

R&D Accounting Best Practices for Clinical Trials

The top two takeaways for clinical finance leaders — purpose-built technology with rigorous SOX-compliant controls.

Biopharma finance and accounting teams manage huge trial budgets and complex operational data — pulled from EDC, CTMS, ERP, CRO invoices, investigator payments, and more — often with as few as 2–3 people and ~50 spreadsheets per trial. The predictable result: late reports, accrual errors, audit findings, and forecasts that can't keep pace with the business.

THE TWO TAKEAWAYS

01 Replace manual spreadsheets with a purpose-built, integrated clinical finance platform

Spreadsheet-driven accruals create single points of failure, version-control issues, and audit risk. Leading teams unify data from EDC, CTMS, procurement, and ERP on one system that automates accruals using three industry-standard costing methodologies — patient-driven, site-based, and timeline-dependent — which together drive roughly 90% of trial costs. The payoff: real-time variance visibility, automated reconciliation of investigator payments, and true scenario modeling.

AUTOMATED ACCRUALS

EDC / CTMS / ERP INTEGRATION

SCENARIO PLANNING

SOX-READY AUDIT TRAILS

BUSINESS IMPACT

90%+

FORECAST ACCURACY

70%+

EFFICIENCY GAINS

\$200K–\$1.4M

SAVINGS PER TRIAL

02 Build SOX-compliant controls and documentation into the close — not a year-end scramble

Clinical accruals are one of the most common sources of material weaknesses, with public-company reports rising ~41% since 2019. Effective SOX compliance rests on four pillars: accrual estimates updated against current trial dynamics, comprehensive audit trails, true cross-functional alignment between accounting, FP&A, and clinical ops, and key controls tested for operating effectiveness. Implement segregation of duties, monthly reconciliations, quarterly CRO validation, and system controls so issues surface before they hit financials.

FOUR-PILLAR CONTROL FRAMEWORK

REPARER / REVIEWER SIGN-OFF

SEGREGATION OF DUTIES

AUDIT-LOG EVIDENCE

THE FOUR PILLARS

01

ACCRUAL ESTIMATES

Industry-standard methods

02

DOCUMENTATION

Clear audit trails

03

COLLABORATION

Account · FP&A · Clinical

04

CONTROL DESIGN

Tested & effective

KEY TRIGGERS FOR CHANGE

01

Frequent errors and reporting delays

02

Inability to scale trials due to cost visibility issues

03

Compliance concerns from inaccurate accruals

04

Investor pressure for financial transparency