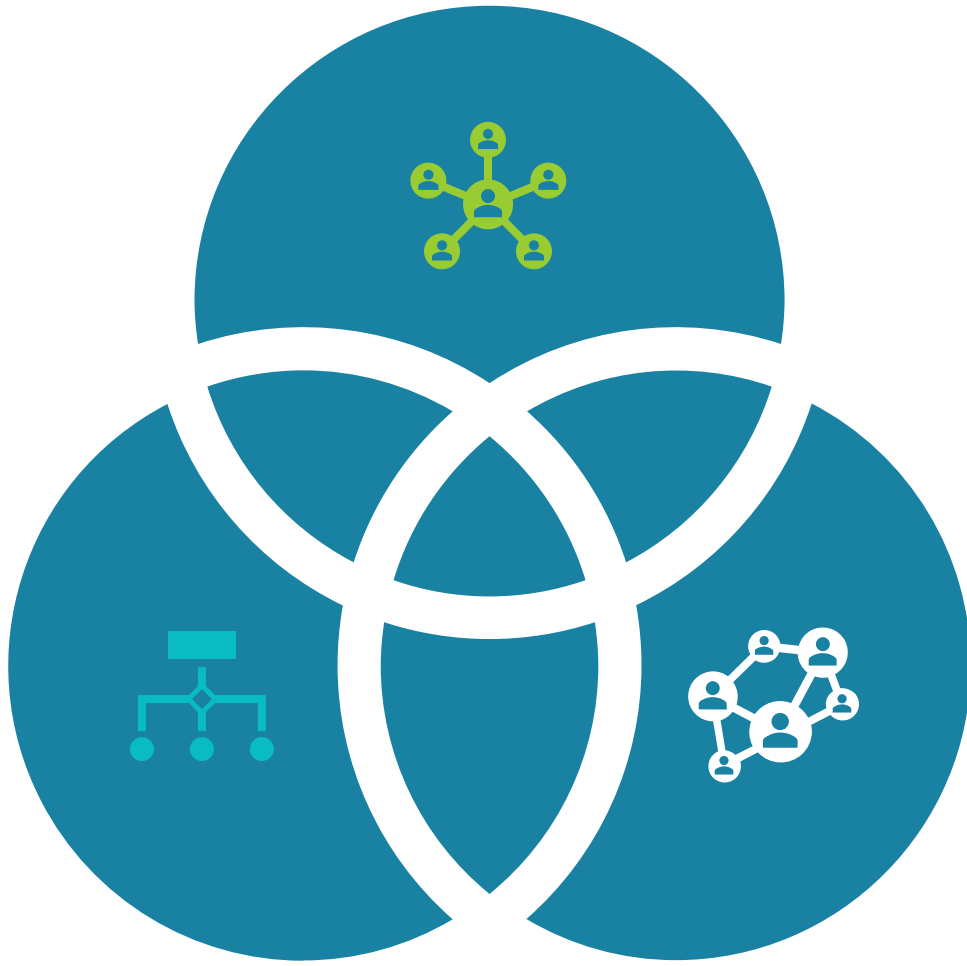
# SUCCESS FACTORS

## Joint Business Plans

- ✓ Multi year
- ✓ Common goals
- ✓ What each partner hopes to achieve through the partnership
- ✓ Risks/barriers with mitigation plan
- ✓ Commitments and investments made by each partner



# MORE SUCCESS FACTORS



## Multi-Level Governance

- ✓ Identify and frame important decisions
- ✓ Right people make the right decisions using the right information
- ✓ Accountability for implementation
- ✓ Clear escalation pathway
- ✓ Lessons learned shared across all studies, therapeutic areas

# JOINT TRAINING

**How work will be done (Work Instructions, roles and responsibilities)**

## **Common vocabulary**

- ✓ Collaborative problem solving
- ✓ Joint decision making
- ✓ Conflict management
- ✓ Change management

**CRO staff - Shift from executing tasks to delivering results**

**Sponsor staff – shift from micromanaging to collaborative oversight**



# MEASURE WITH A TWO-WAY SCORECARD

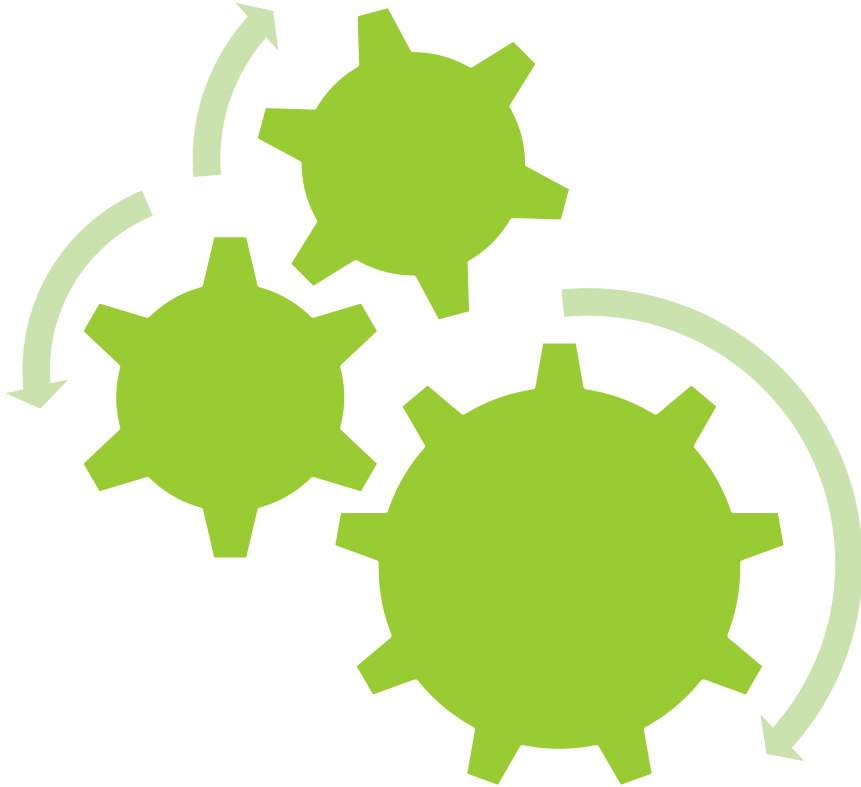
CROs can give feedback to sponsor

Operational and strategic KPIs, leading and lagging indicators

- ✓ Lagging – audit findings, cost variance, change orders
- ✓ Leading – progress against upcoming milestones, level of trust between partners



# HOW DO I FIND A SUITABLE PARTNER?



Size and fit matter

Alignment of values between parties matters

Relationships take time

SPONSORS MAY REQUIRE ONE OR BOTH

**FLAWLESS  
EXECUTION**

**DRUG  
DEVELOPMENT/THERAPEUTIC  
EXPERTISE**





## IS STRATEGIC PARTNERSHIP THE ONLY WAY?

- ✓ Of course not
  - ✓ Single study, transactional or peak activity resource engagement is fine
  - ✓ As long as expectations are clear on both sides
-

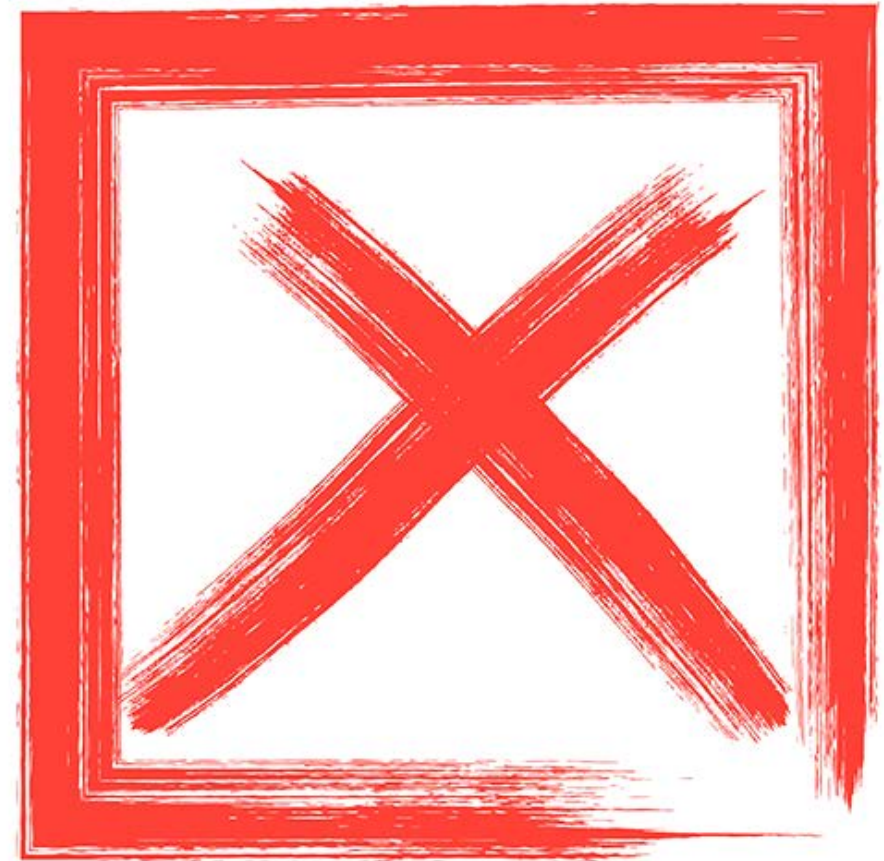
# CHARACTERISTICS OF THE **MOST SUCCESSFUL** PARTNERSHIPS

- › Differences are acknowledged and jointly managed
- › “We are all colleagues”
- › Sponsors provide high degree of transparency regarding development plans
- › Policies, process and procedures are aligned and integrated so the team can function smoothly as one
- › Clear roles and responsibilities
- › Potential problems are identified early in an atmosphere of trust. Root cause analysis and solutions are done together



# CHARACTERISTICS OF THE **LEAST SUCCESSFUL** PARTNERSHIPS

- › Unclear or unrealistic expectations on one or both sides
- › “You work for us; we don’t work for you.”
- › Sponsor provides limited visibility into development plans
- › Lack of clarity around roles, responsibilities, process and procedures
- › Sponsor either micro-manages or silos the CRO
- › Problems are hidden from the other party until it becomes difficult to solve without significant detriment to the study
- › Blaming and shaming



## SUMMARY

- › Performance problems, high staff turnover, lack of team cohesion may be related to sponsor/CRO relationship problems
- › It takes a lot of early work and planning to create a sustainable partnership that works for both sides but the work pays dividends
- › Sponsors and CROs who invest in strategic partnerships often report faster, more cost-effectively run studies
- › Building the relationship takes time. Don't try shortcuts.



**Thank You! Any Questions?**

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