

*Pharmaceutical Regulatory and Compliance Congress
and Best Practices Forum*

**Robust Vendor Relationships,
Agreements, and Training:
Why, When, Where, and How**

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Monitoring and Auditing of Third Parties

Disclaimer

The views expressed in this presentation are those of the presenters and do not necessarily conform to or represent the official views of their employers.

Agenda

- Overview- Dr.Mark DeWyngaert
- Vendor Oversight: The Sponsors' Compliance Role –Janis Crum, Esq.
- The CRO Perspective, with an Emphasis on Drug Safety- Dr.Ned Kelly
- Panel Discussion
- Questions

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OVERVIEW

The demands and complexity of current drug development call for a new approach. This is coupled with BioPharma's increasing use of third party vendors to provide risk reduction (or does it?), cost reduction, speed, efficiency, and flexible resources.

The panel today will address some of the complex issues around this relationship and the challenges in monitoring this arrangement in a rapidly changing regulatory environment.

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Some Outsourcing Pros and Cons



- Pros
 - Cut costs
 - Extends capacity, especially when development pipeline is full or when workload fluctuates significantly
 - Leverage experience and expertise of vendor, especially in areas where vendor's expertise exceeds sponsor's expertise
- Cons
 - Regulatory compliance risk
 - Business risk – will vendor deliver as contracted?
 - Clinical trial management risk – outsourcing to vendor(s) adds another layer of complexity

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The Big Picture: Outsourcing Risk Management

- VVW = vet vendors well
- MCC = monitor critical controls
- A³ = Audit, audit, audit

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PharmaCongress Vendor Relationships, Agreements & Training

Janis Crum, Esq.
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Vendor Oversight: Compliance's Role

- Risk mitigation fundamentals for corporate activities apply equally to outside vendors:
 - **Policies:** Ensure policies cover vendor activities
 - **Training:** General vs. specific compliance training
 - **Audit/Monitoring:** Include audit rights in vendor contracts and performance metrics
 - **Communication:** Identify single point of contact for compliance

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Vendor Oversight: Compounded Compliance Challenges

- Vendors compound compliance challenges
- Creates another layer of individuals acting as corporate agents
- Vendors are not likely to be 100% personally vested in your compliance objectives
- The vendor's compliance capabilities are only as good as the businessperson overseeing the project & the compliance systems in place

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Vendor Oversight: Diffuse Compliance Responsibilities

- Risk mitigation responsibilities for vendors is often diffuse:
 - **Legal:** Contract language & key provisions
 - **Business:** Project development & day to day management
 - **Finance:** Payments
 - **Compliance:** Vendor training, monitoring & auditing, corrective action

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Vendor Risk Mitigation: Deploy compliance resources strategically

- Identify the major vendor risk areas:
 - Substantive: Criminal laws, CIA areas, deferred prosecution agreements
 - Business Unit Focus/Compliance Challenges
 - Vendor-specific focus
 - New laws & regulations/New government focus
- Key question: Is it wise to use vendors to close a compliance gap?
- Collaborate with the business (!!!)
 - Review the vendor's response to an RFP
 - Attend vendor capability presentations & pitches
 - Conduct vendor training yourself or “train the trainer”

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Vendor Selection: Promises, promises

- Can they really build the system they describe?
- Will the system achieve the Corporate compliance objectives?
- Can you ensure that vendor turnover will not negatively impact contract performance?
- Does the vendor appreciate the nuances of the risk areas?
- Does the system need to be flexible? Can they change the system as laws & risks change?

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Vendor Management: Key Risk Mitigation Tactics

- Mandatory training:
 - Live, all day training
 - CD Rom/web-based
 - Specialized training on key policies & risk areas
- Contract provisions: Right to monitor & audit
 - Include open-ended provisions regarding when, where & how
- Document retention – a MUST!!!!
 - Especially if required by law or if quick access is needed for an audit or investigation (make this part of your due diligence)
- Communication:
 - Who does the vendor call with compliance questions?
 - Understand & protect the attorney-client privilege
- Clear accountability for policy/legal violations

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One Challenging Example

- Watch out for “risk intersections:” The crossroads where Clinical and Commercial risk areas meet.
- **Example:** Phase IV and other post-marketing studies.
 - Patient recruitment relies on payments to a large number of investigators.
 - Drug use & reimbursement (especially in Medicare/Medicaid populations)
 - Avoid appearance of Off-label promotion/”Seeding” studies
- CRO’s are experts in FDA and global pharmacovigilance regulations. Their primary focus – and your clinical organization’s – is data collection, reporting, etc.
- Identify the **high risk** areas that are secondary to the CRO’s primary business purpose.

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One Challenging Example

- High/Moderate Risks in Ph. IV observational studies:
 - Federal & state anti-kickback laws
 - False Claims
 - State disclosure laws
- Does the CRO understand the laws, your policies and the “gray areas?”
 - Examples: Investigator selection, payments, refunds, removal of investigators
- Do they have a process in place to comply with these laws? Is their system compatible with yours?
- Can the CRO provide the type of data that is necessary for you to comply?

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Partnership With Governance Structure: Optimal Management of Third Parties

The CRO Perspective, with an
Emphasis on Drug Safety

Ned Kelly, MD

VP Global Pharmacovigilance

Quintiles

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All-Too-Typical Clinical Trial Outsourcing

- Develop protocol, send out RFP to competing CROs
- CRO proposals may offer good ideas (i.e. “free consulting”), serve as basis for selecting top 2-4 candidates for project
- From top candidates’ presentations, sponsor gains familiarity and comfort with the winning team
- Sponsor is very worried that vendor will not deliver as promised (often justified), and is quick to condemn vendor as soon as inevitable first mistake is made
- Relationship between sponsor and vendor remains tense throughout project, thereby inhibiting transparency

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Sponsor Risk Mitigation Strategies

- Audit vendors, audit investigative sites for investigator performance and vendor monitoring performance
- Smorgasbord: outsource different functions (“pick the best” from clinical monitoring, data management, etc.) to different vendors;
 - risk of suspicion, blame and poor collaboration among vendors;
 - inefficient duplication of management across vendors;
 - complex management challenge for sponsor
- Micro manage
- Financial penalties for poor delivery/missing milestones, and sometimes rewards for exceeding standards

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Attributes of Partnership

- Shared risk – both win, or both lose
- Transparency
- Governance structure with communication plan and issue escalation pathway
- Service level agreements (SLAs) based on sponsor benchmarks, to be surpassed as program matures
- Robust training program, curriculum updated regularly
- Frequent, metrics-driven assessments
- Mutual trust is essential
- Usually a long-term commitment
- Key goal is improved productivity and quality resulting from continuous process improvement

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Partnership Governance



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Governance & Oversight Concept

Executive Steering Committee [EsC]

Responsibilities:

- Senior oversight of the Program, and
- Overall responsibility for identifying its operational goals and evaluating whether such goals are satisfied

Composition:

- At least three executive management team members each from Vendor and Sponsor, serving as Core Members
- Sponsor Program Director and Vendor Program Director also serve in an advisory role
- A mutually acceptable Objective Observer (not employed by Vendor or Sponsor) may serve as an advisor

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Governance & Oversight Concept

Operational Committee [OC]

Responsibilities:

- Ensuring the overall success of Program operations and services; design and review of metrics reports
- Change management and issue resolution/escalation

Composition:

- Established during start-up phase for duration of project
- Sponsor and Vendor project leads, with key supporting functions (e.g., Quality Management, HR) serving as either Core Members or as advisors.
- Vendor and Sponsor will each appoint an equal number of appropriate representatives.

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Governance & Oversight Concept

Operational Review Teams [ORTs]

Responsibilities:

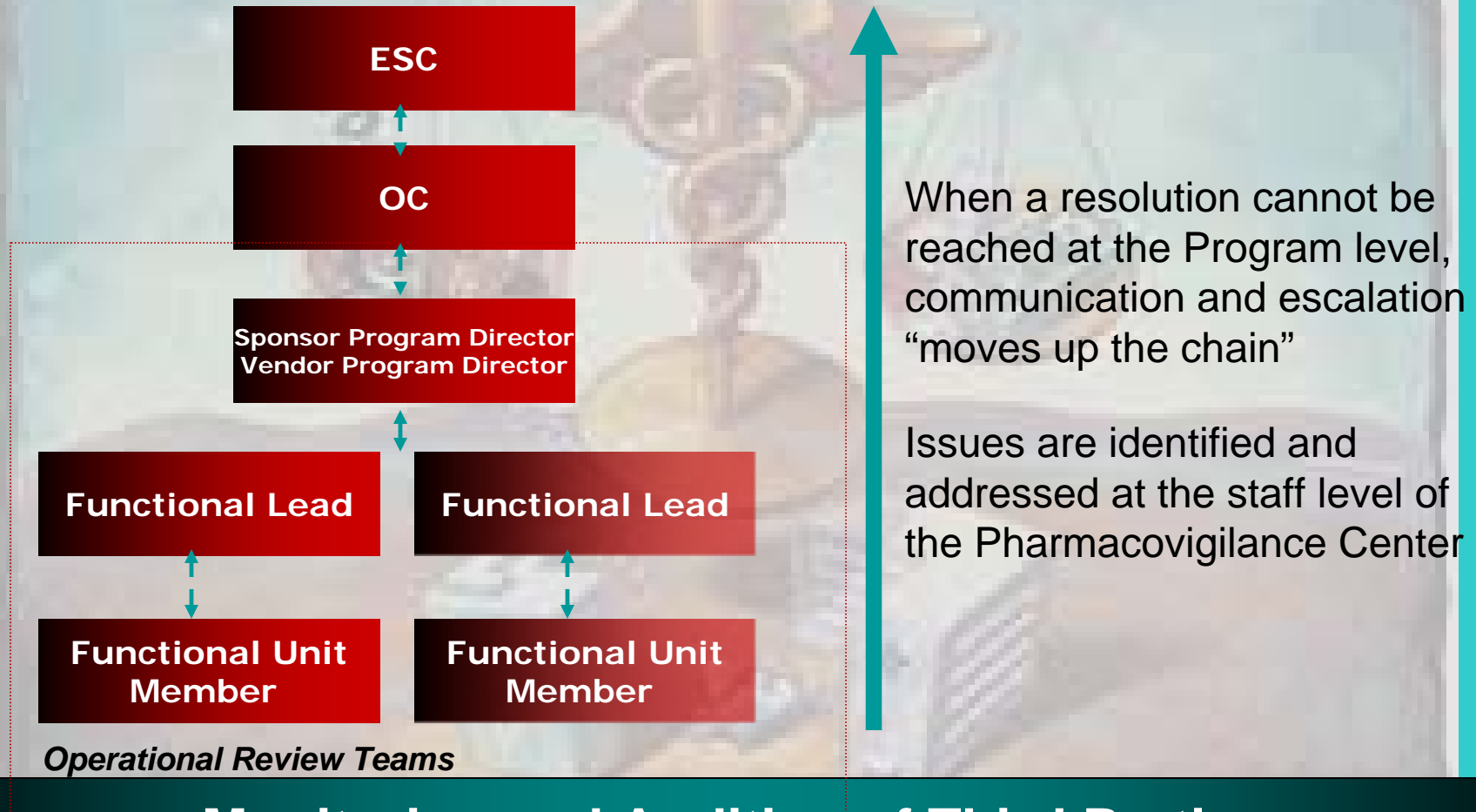
- Ensuring alignment of each of the Program's functional areas (e.g., case processing, aggregate reporting) with Sponsor objectives
- Delivery of delegated activities; metrics reports of their activities

Composition

- OC will identify ORTs during the Start-Up Phase or later as needed
- May be function-specific or across 2 or more functions
- Composition: Line managers, team leads or subject matter experts for concerned functional areas
- Vendor and Sponsor each appoints members to the ORTs via OC
- May be further aligned by role or product grouping
- OC approves the formation and dissolution of ORTs

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Partnership Governance: Issue Escalation & Communication Pathway



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Functional Service Provider Programs: A Growing Sector of Outsourcing

- Functional Service Provider (FSP) – outsourcing one service across multiple studies and/or one or more marketed products
- More common for “commodity” services, e.g., Data Management or Pharmacovigilance
- Pharmacovigilance (PhV) as example:
 - For larger customers, FSP group becomes an additional safety case processing center to enhance capacity, manage variations in work load, and lower cost
 - For smaller customers:
 - Ersatz PhV dept when company lacks resources
 - Advantage: keep all safety data in one database to facilitate analysis of product’s safety profile or new safety issues

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Training Program within an FSP Partnership

- Trainers from both sponsor and vendor collaborate on development of training curriculum and materials
- Leverage training technology platforms from both partners
- “Train the trainer” model – vendor’s project-dedicated trainers learn from sponsor’s and vendor’s trainers
- Training based on program SOPs (usually sponsor’s, with gaps filled by Project Instructions created by vendor and sponsor)
- Intense mentoring during transition phase from both sponsor’s and vendor’s subject matter experts

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FSP Programs in Partnership Context: Challenging Issues

- Sponsor's operational personnel must see value for themselves, e.g.:
 - Smoothing out peaks and valleys in workload
 - Vendor handles out of hours coverage
 - Improved coverage in global areas where sponsor has gaps
 - Relief from less interesting, routine work so that attention can be focused on more challenging areas that require greater expertise
- **The elephant in the room: sponsor outsourcing to FSP vendor often means loss of jobs for sponsor personnel**
 - Can compromise the spirit of partnership

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Partnership Performance Assessment: Frequent Metrics-Driven Reports

- Sponsor and vendor must agree on metrics, derived from process mapping – OC level decision, with approval/modification by ESC
- Frequency:
 - Weekly in start-up phases
 - Frequency may decrease as program matures
- Report should include:
 - Time-linear graphic representation of each metric
 - Identify week-on-week changes and explain why
 - Design and implement action plan, e.g., process improvement and/or staff re-training/mentoring
 - Follow-up/reassess weekly, or as appropriate

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Example FSP Project

Status Dashboard - Operational Performance

Focus Area	Source	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Rating Criteria
Consistency of reviewers	Quality Reviews	●	●	●	●	▲	●	▲	▲	●	●	<ul style="list-style-type: none"> ● Acceptable ▲ Nds Improvement ◆ Puts project at risk
Language/ Grammar	Quality Reviews	▲	●	▲	●	▲	●	●	●	●	●	<ul style="list-style-type: none"> ● Acceptable ▲ Nds Improvement ◆ Puts project at risk
Narrative content	PvMDs, Quality Reviews	▲	▲	●	●	▲	▲	●	▲	●	●	<ul style="list-style-type: none"> ● Acceptable ▲ Nds Improvement ◆ Puts project at risk
Quality	QC Error Rate	●	▲	●	●	▲	●	●	●	●	●	<ul style="list-style-type: none"> ● Acceptable ▲ Nds Improvement ◆ Puts project at risk
Timelines	Daily reports	◆	◆	◆	●	◆	●	●	●	●	●	<ul style="list-style-type: none"> ● Contract Timelines met ◆ Contract Timelines missed
Compliance	QA & Daily Reprts	●	●	●	●	●	●	●	●	●	●	<ul style="list-style-type: none"> ● Acceptable ▲ Nds Improvement ◆ Puts project at risk
Process	Quality Reviews LMs, Mentors	▲	▲	▲	▲	●	▲	▲	●	●	●	<ul style="list-style-type: none"> ● Acceptable ▲ Nds Improvement ◆ Puts project at risk

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Routine Outsourcing vs. Partnership

- Unilateral, risk-mitigation strategies imply mistrust, leave most of risk with sponsor
- Partnership built on trust, in which vendor can take on more of the risk and benefit (mainly as project success)
- Routine outsourcing often fails to leverage strengths of vendor
- Partnership includes vendor in mission-critical design and decisions, at least as advisor
- Partnership can imbed vendor personnel within sponsor and/or sponsor personnel within vendor, thereby promoting better mutual understanding

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When to Use Partnership

- Vendor who has earned trust
- Preferably vendor has record of similar partnerships
- Vendor and sponsor share partnership philosophy
- Long-term, larger projects
- Alliance management – for example, sponsor and vendor jointly develop a product or products in risk/benefit sharing context
- Large functional service provider (FSP) projects for single service, e.g., Pharmacovigilance or Data Management

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Panel Discussion

- Can a Sponsor ever really transfer risk and liability to a vendor?
- Even if a behavior is “allowable” companies should watch out for the Grassley Waxman effect.
- What additional steps can we take to promote compliance and cost effectiveness?

A painting of a balance scale, symbolizing justice or balance. The scale is positioned in the center, with two pans hanging from a horizontal beam. The background is a soft, hazy landscape. The word "QUESTIONS?" is written in large, bold, black capital letters across the middle of the image, centered over the scale's beam.

QUESTIONS?

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