Revolutionizing Clinical Quality: A Frontier Approach with Quality by Design (QbD), Infrastructure Modernization and Data-Driven Analytics

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Agenda

Why Risk Based Quality Management

The shift to proactive Quality

QbD Foundations

Designing quality upfront

Infrastructure Modernization

Near Real-Time Dashboards

Three Stack Data Analytics

Unified eco system - Insights that drive actions

Case Studies including small trial

Scalable RBQM approaches demonstrating Real-World Implementation Wins

Innovation with AI

Future Forward with simulated trial intelligence and signal prediction

Lean Trial for Accelerated Outcomes – A case study

Smaller Size and Bigger Statistical Power

AI Regulatory Governance & Implementation roadmap

(Guidelines and Strategies for phasic adoption)

Final Thoughts

Operating models for sustainable quality

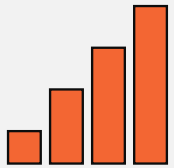
Why RBQM? The Evolution From Compliance to Competitive Advantage

Data Volume Crisis

3.5M+ data points in phase III alone

Risk Proportionality

FDA and EMEA mandate end-to-end risk-based approaches.



Industry Shift: 53% → 96%

RBQM adoption skyrocketed from 2019 to 2024 by almost two folds.

THE INFLECTION POINT

From Reactive to Proactive

Traditional: Find issues post-hoc. Assess Damage. Fix Processes

RBQM: Predict risks upfront. Prevent Issues. Implement Quality by Design.

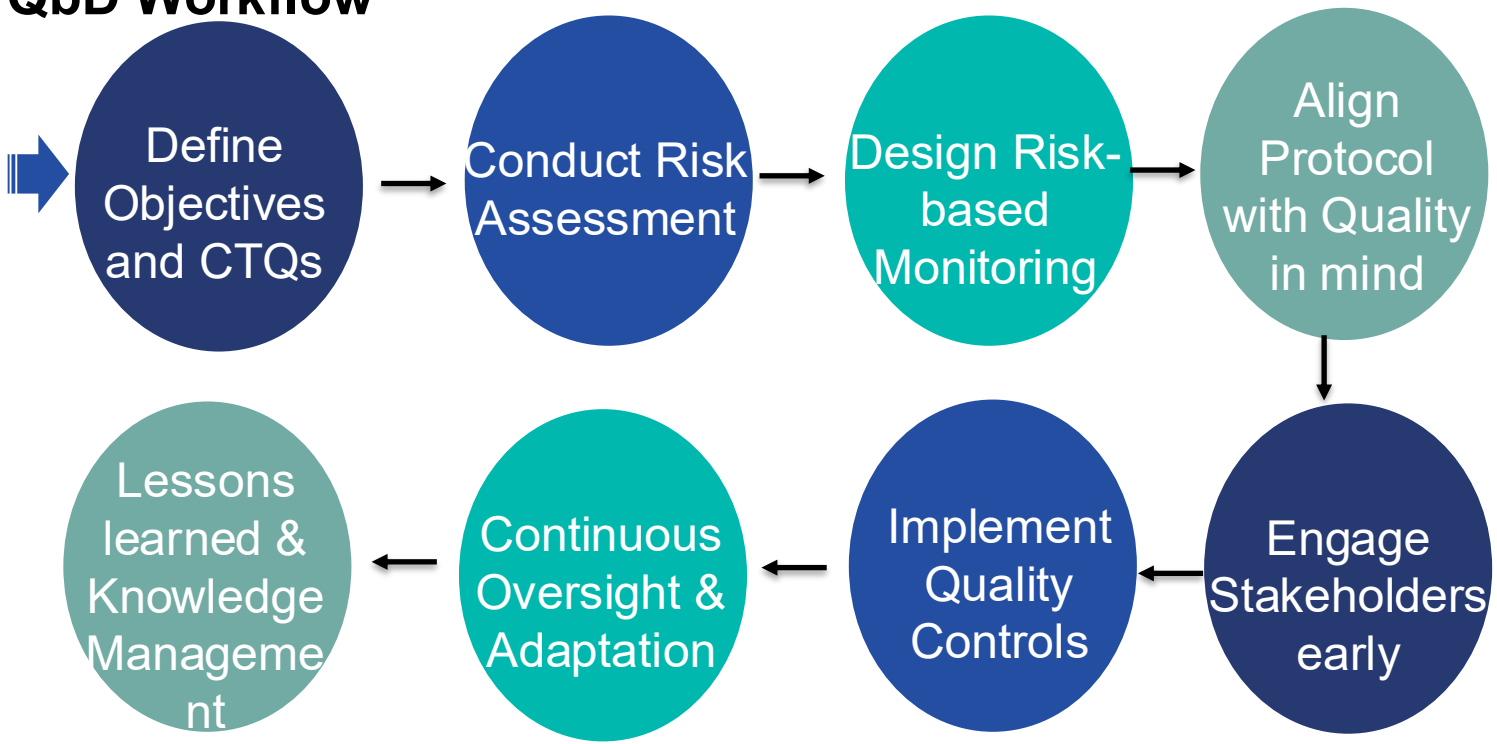
Impact: Transition from firefighters to architects

How Quality By Design(QbD) Elevates Clinical Trial Quality

Data Quality Improvements

Higher first-time data entry accuracy ↑	Lower Query Rates ↓	Less Protocol Deviations ↓
Faster data base lock speed	Fewer Protocol amendments	Better Risk Handling

QbD Workflow



OUTCOMES

Operational Efficiency	Reliable Decisions	Regulatory Success

QbD aligns design, data and decisions across the entire development lifecycle

Infrastructure Modernization

The Tech Stack Evolution

Traditional Modern Stack

~~Paper CRFs~~ → Cloud EDC

~~Site Visits~~ → Remote Monitoring

~~Manual SDV~~ → Centralized Monitoring

~~Siloed Systems~~ → Integrated Platforms

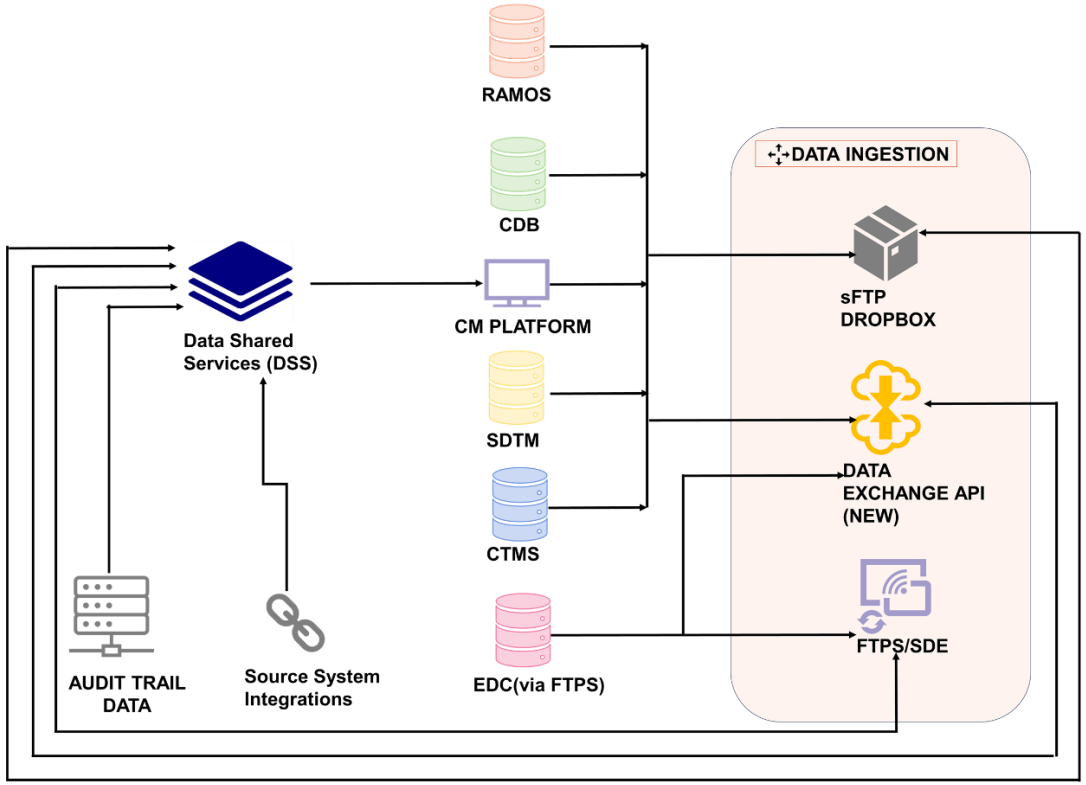
~~Batch Reports~~ → Near Real-Time Dashboards

Cloud Infrastructure

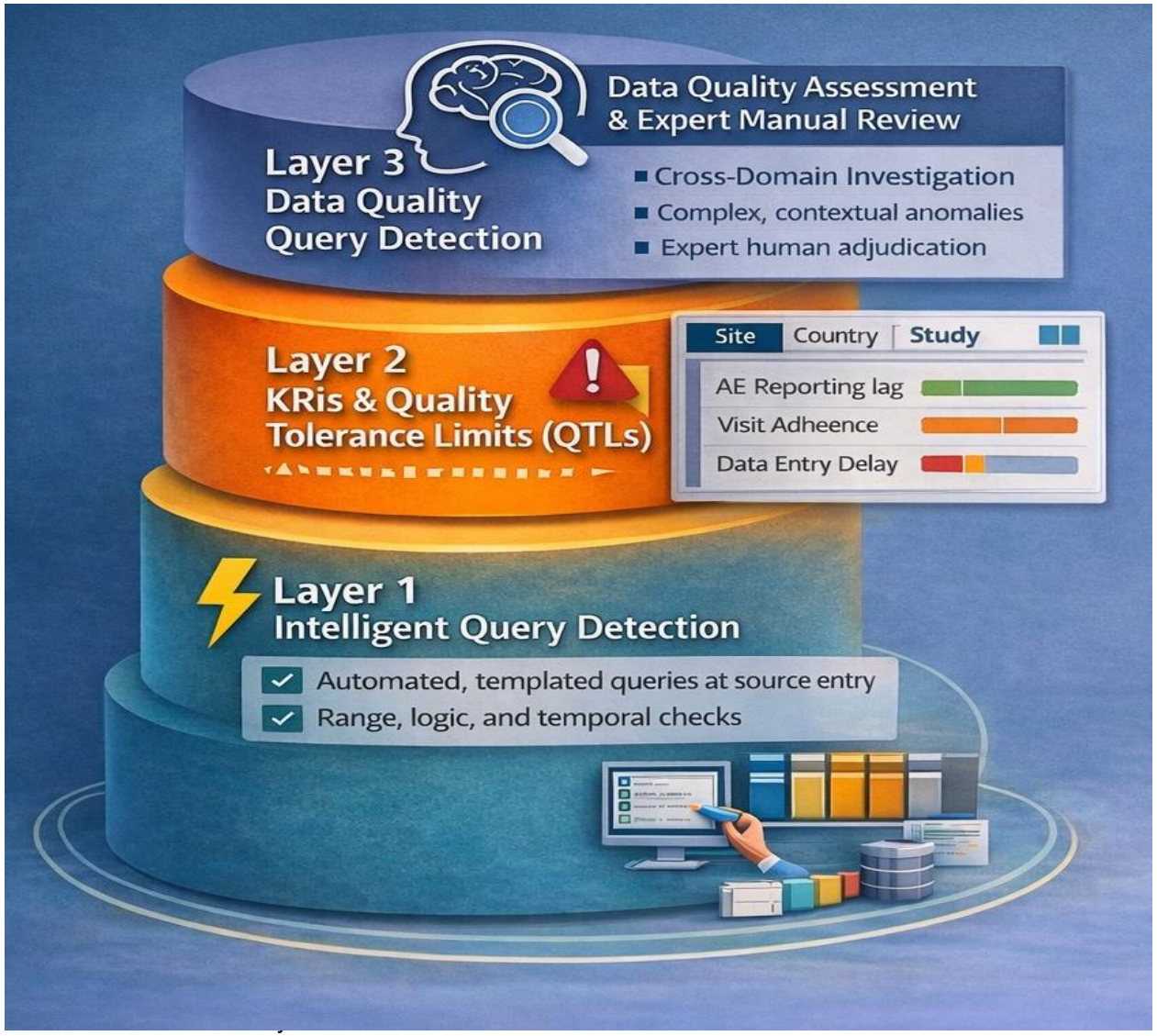
Data Integration

Near Real-Time Sync

The Enablers



THREE- LAYER QUALITY OVERSIGHT MODEL – Proactive, Proportionate & Human-Centred



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CASE STUDY 1

LARGE PHASE III ONCOLOGY TRIAL

Number of Participants enrolled: 300

Sites: 40 global

CTQ Factors:

i. Imaging-based assessment of tumor response

i. Timely SAE reporting

ii. Correct dosing

Adapted Framework

Key Outcomes

Duplicate enrolment prevention

Improvement in efficacy data

Safety Reporting Timeliness

Estimated cost avoidance was approximately USD 150,000-200,000 in avoided monitoring, reanalysis and remediation work.

CASE STUDY 2

SMALL PHASE 1 RARE DISEASE STUDY

Dose-escalation study

Indication: Rare metabolic disorder

Number of Participants enrolled: 24 **Sites**: 3

Adapted Framework

Challenges:

i. Low statistical power

ii. High duplicate enrollment

iii. Resource constraints

iv. Manual data entry

Key Outcomes

Eligibility Flag Identification

Early safety signal detection

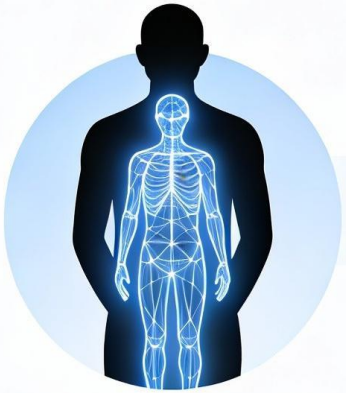
Data quality improvement

Cost avoidance relative to traditional weekly on-site visits: approximately USD 40,000-60,000 over the study duration.

Advanced Analytics and AI/ML Integration

Digital Twins in Clinical Trials

A digital twin is a virtual replica of an individual patient or trial that uses real data and AI models to simulate outcomes



Step 1: Data Ingestion

EHR
Wearables, Lab data

Step 2: AI Modeling

predict disease trajectory, simulate control arm

Step 3: Trial Optimization

Study

refine design, personalize dosing, reduce sample size

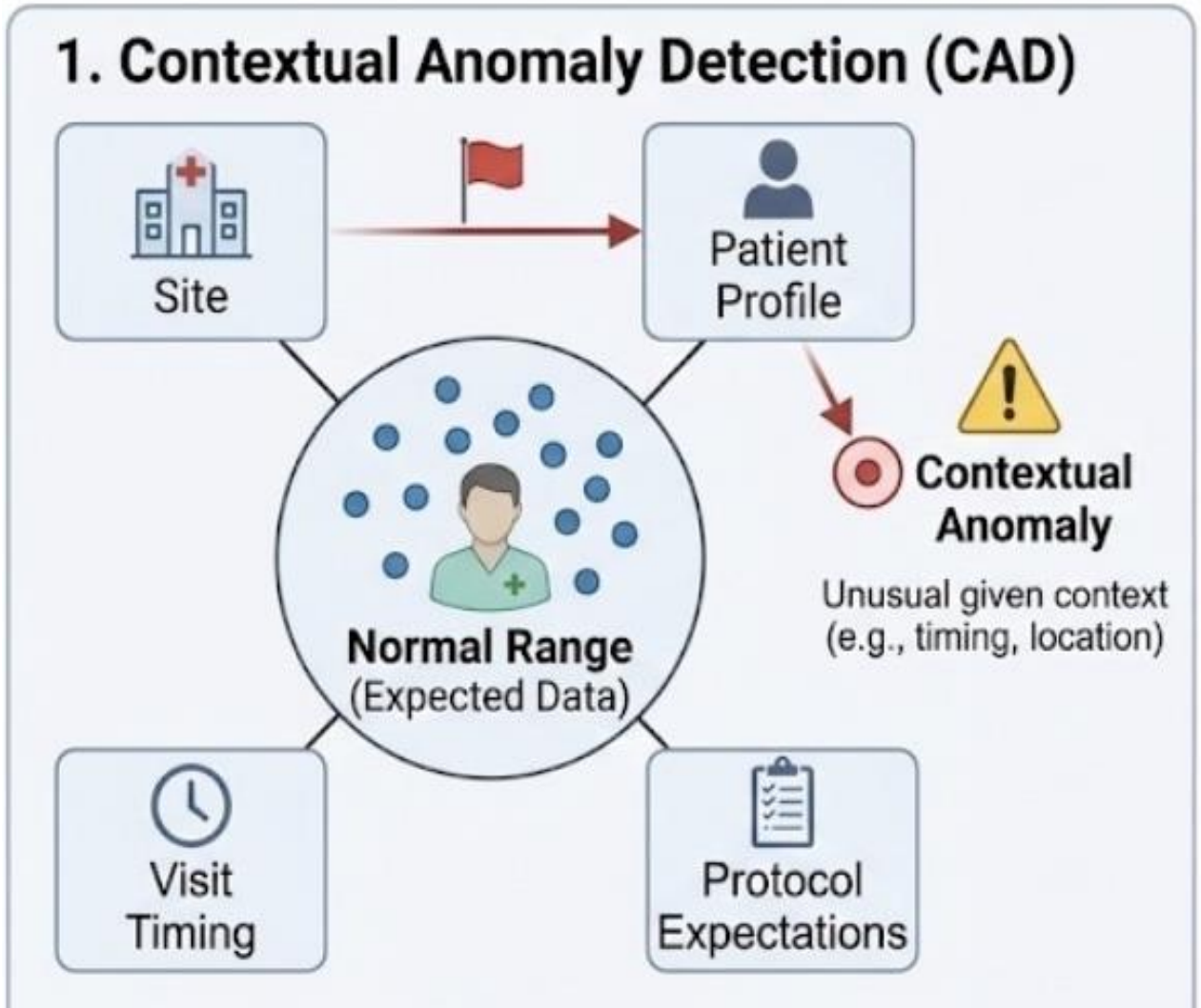
Key Benefits

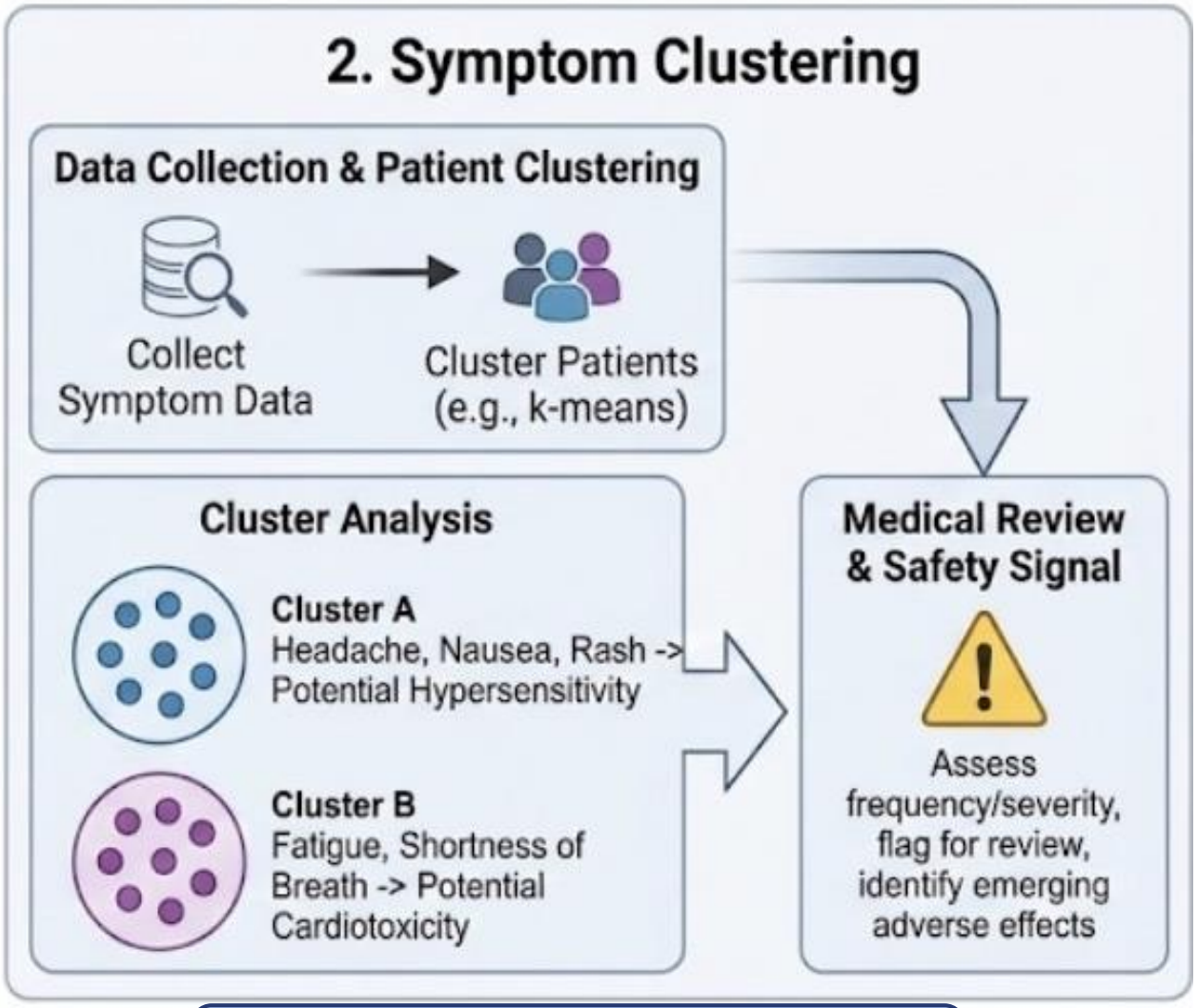
- Faster trial timelines
- Improved patient safety
- Smaller or synthetic control arms
- More personalized insights

Challenges

- data quality
- bias & fairness
- regulatory acceptance
- privacy & security

Contextual Anomaly Detection and Symptom Clustering





Signals: Protocol Deviations, Atypical Site Behaviour, Inconsistent Data, Risk to Data Integrity/Safety

Enhanced Data Integrity, Patient Safety and Compliance

Source Gemini Pro

Dose Optimization & Digital Twin Approach: Phase II Diabetes Trial Case Study

Study Design

Phase II Trial in Type 2 Diabetes

Goal: Reduce Sample Size & Accelerate Timeline

Stage 1: Dose Optimization Lead-In → **Stage 2: Confirmatory Trial**

40 Patients → Select Optimal Dose → 240 Patients Total

+40 → 240 Patients Total

240 Patients Total

Future-State Approach

Dose Optimization
Early Lead-In Cohort

Digital Twin Augmentation
Virtual Control Patients

Three-Layer Analytical Model
CAD, AI Alerts & KRIs

33% Smaller Size
360 → 240 Patients

88–90% Power
↑ Statistical Power

3 Months Faster
12 → 9 Months Timeline

$3.5M–$4M Saved

Summary of Benefits

Sample Size	360 → 240 (-33%)
Statistical Power	80% → 88–90%
Timeline	12 Months → 9 Months
Cost Savings	$9M → $5M

Smaller, Faster Trials with Enhanced Power & Lower Costs

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EMA – FDA 10 Guiding Principles for Good AI Practice

1. Human-centric by Design
2. Risk-based Approach
3. Adherence to Standards
4. Clear Context of Use
5. Multidisciplinary Expertise
6. Data Governance & Documentation
7. Model Design & Development Practices
8. Risk-based Performance Assessment
9. Lifecycle Management
10. Clear, Essential Information

Phased AI Implementation Roadmap for Clinical Quality Oversight

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The Frontier of Clinical Quality Oversight

Current State

Closed-loop, Risk-Proportionate Quality System

Quality by Design (QbD)	Infrastructure Modernization	Data-Driven Analytics
Embed CtQ factors & proportionate monitoring	*Unified cloud data ecosystem & sub-24h latency*	*Layered analytics: IQD, KRis/QTLs, Expert Review*

Fit for Purpose Data

Future State

AI-Enhanced, Data-Driven Quality Oversight

- Digital Twins & Synthetic Data
- Contextual Anomaly Detection
- AI/ML-Driven Automation
- Predictive, real-time quality oversight

Frontier Quality = Safety + Efficacy + Compliance

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