Vendor Oversight Track
Day 1
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wcg™ Metrics Champion Consortium

CLINICAL TRIAL RISK AND PERFORMANCE MANAGEMENT SUMMIT

SEPTEMBER 4-5, 2019
PHILADELPHIA, PA USA

Welcome!

Agenda

1-1:45 PM PRESENTATION: Vendor Oversight • Terminology, ICH GCP E6 R2 • What is Vendor oversight? • Regulatory authority inspections
1:45-2:15 PM PRESENTATION: Managing the Business of Inefficient Oversight: How Heavy (or Light) is Your Touch When it Comes to Overseeing Vendors?
2:15–3:00 PM PANEL: Vendor Oversight Approaches and the Keys to Developing "Healthy" Sponsor/Vendor Engagements and Teams
3-3:30 PM BREAK
3:30-4:15 PM CASE STUDY: An Evolving Approach to CRO Oversight — Challenges, Lessons and Takeaways
4:15-5:30 PM EXERCISE: Vendor Oversight Part 1
5:30-6:30 PM NETWORKING RECEPTION
6:45 PM – 8:30 PM MCC MEMBER DINNER


QUESTIONS

POLLING

QUESTIONS

Polling Question #1

Does your organization have a Vendor Oversight SOP?

1. Yes
2. No
3. Don’t Know

Polling Question #2

Does your organization utilize Vendor Oversight Plans?

1. Yes
2. No
3. Don’t Know

Polling Question #3

In ONE word, what is the key challenge for implementing Vendor oversight in your organization?


QUESTIONS

ICH GCP E6 R2

Contract Research Organization (CRO) - Vendor

A **person or an organization** (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's **trial-related duties and functions**.

ICH GCP E6 R2 1.20

ICH GCP E6 R2 5.2.2

The sponsor should ensure **oversight of any trial-related duties and functions** carried out on its behalf

- Includes trial-related duties and functions that are **subcontracted to another party by the sponsor's contracted CRO(s).**

ICH GCP E6 R2 5.2.2

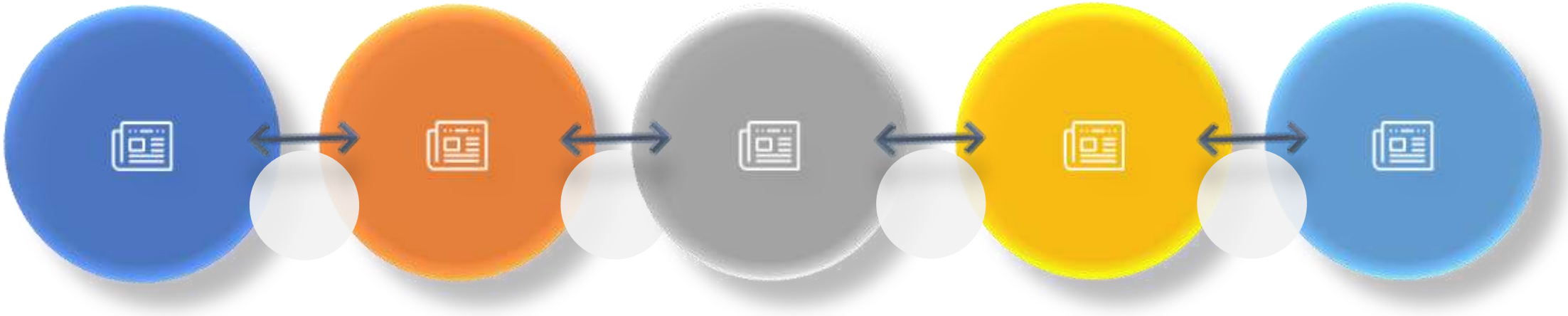
Regulatory authorities inspect your:

- Adherence
- Staff for oversight
- Processes
- Procedures
- Quality, quality management system
- Documentation for oversight
- **Checking that your oversight is effective**

Vendor Oversight vs. Vendor Management


VENDOR
OVER
SIGHT

Vendor Oversight



Utilize databases to assess staff performance for trends/patterns

Review work product

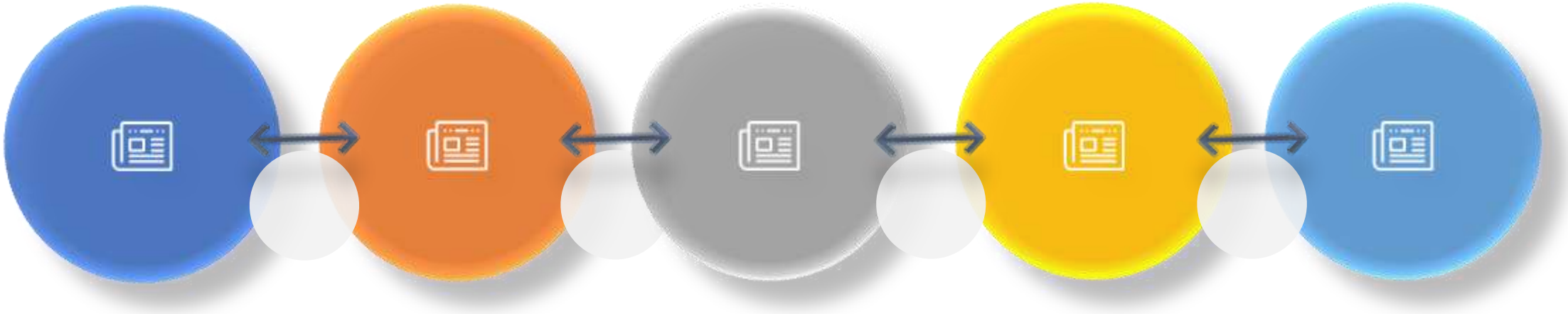
On-site assessment visits

Vendor assessments of staff performance

File, documentation assessment

MHRA GCP Grey Guide

Vendor Oversight



Early issue escalation, management and documentation

Regular meetings, decision log, issues identified and addressed (issue log)

Face-to-face meetings project progress, etc.

Progress Reports: Define what review means/ assessments made and document

Signatories: Key Trial Documents *(study plans, protocol, IB, etc.)*

MHRA GCP Grey Guide

Vendor Oversight Plan Template

1. Cover Page
2. Introduction
3. Study Contacts
4. Governance
5. Staff Qualification & Selection
6. Team Training
7. **Oversight Activities & Responsibilities**
8. Feedback: Performance and Quality
9. Oversight of Vendor Sub-Contractors
10. Communication Plan
11. Risk Management Plan
12. Effectiveness Checks
13. Vendor Transition
14. Procedural Documents
15. Metrics

Sponsor & Vendor Staff Assignments, Timelines

Vendor Function/Name Primary Responsibilities	Sponsor Function Name Responsible Person(s) for Oversight	Activity-Task-Document	Due Date(s), Completion Timelines
Trial Management Lead- On-Site Monitoring	Study Manager	Monitoring Plan (review, approval)	28Jan2019

Sponsor Oversight Activities: Details!

Activity-Task-Document	Sponsor Function Name Responsible Person (s) for Oversight	Frequency	Reference Standards for Review of Work Product, Deliverables	Documentation and Feedback to the Vendor	Effectiveness of Oversight Methods and Documentation
Monitoring Plan	Study Manager	Initial, updates as indicated	Monitoring Plan SOP and Associated Documents	Draft reviews Final approval signature	Completed per SOP Monthly Operational Oversight Meetings Meeting Minutes

CS Electronic System Name	System Description	How used for the study? – List All	Vendor Responsible Person	Sponsor Function Name, Responsible Person(s) for Oversight


QUESTIONS


INSPECTIONS

Inspections

Sponsor oversight of the trial and CRO - Vendors for Quality

CRO - Vendor Selection Criteria, Selection, Qualification

CRO - Vendor Oversight Practices

CRO - Vendor Oversight Plans

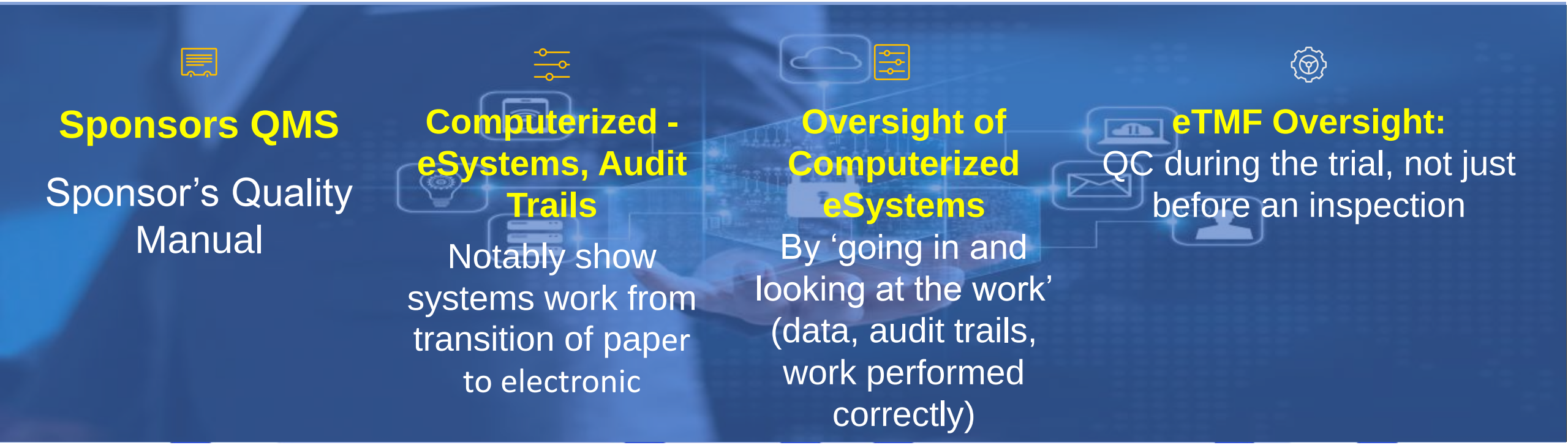
SOPs governing the trial

Inspect sponsor and not the CRO- interviewed on the governing SOPs for the trial

Review and approve CRO SOPs – what reference did you use? Where is the documentation of the review and approval?

Access to CRO SOPs to perform oversight

Inspections



Sponsors QMS

Sponsor's Quality Manual

Computerized - eSystems, Audit Trails

Notably show systems work from transition of paper to electronic

Oversight of Computerized eSystems

By 'going in and looking at the work' (data, audit trails, work performed correctly)

eTMF Oversight:

QC during the trial, not just before an inspection

MHRA Blog Post – CRO Oversight Part 1

CRO Oversight: Part of Sponsor's QMS

Ensure your **sponsor oversight activities** are clearly **defined within your Quality Management System (QMS)** and retain documentation and evidence of oversight in the Trial Master File (TMF)

Available at: https://mhrainspectorate.blog.gov.uk/2018/07/26/sponsor-oversight-part-1/

MHRA Blog Post – CRO Oversight Part 1

Documentation Trial Master File (TMF)

- **During inspections**, we are commonly told that TMF management is outsourced **and held by the vendor**.
- However, the **sponsor** should be able to **demonstrate their oversight of trial activities** which have been **delegated**, and to demonstrate this oversight during an inspection.

This <u>oversight</u> can be in the form of an oversight file which forms part of the overall TMF but remains with the sponsor.

- We have seen on inspection that at the end of the trial the TMF retrieved from the vendor was amalgamated with the sponsor's oversight file (and sponsor oversight documentation removed).
- It was therefore not possible to reconstruct what oversight the sponsor had of the trial whilst it was ongoing.

MHRA Blog Post – CRO Oversight Part 2

A commercial organisation was given a Major finding for the organization's oversight of clinical trials of IMP due to the following:

- **No evidence to demonstrate the sponsor oversight activities** as specified in the CROs plans had been complied with (for example oversight of approvals).
- **Inadequate documentation to demonstrate review of protocol deviations** occurring in the trials.
- **Co-monitoring visits were not performed in accordance with the monitoring oversight plan**. There was a lack of co-monitoring visits performed and when performed they had not been reviewed as required.
- **Inadequate documentation to demonstrate when MVRs created by CROs were reviewed,** by whom and the outcome of the review.
- **Lack of oversight of TMFs held by CRO -Vendor** to ensure they were up to date and complete.

Inspection Experiences

Activity	FDA Inspection	MHRA Inspection	EMA Inspection
Selection	x	x	x
Qualification	x	x	x
Oversight & Oversight Documentation, Issue Escalation and Management, Trial Master File	x	x	x
Contracts	x	x	x


QUESTIONS