

***A Quick Review of the
Fundamentals for Preparing a
Clinical Trial Budget & GCIG
Budgeting Template***

GICOM

**Fundamentals for Preparing a Clinical
Trial Budget**

1. Identify the Potential Members of a Budgeting Team
2. Identify your Clinical Trial Team
 - ✓ Project Lead
 - ✓ Clinical Trial Manager
 - ✓ Medical Manager
 - ✓ Trials Assistant
 - ✓ Data Manager
 - ✓ Safety
 - ✓ Etc.

**Fundamentals for Preparing a Clinical
Trial Budget**

3. Work with the final version of the study protocol and CRFs
4. Dissect the Protocol
 - Study Calendar
 - Laboratory Assessments
 - Procedures, etc.

BUDGETING

Study Calendar

Procedure	Pre-Study	Treatment		
		Day 1	Day 8	Day 15
Eligibility criteria/Signed informed consent	X			
Demographic data/tumor characteristics	X			
Tumor history surgery, radiotherapy, systemic therapies	X			
Medical history	X			
Baseline conditions	X			
Physical exam	X	X		
Non drug therapies for tumor	X			If appropriate
Other diagnostic procedures				If appropriate
Vital signs (BP, pulse)	X	X		
ECG and chest X-ray (if not already performed to follow tumor.)	X			Only if clinically indicated
ECOG PS	X	X		
Hematology	X	X	X	X
Blood chemistry	X	X	X	X

*Fundamentals for Preparing a Clinical
Trial Budget*

5. Categorise Budget Items

- Upfront /Start Up Costs
- Per-Subject Costs
- Pass through costs (per invoice, IRB fees, etc.)
- Additional Costs



**Fundamentals for Preparing a Clinical
Trial Budget**

▪ **Start Up Costs**

- Funds that are needed before enrolling the first subject. Separate from the per subject costs and non-refundable regardless if trial enrolls subjects or not.

**Fundamentals for Preparing a Clinical Trial
Budget**

▪ **Per Patient Costs**

- Costs related to Subject visits:

- ✓ IC process
- ✓ Physical Exam
- ✓ Types and Number of Procedures
- ✓ Lab Exams
- ✓ Dispensing of Drug
- ✓ All Clinical Visits
- ✓ Unscheduled visits
- ✓ Etc.

GYNECOLOGIC CANCER INTERGROUP

An Organization of International Cooperative
Groups for Clinical Trials in Gynecologic Cancers

BUDGETING

Per Patient

	Cost	Screen Day -14 to -1	Cycle 1 28 Day Cycle				Cycle 2 28 Day Cycle				Cycle 3 28 Day Cycle			
		Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22	Day 1	Day 8	Day 15	Day 22	
OFFICE VISITS														
Physical Examination	\$145.00	RC	RC				RC				RC			
LABS														
Hematology - CBCPD	\$75.00	RC	RC	\$75.00	RC	\$75.00	RC			RC				RC
Serum Chemistry - COMP	\$75.00	RC	RC		RC		RC			RC				RC
Direct Bilirubin	\$30.00	\$30.00	\$30.00		\$30.00		\$30.00			\$30.00				\$30.00
Uric Acid	\$45.00	\$45.00	\$45.00		\$45.00		\$45.00			\$45.00				\$45.00
LDH	\$50.00	\$50.00	\$50.00		\$50.00		\$50.00			\$50.00				\$50.00
Serum Pregnancy Test	\$50.00	INVOICE	INVOICE				INVOICE							INVOICE
Urinalysis - Macro	\$25.00	RC	\$25.00				RC							RC
Urinalysis - Micro	\$25.00	\$25.00	\$25.00				\$25.00							\$25.00
PROCEDURES														
CT Scan - Abdomen	\$1,500.00	RC												RC
CT Scan - Chest	\$1,500.00	RC												RC
CT Scan - Pelvis	\$1,500.00	RC												RC
Bone Marrow Aspirate	\$500.00	RC		INVOICE			\$500.00							RC
Bone Marrow Biopsy	\$1,000.00	RC		INVOICE			\$1,000.00							RC
ECG (12 Lead)	\$100.00	\$300.00	\$600.00	\$600.00	\$600.00	\$600.00	\$300.00	\$300.00	\$300.00	\$300.00		\$300.00		\$300.00
MEDICATIONS														
DSY-1203 Prep	\$50.00		\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00	\$50.00
DSY-1203 Infusion	\$475.00		\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00	\$475.00
PERSONNEL														
Principal Investigator	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00	\$150.00
Research Nurse	\$375.00	\$568.00	\$568.00	\$350.00	\$568.00	\$350.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00	\$375.00
Medical Assistant	\$75.00	\$141.50	\$141.50	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00	\$75.00
Data Manager	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00	\$250.00
Regulatory Associate	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00	\$100.00



BUDGETING

Per Patient

Visit Total	\$1,859	\$2,509	\$2,125	\$2,393	\$2,125	\$3,425	\$1,775	\$1,900	\$1,775	\$1,625	\$1,775	\$1,600	\$1,775
Overhead	\$414	\$627	\$531	\$598	\$531	\$856	\$443	\$475	\$443	\$406	\$443	\$400	\$443
TOTAL	\$2,074	\$3,136	\$2,656	\$2,991	\$2,656	\$4,281	\$2,218	\$2,375	\$2,218	\$2,031	\$2,218	\$2,000	\$2,218

Screen, Cycle 1		Cycle 2		Cycle 3	
Per patient total	\$10,812	Per patient total	\$8,875	Per patient total	\$6,775
Overhead	\$2,703	Overhead	\$2,218	Overhead	\$1,683
TOTAL	\$13,515	TOTAL	\$11,093	TOTAL	\$8,468

GRAND TOTAL	
Per patient total	\$26,482
Overhead	\$6,615
TOTAL	\$33,077

**Fundamentals for Preparing a Clinical Trial
Budget**

■ **Additional/Hidden Costs**

Event that may or may not occur during the study, but it has to be in the budget.

- ✓ Screen Failure
- ✓ Queries
- ✓ SAEs
- ✓ Protocol Amendments
- ✓ Delayed Start
- ✓ Overhead
- ✓ Audits

GCIG BUDGETING TEMPLATE (Draft)

	Y1	Y2	Y3	Y4	Y5	Total USD
Total expenses	Total USD per Year					
						\$
Start-up expenses	\$ 3,600	\$ -	\$ -	\$ -	\$ -	3,600
Administrative expenses	\$ 4,800	\$ 4,800	\$ 4,800	\$ 4,800	\$ 4,800	24,000
						\$
Drug Costs	\$ 1,840	\$ 1,840	\$ 1,840	\$ 1,840	\$ 1,840	9,200
						\$
Central Lab Costs	\$ 1,440	\$ 1,440	\$ 1,440	\$ 1,440	\$ 1,440	7,200
Travel & Subsistence	\$ 32,832	\$ 32,832	\$ 32,832	\$ 32,832	\$ 32,832	164,160
Monitoring	\$ 20,344	\$ 20,344	\$ 20,344	\$ 20,344	\$ 20,344	101,720
Regulatory	\$ 26,280	\$ 26,280	\$ 26,280	\$ 26,280	\$ 26,280	131,400
Other Costs	\$ 12,280	\$ 12,280	\$ 12,280	\$ 12,280	\$ 12,280	61,400
FTE Expenses	\$ 3,711,200	\$ 3,785,424	\$ 3,861,132	\$ 3,938,355	\$ 4,017,122	19,313,234
Total expenses	\$ 3,814,616	\$ 3,885,240	\$ 3,960,948	\$ 4,038,171	\$ 4,116,938	19,815,914

GCIG BUDGETING TEMPLATE

Lead and Participant Groups:

- **Who would be the final Control Data Consolidator?**
- **For groups using their current template, having a GCIG template would it be useful?**
- **Should we have one template for both Lead and Participant groups?**

COMMENTS ?????

THANK YOU !!

