OPRA
RBQM TECHNOLOGY

OPRA Risk-Based Architecture Across the Study Timeline

How OPRA Risk Assessment and OPRA Central Monitoring Support Continuous Oversight From Protocol to Close Out

A time based view of how OPRA's architecture supports risk assessment, management, and centralized monitoring throughout the lifecycle of a clinical study.

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Study Stage 1

Protocol Design & Initial Risk Assessment

Defining risk before data collection begins.

OPRA RAM supports structured, protocol driven risk assessment to identify and prioritise critical risks at the outset of the study.

- Protocol led risk identification and categorisation
- Risks assessed at study and domain level
- Documented rationale aligned to RBQM principles

OPRA RAM: Structured risk assessment and initial risk scoring

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Study Stage 2

Monitoring Planning & Risk Control Definition

Translating risk into monitoring strategy.

Identified risks are mapped to indicators, controls, and thresholds to support consistent, scalable monitoring once the study goes live.

- Mapping of risks to KRIs, KPIs, and QTLs
- Definition of thresholds and review expectations
- Clear linkage between risks, indicators, and actions

OPRA RAM: Risk to indicator and control mapping
OPRA Central Monitoring: Monitoring framework configured and ready

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Study Stage 3

Active Study Conduct & Central Monitoring

Continuous oversight as data accumulates.

As clinical and operational data is refreshed, OPRA Central Monitoring enables ongoing review of indicators, trends, and emerging signals.

- Automated, timely data refresh from source systems
- Dynamic recalculation and visualisation of indicators
- Structured logging of observations and actions

OPRA RAM: Risks reviewed and updated as study conditions change
OPRA Central Monitoring: Ongoing centralized monitoring and issue identification

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Study Stage 4

Risk Review, Mitigation & Oversight

Responding to change with documented, auditable control.

Risks, thresholds, and monitoring focus are reviewed as the study evolves, ensuring oversight remains proportionate and aligned with current risk.

- Trend based review of indicators and thresholds
- Assignment and tracking of actions and mitigations
- Full traceability of changes, decisions, and outcomes

OPRA RAM: Dynamic risk assessments with historical visibility
OPRA Central Monitoring: Proactive identification of emerging patterns and risks

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Study Stage 5

Study Close Out & Oversight Review

Demonstrating effective RBQM through evidence.

OPRA provides a complete, auditable record of how risks were identified, monitored, and managed throughout the study.

- Centralized record of risks, indicators, and actions
- Clear audit trail supporting regulatory inspection
- Review of risk trends over the full study timeline

OPRA RAM: End to end risk lifecycle documentation
OPRA Central Monitoring: Evidence of continuous monitoring and oversight

What This Delivers Across the Study Lifecycle

- Continuous, proportionate risk based oversight
- Clear linkage between risk assessment and monitoring
- Auditable evidence aligned with ICH E6 (R3) expectations

RBQM that evolves with your study.

TRI

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