January 23, 2026

Clinical Research Sponsorship

Key Considerations & Best Practices

Heidy Morales
Research Quality Associate
University Health Network

Who is the Sponsor?

Sponsor Responsibilities (High Level)

- Initiates and oversees the clinical trial
- Accountable for participant safety
- Accountable for data integrity
- Responsible for regulatory compliance
- Accountability cannot be delegated

ICH E6 (R3): Why It Matters

Modernized Good Clinical Practice Framework

- Principle-based, not checklist-based
- Quality by Design
- Risk-proportionate oversight
- Lifecycle approach to trials
- Supports decentralized and innovative designs

Sponsor Duties Under ICH E6 (R3)

KEY EXPECTATIONS

- Maintain End-to-End Study Oversight
- Apply Quality by Design throughout the Study Lifecycle
    - Identify Critical-to-Quality (CTQ) factors early
- Apply risk-based monitoring
- Maintain essential records and audit trails
- Oversee service providers (e.g. CROs) and vendors effectively

CRO = Clinical Research Organization

Sponsor-Investigator & Investigator-Initiated Trials (IITs)

What Changes?

- Investigator assumes both sponsor and investigator roles
- Same regulatory obligations apply
- Institutional support becomes critical
- High risk for compliance gaps if roles are unclear

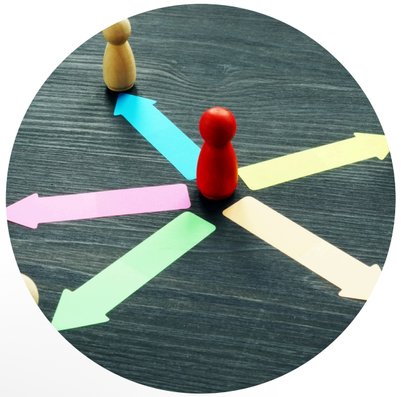
Sponsor-Investigator: Practical Obligations

Commonly Overlooked Responsibilities

- Regulatory submissions (CTA if Health Canada / IDE if FDA)
- Safety reporting to regulators and REBs / IRBs
- Monitoring plan and execution
- Service Provider / Vendor qualification and oversight
- Record retention and inspection readiness

CTA = Clinical Trial Application
IDE = Investigational device exemption
REB = Research Ethics Board
IRB = Institutional Review Board

Roles & Accountability



SPONSOR

- Overall regulatory accountability
- Trial design, oversight, and quality system
- Regulatory submissions and reporting
- Safety oversight and monitoring

INVESTIGATOR

- Conducts the trial at the site
- Ensures compliance with trial protocol
- Responsible for informed consent process oversight
- Reports safety events to sponsor

INSTITUTION

- May act as sponsor of record (IITs)
- Provides SOPs, infrastructure, insurance
- Oversees compliance and audits / inspections
- Supports monitoring and quality systems

Case Example 1: Drug Trial (IIT)

Scenario

- Investigator-initiated Phase II drug study
- Institution listed as sponsor; Principal Investigator (PI) acts as sponsor-investigator

INSPECTION FINDINGS

- Inadequate safety surveillance process
- Delayed SUSAR reporting to Health Canada
- No documented medical review of safety data

SUSAR = Suspected Unexpected Serious Adverse Reaction

REGULATORY IMPACT

- Major observation for sponsor safety oversight
- CAPA required; enhanced pharmacovigilance (monitoring) implemented

CAPA = Corrective and Preventive Action

Case Example 2: Device Trial (IDE)

Scenario

- Investigator-initiated medical device feasibility study
- IDE held by sponsor-investigator

INSPECTION FINDINGS

- No documented monitoring visits
- Inadequate device accountability records
- Unreported unanticipated adverse device effect

SUSAR = Suspected Unexpected Serious Adverse Reaction

REGULATORY IMPACT

- FDA Form 483 citing failure to monitor
- IDE placed on hold until corrective actions implemented

IDE = Investigational device exemption

Case Example 3: Behavioural (Low-Risk)

Scenario

- Investigator-initiated behavioural intervention study
- CTA-exempt but GCP still applicable

INTERNAL AUDIT FINDINGS

- No documented risk assessment
- Inconsistent informed consent process across sites
- Data privacy controls not clearly defined

SUSAR = Suspected Unexpected Serious Adverse Reaction

REGULATORY IMPACT

- Findings for inadequate quality management
- Requirement to formalize oversight and consent procedures

CAPA = Corrective and Preventive Action

Health Canada: Sponsor Expectations

Modernized Canadian Framework

Clinical Trial Application required for most interventional trials

GCP applies even to CTA-exempt studies

REB approval mandatory

Risk-based review & conditions possible

15-year record retention

Health Canada & IITs

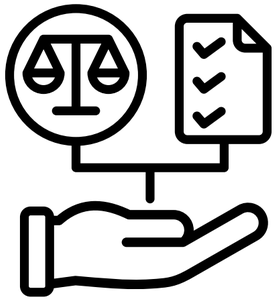
Canadian Context

- Institution often acts as sponsor of record
- Clear delegation and oversight agreements required
- Pre-CTA meetings recommended for complex IITs
- Sponsor-investigator remains accountable

Harmonization Across Jurisdictions

Common Themes

GCP COMPLIANCE IS UNIVERSAL

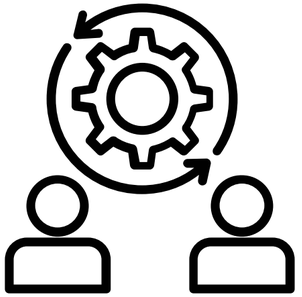


RISK-BASED OVERSIGHT IS EXPECTED

ETHICS REVIEW IS ESSENTIAL BUT NOT SUFFICIENT

DOCUMENTATION MUST CLEARLY SHOW OVERSIGHT

SPONSOR ACCOUNTABILITY IS CENTRAL



Best Practices for Sponsors & Sponsor-Investigators

What Works Well

- Define roles and responsibilities early
- Build quality into protocol design
- Train teams on sponsor obligations
- Engage regulatory expertise early

Best Practices for Sponsors & Sponsor-Investigators

Review your team / study SOPs

-Ensure SOPs clearly reflect E6(R3) language
-Revise SOPs to include data lifecycle controls, e-signatures, computerized system validation, and privacy protections
-Revise SOPs to reflect continuous, risk-based vendor/service provider oversight

Define CtQ factors at protocol level

-Define procedures essential to participant safety
-Define data necessary for primary endpoints
-Identify risks that could threaten scientific validity

Establish a cross-functional oversight

- Build strong communication channels with team and / or sites (if multi-centre)
-Be transparent in communicating trial design and conduct to participants & all other stakeholders

Document decisions with rationale

-Document rationale as to why certain risks were prioritized or deprioritized during study
-Delegate ownership for decisions & corresponding follow-up actions

Apply Risk-based monitoring

-Detect data trends and outliers
-Monitor site performance indicators
-Identify emerging safety or operational risks

Key Takeaways

Final Messages

- Sponsorship is about accountability, not paperwork
- ICH E6(R3) focuses on thoughtful, risk-based approaches
- IITs carry full sponsor obligations
- Institutional support is essential for IITs
- Good sponsorship protects participants safety and study data

References

- ICH Efficacy Guidelines
- Health Canada Consultation: Modernizing the framework for clinical trials
- Health Canada: Draft guidance on clinical trial applications for clinical trial sponsors
- Clinical Trials Ontario: ICH E6(R3) Guideline Update
- Cyntegrity: ICH E6(R3) Sponsor Responsibilities

Thank You

heidy.morales@uhn.ca

https://www.uhn.ca