**Checklist for a GCIG Clinical Trial Budget**

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| --- | --- | --- | --- | --- |
| **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 |  |  |
| Review/prepare/modify informed consent |  |  |
| Review/prepare/modify protocol synopsis |  |  |
| Review/prepare Protocol amendments |  |  |
| Review/prepare/modify (electronic) CRF |  |  |
| Translation of Protocol |  |  |
| Translation of study documents |  |  |
| Back translation of documents |  |  |
| EC Fee Initial |  |  |
| Regulatory Submission Fee |  |  |
| Insurance |  |  |
| Review/prepare/modify study manuals (Monitoring plan, eCRF guidelines, lab manual, TR, communication plan, etc.) |  |  |
| Preparation and distribution of Investigator Site Files |  |  |
| Site initiation costs (including sites initial training) |  |  |
| Advertising | ☐ |  |
| Site Set-Up Fee & Investigator Fee during trial | ☐ |  |
| Pharmacy Set-Up Fee & Pharmacy Fee during trial | ☐ |  |
| Contracting (i.e Lawyer’s fees) | ☐ |  |
| Printing |  |  |
| Estimated Screen Failure |  |  |
| Other (specify) |  |  |
| ***ADMINISTRATIVE*** |  |  |
| Office supplies |  |  |
| Office expense |  |  |
| Equipment PC & Communications |  |  |
| Lab Equipment (Freezers, Centrifuges, Thermometer, etc.) |  |  |
| Archiving |  |  |
| Courier/Mailing |  |  |
| Shipping |  |  |
| Project Specific Consumables (Dry Ice, etc.) |  |  |
| Publications |  |  |
| Pharmacy support |  |  |
| Teleconferences |  |  |
| Other (Specify) |  |  |
| ***DRUG COSTS*** |  |  |
| Drug cost |  |  |
| Drug Storage |  |  |
| Drug labelling |  |  |
| Drug packaging/distribution |  |  |
| Drug Destruction |  |  |
| ***CENTRAL LAB COSTS*** |  |  |
| Sample Analysis | ☐ |  |
| Storage | ☐ |  |
| Lab Supplies | ☐ |  |
| Shipping (serum and tissue samples) |  |  |
| Sample tracking |  |  |
| ***REGULATORY*** |  |  |
| |  | | --- | | IRB/EC amendment Fee | | ☐ |  |
| |  | | --- | | IRB Annual Fee Renewal | | ☐ |  |
| |  | | --- | | MOH amendment Fee | | ☐ |  |
| MOH Safety Report fee | ☐ |  |
| MOH Study Close Out Notification | ☐ |  |
| SAE notifications | ☐ |  |
| Import / Export license | ☐ |  |
| Customs drop / clinical supplies | ☐ |  |
| ***TRAVEL AND SUBSISTANCE*** |  |  |
| Travel to meetings |  |  |
| Monitoring expenses |  |  |
| Air |  |  |
| Land |  |  |
| Accommodations |  |  |
| Meals |  |  |
| Other |  |  |
| ***SITE MANAGEMENT*** |  |  |
| Feasibility process |  |  |
| Collection of essential documents |  |  |
| Pre-Study Visit Local |  |  |
| Pre-Study Visit Foreign |  |  |
| Site Initiation Visit local |  |  |
| Site Initiation Visit Foreign |  |  |
| Monitoring visit routine- local |  |  |
| Monitoring visit for cause- local |  |  |
| Monitoring visit routine- foreign |  |  |
| Monitoring visit for cause- foreign |  |  |
| Remote monitoring |  |  |
| Site Maintenance |  |  |
| Co- monitoring - local |  |  |
| Co-monitoring foreign |  |  |
| Close-out visit local |  |  |
| Close-out visit foreign |  |  |
| ***FTE COSTS*** |  |  |
| Project lead |  |  |
| Clinical Project Manager |  |  |
| Trial Manager |  |  |
| Clinical Research Associate or Trial Physician |  |  |
| Data Manager |  |  |
| Trials assistant |  |  |
| Randomization / drug supply programmer |  |  |
| Statistician |  |  |
| Data services |  |  |
| Medical writing |  |  |
| Quality Assurance/Pharmacovigilance Manager |  |  |
| Regulatory Manager |  |  |
| ***OTHER COSTS/CHARGES*** |  |  |
| Patient and public involvement |  |  |
| Inspections/Audits |  |  |
| Safety |  |  |
| Facility/Access charges |  |  |
| Investigator Meeting |  |  |
| Monitor Training & Meetings |  |  |
| Trial Steering Committee Meetings |  |  |
| DSMB / IDMC Meetings |  |  |
| Newsletter |  |  |
| Statistical Analysis plan |  |  |
| Final Study Report |  |  |
| Fee for public registries |  |  |
| Fee for Quality of Life questionnaires |  |  |
| Overhead (specify percentage %) |  |  |
| Inflation |  |  |
| VAT |  |  |
| Other |  |  |

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|  | | |
| Checklist completed by: | Name: |  |
| Date: |  |
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