How to Get the Best from Supplier Audits

A webinar for clinical trial sponsors and service providers

November 3, 2021
8am Pacific · 11am Eastern · 3pm UK · 4pm CET

DILIGENT® QUALIFICATION PLATFORM

Welcome and Introductions

Panel Members

Steve Gilbride,

President of SG Research International (SGRI)

Mary Mackney,

QA Consultant, Pharma QA

Joseph Schenk,

CEO at Quality Bridge

Jennifer Sessions,

Sr. Director, Diligent Pharma

Key steps to effective supplier quality audits:
From an auditor's perspective

Optimize Preparation

Setting the Agenda
Plan/Schedule
To Checklist or Not

Perform Audit

Identify discrepancies
Document results
Stay on track

Finalize CAPA/ Generate Report/ Action Tasks/ Closeout

Are action items addressed?
Are all responses captured?
Have appropriate sign-offs been received?

Key Learning Objectives

1. Hear challenges faced when qualifying service providers
2. Learn tips to conduct assessments of clinical trial service providers to maximize efficiency and speed
3. Discover how to prioritize strategically so internal resources can focus on the highest business risks

Q&A Box is open – you may submit your questions at any point

Preparing for the Assessment

- Perform homework on the Vendor
  - How long in Business
  - Consider the Phase of Development (I,II,III,IV)
  - Identify what to monitor
  - Identify Risks
  - Assess Risks
- Create an agenda which tries to elicit feedback
  - Follow up with a meeting after the agenda is sent
  - Determine strengths and weaknesses
- Go into the audit with an open mind

Conduct and Follow-Up of the Assessment

- Determine if Vendor is in a "State of Control"
- Don't be Afraid to Look beyond the Agenda
  - Recognize behaviors
  - Keep your ears and eyes open
- Try to Identify Gaps
  - Identify Risks and Assess Them
- Be Diplomatic, but be Honest During Interviews
- Explain the Next Steps
- Good Report Writing can Depend on how you left the Vendor
  - You may need additional information
- Be Clear in Writing the Observations
- CAPA Responses Should Address the Observation
- CAPAs Should Drive Improvement

Poll Question 1

In the past 24 months, have you been involved in a trial with a quality and/or timeline problem due to a vendor?

Yes
No
Not Sure

Why conduct vendor audits?

- Part of a vendor selection
- Annual/periodic review of the vendors and prior to contracts being renewed
- Proactive measure to determine their third-parties' compliance with legislation and contract
- Investigations into allegations of misconduct or overbilling by the third-party

Preparation

Communicating the process

- Establish the scope of the audit
- Develop the agenda with the vendor
    - Sessions and interviews to be scheduled
    - Identify staff to attend opening and closing meetings
- Request documentation and review prior to audit
    - Organogram
    - SOP/Work Instruction Index list
    - Request and review selected SOPs if possible
    - Request access to electronic systems such as Electronic Case Report Form, Electronic Trial Master File, electronic quality management system

Auditor's Perspective – Mary Mackney

Performing the audit

- Facilities tour
- Interviewing staff
- Reviewing documentation
  - Assessing level of compliance with existing processes
- Identifying issues / areas of non compliance

Report and CAPA

- Drafting report
- Report reviewed and finalised
- CAPA sent to vendor
- Closure and certificate issued

What can go wrong ?

Poll Question 2

In the past 24 months, have you been involved with a vendor that was new to implementing a Quality Management System?

Yes
No
Not Sure

What could happen if a supplier is not assessed?

FDA Actions in last 5 years:

- Over thirty (30+) FDA 483s issued to CMOs, CROs, CLOs
  - Over 70% Include **Data Integrity** Findings
- Over eleven (11+) FDA "Complete Response Letters (CRLs)" issued which cite **Third-Party Issues**
  - This is greater than the CRLs asking for more clinical data!
  - Impact: Delays in NDA or BLA Approval
  - Impact: Additional Rework, Oversight, and Stress

Preparation, Conduct and Follow-up of Assessment

Preparation

- Knowing how many the audits the supplier has hosted in the last 12 months can be a leading indicator of how prepared they will be for this audit.

Conduct

- Building Rapport with the Supplier Host and Host's Team is critical at the beginning to help the audit achieve the objectives:
  - Thanking them in advance for their hard work in preparation of the audit
  - Letting the audit participants know the "What and Why"
    - Audit objectives and standards
    - Audit's role in information flow to the Sponsor to enable contract continuance and growth

Assessment

- Writing the Audit Report for **multiple** Sponsor Stakeholders is a key to success

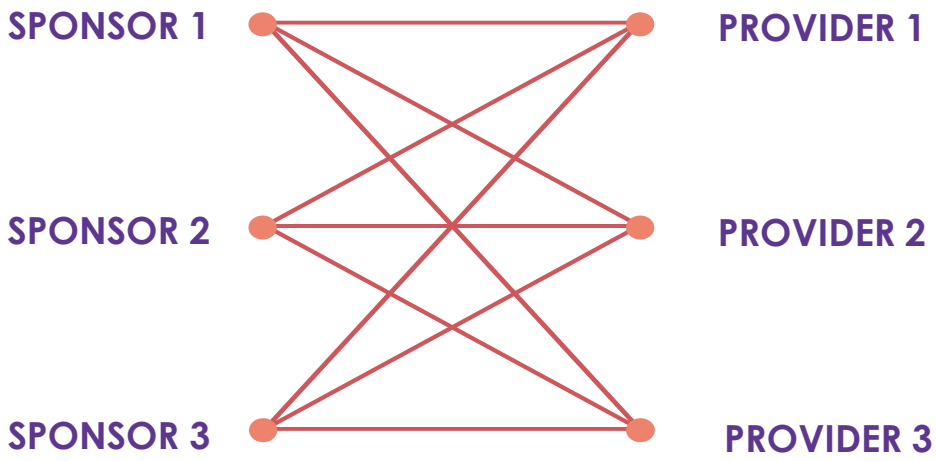
Poll Question 3

In the past 24 months, have you been involved with a vendor audit that uncovered “Critical” findings?

Yes
No
Not Sure

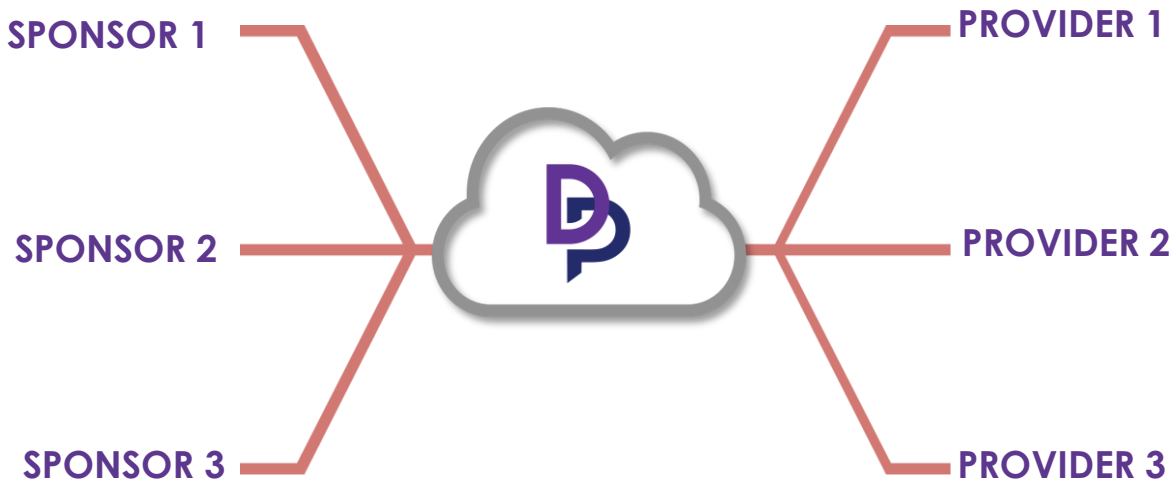
Strategic Prioritization

Traditional model of clinical trial vendor qualification



Every sponsor qualifies every vendor
= Complex & time-consuming

Diligent system for clinical trial vendor qualification



One central database with completed, searchable RFI questionnaires and anonymized VQAs

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Let's Hear from You!

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Thank you for your participation

We will send you a link to these slides and a recording of this webinar

More questions for our panel?

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