

Budget & Contract Management in Clinical Research

Cost Management • Compliance • Expense Tracking • Contract Basics • Future Trends | Presenter: Khurram Shah

Cost Management

Understanding how budgets affect trial costs leads to better financial decisions.

Improved Negotiation

Training cultivates skills for negotiation, enhancing contract terms for all.

Audit Preparedness

Knowledge of budgets and contracts ensures compliance and audit readiness.

Collaboration

Effective communication fosters collaboration and streamlines the budget process.

Budget Development Process

IDENTIFY	Gather all necessary information related to trial expenses.
DRAFT	Create a preliminary budget based on identified costs and study requirements.
REVIEW	Collaborate with stakeholders to evaluate and refine the initial budget draft.
FINALIZE	Submit the completed budget for approval before initiating the study.
MONITOR	Continuously track and manage budget throughout the study duration.

Contract Basics

KEY COMPONENTS	Understand essential terms and conditions included in all contracts.
CONFIDENTIALITY	Protect sensitive information through confidentiality clauses.
TERMINATION	Clarify circumstances under which the contract can be terminated.
BUDGET LIMITS	Align contract terms with the available budget and funding sources.
COMPLIANCE	Identify all regulatory and compliance obligations outlined in the contract.

Clinical Trial Budget Overview

COST ESTIMATION	Accurately estimating costs ensures adequate funding and resource allocation.
BUDGET PLANNING	Systematic planning forecasts expenses and aligns with sponsor expectations.
FINANCIAL OVERSIGHT	Regular monitoring tracks spending and facilitates timely adjustments.



Expense Tracking & Future Trends

- Regularly review budget vs. actuals; categorize by expense type for accuracy.
- Use tracking software; keep audit-ready records; submit reports promptly.
- Automation & real-time tools drive future clinical budget management.
- Risk-based and patient-centric models define emerging budgeting best practices.

Compliance Considerations in Trials

- IRB Approval & Informed Consent: required before and throughout the study.
- Data Protection: implement measures to protect participant data and privacy.
- Stay updated with FDA regulations; maintain full regulatory compliance.

Aligning Budgets with Clinical Goals

- Define clinical objectives clearly; involve stakeholders early for budget input.
- Track performance against trial indicators; adapt budgets in real time.