Primary Site Workload

The approximate time in hours for the additional work required by the primary site to initiate a tele-trial is as follows:

|  |  |  |
| --- | --- | --- |
| **Primary Site Activity** | **Experienced****Site****Time in Hours** | **Tele-Trial Naïve Site****Time in Hours** |
| Additional review of protocol for suitability for Tele-Trial Model | 1  | 1 |
| Sponsor discussion. Time will vary according to sponsor’s experience with tele-trials and proposed trial sites | 1-3  | 1-3 |
| Collaborate/meetings/site visit or SSV assessment with satellite sites (PI discussion, SC and RGO) to assess their willingness and capacity to participate in the Teletrial cluster and complete the feasibility assessment. Assist sponsor with satellite site evaluation visits as required.  | 1 | 3-4 |
| Provide the sponsor with all contact details, finance information and addresses including the e-mail address of satellites for the transfer of the online SSA form. | 1 | 2 |
| Preparation of additional documents for RGO submission in collaboration with sponsor and sites including supervision plan, subcontract with satellite site plus amended primary contract with sponsor, logistical plan for IMP management and/ or pathology, discussion of fees to align the sites  (if not within a set cluster), staff or site capabilities for trials (depending on site experience). Preparation of lead HREC amendment submission | 16 | 40 |
| Meetings with satellite site(s) to check RGO submission progress.  | 1 | 2 |
| Approved Primary site RGO submission package and sponsor package sent to each satellite site for satellite site RGO submission. | 1-2 | 2 |
| Assist as required for satellite site RGO submission including preparation of documents, correspondence and Ethical Review Manager submission or alternative submission portal for SSA. | 4-8 | 4-8 |
| Facilitation of protocol specific staff training for the cluster either at site initiation visit or prior | 1-2 | 3 |
| Training, contact lists, EDC capability or access for satellite site staff. Arrange with sponsor training required of all staff working across cluster | 2-4 | 2-4 |
| Delegation and training logs preparation and distribution | 1 | 1 |
| **Total number of hours required at the primary site to set up the tele-trial model**  | **30-40**  | **61-70** |

Some primary sites have instituted a Primary Site Oversight Fee for tele-trials of $1500 per satellite site per year to cover the additional workload cost associated with the establishment and oversight of a tele-trial cluster.