Clinical Trial Budgets

Understanding Budget Components and Management

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Dir. of Operations at USTMA Consortium
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Workshop Objectives

Overview of key components in clinical trial budgeting and management.

Identify **BUDGET COMPONENTS**

Identify the essential elements of a clinical trial budget, notably start-up, per-patient, overhead, and screen failure costs, particularly for industry-sponsored trials.

Apply **BUDGET DEVELOPMENT STEPS**

Apply detailed methods for constructing a trial budget, including reviewing protocols, estimating visit costs, and recognizing hidden expenses.

Understand **POST-AWARD MANAGEMENT**

Understand the principles of managing the budget after award, focusing on invoicing, tracking milestones, and managing amendments.

ENGAGEMENT ACTIVITIES

An overview of interactive engagement techniques during the session.

QUESTIONS

Encourage participants to submit their questions either via the chat feature or through the dedicated Q&A section to promote interaction and clarity.

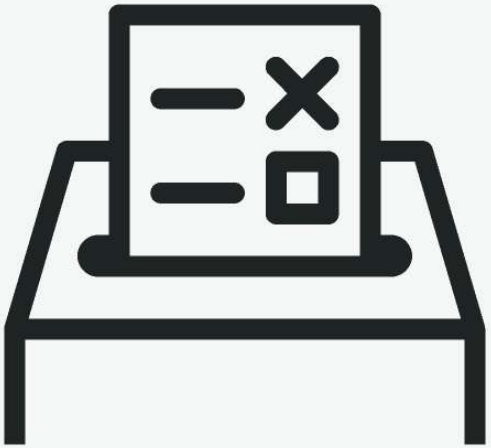
POLLS

Use Mentimeter to conduct polls that gather real-time feedback and opinions from participants, enhancing engagement.

https://www.menti.com/aluaqmh98axi

BREAKOUT SESSIONS

Facilitate interactive breakout sessions focused on key principles of post-award budget management, covering invoicing, milestone tracking, and the amendment process.



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TRIAL BUDGET ESSENTIALS

Overview of key components for budgeting in clinical trials.

START-UP COSTS

These are initial expenses incurred before the trial begins, including planning and setup costs. They are critical for ensuring that all necessary resources are in place prior to participant enrollment.

PER-PATIENT COSTS

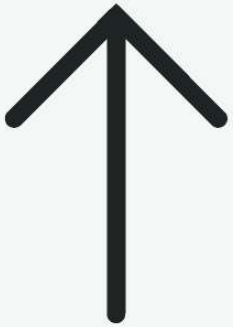
These costs represent the expenses for each participant involved in the trial, encompassing treatments and assessments. Accurate estimation is essential to reflect the true financial impact of each subject.

OVERHEAD COSTS

These are indirect costs associated with conducting the trial, such as administrative support and facility use. Understanding overhead is vital for a realistic budget.

HIDDEN EXPENSES

These are often overlooked costs that can arise during the trial, such as additional regulatory fees or unforeseen delays. Budgeting for hidden expenses is crucial to avoid financial shortfalls.



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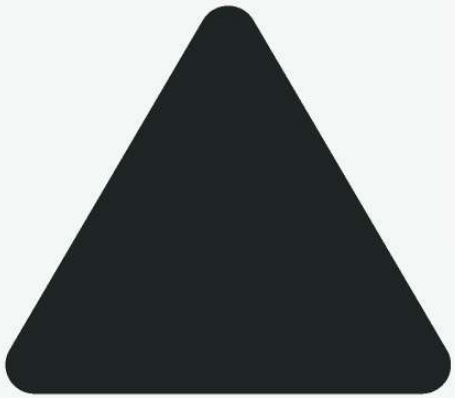

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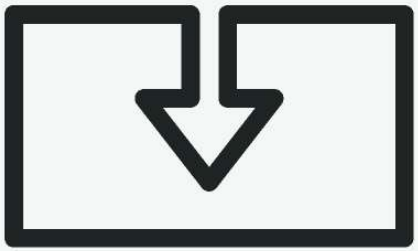

TRIAL

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How does accurate budgeting impact the success of clinical trials?

Implementing robust budgeting practices is essential for fostering stakeholder trust and maximizing resource efficiency in clinical trials.

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A well-structured budget is critical for maintaining the viability of clinical trials. It not only ensures adherence to financial guidelines but also promotes transparency, allowing stakeholders to have a clearer understanding of the resource allocation process. This openness fosters a collaborative environment, which is essential for successful research outcomes and regulatory compliance.

BUDGET SOURCES

Comparing funding sources and management styles in research budgets.

FUNDING SOURCE

Budgets can originate from pharmaceutical/biotech corporations or from academic institutions and grants, influencing the research's direction and priorities.

PROTOCOL DEVELOPMENT

The development of research protocols can be spearheaded by the sponsor or investigator, affecting how studies are conducted and who has the final say.

DATA OWNERSHIP

Ownership of data generated during the research typically lies with the sponsor or the investigator/institution, which can impact future research and publishing rights.

REGULATORY OVERSIGHT

Regulatory oversight can either be managed by the sponsor, focusing on compliance with external regulations, or by the investigator, prioritizing study integrity and accountability.

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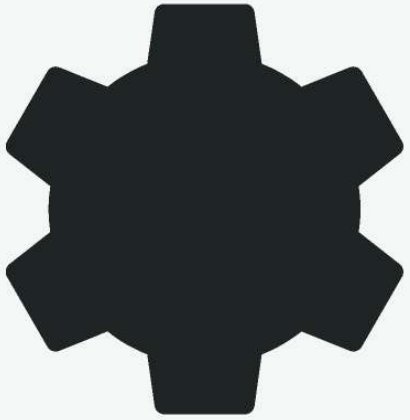

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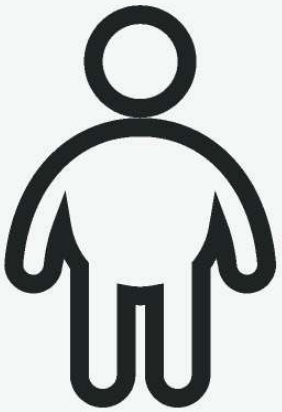

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COMPLIANCE ESSENTIALS

Understanding compliance standards is key to successful budgeting and negotiations.

FAIR MARKET VALUE (FMV)

Adhering to FMV standards ensures that financial transactions are justifiable and in line with market comparisons.

ANTI-KICKBACK STATUTE

Compliance with the Anti-Kickback Statute is vital for preventing illegal compensation and fostering ethical relationships in business.

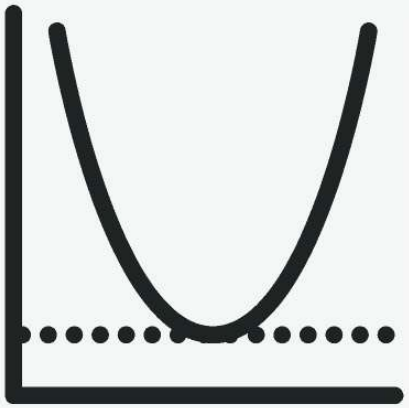
LEGAL SAFEGUARDS

Implementing compliance measures acts as a safeguard against potential legal issues, protecting the integrity of negotiations.

CREDIBILITY ENHANCEMENT

Upholding compliance standards boosts credibility with sponsors and stakeholders, leading to more favorable financial negotiations.

https://tinyurl.com/RPNCTB



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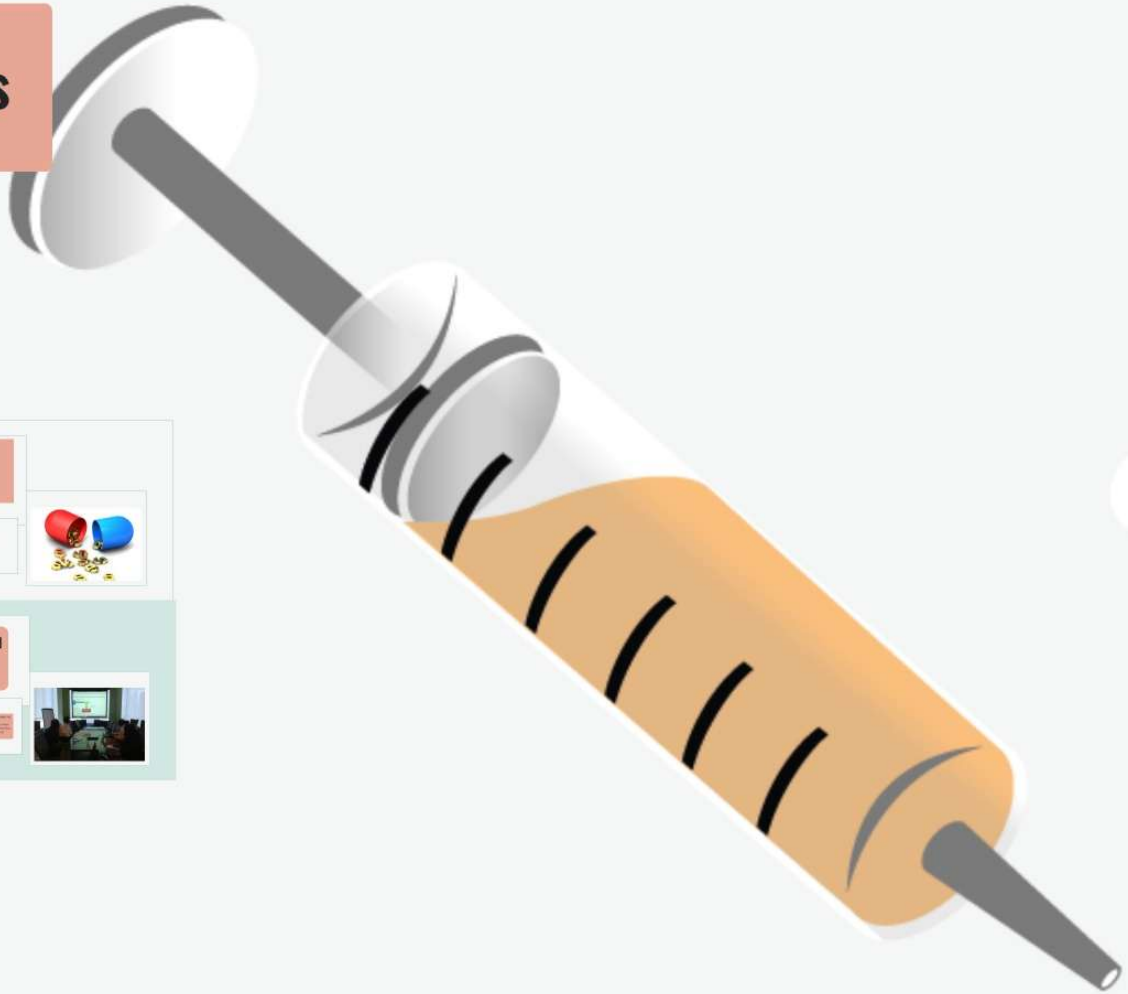
Key Budget Elements



Key Budget Elements

Start-Up Costs

Start-Up Costs

Start-up costs:
- Pre-trial expenses
- Regulatory submissions & IRB fees
- Site prep: staff training & contracts
- Tech setup: EDC systems & licenses

Crucial for trial success.

Overhead Costs

Overhead costs support the infrastructure of clinical trials, covering indirect expenses. Major components involve institutional overhead for facilities and utilities, administrative support costs, and indirect costs represented as a percentage of direct costs.

Per-Patient Costs

PER PATIENT COST ANALYSIS

Understanding per-patient costs is essential for budget estimation in patient engagement.

CLINICAL PROCEDURES

Costs associated with necessary clinical interventions, such as laboratory tests, that contribute to patient care.

PATIENT COORDINATION

Efforts to organize and manage patient visits, ensuring smooth engagement with the healthcare system.

DATA MANAGEMENT

The administrative costs related to managing data collected during patient participation, crucial for tracking progress and outcomes.

PARTICIPANT COMPENSATION

Reimbursements or stipends provided to participants for travel and engagement, incentivizing participation in the study.

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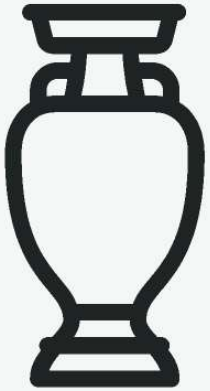

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Screen Failures and other hidden costs

Screen failures lead to financial penalties as non-qualifying participants incur costs.

Expenses arise from both the screening process and compensating missed recruitment efforts.

Proper budgeting needs to anticipate these costs to minimize the financial impact.

Budget Development Best Practices

Best practices for budget development emphasize early engagement with finance teams and detailed documentation. Regular reviews of expenses and educating staff on compliance enhance budget accuracy and reliability throughout the trial lifecycle.

BUDGET PREPARATION

Essential components needed for constructing an effective research budget.

ASSESSMENT SCHEDULE

Gather the schedule of assessments outlined in the research protocol to ensure all evaluations are accounted for.

INSTITUTIONAL FEES

Obtain standard fees charged by your institution to include them in the total budget, as these are critical for accurate financial planning.

STAFFING COSTS

Determine the allocation of staff members and their respective hourly rates to appropriately budget for personnel costs.

INDIRECT COSTS

Calculate the indirect cost rate that applies to your budget, as this can significantly affect overall funding requirements.

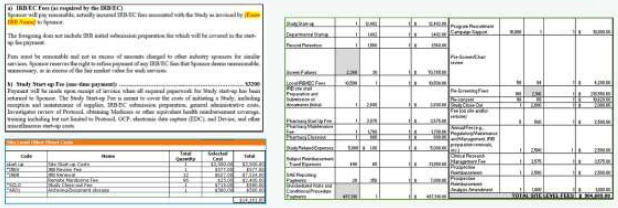
INTERNAL BUDGET STRATEGY

Overview of internal budget development and cost management for research studies.

ACTUAL COSTS

- Review the **protocol and timeline for assessments**, along with the detailed schedule of visit descriptions.
- Pay attention to the specifics outlined in the schedule of assessments.
- Develop an i**nternal budget that incorporates all associated costs** and the time and effort required from personnel to carry out the trial.
- Decide whether laboratory tests and procedures will be conducted in-house or at the sponsor's location.
- Ensure to account for **site-level costs** in the overall budget.

Sponsor Budget Site Level Cost Examples



Service Rate versus Your Cost (Research Rate)

Industry funded studies typically request full price of services
Difference Can be applied to effort/personnel costs

Example: HB 12 Lead ECG Tracing Only (CPT 93005)
Service rate $118 = fee sponsor pays
Your cost $22.42= research billing amount study will pay
Difference = $95.58 = personnel costs/contingency funds

CONTINGENCY FUNDS

Remaining funds from the difference are typically categorized as contingency or development funds that can be used for unforeseen research expenses.

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Resources for Budget building

Before you start putting together your research budget, you must gather the following:

- **Schedule of assessments** from the protocol
- **Standard institutional fees** from your institution
- Evaluation and **procedural costs**
- **Site costs**
- **Staff allocation** and their hourly rates
- **Indirect cost rate**
- **Subject compensation** costs
- **Data storage fee** estimate
- Long term **chart storage**

Sponsor Budget Site Level Cost Examples

a) IRB/EC Fees (as required by the IRB/EC)
Sponsor will pay reasonable, actually incurred IRB/EC fees associated with the Study as invoiced by *{Enter IRB Name}* to Sponsor.

The foregoing does not include IRB initial submission preparation fee which will be covered in the start-up fee payment.

Fees must be reasonable and not in excess of amounts charged to other industry sponsors for similar services. Sponsor reserves the right to refuse payment of any IRB/EC fees that Sponsor deems unreasonable, unnecessary, or in excess of the fair market value for such services.

b) Study Start-up Fee (one-time payment): $3200
Payment will be made upon receipt of invoice when all required paperwork for Study start-up has been returned to Sponsor. The Study Start-up Fee is meant to cover the costs of initiating a Study, including reception and maintenance of supplies, IRB/EC submission preparation, general administrative costs, Investigator review of Protocol, obtaining Medicare or other equivalent health reimbursement coverage, training including but not limited to Protocol, GCP, electronic data capture (EDC), and Device, and other miscellaneous start-up costs.

Site Level Other Direct Costs

Code	Name	Total Quantity	Selected Cost	Total
start up	Site Start-up Costs	1	$2,500.00	$2,500.00
*IREV	IRB Review Fee	1	$577.00	$577.00
*IRBR	IRB Renewal	12	$627.00	$7,524.00
	Remote Monitoring Fee	96	$25.00	$2,400.00
*SCLO	Study Close-out Fee	1	$715.00	$580.00
*AR01	Archiving/Document storage	1	$580.00	$580.00
				$14,161.00

Study Start-up	1	12,402	1	$	12,402.00
Departmental Startup	1	1,482	1	$	1,482.00
Record Retention	1	1,560	1	$	1,560.00
Screen Failures	2,360	30	1	$	70,785.00
Local IRB/IEC Fees	10,500	1	1	$	10,500.00
IRB site staff Preparation and Submission of documents (Initial	1	2,600	1	$	2,600.00
Pharmacy Start Up Fee	1	3,575	1	$	3,575.00
Pharmacy Maintenance Fee	1	1,700	1	$	1,700.00
Pharmacy Closeout	1	800	1	$	800.00
Study Related Expenses	5,000	$ 1.00	1	$	5,000.00
Subject Reimbursement - Travel Expenses	490	65	1	$	31,850.00
SAE Reporting Payments	20	350	1	$	7,000.00
Unscheduled Visits and Conditional Procedure Payments	497,910	1	1	$	497,910.00

Program Recruitment Campaign Support	10,000	1	1	$	10,000.00
Pre-Screen/Chart review	50	84	1	$	4,200.00
Re-Screening Fees	100	2,186	1	$	218,550.00
Re-consent	90	118	1	$	10,620.00
Study Close Out	1	2,000	1	$	2,000.00
Fee (on site and/or remote)	5	500	1	$	2,500.00
Annual Fee (e.g., Regulatory Mainenance and Management, IRB preparation renewals, etc.)	1	2,500	1	$	2,500.00
Clinical Research Management Fee	1	3,575	1	$	3,575.00
Prospective Reimbursement	1	2,500	1	$	2,500.00
Prospective Reimbursement Analysis Amendment	1	1,000	1	$	1,000.00
				TOTAL SITE LEVEL FEES	**$ 904,609.00**

Handling Unexpected Costs

Unexpected costs can arise from protocol changes, staffing issues, or additional clinical services. Proactively strategizing by allocating contingency funds in the original budget can mitigate financial impacts from unforeseen events.

Budget Detective Activity

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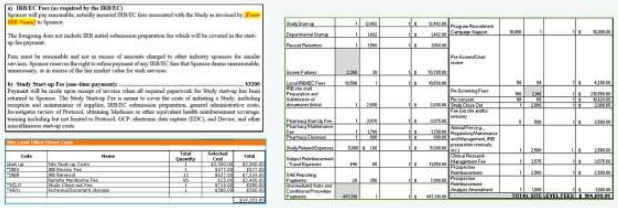

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Internal Budget Example

Personnel with actual salaries

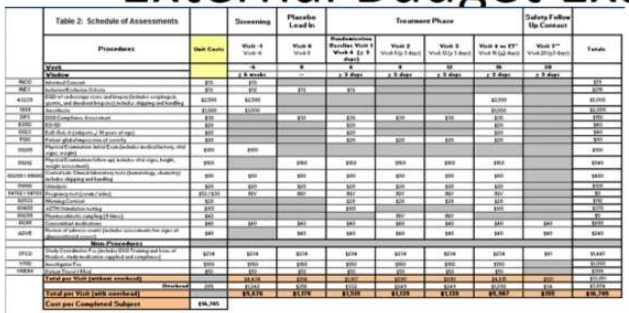
Materials/Supplies/Shipping

IDS fees, CTRC fees, OCT fees, subject payments, core charges, hospital/physician charges

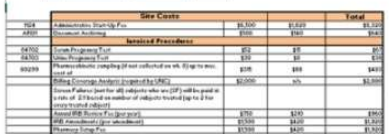
Overhead (F&A) calculations

Total

External Budget Example



Automated Payments Based on EDC (typically)



Invoiceables

Internal Budget Example

IPF:				PI:		Project Title:						
Project ID:			Salary Cap	Due:		PA/RFA:						
		Calendar	$ 1,000,000	RAMSeS:	#NUM!			Animal Subj:				
		Academic	$ 1,000,000	Project Start:	9/1/2020			Human Subj:			Exempt:	
		Summer	$ 1,000,000	Project End:	8/31/2025			Clinical Trial:			Phase III:	
PERSONNEL						Year 1	9/1/2020	—	8/31/2021		364	
Fringe Type	Appt	FTE	Base Salary	Personnel	Role	Salary	% Effort	PM	Salary	Fringe	Total	
1	12	1	150,000	NAME	PD/PI	154,500	5.0%	0.60	7,725	2,722	10,447	
2	12	1	150,000	NAME	Co-Investigator	154,500	2.5%	0.30	3,863	1,118	4,981	
2	12	1	55,000	NAME	Research Coordinator	56,650	25.0%	3.00	14,163	5,098	19,261	
2	12	1	45,000	NAME	Research Assistant	46,350	15.0%	1.80	6,953	2,675	9,628	
-	12	1	45,000	NAME	Research Assistant	46,350	15.0%	1.80	6,953	FALSE	6,953	
-	12	1	-			-	0.0%	-	0	FALSE	0	
				Total					39,657	11,613	$1,270	
				Materials & Supplies					# of Units	Price/Unit		
				Supplies and Shipping							1,500	
				Total							$1,500	
				Travel					# Trips	Cost/Trip		
				Domestic							-	
				Foreign								
				Total Travel							$0	
				Other Direct Costs					# of Units	Price/Unit		
				IDS Fees							8,000	
				CTRC Fees							2,000	
				OCT Admin Fees							3,500	
				OCT Fee Per Subject							500	
				Patient Payments							2,500	
				Translational Pathology							1,200	
				Outpatient Pare Costs							8,000	
				Total Other							$25,700	
				Total UNC Direct							$78,470	
				UNC Directs plus Subcontract Directs				MAX	499,999		$78,470	
				Indirect Cost Calcuation								
				UNC Direct							$78,470	
				Base (Excludes items not subject to OH)							$74,470	
				Indirect Total	Clinical Trials (Non-Federa	28.00%					$20,852	
				Total							$99,322	

Personnel with actual salaries

Materials/Supplies/Shipping

IDS fees, CTRC fees, OCT fees, subject payments, core charges, hospital/physician charges

Overhead (F&A) calculations

Total

External Budget Example

	Table 2: Schedule of Assessments		Screening	Placebo Lead In	Treatment Phase				Safety Follow Up Contact	
	Procedures	**Unit Costs**	**Visit -1** Week -6	**Visit 0** Week 0	**Randomization Baseline Visit 1 Week 4 (± 3 days)**	**Visit 2** Week 8 (± 3 days)	**Visit 3** Week 12 (± 3 days)	**Visit 4 or ET*** Week 16 (±3 days)	**Visit 5**** Week 20 (±3 days)	**Totals**
	Week		-6	0	4	8	12	16	20	
	Window		≤ 6 weeks	--	± 3 days	± 3 days	± 3 days	± 3 days	± 3 days	
INCO	Informed Consent	$78	$78							$78
INEX	Inclusion/Exclusion Criteria	$72	$72	$72	$72					$216
43239	EGD w/ endoscopy exam and biopsy (includes esophageal, gastric, and duodenal biopsies) includes shipping and handling	$2,500	$2,500					$2,500		$5,000
1999	Anesthesia	$1,000	$1,000					$1,000		$2,000
GPS	GSS Compliance Assessment	$30		$30	$30	$30	$30	$30		$150
EQ5D	EQ-5D	$20			$20			$20		$40
QOLS	Kidney Disease Quality of Life (KDQOL)	$20			$20			$20		$40
PGIS	Patient global impression of severity	$20			$20	$20	$20	$20		$80
99205	Physical Examination Initial Exam (includes medical history, vital signs, weight)	$100	$100							$100
99212	Physical Examination Follow up(includes vital signs, height, weight assessment)	$160		$160	$160	$160	$160	$160		$640
80299 / 89999	Central Lab: Clinical laboratory tests (hematology, chemistry) includes shipping and handling	$80	$80	$80	$80	$80	$80	$80		$400
81000	Urinalysis	$20	$20	$20	$20	$20	$20	$20		$100
84702 / 84703	Pregnancy test (serum / urine)	$52 / $30	INV	INV	INV	INV	INV	INV		$0
82533	Morning Cortisol	$26			$26	$26	$26	$26		$152
80400	ACTH Stimulation testing	$165			$165			$165		$330
80299	Pharmacokinetic sampling (3 times)	$42				INV	INV			$0
RCM	Concomitant medications	$40	$40	$40	$40	$40	$40	$40	$40	$280
ADVE	Review of adverse events (includes assessments for signs of glucocorticoid excess)	$40		$40	$40	$40	$40	$40	$40	$240
	Non-Procedures									
ITCO	Study Coordinator Fee (includes GSS Training and time of Protocol, study medication supplied and compliance)	$234	$234	$234	$234	$234	$234	$234	$41	$1,645
YIYI0	Investigator Fee	$150	$150	$150	$150	$150	$150	$150		$1,050
VREIM	Patient Travel / Meal	$50	$50	$50	$50	$50	$50	$50		$300
	Total per Visit (without overhead)		$4,434	$956	$1,107	$920	$920	$4,445	$321	$13,083
	Overhead	24%	$1,042	$206	$332	$243	$243	$1,052	$34	$3,654
	Total per Visit (with overhead)		**$5,476**	**$1,170**	**$1,519**	**$1,139**	**$1,139**	**$5,507**	**$155**	**$16,705**
	Cost per Completed Subject	**$16,705**								

	Site Costs			Total
T124	Administrative Start-Up Fee	$6,500	$1,820	$8,320
AF001	Document Archiving	$100	$140	$640
	Invoiced Procedures			
84702	Serum Pregnancy Test	$52	$15	$67
84703	Urine Pregnancy Test	$30	$8	$38
80299	Pharmacokinetic sampling (if not collected on wk. 0) up to max. cost of	$315	$88	$403
	Billing Coverage Analysis (required by UNC)	$2,000	n/a	$2,000
	Screen Failures (set fee of) subjects who are (SF) will be paid at a rate of 2:1 based on number of subjects treated (up to 2 for every treated subject)			
	Annual IRB Review Fee (per year)	$750	$210	$960
	IRB Amendment (per amendment)	$1,500	$420	$1,920
	Pharmacy Setup Fee	$1,500	$420	$1,920
	Pharmacy Fees (Monthly)	$232	$82	$314
	Monitor Training Fee (invoiced $500/monitor)	$100	$140	$640
	Monitoring Visits	$950	$42	$992
	Initial IRB Fee (Central IRB)	$2,000	n/a	$2,000
VR02	Study Coordinator Hourly (4 hour) for PK sampling	$160	$45	$205
	Invoiced Total	$16,249	$3,430	**$19,679**

Automated Payments Based on EDC (typically)

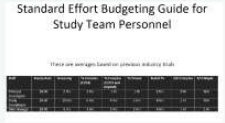
Invoiceables

- Assess and compare internal versus external budget allocations.
- Examine payment terms, including any hold back funds required.
- Analyze the screen failure ratio to determine impact on project costs.
- Evaluate invoiceables to ensure accurate billing and financial tracking.
- **Determine project feasibility based on budget analysis and associated metrics.**

Negotiations

Purpose: Improve skill and confidence in budget negotiations

Effective negotiation begins with asking the right questions.


Standard Effort Budgeting Guide for Study Team Personnel


Tools for Setting Priorities

- Complete Medicare Coverage Analysis
- Budget worksheet
- Back-up Documentation
- PI flexibility (How important is the study to the PI)
- Ancillary costs

Define your "Must haves"

- Coverage of personnel time
- Institutional fees
- Technology fees
- Storage fees

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Effective negotiation begins with asking the right questions.

Understanding your needs and those of others ensures better outcomes.

Confidence in asking leads to valuable insights and opportunities.

Define your "Must haves"

- Coverage of personnel time
- Institutional fees
- Technology fees
- Storage fees

Standard Effort Budgeting Guide for Study Team Personnel

These are averages based on previous industry trials

Staff	Hourly Rate	Screening	Tx Complex (C1D1)	Tx Complex (C2 D1 and beyond)	Tx Simple	End of Tx	F/U Complex	F/U Simple
Principal Investigator	$0.00	2 Hrs	2 Hrs	1 Hr	1 Hr	2 Hrs	.5 Hr	N/A
Study Coordinator	$0.00	10 Hrs	6 Hrs	4 Hrs	2 Hrs	8 Hrs	1 Hr	N/A
Data Manager	$0.00	6 hrs	3 Hrs	2 Hrs	2 Hrs	4 Hrs	1 Hr	1 Hr

Tools for Setting Priorities

- Complete Medicare Coverage Analysis
- Budget worksheet
- Back-up Documentation
- PI flexibility (How important is the study to the PI)
- Ancillary costs

Objection: 'Your fees are too high' or 'This is the cost of doing business'

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Negotiation
Solution
Brainstorm

Identify the rationale behind the project scope.

Estimate the associated costs to implement the strategy.

Define the required effort and set performance benchmarks.

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RE-NEGOTIATION TIPS

Effective strategies for successful re-negotiation.

DOCUMENT CHANGES

Keep a clear record of any modifications made during the re-negotiation process to ensure all parties are aligned and can refer back to them as needed.

SUBMIT EARLY

Present your proposal well in advance to allow ample time for review and adjustments based on feedback received.

INCLUDE UPDATED FEES

Provide justified updates on any changes to fees to maintain transparency and foster trust between negotiating parties.

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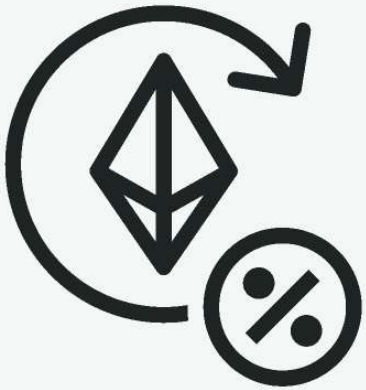

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Post-Award Budget Management

Post-award budget management involves ongoing monitoring and adjustments to ensure compliance with financial agreements. Essential practices include timely invoicing, milestone tracking, and addressing any necessary amendments promptly, which help in maintaining financial control and stakeholder trust.

REVENUE PROTECTION

Implement systematic approaches to prevent revenue loss in studies.

MONTHLY AUDITS

Conduct regular monthly audits to identify and address potential sources of revenue loss before they escalate.

WEEKLY TRACKING

Track patient progress on a weekly basis to ensure accurate data collection and billing processes.

PAYMENT RECONCILIATION

Perform weekly payment reconciliations to ensure all transactions align with services provided and avoid discrepancies.

CTMS TRAINING

Ensure study teams are well-versed in using the Clinical Trial Management System (CTMS) to effectively capture invoiceable items while avoiding accidental triggers.

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PATIENT COMPLIANCE

Ensuring equal treatment and adherence to guidelines for all patients.

EQUAL TREATMENT

What we do for one patient we must do for all patients to maintain fairness and integrity in our processes.

MCA GUIDELINES

Ensure that the MCA is consistently followed by the study team to uphold regulatory standards and protect patient rights.

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BUILDING SPONSOR TRUST

Essential strategies to maintain and strengthen relationships with sponsors.

OFFER REFUNDS

When appropriate, providing refunds to sponsors can help maintain trust and confidence in your organization. This act demonstrates responsibility and accountability, ensuring sponsors feel valued.

COLLABORATIVE MINDSET

Accepting push back from sponsors and working collaboratively shows flexibility and adaptability. A partnership that respects input fosters a stronger bond and a more productive relationship.

TRANSPARENT COMMUNICATION

Establishing open lines of communication with sponsors enhances trust. Regular updates and honest discussions help to align expectations and build a foundation of reliability.

ACTIVE LISTENING

Actively listening to sponsors' concerns and feedback is crucial. It ensures that they feel heard and appreciated, which is key to maintaining a healthy partnership.

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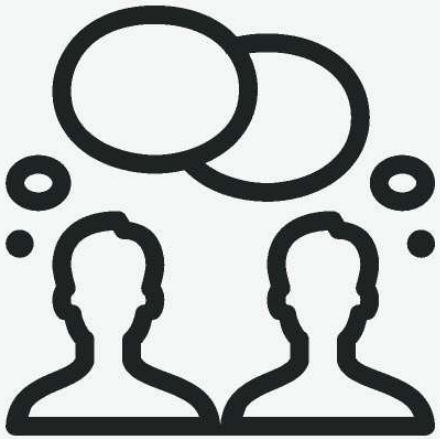

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What strategies enhance effective communication during budget negotiations in clinical trials?

Successful budget negotiations hinge on transparency, relevant data, and alignment with policies.

What strategies enhance effective communication during budget negotiations in clinical trials?

Establish clear pricing models to improve negotiation outcomes.

Support each expense with credible evidence from prior analyses.

Utilize this data to back up proposals while exploring different options.

Establish clear pricing models to improve negotiation outcomes.

Budgeting Tools Overview

Budgeting tools like CTMS (Clinical Trial Management Systems) integrate workflows, enable real-time budget updates, and support budget-to-actual reconciliations. Tools such as OnCore and Medidata offer scalability with centralized access for real-time project tracking and enhanced compliance with FMV (Fair Market Value) guidelines.

Utilizing standardized budget templates ensures uniformity in studies.

By implementing a version control system with date-stamped file names, teams can easily track the latest template.

Regularly updating cost data is essential to maintain budget accuracy and compliance.

Best Practices for MultiSite Trials and Subawards

About Multisite Trial Budgets

Larger budgets than single-site trials
- manage multiple sites
- coordinate data
- potentially deal with variations in procedures across locations

Key areas where multisite budgets differ:
- site initiation fees
- study coordination
- travel expenses

Subawards

A legal agreement where a funding recipient (PTE) transfers a portion of their grant award to another organization (Sub-recipient) to perform specific, substantive work on the clinical trial

MultiSite Trial Considerations

- Site Initiation Fees
- Study Coordination
- Travel Expenses
- Overhead Costs
- Data Management and Analysis
- Regulatory Compliance

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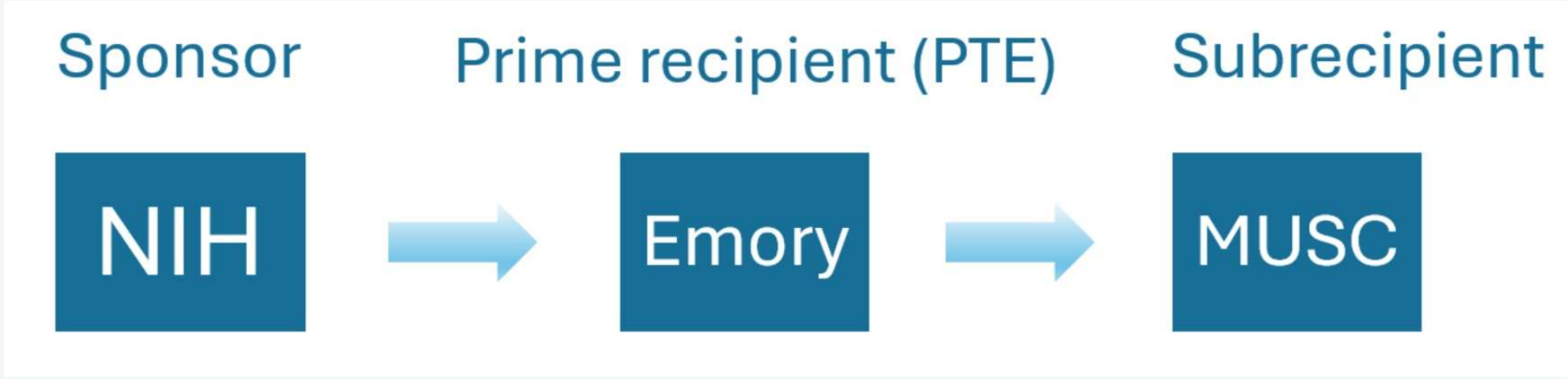

Subaward Budget Considerations

- Site Initiation Fees
- Study Coordination
- Travel Expenses
- Overhead Costs
- Data Management and Analysis
- Regulatory Compliance

Summary and Key Takeaways

Employing the right budgeting tools and techniques can significantly enhance the management of clinical trial finances. Consistency in using templates and effective negotiation practices not only streamline the budgeting process but also foster trust with stakeholders and sponsors, ultimately leading to successful trial outcomes.

“

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Clinical Trial Budgets

Understanding Budget Components and Management

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