



Checklist for a GCIG Clinical Trial Budget

CLINICAL TRIAL INFORMATION	DATE:
Lead GCIG Group:	
CRO (if any):	
Protocol Name:	
Project Manager's Name:	Email:
Prepared by Name:	Email:

CLINICAL TRIAL BUDGET		
EXPENSES	CONSIDERED	ESTIMATE COST PER YEAR/ COMMENTS
START-UP		
Review of Protocol	<input type="checkbox"/>	
Review/prepare/modify informed consent	<input type="checkbox"/>	
Translation of Protocol	<input type="checkbox"/>	
Translation of study documents	<input type="checkbox"/>	
Back translation of documents	<input type="checkbox"/>	
EC Fee Initial	<input type="checkbox"/>	
Regulatory Submission Fee	<input type="checkbox"/>	
Insurance	<input type="checkbox"/>	
Site initiation costs (including sites initial training)	<input type="checkbox"/>	
Advertising	<input type="checkbox"/>	
Pharmacy Set-Up Fee	<input type="checkbox"/>	
Contracting (i.e Lawyer's fees)	<input type="checkbox"/>	
Printing	<input type="checkbox"/>	
Estimated Screen Failure	<input type="checkbox"/>	
Other (specify)	<input type="checkbox"/>	

CLINICAL TRIAL BUDGET

EXPENSES	CONSIDERED	ESTIMATE COST PER YEAR/ COMMENTS
ADMINISTRATIVE		
Office supplies	<input type="checkbox"/>	
Office expense	<input type="checkbox"/>	
Equipment PC & Communications	<input type="checkbox"/>	
Lab Equipment (Freezers, Centrifuges, Thermometer, etc.)	<input type="checkbox"/>	
Archiving	<input type="checkbox"/>	
Courier/Mailing	<input type="checkbox"/>	
Shipping	<input type="checkbox"/>	
Project Specific Consumables (Dry Ice, etc.)	<input type="checkbox"/>	
Publications	<input type="checkbox"/>	
Pharmacy support	<input type="checkbox"/>	
Teleconferences	<input type="checkbox"/>	
Other (Specify)	<input type="checkbox"/>	
DRUG COSTS		
Drug cost	<input type="checkbox"/>	
Drug labelling	<input type="checkbox"/>	
Drug packaging/distribution	<input type="checkbox"/>	
Drug Destruction	<input type="checkbox"/>	
CENTRAL LAB COSTS		
Sample Analysis	<input type="checkbox"/>	
Storage	<input type="checkbox"/>	
Lab Supplies	<input type="checkbox"/>	
Shipping (serum and tissue samples)	<input type="checkbox"/>	
Sample tracking	<input type="checkbox"/>	
REGULATORY		
IRB/EC amendment Fee	<input type="checkbox"/>	
IRB Annual Fee Renewal	<input type="checkbox"/>	
MOH amendment Fee	<input type="checkbox"/>	
MOH Safety Report fee	<input type="checkbox"/>	

CLINICAL TRIAL BUDGET

EXPENSES	CONSIDERED	ESTIMATE COST PER YEAR/ COMMENTS
MOH Study Close Out Notification	<input type="checkbox"/>	
SAE notifications	<input type="checkbox"/>	
Import / Export license	<input type="checkbox"/>	
Customs drop / clinical supplies	<input type="checkbox"/>	
TRAVEL AND SUBSISTANCE		
Travel to meetings	<input type="checkbox"/>	
Monitoring expenses	<input type="checkbox"/>	
Air	<input type="checkbox"/>	
Land	<input type="checkbox"/>	
Accommodations	<input type="checkbox"/>	
Meals	<input type="checkbox"/>	
Other	<input type="checkbox"/>	
SITE MANAGEMENT		
Feasibility process	<input type="checkbox"/>	
Pre-Study Visit Local	<input type="checkbox"/>	
Pre-Study Visit Foreign	<input type="checkbox"/>	
Site Initiation Visit local	<input type="checkbox"/>	
Site Initiation Visit Foreign	<input type="checkbox"/>	
Monitoring visit routine- local	<input type="checkbox"/>	
Monitoring visit for cause- local	<input type="checkbox"/>	
Monitoring visit routine- foreign	<input type="checkbox"/>	
Monitoring visit for cause- foreign	<input type="checkbox"/>	
Remote monitoring	<input type="checkbox"/>	
Site Maintenance	<input type="checkbox"/>	
Co- monitoring - local	<input type="checkbox"/>	
Co-monitoring foreign	<input type="checkbox"/>	
Close-out visit local	<input type="checkbox"/>	
Close-out visit foreign	<input type="checkbox"/>	
FTE COSTS		
Project lead	<input type="checkbox"/>	

CLINICAL TRIAL BUDGET

EXPENSES	CONSIDERED	ESTIMATE COST PER YEAR/ COMMENTS
Clinical Project Manager	<input type="checkbox"/>	
Trial Manager	<input type="checkbox"/>	
Clinical Research Associate	<input type="checkbox"/>	
Data Manager	<input type="checkbox"/>	
Trials assistant	<input type="checkbox"/>	
Randomization / drug supply programmer	<input type="checkbox"/>	
Statistician	<input type="checkbox"/>	
Data services	<input type="checkbox"/>	
Medical writing	<input type="checkbox"/>	
Quality Assurance/Pharmacovigilance Manager	<input type="checkbox"/>	
Regulatory Manager	<input type="checkbox"/>	
OTHER COSTS/CHARGES		
Inspections/Audits	<input type="checkbox"/>	
Safety	<input type="checkbox"/>	
Facility/Access charges	<input type="checkbox"/>	
Investigator Meeting	<input type="checkbox"/>	
Overhead (specify percentage %)	<input type="checkbox"/>	
Inflation	<input type="checkbox"/>	
VAT	<input type="checkbox"/>	
Other	<input type="checkbox"/>	

Checklist completed by:	Name: Date:
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