

Governance Managing Conflict

7th February 2019

PCMG Conference



Topics

Conflict defined

UCB:PAREXEL Governance in 2014

Evolving Governance

- Process Map Core Team
- Oversight model for Project Management
- Commercial Governance
- Best practices
 - Open and honest communication
 - Recognition
 - Early engagement
 - Steering Committee



Conflict in Clinical Outsourcing

Oxford Dictionary Definition

- A serious disagreement or argument, typically a protracted one

Root causes:

- Missed milestones
 - Budget amendments & negotiations
 - Poor delivery
 - Constrained timelines
 - Other examples?
-
- Is all conflict bad?



UCB's History: Not Very Strategic

Transactional model with ~ 40 CROs

2010 – 2011: Industry shift to strategic partnering



Pfizer Announces New Strategic Partnerships With ICON and PAREXEL International Corporation; Streamlining Clinical Trial Execution to Improve Focus, Flexibility and Performance
May 2011

The new partnership model for clinical trial execution will enable Pfizer to focus internally on its core capability in clinical trial design, while leveraging the strengths and scale of ICON and PAREXEL to implement clinical development programs with greater efficiency and rigor.



Pathwork Diagnostics, Novartis Strike Rare Research Deal
July 2010

Venture-backed Pathwork will work with Novartis's new molecular-diagnostics unit to discover biomarker signatures that can serve as the basis for diagnostics across a range of tumor types. Both companies have the right to develop and sell diagnostics, but they could extend this alliance, or form a second one, to advance products jointly.



sanofi aventis

Sanofi, Covance in 10-Year R&D Outsourcing Deal
September 2010

French drug giant Sanofi-Aventis S.A. (SNY) has signed a 10-year agreement to outsource research and development services to Covance Inc. (CVD) in a deal that could be worth up to \$2.2 billion. The deal is the latest sign of increased outsourcing by pharmaceutical companies as they seek to cut the costs of searching for new products in the face of looming generic competition for top-selling drugs in coming years.



GlaxoSmithKline

Glaxo Says Working On Contracts With Parexel, PPD
September 2010

GlaxoSmithKline PLC (GSK) said Friday it is negotiating contracts to enter "strategic relationships" with contract-research organizations Parexel International Corp. (PRXL) and Pharmaceutical Product Development Inc. (PPDI). The relationships are part of the U.K. pharmaceutical giant's move to increase its productivity and simplify clinical development

UCB enters into strategic partnerships in clinical development with PAREXEL and PRA

(Ref: UCB)

November 15th, 2011

Tags: [Press Release](#) [Parexel](#) [PRA](#) [UCB](#)

Brussels (Belgium), 15 November 2011 - 18:00 (CET) UCB announced today that it has entered into strategic partnerships with PAREXEL and PRA to drive UCB's operational clinical development activities. The agreements are effective for all of UCB's new clinical study programs on a global basis.

"We are pleased to announce these strategic partnerships as UCB aims to expand its global drug development activities, including in Asia. These partnerships represent long-term, win-win commitments to an outsourcing model focused on maximizing the effectiveness of each participant's resources in clinical operations. These relationships are based upon integrity, trust and dedication to common goals", said Tris Loew-Friedrich, Executive Vice President and Chief Medical Officer of UCB. "Our strategic partnerships with PAREXEL and PRA will improve efficiency and cost effectiveness, as well as increase opportunity for innovation, collaboration, and the continuous improvement of quality and services - helping us to deliver new medicines to patients worldwide. By putting these new arrangements in place, PAREXEL and PRA essentially become integrated members of our study teams."

0

+1

0

Like

in

Share

0

Tweet

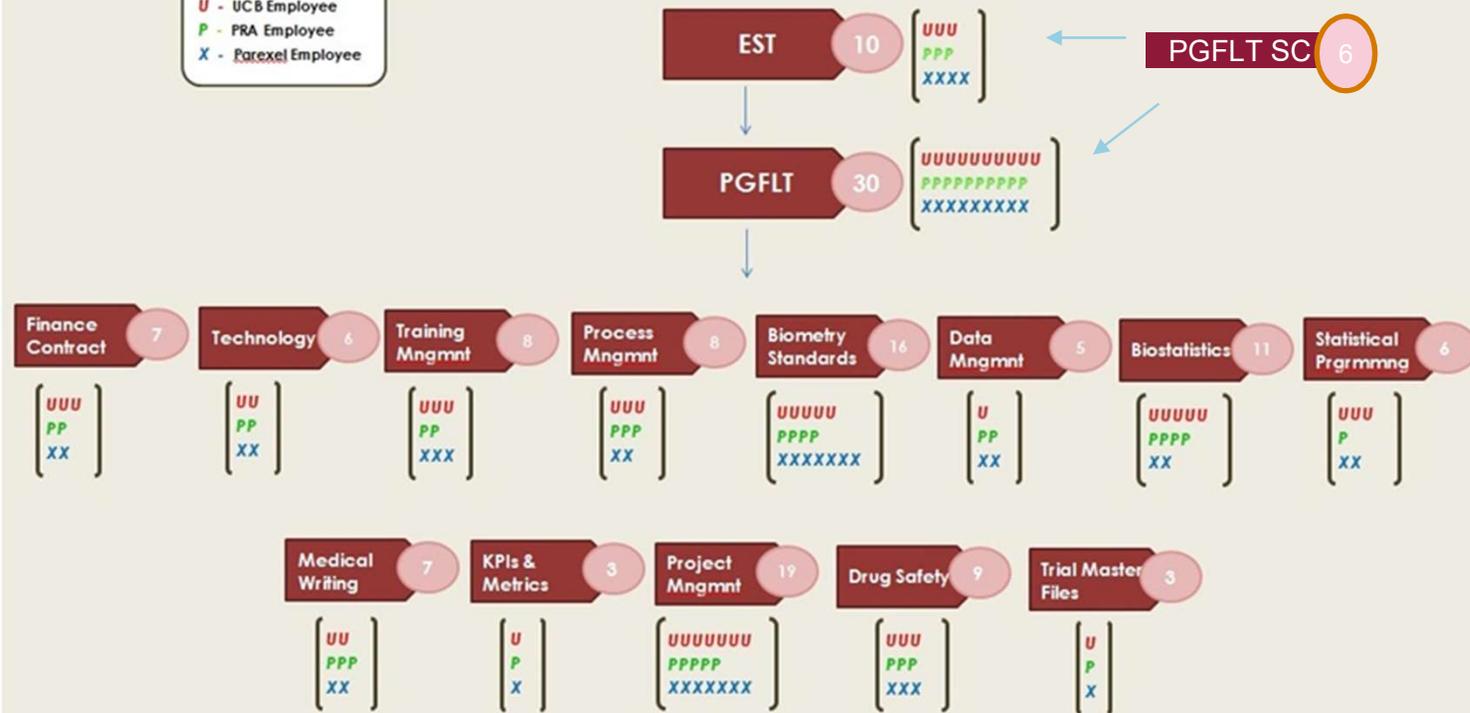
Email

Print



SPI Governance Structure

U - UCB Employee
 P - PRA Employee
 X - Parexel Employee



JCST 10 to 30



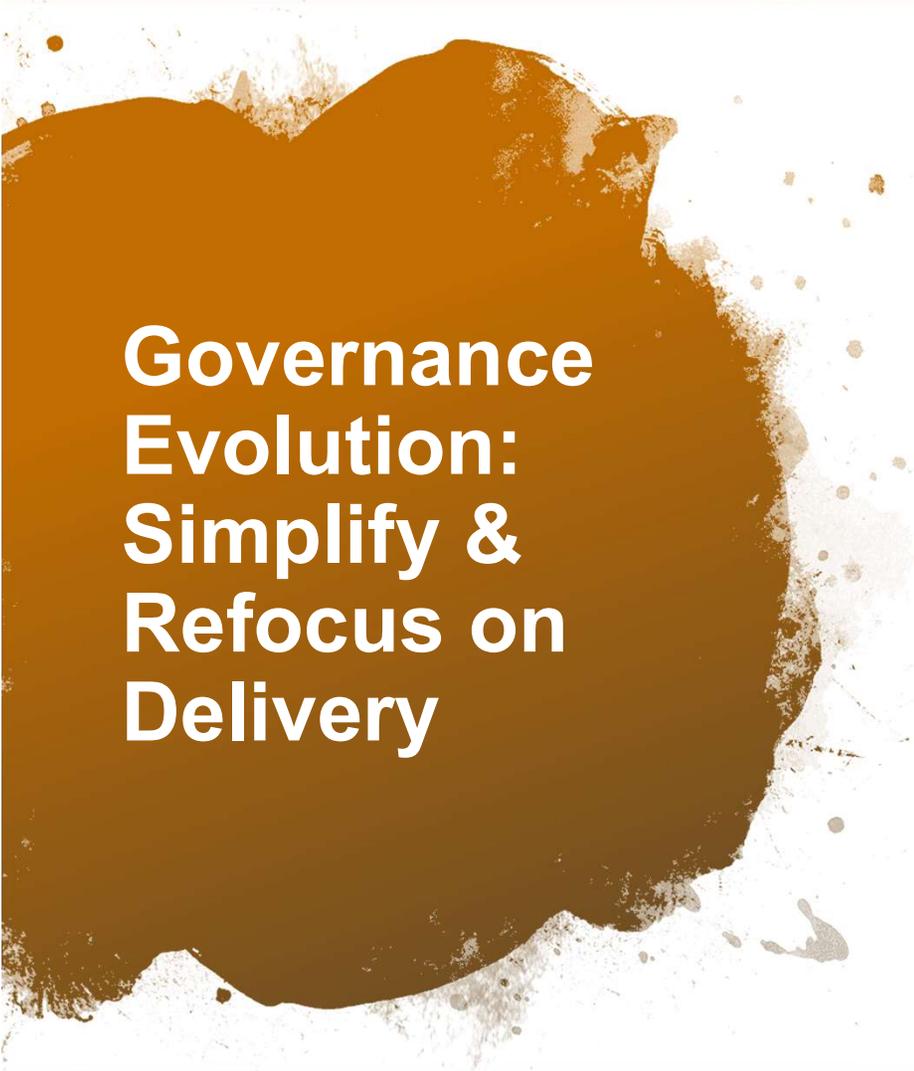
Is this an
efficient
governance
model?

Governance Assessment in 2014

Change needed, tensions high

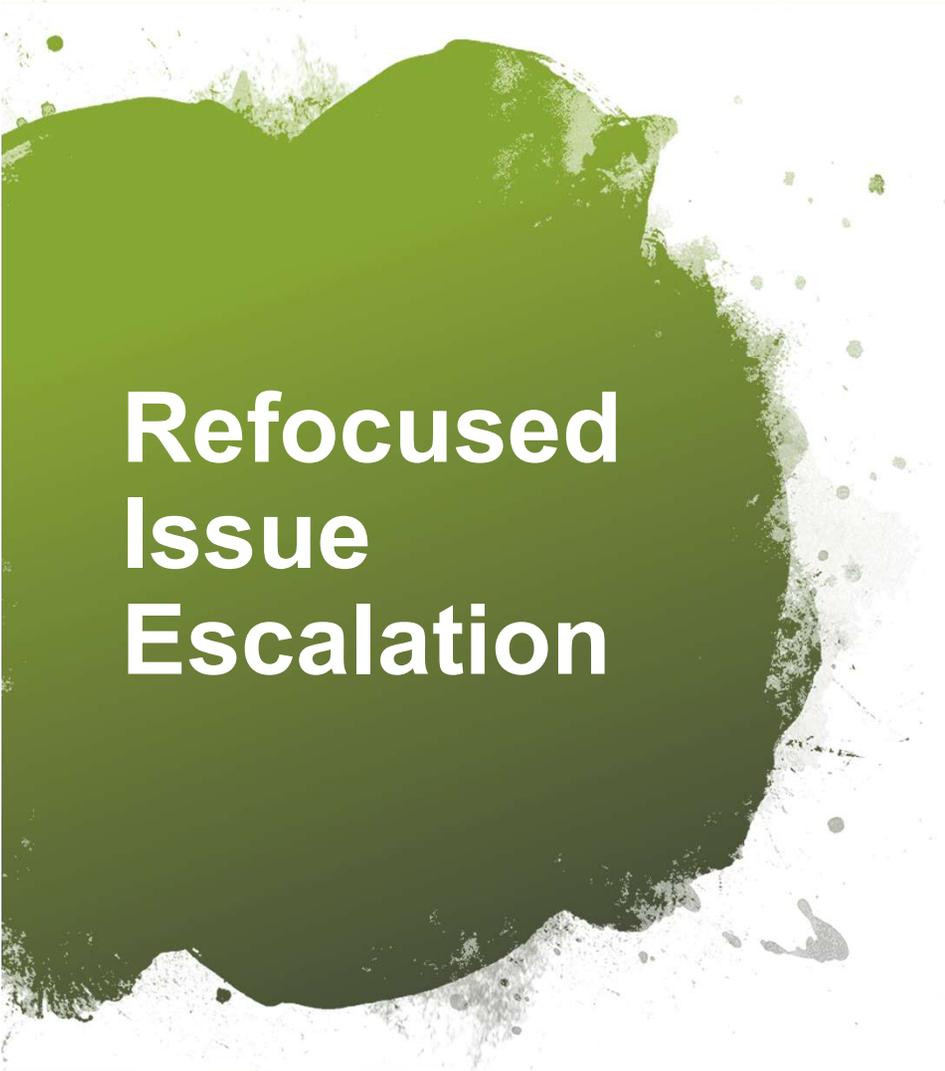
- Overly complex, too many layers and players
- Focus on initiatives, not on execution
- Unclear roles and responsibilities within partnership
- Financial framework more punitive than supportive
- Formalized escalation process, backfired





Governance Evolution: Simplify & Refocus on Delivery

- Removed several layers
- Optimized remaining structures
 - Reduced membership
 - Refined meeting management
 - Increased focus on project delivery and associated risk/issue management
 - Elevated role of project team's behaviors and collaboration
 - Increase TA engagement & transparency
- Initiated Commercial Governance Team
- Build stronger relationship with Quality Governance Team
- Transition Partnership Manual to Process Map approach



Refocused Issue Escalation

- **Reinforced accountability throughout**
 - Study Level
 - **Primary accountability** for management of their issues/risks
 - Supported by line management within UCB and Partners
 - Functional Level (ie, Partnership SMEs)
 - Accountable for processes and minor performance related issues
 - Partnership / TAs
 - Not appropriately managed within team/function
 - Partnership – Partner/UCB resourcing, process, or performance
 - PST - Protocol strategy or feasibility and related budgetary impacts

Escalation process encourages collaboration & problem solving, eliminates unnecessary & inefficient communications, elevates accountability of the study team

Simplified Governance Structure



1 – Meets quarterly, 2 – Meets monthly

Evolving Governance

11

Culture

Oversight Model for Project Management

Process Governance

Commercial Governance

Living our escalation process



Organizational Culture

Divergent and dysfunctional cultures create ample space for deep conflict

What makes a partnership-friendly culture?

Awareness

An awareness of nature and impact of organizational culture is an important starting point. Review internal culture and reflect on how this will impact external relations.

Openness

Show your potential partner who you are and how you operate, sharing values and aspirations, and not trading stereotypes and expectations.

Flexibility

Listen to the views and aspirations of the partner organization – recognize the values that lies in diversity of ideals and approaches.

Consistency of Purpose

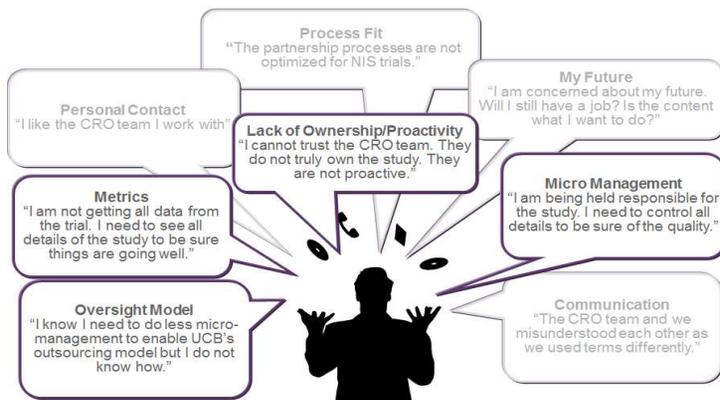
Exhibit a consistency of principals and behavior which enables an external partner to predict its partner's actions and responses.



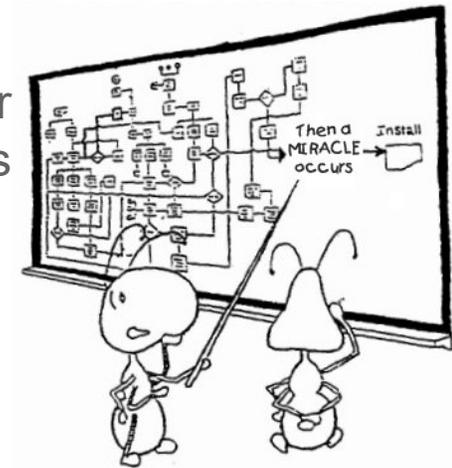
GCPM Oversight Redefined 2015

Focus on the challenges

Perceived lack of ownership vs. Perceived micromanagement



Unclear Expectations



Lack of agreed deliverable and defined oversight



"But... shouldn't we be more specific here in this step?"



Oversight?

None of the regulations tell us HOW

Find the right balance between micro management and laissez-faire approaches



SPI Oversight Concept Implemented in 2016

The goal?

- A true team experience with:



- Clarity on process and responsibility
- Granting and Taking Ownership
- An open exchange on issues

Or, in other words: **Trust**

based on positive experience

- Reports that allow the team to focus their discussions on the things that matter
 - Clarity on expectations through visualization
 - Clarity in expectations through defined timeframes



Embedded Partner Liaisons

Increase connectivity & demystify partner

- Experienced, senior-level manager from partners who will embed at UCB for 6-9 months
 - Embedded within UCB in Raleigh, NC, Brussels, Belgium and Monheim, Germany
 - Full access to the UCB offices and staff
 - Publicly Supported by UCB Management
 - CRO Partner becoming everyday colleague – a real person, not a distant contractor
 - Immediately available for questions
 - External senior resource



Embedded Strategic Partnership Liaison Role



Responsibilities include:

- Advise how to more efficiently and effectively work with PAREXEL by explaining organizational structure, processes, & culture
- Provide broader pharma perspective on how different sponsors work with CROs in a strategic partnership
- Advise and support the development of UCB partnership communications and training efforts
- Perform process analyses to identify opportunities for continuous improvements
- Support partnership change management activities
- Advise on relevant KPIs to more effectively measure partnership performance

Strengthening CPM Oversight of Partners

Playbook & Scorecard Development

26 Oversight Areas

- | | | |
|---|--|--|
| <p>Startup</p> <ul style="list-style-type: none"> Budget Management IXRS set-up, on time and quality Drug Supply Set up Protocol Development Regulatory Status Startup Strategy Study Project Plan / Timelines Other Project Plans Startup Execution Feasibility - Country, site | <p>Execution</p> <ul style="list-style-type: none"> Third Party Vendor (TPV) Mgmt Data Cleaning Delayed SIVs Recruitment Safety Risks Data Quality / Monitoring IMP TMF Quality (Audits) Budget Management Communication | <p>Closeout</p> <ul style="list-style-type: none"> CSR Agreement on Key Messages at RIM Data Cleaning up to DB Lock Final QC check at TMF Final Regulatory Notifications Timely Delivery of TFLs |
|---|--|--|



CPM Oversight Defined

Activity	Ownership / Process Owner	Time Frame	J&A M/F/A	J&A M/F/A
Review and approve all study related documents	CPM	As needed		
Review and approve all study related documents	CPM	As needed		
Review and approve all study related documents	CPM	As needed		
Review and approve all study related documents	CPM	As needed		
Review and approve all study related documents	CPM	As needed		

Partner Dashboard: Metrics + Risk Management



What we want to avoid!



Process Governance



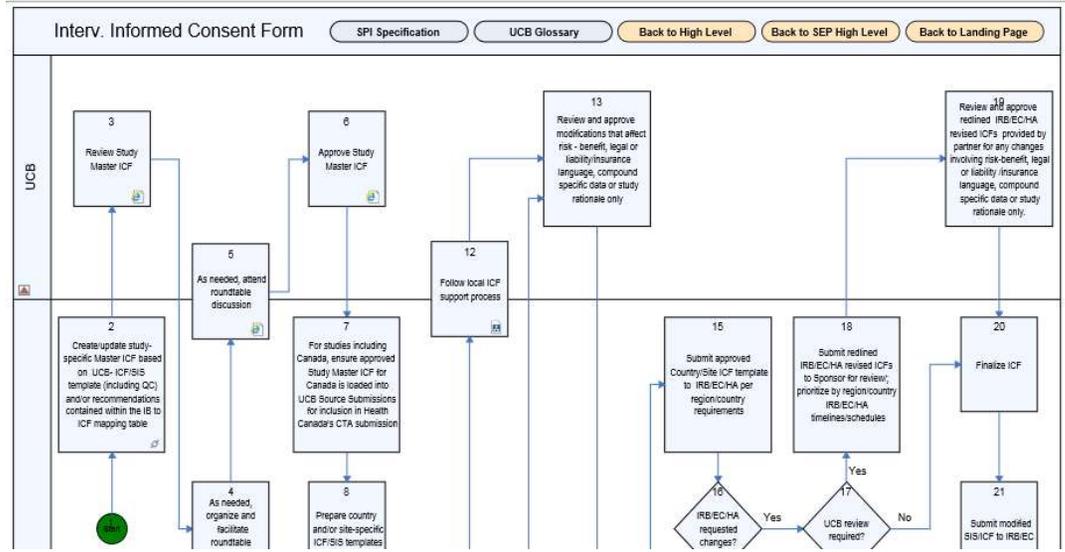
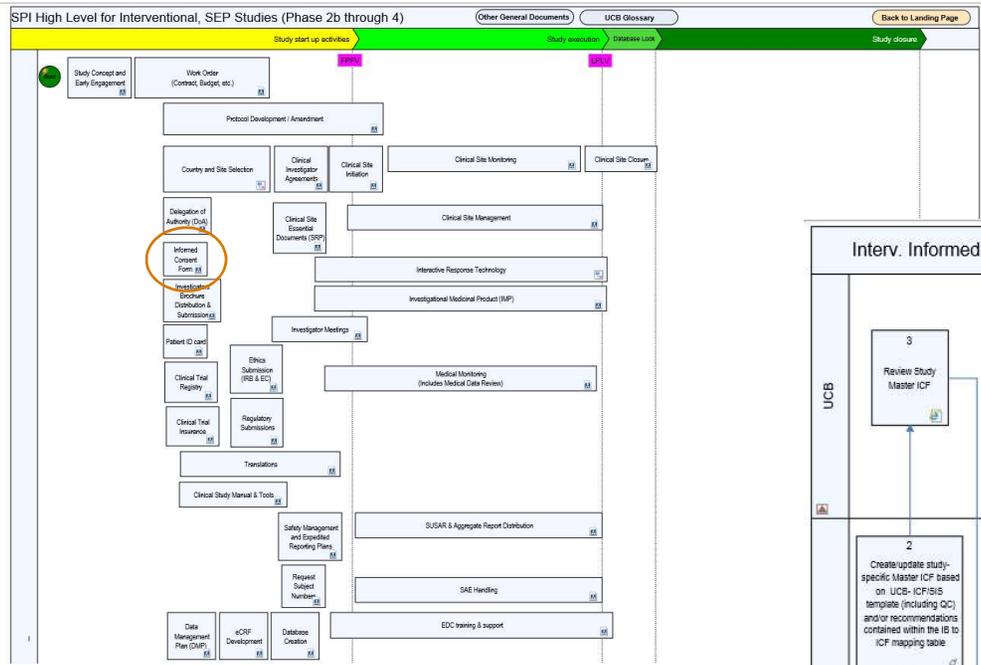
Alignment by SMEs: Each Process has an Owner at each Partner

SME Network

- One SME in each company for each important area (start-up, logistics, DM, S&P...)
- SMEs are...
 - Responsible for the development of their functional processes in the process landscape
 - Work directly with their UCB counterpart and representatives from other CROs where applicable
 - Empowered to make process decisions on behalf of the functional group
- Regular communication between functional SMEs
- Regular partnership communication to/between all SMEs

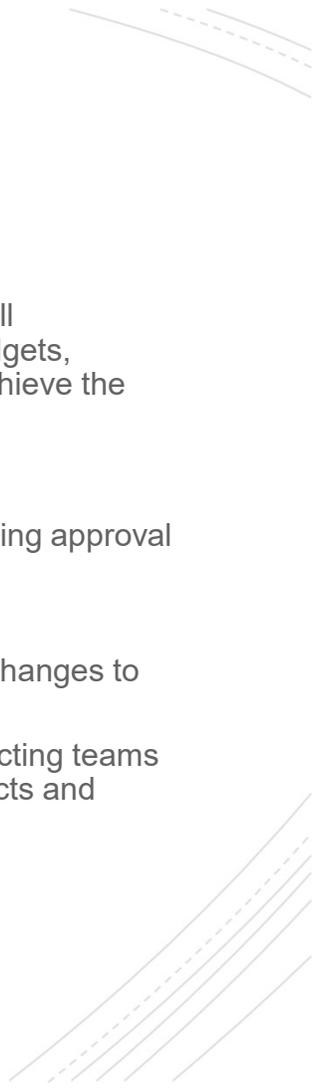
Process Landscape

What types of process documentation do you use in your partner governance?
What are your experiences?





Commercial Governance Team (CGT)

- **Purpose:**
 - Oversee the development and modification of all processes, tools, and documents related to budgets, contracts, and commercial terms required to achieve the strategic objectives of this Partnership.
 - **Responsibilities:**
 - Creation of and revisions to pricing tools, including approval of changes to unit prices
 - Updating task allocation matrices
 - Updating the Master Services Agreement and changes to pricing structure or other terms and conditions
 - Providing leadership to study teams and contracting teams as needed to ensure timely execution of contracts and changes in scope
- 



CGT Value

- **Conflict Avoidance**
 - Built RESPECT - Honest discussion about units and appropriate resourcing required to meet sponsor expectations
 - Addressed GAPS – Developed units for activities not covered
 - Created STANDARDS - Central review and approval of new activities
 - Supported TEAMS – Proactively identify/mediate difficult negotiations

Major Achievements

After all of this, what UCB was saying about the partnership?



- Better sponsor understanding of PAREXEL Processes, Structures and Culture
- Strong Momentum on Change in Trial Oversight and Continuous Improvement
- Change in Perception: From Contractor to Partner
- More consistent and transparent Measurement of Trial Performance
- Improved Team Cooperation

Partnership Health Survey 2018: Results

- Robust Response Rate: 83 %
- Very positive scores throughout with a strong communication theme
 - 11/14 questions received >80% for "Strongly agree + somewhat agree"
 - 7/14 questions received >95% for "Strongly agree + somewhat agree"
 - Honest & Transparent **Communication**
 - **Communication** Frequency
 - Timely **Responses**
 - **Communication** Methods
 - PAREXEL **contact** clarity
 - UCB receptiveness to PAREXEL alternate solutions
 - **Collaboration**



Best Practices

Incorporate into all governance aspects

Open and honest communication	Recognition	Early engagement	Steering Committee	Deal with disruptive people/voices	Escalation Process
<ul style="list-style-type: none"> • Ask for feedback and input • Conduct Partnership Surveys in both companies (and follow up) • Avoid closed feedback circles 	<ul style="list-style-type: none"> • Failure lasts long, success is fast forgotten • Regularly communicate about successes! 	<ul style="list-style-type: none"> • Involve CRO early into any development plans • Set funds aside to do so 	<ul style="list-style-type: none"> • Use functional steering committees to drive major business areas • Avoid working in functional silos 	<ul style="list-style-type: none"> • Understand true motivation of disruptive voices • Validate the individual. Sometimes they have a reason to be upset. • Manage impact of disruptive comments on the partnership 	<ul style="list-style-type: none"> • Establish, train and encourage a meaningful escalation process • Have formal tracking in place • Often escalation is about accountability • Ensure functional escalation paths

Takeaways

- **Governance can be a powerful tool to manage conflict when designed well, or the cause of conflict when not**
- **Regularly assess governance to ensure its achieving its objectives**
- **Simplify wherever possible**
- **Build a culture of respect and openness throughout the partnership**



Thoughts about Perseverance and Longevity

A True Partnership...

7-year relationship so far but we didn't bail on each other when we hit some challenges (which will inevitably occur in all relationships)

Turning over partners after hitting a rough patch may not be advantageous

Perhaps more is gained if one works through the challenges and benefits from the lessons learned instead of constantly starting over with new partners



This relationship is a great example of the success that can come from such behavior

Thank You



CONFIDENTIAL

PAREXEL®
YOUR JOURNEY. OUR MISSION.®