

Budgeting Of Clinical Trials



Module 8 Topic 3

Budget

- Itemized summary of estimated or intended expenditures for a given period along with proposals for financing them

OR

- A systematic plan for the expenditure of a usually fixed resource, such as money or time, during a given period



Why Budgeting?

- Every activity costs money
- Prior to taking up any activity it is essential to calculate the cost of the entire project.
- Finances should be organized so that work does not get held up and hence cost more

Financial planning is the key to success!



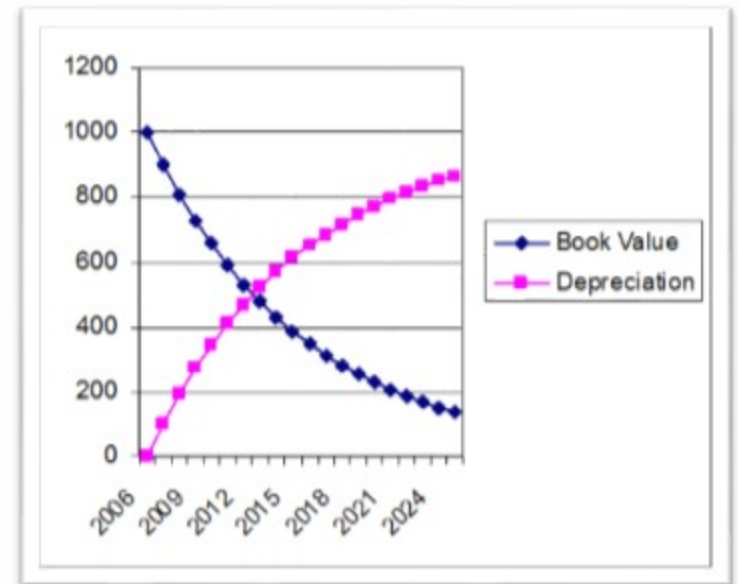
Types of Expenditures

- **Capital** – usually one time expenses (eg., land, plant, machinery or what are known as fixed assets.)
- **Recurring** – regular expenses (wages, raw materials, supplies, services, travel)



Depreciation

- Depreciation is an accounting and finance term for the method of attributing the cost of an asset across the useful life of the asset.



Who all do you think will need to **prepare a budget** in a clinical trial?

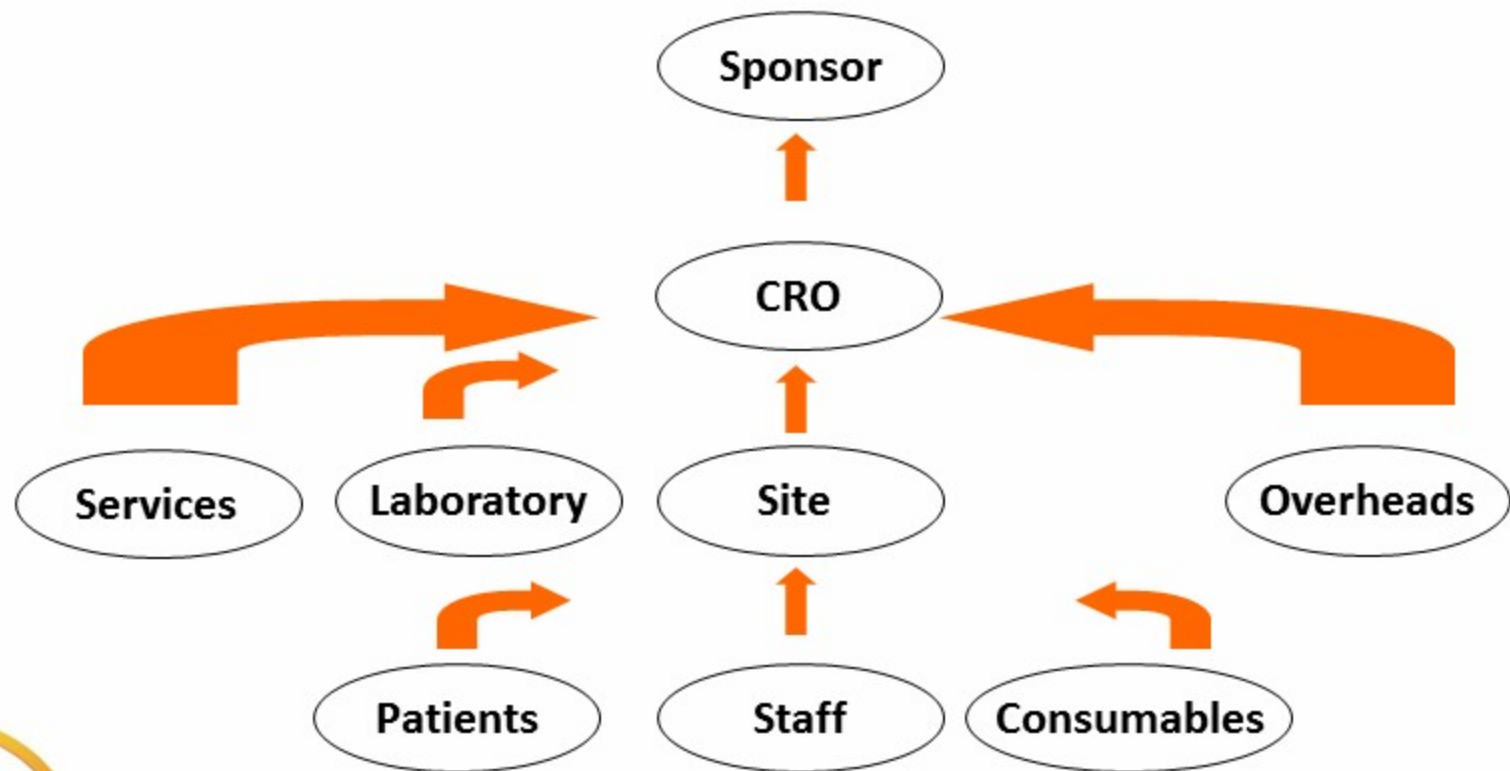


List

- Sponsor
- **CRO**
- Data management
- IP management
- **Laboratory**
- **Investigator**
- Other services



Cost distribution



Investigator's Site



Investigator Site Costing

- Investigator asks for a study protocol
- Studies the protocol carefully
 - Is the research right for his site
- Reviews the Protocol Schematic
 - Hospital procedures
 - Physician practice costs
 - Lab costs
 - How many visits / Length of study
 - Length of coordinator procedures



Budget Building

- Per Patient
- Study Level



Table 7-1 Assessment schedule

Study Period		Washout	Single-blind Screening Period			Double-blind Treatment Period					
Visit	Category	1	2	201 ²	3	4	5	6	7	83	
Day		-21 (-35)	-14 (-28)	-14	1	7	14	28	42	56	
Informed Consent	S	X									
Inclusion/Exclusion Criteria	S	X	X	X	X						
Taper antihypertensive medications	S	X*									
Medical History	D	X									
Hypertension History	D	X									
Smoking History	D	X									
Height	D				X						
Weight	D				X					X	
Waist Circumference	D				X						
Blood Pressure and Pulse	D	X	X	X	X	X	X	X	X	X	
Screening Physical Examination	S	X									
Complete Physical Examination	S				X					X	
ECG	D	X			X					X	
Complete Laboratory Evaluations	D	X			X					X	
Renin and Angiotensin-II Measurement ⁵	D				X					X	
Electrolytes	D							X			
Serum/Urine Pregnancy Test ¹	D	X			X					X	
Pharmacogenetic Sample ⁴	D				X						
Adverse Events	D		X	X	X	X	X	X	X	X	
Concomitant Medications	D	X	X	X	X	X	X	X	X	X	
Prior Antihypertensive Meds	D	X									
Drug Accountability	S	X		X	X	X	X	X	X	X	
IVRS	S	X	X	X	X	X				X	
Screening Log	D	X									
Randomization	D				X						
Dispense Study Medications	S		X	X	X	X					
End of Study Information	D									X	

Per Patient

Study Period		Washout	Screening	Double-blind Treatment Period						
Visit		1	2	3	4	5	6	7	8	
PROCEDURES:	Cost	-21	-14	1	7	14	28	42	56	Totals
Informed Consent	\$75	\$75								\$75
Inclusion/Exclusion Criteria	\$25	\$25	\$25	\$25						\$75
taper AntiHyp Meds	\$40	\$40								\$40
Medical History (inc. Hyp & Smokin	\$85	\$85								\$85
Height/ Weight	\$15			\$15						\$15
Waist Circumference	\$15			\$15						\$15
BP and Pulse	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$200
Screening PE	\$125	\$125								\$125
Complete PE	\$175			\$175					\$175	\$350
EKG	\$63	\$63		\$63					\$63	\$189
EKG Interpretation	\$37	\$37		\$37					\$37	\$111
Collect Labs	\$25	\$25		\$25			\$25		\$25	\$100
Lab Interpretation	\$25	\$25		\$25			\$25		\$25	\$100
Pharmacogenetic Consent	\$25			\$25						\$25
Adverse Events	\$20		\$20	\$20	\$20	\$20	\$20	\$20	\$20	\$140
Concomitant Medications	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$15	\$120
Drug Accountability	\$25			\$25	\$25	\$25	\$25	\$25	\$25	\$150
VRS	\$40		\$40	\$40	\$40				\$40	\$160
Screening Log	\$25	\$25								\$25
Randomization	\$25			\$25						\$25
Dispense Study Meds	\$20		\$20	\$20	\$20					\$60
Echocardiogram	\$40								\$40	\$40
Pt Reimbursement for Travel	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$25	\$200
Coordinator Fee:	\$60	\$60	\$60	\$60	\$60	\$60	\$60	\$60	\$60	\$480
Total per procedure		\$650	\$230	\$660	\$230	\$170	\$220	\$170	\$575	\$2,905
Institutional overhead	26%	\$169	\$60	\$172	\$60	\$44	\$57	\$44	\$150	\$755
Total w/ overhead		\$819	\$290	\$832	\$290	\$214	\$277	\$214	\$725	\$3,660
										9 Patients: \$32,947.70



Study Level

- Start- up costs (non-refundable)
 - Investigator Meeting, IRB Fee: Protocol submission, administrative Fee
- Other Costs
 - Travel, advertisement, equipment, record storage
- Personnel Cost
 - PI fee, co-investigator, nurse, technician etc
- Other Invoice Items
 - Screen failures, unscheduled visits, amendments, queries,



Patient Reimbursement

- Reimbursement for patients is often required
- Estimate traveling expenses paid to patients
- Estimate per day refreshment expenses due to patients
- Calculate patient expenses per visit



Pharmacy & Archival Charges

- The pharmacy may have to store investigational products under specific conditions for varying amount of time
- Trial documents have to be stored for periods ranging between 3 to 5 years
- Site may have some charges for this work.



Payment Terms

- What is the initial payment
- What is the payment schedule
- Will they rely on you to Invoice
 - For all payments
 - Study Level Costs



Payment Schedules

- Single Flat-fee Based Report
 - The contract will specify the definition of a reimbursable patient
 - Patients screened successfully
 - Patients randomized successfully
 - Patients who successfully complete their first study visit



Payment Schedules

- Mile stone payments
 - Visit performed
 - Procedures performed
 - Enrollment based incentives



Laboratory



Laboratory Costing

Item	Amount
Lab Testing Fee	
Kit Fee	
Sample Management	
Miscellaneous and Bulk Supplies	
Pass through Costs—estimated shipping charges	
Pass through costs- Estimated travel cost for the investigator meeting	



Budget preparation of CRO



Expenses in a CRO

- Capital
 - Office, computers, servers, Photostat, archiving cupboards, software's etc
- Recurring
 - Wages, marketing activities, admin expenses, interests, travel costs



Expenses

Expenses begin before projects do

- Office Rent
- Utilities
- Hiring costs
- Training costs
- Marketing costs



Expense Heads

- Fixed and Variable
 - Fixed costs are those which are to be paid irrespective of the trial
 - Variable costs are those incurred for the trial, and vary with each trial and its size.



Steps of Preparing a RFP

- Understand the services required by the sponsor
- Finalize the **responsibility matrix**
- Finalize the **check list**
- Get the **budget** from the investigator
- Prepare the study budget
- Submit the **RFP**



Points to Remember

- Planning a long term relationship
- Transparent scope of work at RFP stage
- Define: Eliminate ambiguity by defining even basic terms of your organization
- Define study specifications clearly in the contract

Communicate upfront to prevent friction!



Points to Remember

- Be aware of all expenses of your organization
- Understand ALL cost drivers involved in conducting clinical trials
- Allow for contingencies

