Sponsor Oversight in Clinical Trials

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Introduction

- Director Clinical Science & Trial Operations, Pharma IT
- Principal Consultant for Pharma Companies
- 20 years of experience in clinical trials project management

Why are Sponsor Oversight Important?

Sponsor oversight is essential to ensure participant safety, data integrity, and compliance with regulatory requirements both in relation to CROs, vendors, and internal teams



Fit for Purpose

No one-size-fits-all





ALIGN OVERSIGHT
with project complexity and risk

SCALE PROCESSES
to company size and trial scope

SMALLER FIRMS / LOW-RISK STUDIES
streamlined oversight

LARGE ORGANIZATIONS / HIGH-RISK TRIALS
structured governance, frequent monitoring

Sponsor Oversight according to ICH GCP E6(R3) section 3.9

1. Ultimate Responsibility
2. Risk-Proportionate Oversight
3. Quality by Design (QbD)
4. Active and Documented Oversight
5. Data Governance and Visibility
6. Shared Accountability Across Partners

1.Ultimative Responsibility

Trial management activities can be conducted in-house, or activities can be partly or completely in-sourced or outsourced to third party organizations (e.g. Contract Research Organizations (CROs) and different vendors)

Sourcing strategy depends on the Sponsor organization and the trial, but when outsourcing to a 3rd party the sponsor must **ALWAYS** have systems and procedures in place to ensure adequate **sponsor oversight**

How to perform oversight of vendors sub-contractors?

REQUIRE TRANSPARENCY: Vendors disclose all sub-contractors
APPROVAL & FLOW-DOWN: Sponsor approves, GCP obligations included
GOVERNANCE: Oversight plan, delegation logs, audit reports
OPERATIONAL CHECKS: KPIs system access, audit rights
RISK-BASED APPROACH: Focus on critical processes
COMMUNICATION: Include sub-contractors in governance meetings

Example | CRO sub-contracting a Laboratory

Procestrin	Sponsor Handling	Dokumentation
Disclosure	CRO informerer sponsor om laboratoriet og dets r olle	Liste over sub-contractors, e-mail fra CRO
Godkendelse	Sponsor vurderer kvalifikationer og godkender lab oratoriet	Godkendelsesmail, opdateret oversight-plan
Kontraktkrav	Flow-down af GCP-forpligtelser, auditret i kontrakten	Kontrakt med flow-down klausuler
Dokumentation	Arkiver godkendelse og sub-contractor-liste i eTMF	Oversight-plan, eTMF-dokumenter
Opfølgning	Monitorér KPI'er, review af laboratoriets performance	KPI-rapporter, auditrapport, mødenoter

2. Risk-Proportionate Oversight

- Oversight tailored to trial complexity and risk level
- Focus on Critical-to-Quality factors
- Early risk assessment during trial design
- Implement proactive monitoring strategies
- Goal: Efficiency without compromising safety or compliance

3. Quality by Design (QbD)

- Build quality into the trial from the start
- Design processes to prevent errors impacting safety or data integrity
- Identify Critical-to-Quality factors early in design
- Integrate quality objectives into protocol and operational plans
- Focus on prevention rather than reactive problem-solving

4. Active and Documented Oversight

- Oversight must be continuous and operationalized
- Define roles, responsibilities, and escalation pathways clearly
- Document all oversight activities
  (e.g., governance meetings, monitoring plans)
- Maintain evidence of ongoing review of CRO/vendor performance
- Track and close corrective actions promptly

5. Data Governance and Visibility

- Ensure real-time access to operational and quality data
- Implement data integrity controls and verify compliance
- Establish systems to detect deviations and emerging risks
- Define clear governance processes for review and decision-making
- Enable transparent reporting and timely corrective actions

6. Shared Accountability Across Partners

- Foster collaboration and transparency between sponsor and service providers
- Define clear roles and responsibilities in agreements
- Establish joint governance structures for decision-making
- Share performance metrics and quality data openly
- Promote mutual accountability throughout the trial lifecycle

Sponsor Oversight Plan

AN OVERSIGHT PLAN IS KEY spend sufficient time on this before the study kicks off

- Make sure to have a clear overview of how the different aspects of oversight are documented
- Sponsor Oversight Tracker can be used to keep track of oversight activities to be performed, however can not be used as stand-alone documentation

AGREE UP FRONT WITH THE CRO exactly which reports you expect to receive on a regular basis

EXAMPLE OF OVERSIGHT MATRIX

To be described in Sponsor Oversight Plan

TITLE: SPONSOR OVERSIGHT PLAN	TRIAL ID:
	VERSION: 1.0

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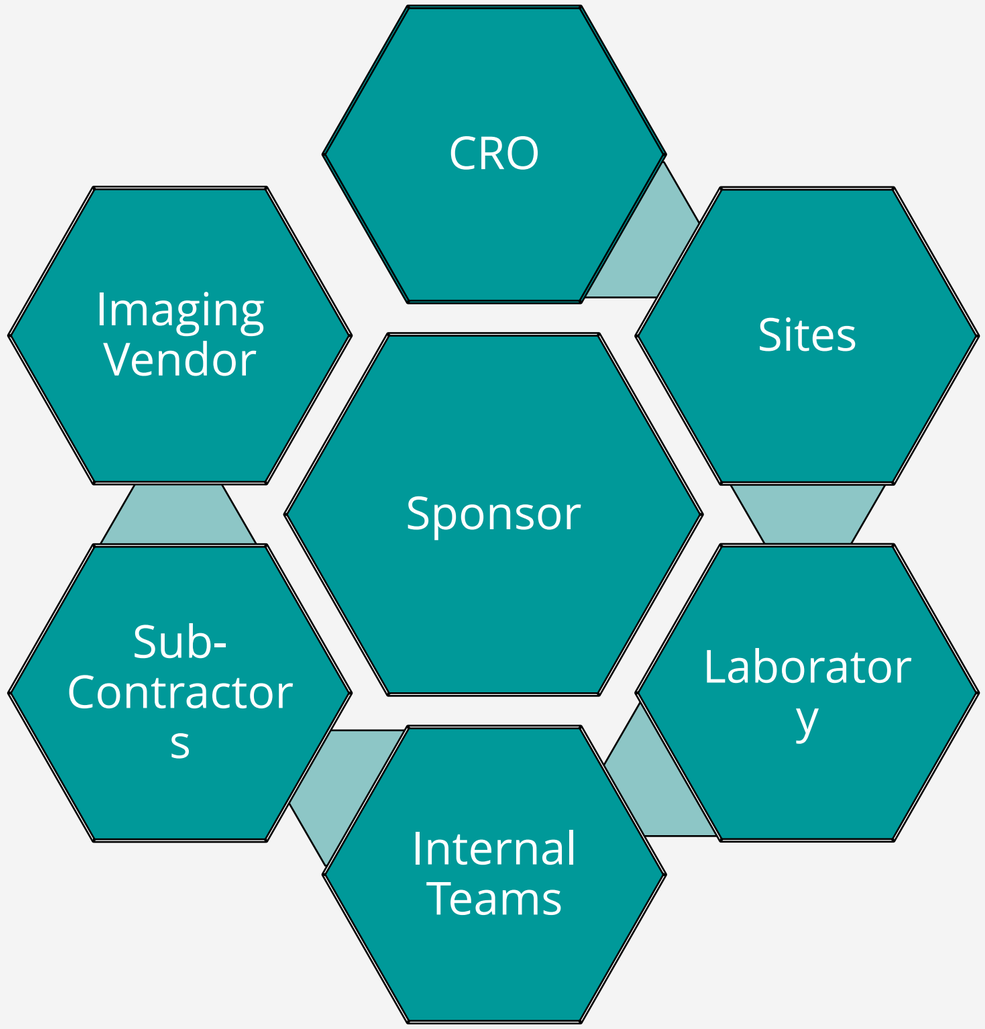


Sponsor Oversight Tracker

Writing the study plans is key but following them is equally IMPORTANT!

Tracking of central monitoring and oversight activities

							12-Apr-21	19-Apr-21	26-Apr-21	3-May-21	10-May-2
Category	**Sub-category/mitigating actions**	**Frequency**	**When**	**Responsible**	**Name of plan (if applicable)**	**Link to oversight folder**	**week** *15*	**week** *16*	**week** *17*	**week** *18*	**week** *19*
	Eligibility review	Bi-weekly	FSFV→LSR	**CPM**	Medical Monitoring/OTOP					07-May CPM	
	Laboratory value surveillance	Monthly	FSFV→LSR	**CPM**	Medical monitoring						
	Safety surveillance (documented in medical monitoring memo)	Monthly	FSFV→LSLV	**DSA/ME**	Medical monitoring						
	Investigator SAE reporting timelines (late reporting)	Monthly	FSFV→LSLV	**CPM**	OTOP/RACT - PD review						
Complexity (protocol and operational)											
	Submission status review	According to OTOP	From site identification to SIV	**CPM**	OTOP		15-Apr CPM	22-Apr CPM	29-Apr CPM	06-May CPM	N/A
	Site Green Light Package Review	Ad Hoc	From first country SIV to last country SIV	**CPM**	OTOP		06-apr		27- Apr 29- Apr		

Tracking sheet | E-Diary-PRO Compliance | RBM log | SIV-MV Report | Monitoring oversight vis ...

Important Documents in Sponsor Oversight

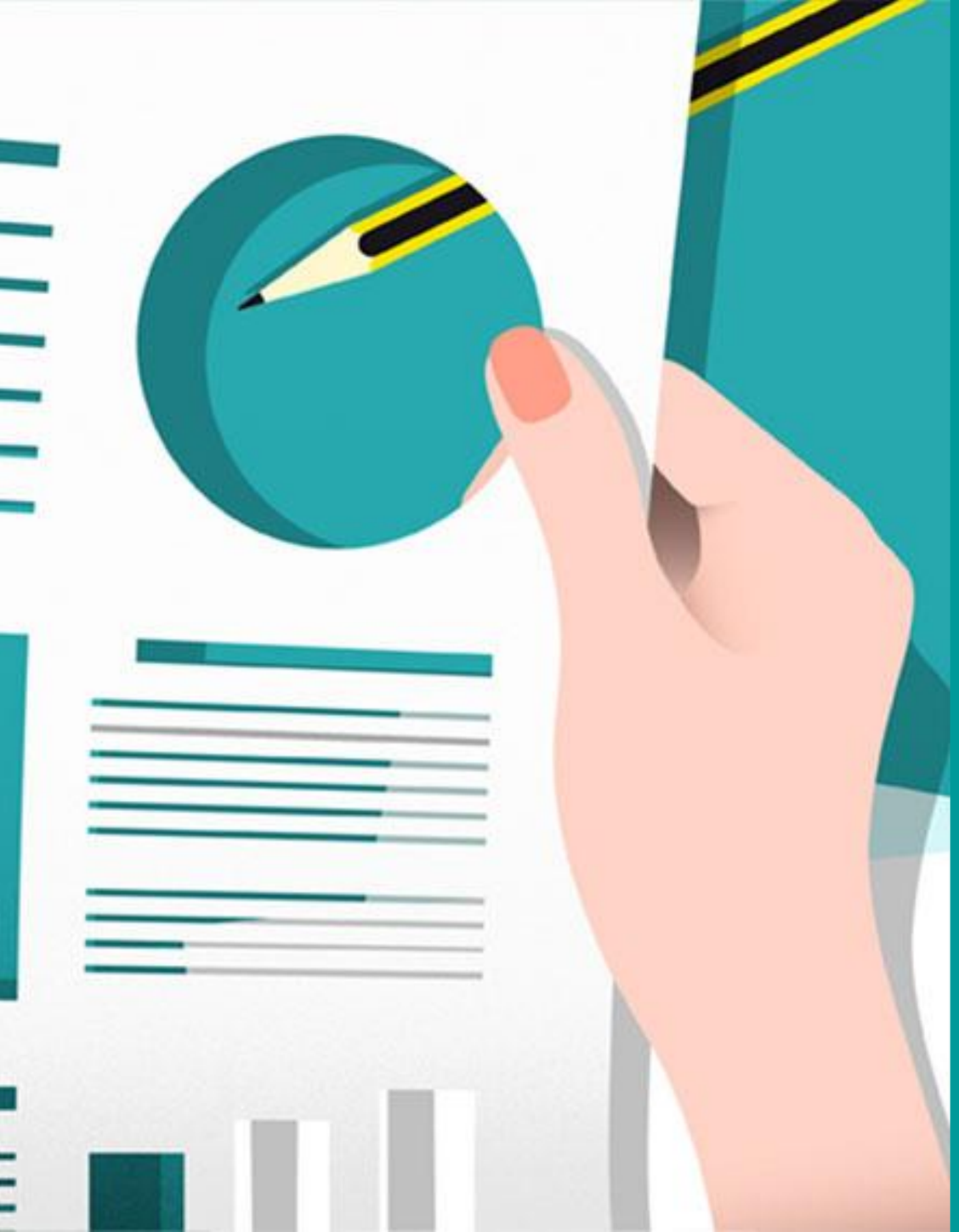
- Governance & Oversight: Oversight Plan, Delegation Logs, Meeting Minutes
- Quality & Performance: KPI-reports, Risk Assessment (RACT), Monitoring Reports
- Deviations & CAPA: Issue Logs, CAPA-documentation
- Compliance & Training: Training Records, Audit Reports
- Data Governance: Data Access Logs, Data Integrity Checks

Risk Assesment (RACT)

Creating the RACT is important but reviewing it and updating it on regular basis is even more important!

Owner: Sponsor vs. CRO

Risk Assessment and Categorization Tool							Trial: *XXX-YYYY*		Version: *Z.0*
Category	**Critical data**	**Critical process**	**Risk Description**	**Impact**	**Likelihood**	**Detectability**	**Risk level** (Use Risk matrix in for determination of Risk level)	**Mitigating actions**	**Monitoring actions**
Endpoints	*Primary endpoint*	*Process for collection of primary endpoint*	*Risk of missing results for primary endpoint*	*Critical*	*Possible*	*Easy*	*Medium*		



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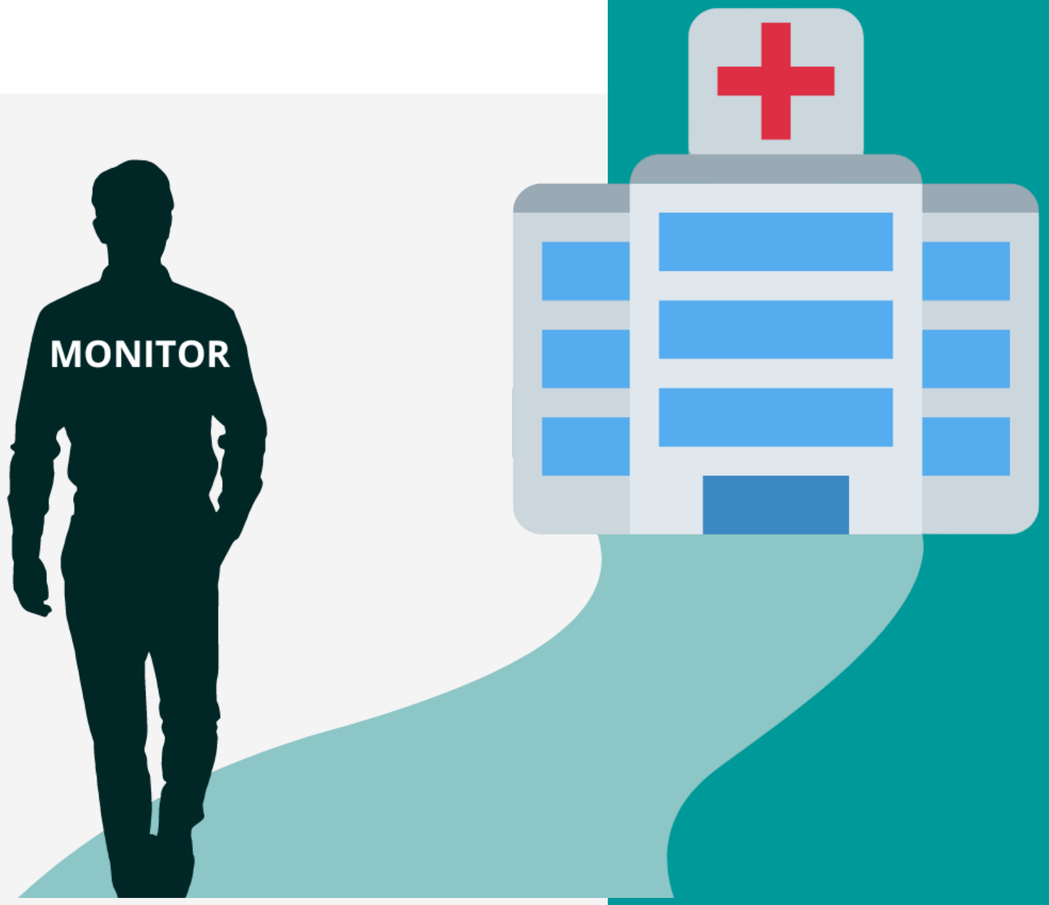
Meeting Minutes

Project meetings and status/metric reports to keep track of trial progress (minutes)

Monitoring

Explain to sites, why you (*Sponsor*) are attending the visit!



SPONSOR OVERSIGHT

must be demonstrated through **review and approval of key documents** (e.g., Monitoring Visit Reports, Data Management Plans, Statistical Analysis Plans, deviation logs).

THE OVERSIGHT PLAN/QM

must clearly define **which documents require sponsor review and what the review entails.**

SPONSOR OVERSIGHT VISITS

must be documented, including activities performed and issues identified with CAPA.

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eTMF final completeness

Sponsor failure to oversee TMF is one of the most common findings during inspections ! Why?

Do not wait until the finalization phase to get your documents archived!

Improving the standards of pharma consulting

1

LACK OF ONGOING FILING, FROM ALL STAKEHOLDERS

2

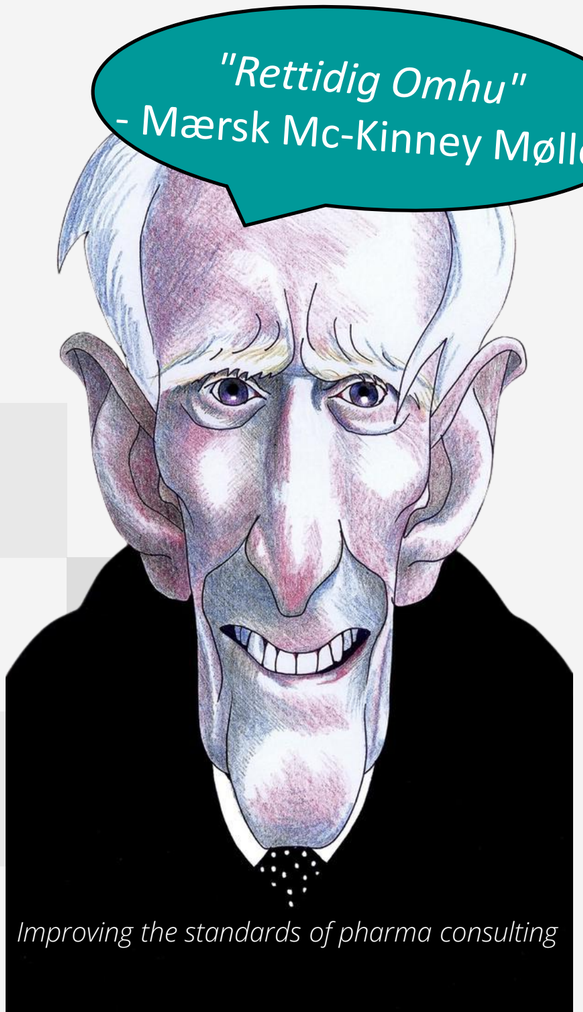
LACK OF REGULAR, SYSTEMATIC SPONSOR REVIEW OF THE TMF, CAUSING A HUGE WORKLOAD BEFORE AN INSPECTION OR FINALIZATION OF THE TMF

3

SPONSOR NOT UNDERSTANDING CRO TMF COMPLETIONS METRICS:

Example: TMF is 95% complete – often means 95% of the documents sent to the TMF have been filed, but if you include documents not sent, the true picture might be 65%

Conclusion



Regulatory Requirement:
Sponsors hold ultimate responsibility under ICH-GCP and must demonstrate oversight.

Protects Patients & Data:
Ensures subject safety and integrity of trial data.

Controls Risk:
Detects issues early and enables timely CAPA.

Demonstrates Accountability:
Confirms sponsor fulfils obligations for trial quality and compliance.

Thank you for your time

Want to get in touch?

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