



The Cost of Not Monitoring

Reactive QTL oversight vs. OPRA proactive control

Reactive QTL Monitoring

Study Kick-Off

QTLs defined, no live signals

Early Study Phase

Data drift accumulates silently

Late Study Phase

QTL breach flagged too late

Audit Findings

Rework, Queries, CAPA Burden

Database Lock Delayed

Timeline impact, unplanned cost, inspection risk

Impact

Timeline impact and rework costs

OPRA Centralized Monitoring

Study Kick-Off

QTLs, risks and controls mapped

Early Study Phase

Threshold alert triggers follow-up

Late Study Phase

Documented, traceable, closed

Continuous Governance

Audit trail built automatically

Clean Database Lock

Inspection ready and compliant to ICH E6(R3)

Saving

Greater operational efficiency with avoided rework



Detect Earlier. Spend Less Later.