## Teletrial Budget and Costing Guideline

### Considerations for Sponsors

Investing in the teletrial model is an investment in site infrastructure and readiness for future clinical trial opportunities. Benefits include reduced travel for participants resulting in greater compliance, the potential for increased generalizability of results by including a diverse population from remote and rural areas, and an estimated return of $58.00 for every $1 invested in randomized clinical trials.[[1]](#footnote-2)

# Budget considerations for teletrials are undertaken with the Primary Site.

Trial budgets include costs associated with the Satellite sites and are included in the initial Clinical Trial Research Agreement (CTRA), or via a CTRA amendment for established contracts, alongside the Primary Site costs. The Primary Site is responsible for distributing funds to the Satellite Site as documented in the Subcontract. There are additional fees involved with teletrials including costs associated with establishing and maintaining the Satellite Sites, and costs associated with running trial activities at the Satellite Site.

# In all cases:

* The Principal Investigator manages the Cluster from the Primary Site and is the key conduit for Research Governance Approvals and ongoing trial management across the Cluster
* Establishment costs for the Cluster, including research governance, reside principally with the Primary Site, with minimal additional budgetary costs for Satellite Sites.

# Additional costs for the following activities:

* Training satellite staff
* Telehealth consultation fees
* Additional transport, storage and destruction of investigational medicinal product if applicable at satellite sites
* Minimal additional cost for Cluster Research Governance Review via Primary site coordination and site agreement of total budget.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TASK** | **WITHOUT TELETRIALS** | **WITH TELETRIALS** | | **Comment** |
| **PRIMARY SITE** | **SATELLITE SITE** |
| Regulatory approval |  |  |  |  |
| * Ethics | ü | ü | X | Primary Site applies for ethics |
| * Site specific assessment (SSA) | ü | ü | (ü) | Minimal Sign off at Satellite site |
| Project management oversight |  |  |  |  |
| * Contracts | ü | ü | (ü) | Teletrial contract allows for satellite sites to be included. |
| * Satellite Site coordinator | ü | ü | ü | Satellite site staff trained and ready for further trials |
| Site feasibility | ü | ü | ü | All sites contribute |
| Operational set up |  |  |  |  |
| * Equipment acquisition and upgrade | ü | ü | ü | Satellite sites ready for future trials |
| * Telecommunications | X | ü | ü |  |
| Staff training | ü | ü | ü | Investment in regional rural and remote staff upskilling |
| Site initiations | ü | ü | ü |  |
| Supervision plan | X | ü | ü | Primary site and Satellite work to plan |
| Patient visits | ü | ü | ü | Patients visit Satellite site |
| Accommodation | ü | X | X | Patients travel less to attend Satellite site |
| Travel | ü | (ü) | X | Travel costs reduced |
| Overnight stay for adverse events | ü | ü | ü | Local stay for satellite sites |
| Teletrial consultation rooms | X | ü | ü | Infrastructure investment |
| Monitoring visits from sponsor/ auditor | ü | ü | ü | As needed |
| Pharmacy | ü | ü | ü | Some Satellite sites may receive dispensed meds |
| Close out | ü | ü | ü |  |

(ü) indicates where a cost may be incurred

1. Tuffaha, Haitham and Birch, Stephen (2022). A pilot study to prospectively estimate the health and economic return on research investment. Melbourne, VIC Australia: Australian Clinical Trials Alliance. [↑](#footnote-ref-2)