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# Monitoring Services

**Calgary Centre for Clinical Research**

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# Learning objectives

- **Overview of Monitoring Services**
  - *Risk Assessment & Monitoring Plan*
  - *Types of Monitoring Visits*
  - *Review Report and Follow-up*
- **Common observations and insight into possible solutions**

# Overview of Monitoring Services

- Available to all researchers conducting Investigator-Initiated Trials (IITs), sponsored by the University of Calgary
- Drug and Device trials
- Offered on a fee for service basis
- Cost estimates for grant application



Monitoring Service set up process

Study Intake → protocol review and risk assessment

Cost estimate and development of monitoring plan

Agreement execution → communication regarding timelines



## *Monitoring Plan*

- Monitoring Risk Level Tool adapted from an N2 endorsed tool utilized across Canada
- ICH GCP E6 (R3) guideline focus on risk-proportionality
- Both frequency and amount of SDV are based on risk assessment & Critical to Quality Factors(CtQs)

# *Risk Assessment*

## Factors considered are below

- Study objective, endpoints, and design complexity,
- Blinding, and number of trial participants,
- Investigational product, and current knowledge of the safety profile
- Experience of study team

# Initial monitoring visit

- Ensure a team is set up for success
- Essential Documents in place
- Completed required training

## Routine monitoring visit

- To assess compliance with the protocol, GCP and regulatory requirements
- Ensuring accurate and complete data collection
- Identifying and addressing any issues promptly to protect participant safety and data integrity

## Close-out visit

- Ensure the completion of outstanding CRFs and queries
- Return or destruction of study drug/device
- Perform a final review of the study file documents
- Review the plans for record retention

# Monitoring Metrics

## *2024 in review:*

- *9 studies monitored*
- *6 different sites in 2 cities,*
  - *Calgary, Sunnybrook*
- *32 participants files monitored*
- *4 initial visits and 17 Routine interim visits*

## *2025 in review:*

- *15 studies monitored*
- *7 different sites in 4 cities*
  - *Calgary, Edmonton, Ottawa, Burnaby*
- *40 visits*
  - *8 Initial Visits*
  - *24 Routine Interim Visits*
  - *3 close out visits*
- *92 participant files reviewed*

# Common observations and insight into possible solutions



## Trial documents Management

- SOPs and appropriate training
- CFR 21 compliant signature

## Medical oversight

- Eligibility confirmation
- Assessment of AE/SAE
- PD documentation and review

## Good documentation practices

- ALCOA principles

# Tools and Templates

## Quality Assurance for Clinical Trials

### Study Planning

- Protocol M11 Template
- Critical to Quality Factors Table Template
- Risk Management Plan Template
- Data Management Plan Template
- Data Safety Monitoring Board Charter Template
- Investigational Product Management Template

## **During Study**

**[Interactive Clinical Research Study Startup Checklist](#)**

**[Delegation of Authority Log](#)**

**[Team Training Log](#)**

**[Regulatory Binder Table of Contents Template](#)**

**[Site Activation Checklist](#)**

**[Site Activation letter Template](#)**

**[Drug Accountability Log](#)**

**[SAE Report Form](#)**

**[Note to File Template](#)**

**[Corrective Action and Preventive Action \(CAPA\) Plan Template](#)**

# **[Consent Process Checklist](#)**

**[Study Close out Checklist](#)**



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# Thank you

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Questions?

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