MonashPathology
MonashHealth

BUDGETARY INFORMATION FOR SPONSORS

Pathology Research: Clinical Trial Site Costs

These fees cover, but are not limited to the following requirements: (They are exclusive of GST)

Protocol Review, Set-Up Fee

- Review of Protocol, Investigator's Brochure and any corresponding documentation to determine specific requirements and implications to Pathology practices.
- Discuss the protocol with Laboratory staff.
- Ensure Laboratory scientist have the opportunity to review study documents, comments and provide feedback to Clinical trials manager prior to building the quotation.
- Preparation and submission of Quotation along with Letter of Offer document, including quality control information - laboratory equipment logs and maintenance documents, IATA and NATA certification documentation
- Liaisons with trial sponsor and or Principle Investigator/ Study Coordinator for any modification to initial quote submission or any resolution of queries as requested by trial sponsor and or Principle Investigator

Site Set Up

Clinical trials Manager

- Collation of essential documentation establishment of files
- Method development and documentation for ,IT and ,data management, sample storage and despatch to external laboratories
- Completion of set up (as detailed in flow diagram).
- Education/training of all laboratory staff
- Education and liaison with other hospital departments and ward staff as appropriate.
- Receipt and storage of initial study materials.

Laboratory Staff

- Loading of Protocol
- Loading of Billing items and biller demographics.

Additional Protocol or Investigator's Amendments post set up $100.00

- Protocol Amendments to Laboratory Protocols and Billing Protocols completed, upon return of completed and approved documents

Annual Operational Fee

- Trial monitoring to ensure compliance with study requirements.
- Receipt and storage of ongoing study materials and kits.
- Ongoing provision of certification documentation to sponsor PI on request Monitoring and audit of equipment including log maintenance. freezer temperatures, any changes in reference ranges,
- Provision of study labels, labelling of tubes for trial coordinators an despatch to collection centres
- Ongoing provision to trial sponsor or Primary Investigator of all variations to pathology normal ranges.
- Monthly reporting of patient visit and test numbers to trial coordinators

Central LAB and PK's. As per Quote: Additional tests will be charged at 100% CMB rates

Trial Closure Fee - Pathology Clinical Trials Manager

Upon receipt of confirmation of trial closure from PI

- Archiving of records and any back up samples for audit purposes
- ***Storage costs*** – Iron Mountain
- Preparation of documentation reference ranges, methods used for analysis, temperature logs. maintenance certificates
- Final close out meeting with Sponsor or PI trial coordinator.
- Archive the study/ Packing of manual and all documentation for return to Sponsor or department
- Remove from the active data base – archive data base with log storage details
- Generate final account and despatch

Pathology Laboratory

- Closure of electronic protocols, laboratory protocols, send away files to be returned to trial coordinators or disposal
- Closure of billing system