

Embedding Vendor Oversight E2E

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Agenda:

Why Vendor Oversight is Important

Health Authority Expectations and Regulations

Right-sizing your vendor oversight

What Vendor Oversight Is and Is Not

Benefits of a Holistic Approach

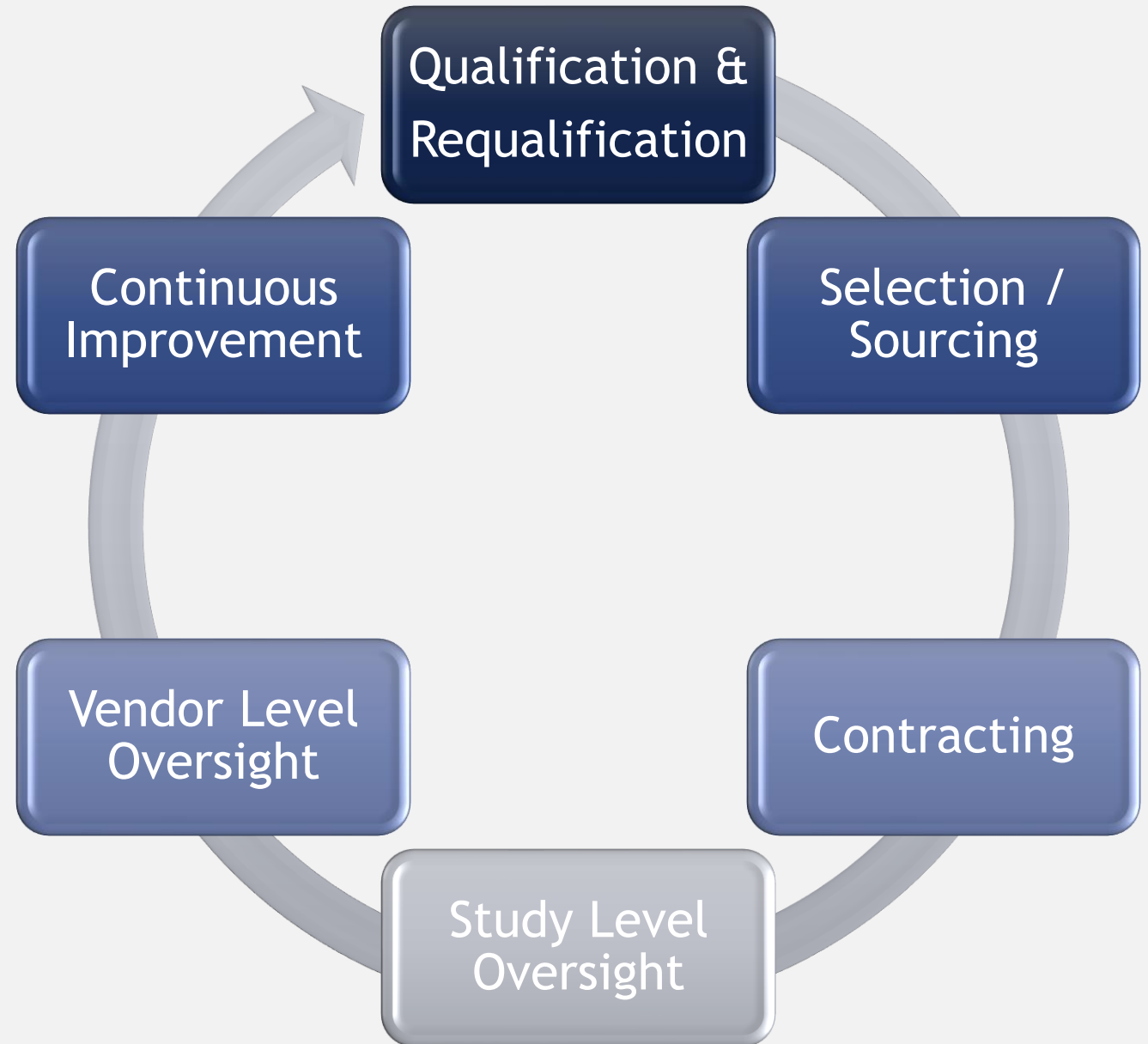
Building Quality into each step of the vendor mgmt. process

Cross-functional Collaboration in Vendor Oversight

Using effective behaviors and engagement with vendors and internal functions



Holistic Approach to Vendor Oversight: End to End



Why is Vendor Oversight so important?

Protect Patient Safety and Data Integrity & Assure Compliance to Regulatory Requirements

Regular oversight ensures that vendors stay aligned with Sponsors Quality Standards, Protocols, Regulatory requirements minimising risk to Patient Safety & Data integrity

Health Authority Inspections

Reduced risk of findings by ensuring appropriate vendor controls in place

Risk Mitigation

Proactive risk identification to implement mitigation strategy & reduce likelihood of event occurring

Issue Management

Address in a timely way to limit impact of issues

Continuous Improvement

Ensure lessons learned are addressed to support continuous Improvement with key Vendor relationships

Budget Control

Ensure work is completed within budget and on schedule.

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What are Health Authorities looking for when assessing a Sponsors Vendor Oversight?



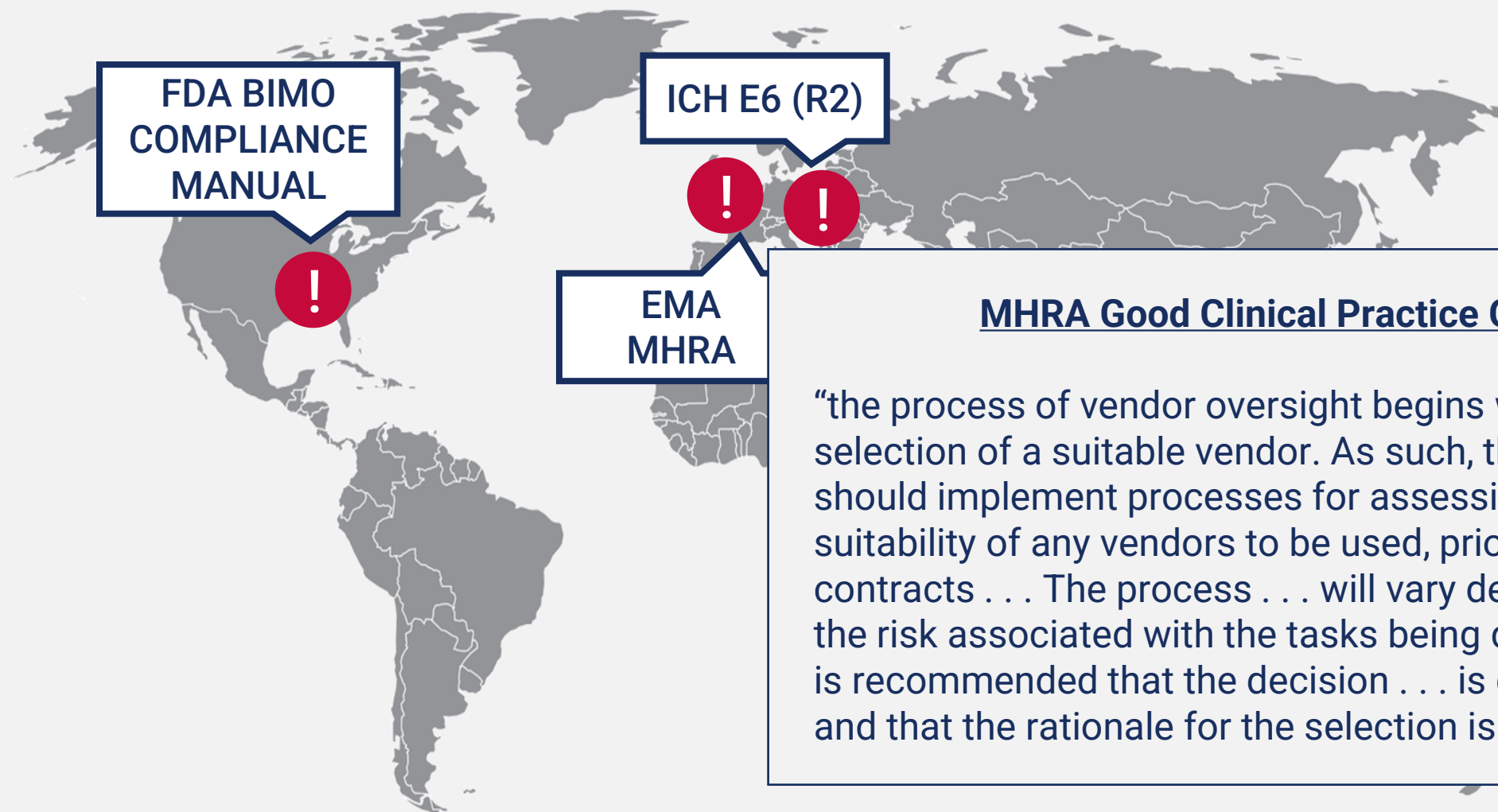
The image features a world map with three callout boxes. The first box, labeled 'FDA BIMO COMPLIANCE MANUAL', points to North America and contains a red circle with a white exclamation mark. The second box, labeled 'ICH E6 (R2)', points to Europe and contains a red circle with a white exclamation mark. The third box, also labeled 'ICH E6 (R2)', is located on the right side of the map and contains a list of bullet points. The title 'ICH E6 (R2)' is underlined, and there is a large 'X' in the top right corner of this box.

FDA BIMO COMPLIANCE MANUAL

ICH E6 (R2)

ICH E6 (R2) X

- Located in Switzerland, the International Council for Harmonization (ICH) published ICH E6 which is an **international** ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve human subjects.
- Ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.
- The sponsor should utilize qualified individuals throughout the trial.
- The Sponsor should ensure oversight of any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are subcontracted to another party by the Sponsor's contracted CRO(s).



FDA BIMO
COMPLIANCE
MANUAL

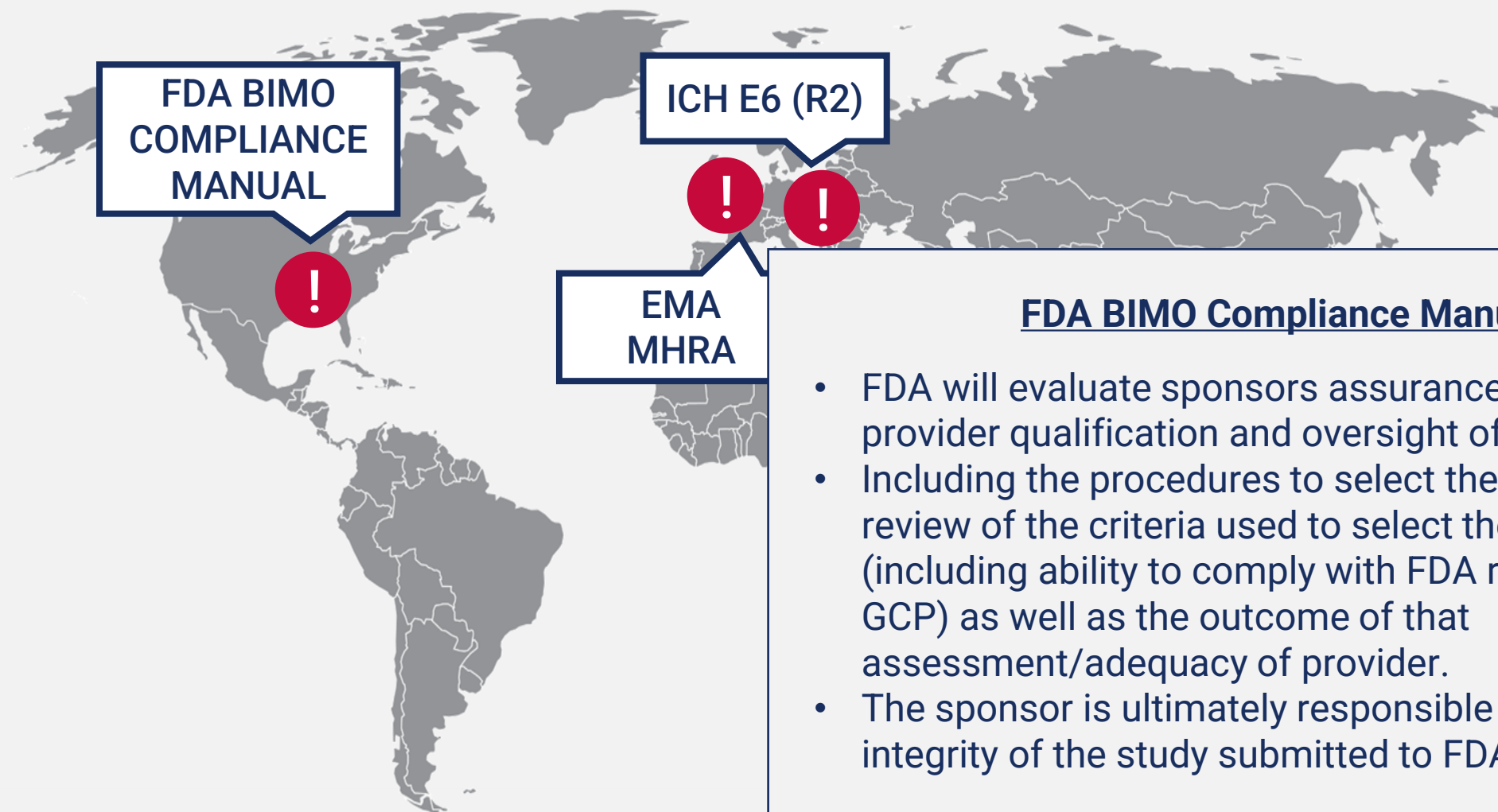
ICH E6 (R2)

EMA
MHRA

MHRA Good Clinical Practice Guide

X

“the process of vendor oversight begins with the selection of a suitable vendor. As such, the Sponsor should implement processes for assessing the suitability of any vendors to be used, prior to signing contracts . . . The process . . . will vary depending on the risk associated with the tasks being delegated . . . It is recommended that the decision . . . is documented and that the rationale for the selection is clear.”



FDA BIMO Compliance Manual

X

- FDA will evaluate sponsors assurance of service provider qualification and oversight of activities.
- Including the procedures to select the provider and review of the criteria used to select the provider (including ability to comply with FDA regulations and GCP) as well as the outcome of that assessment/adequacy of provider.
- The sponsor is ultimately responsible for the integrity of the study submitted to FDA.

Common Vendor Oversight Findings from Health Authorities



Inadequate Vendor Selection & Qualification

Lack of documented qualification process and due diligence in selecting clinical trial vendors

Missing Agreements

Failure to establish formal agreements defining roles and responsibilities between sponsor and vendors

Poor Documentation Control

Insufficient documentation of vendor oversight activities, communications, and performance throughout the clinical trial

Inadequate Performance Monitoring

Lack of regular oversight and performance monitoring of vendor activities against established metrics

Training Deficiencies

Insufficient evidence of vendor personnel training on protocol requirements and GCP guidelines

Risk Assessment Gaps

Failure to conduct and document risk assessments for critical vendor-provided services



Vendor Oversight Findings - some examples

- TMF maintenance was outsourced to a vendor, there was little information available in Sponsor's files to demonstrate effective oversight of clinical trial activities in order to fulfill its obligation as a Sponsor
- Sponsor did not have an oversight on completion of the training for the CRO's study staff...
- No process to ensure access is revoked / system access is disabled in a timely manner who are no longer working on the study.
- Roles and responsibilities were unclear in contract or other study documentation between Sponsor and vendor, therefore the oversight of 3rd party vendor activities were unclear
- Vendor Oversight plans were not put in place per procedure ... or were put in place LATE, after contract execution / GxP services commenced / were not followed (with evidence)



Examples of Health Authority Inspections Findings relating to Vendor Oversight on Clinical Trials? Chat GBT...said

Lack of Oversight on Data Integrity:

- **Finding:** Insufficient monitoring of data collection or analysis by a third-party vendor, leading to concerns about the accuracy and reliability of clinical trial data.
- **Example:** The inspection reveals that the vendor did not follow standard operating procedures (SOPs) for data verification, resulting in data discrepancies or incomplete documentation, which compromises the trial's integrity.

Inadequate Monitoring of Vendor Performance:

- **Finding:** Failure to regularly assess and document the performance of the clinical trial vendor.
- **Example:** The sponsor did not conduct regular performance reviews, and there was no clear documentation of corrective actions when the vendor was behind schedule or failed to meet milestones. This led to delays or issues with data quality.

Non-Compliance with Protocol and SOPs:

- **Finding:** The vendor did not adhere to the trial protocol or relevant SOPs, affecting the trial's consistency or patient safety.
- **Example:** The vendor failed to properly train clinical site staff or mismanaged adverse event reporting, violating regulatory requirements for patient safety.

Inadequate Vendor Qualification and Selection:

- **Finding:** The sponsor or CRO did not properly qualify the vendor before contracting, resulting in a lack of assurance that the vendor could meet trial-specific requirements.
- **Example:** A clinical trial site vendor was hired without a formal risk assessment or qualification process, and it was found that the vendor lacked the necessary experience to handle the trial's complexity, leading to quality issues.

Failure to Ensure Vendor Compliance with Regulatory Requirements:

- **Finding:** The sponsor did not verify that vendors were compliant with regulatory guidelines, such as Good Clinical Practice (GCP).
- **Example:** The vendor was found not to be properly following GCP guidelines for patient informed consent, jeopardizing the trial's compliance with ethical standards.

Poor Communication Between Sponsor and Vendor:

- **Finding:** Inadequate communication between the sponsor and the vendor, which resulted in critical issues being overlooked or delayed.
- **Example:** There was a lack of formal communication channels or regular meetings, leading to gaps in information flow about trial progress, protocol amendments, or patient safety issues.

Failure to Conduct Adequate Risk Management:

- **Finding:** The sponsor did not adequately assess or manage the risks associated with third-party vendors, leading to trial delays or other operational issues.
- **Example:** The sponsor failed to conduct a thorough risk assessment of the clinical trial vendor's capacity, resulting in a shortage of staff to manage trial sites, which delayed recruitment and data collection.

Lack of Monitoring of Subcontracted Vendors:

- **Finding:** Vendors subcontracted critical trial functions to third parties without appropriate oversight or qualification, leading to quality control issues.
- **Example:** A central laboratory used by the trial subcontracted sample analysis to an unqualified third party without the sponsor's knowledge or approval. This led to inaccurate results or missing data.

Inconsistent Documentation of Vendor Oversight Activities:

- **Finding:** Inadequate documentation or lack of evidence showing active oversight and evaluation of vendor activities.
- **Example:** The sponsor did not keep proper records of vendor audits, site visits, or performance reviews, making it difficult to demonstrate that proper oversight was in place during an inspection.

Failure to Implement Corrective Actions:

- **Finding:** When issues were identified with a vendor's performance or compliance, corrective actions were not implemented or were not documented adequately.
- **Example:** A vendor repeatedly failed to meet data submission timelines, but the sponsor did not take timely corrective action, and there was no evidence of the issue being escalated or resolved.



**What would you say if an inspector
asks:**

**How Do You Oversee Your Study?
How Do You Oversee Your
Vendors?**



Vendor oversight is...



Solid Pulse



Is the study enrolling? Is the study in line with the study plan?



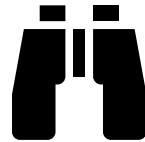
Risk Based Approach



What could go wrong? How bad could it be? What should we do about it?



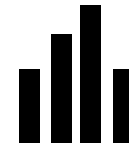
Monitor Performance



Is the vendor delivering per contract? Are milestones met?



Analyze Data



Are there any trends in the data?



Issue Management



Is the escalation plan clear? Is there adequate involvement and communication?

Vendor oversight is NOT...



Duplication
of Work



Do **not** redo the work contracted to a vendor.



Micromanaging



Do **not** focus on the How more than on the What.



Hovering Over
Process



Do **not** hover over the specifics.

Good oversight practices

- 1 Understand agreements, obligations and expectations
- 2 Create and follow study, functional, and vendor oversight plans
- 3 Take a risk-based approach to oversight activities
- 4 Provide a robust vendor audit program



- 5 Stay involved with projects and ask tough questions
- 6 Communicate concerns, issues, and changes early to avoid surprises
- 7 Provide realistic assessment of timelines and needs
- 8 Listen, learn, and respect

Good Key Behaviors

1

Form long term partnership with open communication

2

Understand agreements, obligations and expectations

3

Maximize consistency of practices

4

Remain flexible

Good Key Behaviors

5

Stay involved with projects and ask tough questions

6

Communicate concerns, issues, and changes early to avoid surprises

7

Provide realistic assessment of timelines and needs

8

Listen, learn, and respect



What does a good Vendor Oversight Plan look like?



A single document that can be provided to inspectors that outlines clearly what vendor oversight activities are in place for each Vendor



Performance and Quality checks determined by the risk of the vendor and focused on patient safety, data integrity, and critical data for primary and secondary endpoints



Cross functional oversight responsibilities clearly defined when multiple functions are collaborating on oversight of a vendor



A living document that is utilized throughout the course of the engagement with a vendor

Also consider formalising in Procedural Documentation the requirement to have a Vendor Oversight Plan in place for high- risk vendors

How do we Assess High Risk Vendors ?

To build core oversight processes 4 key areas are considered...



Potential impact to Patient Safety or Regulatory compliance

- **Patient safety/ welfare** impact highlight likely
- **Conducts pivotal studies** or supporting primary / secondary or safety endpoints
- **Inspection likelihood high**

Possible Examples:
CRO services, Lab services (central, specialty, biomarker during clinical trials), eCOA, EDC, IxRS, FSP,, imaging,



Potential Impact to Data Integrity/Interpretability

- **Primary / secondary /safety endpoints** impacted
- **Sponsor Data** is managed, stored or transferred by Vendor
- **Access to confidential study data or Personal information (PI) or Sensitive personal information (SPI)** for study participants.

Possible examples:
CRO services, lab services, Medical Imaging, eCOA, ECG, EDC, PV, IxRS and eTMF



Interaction with government officials or healthcare professionals.

- **Represent Sponsor** position in discussions that could impact regulatory compliance or Sponsor reputation

Possible examples:
DHCP services, call centers for medical info, medical writing etc



Percentage of annual spend/ body of work

- **Business Continuity** is dependent on vendor services
- **Cross –study or TA impact** Provides services on multiple studies or multiple therapeutic areas or accounts for high percentage of spend.

Possible examples:
FSPs, Preferred Vendors in low risk areas

However other considerations may change the risk of the Vendor....

Outsourcing Strategy

- Proactive identification of future risk based on changes to vendor engagement

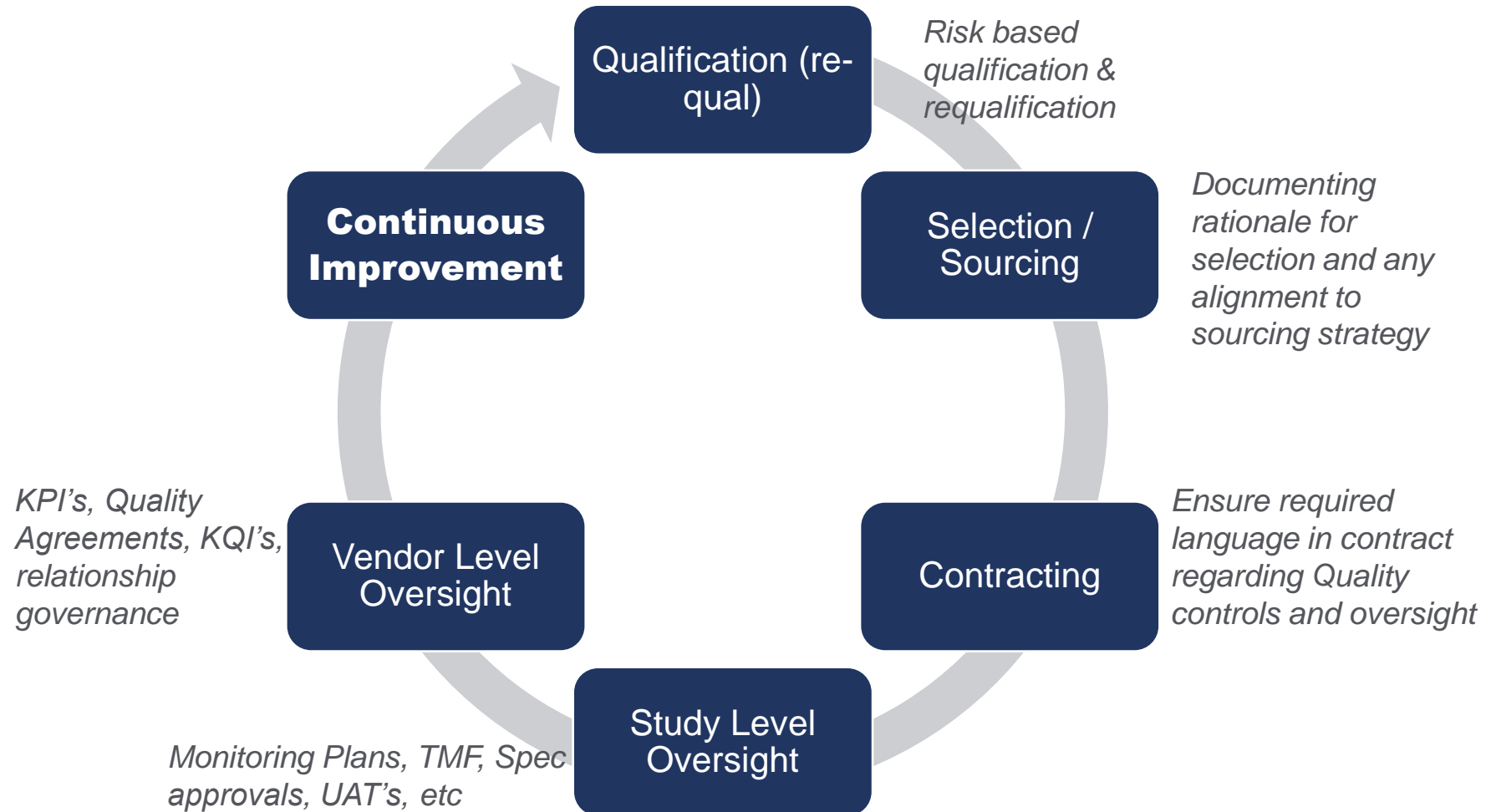
Performance history

- Identify high risk issues that change the risk of working with vendor

Outputs from Qualification, Audits and Key Quality Indicators

- Identify high risk areas that require updates to standard oversight

Benefits of Holistic Approach to Vendor Oversight: End to End



- **Regulators look at it holistically, therefore, so should we!**
- **There are interdependencies between each area and downstream impacts**
- **Cross functional collaboration is required to effectively implement vendor oversight**



What Matters Most: Embedding Vendor Oversight

- 1 Vendor oversight is a regulatory requirement and helps ensure patient safety and data integrity
- 2 Right-size your oversight, taking a risk-based approach
- 3 Take a holistic approach to ensure quality end to end
- 4 Document the oversight appropriately, with necessary evidence and follow through



Thank you!

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