**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** |
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|  **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) | [x]  |  |
| 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*** |  |  |
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| IRB/EC amendment Fee |

 | ☐ |  |
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| IRB Annual Fee Renewal |

 | ☐ |  |
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| 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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