**Description of Protocol Fees:**

The clinical trial budgeting process consists of determining costs for FTE, patient care, start-up activities, and maintenance costs. The process includes many steps, including determining site participation, deciding on payment terms, determining standard of care versus research tests, and identifying accurate CPT codes.

When submitting budgets to industry sponsors, it is essential that an accurate budget be presented for all applicable costs to conduct the study. To accomplish this, a budget template was created to identify potential pre-activation and maintenance costs as well as costs that could be invoiced to the sponsor.

To reduce the time required for budget preparation and to accurately estimate the costs associated with pre-activation activities as well as ongoing maintenance activities that are not necessarily directly tied to patient enrollment, a template summarizing the activities was created. The number of hours associated with pre-activation and maintenance activities is included for trials which are either written by industry or written internally but supported through industry. Specific tasks are detailed along with an estimate of hours associated with each task.

**Description of Time & Task Worksheet:**

The Time & Task tool is used to estimate study coordinator effort for protocol budget purposes.

**Procedure**

**Assumptions Tab**

1. **Assumption of Hours per Visit:** This provides an overview of general CRA tasks associated with study subject visits. Based on the number of tasks to be completed during study visits, the appropriate number of hours should be noted for each year in the Study Coordinator Visits field.

2. **General Administrative Assumptions**
   a. General Administrative Duties: Provides a list of routine (but not necessarily all) trial administration duties required regardless of enrollment or accrual.
   b. Per Patient Administrative Duties: Provides a list of routine (but not necessarily all) administrative duties typically required for each patient enrolled.

**Tab: Years 1 – 5: Study Conduction**

**Note:** Hours are entered in 1 hour increments (no fractions); always round up to the next whole hour for any portion of an hour assumed required for the activity (e.g. 1.25 hours should be rounded to 2 hours).

1. **Screening for Eligibility Per Patient** – for screening and eligibility verification activities of subjects post consent.
2. **Study Visit Related Events (Per Visit and Per Patient)** –

- **eMSR Scheduling Initial Template / Hot Buttons**
  - Hours required to create the initial treatment schedule for study subjects
- **eMSR Scheduling Appointments / Check Status / Re-Scheduling**
  - Time required to schedule, verify subject schedules and re-schedule on a regular basis (e.g. prior to each scheduled visit) or as needed
- **Clinical Notes Documentation**
  - Anticipated episodes of clinical documentation required by the CRA; may or may not equal the number of visits (it is anticipated that most data collection will come from provider notes and that CRA documentation may or may not be necessary at every visit)
  - CRA documentation is indicated for visits when oral drugs are dispensed, questionnaire completion is required, interval toxicity assessments are indicated and Coordinators are obtaining informed consent
- **Study Coordinator Visits (this does not include Data Abstraction and Entry)**
  - See the Assumptions Tab; Hours per Visit for an overview of general CRA tasks associated with study subject visits
  - Study required phone assessments are to be counted as Coordinator visits
  - This may be averaged if the study requires more hours from the study coordinator at certain time points (e.g. Phase I studies requiring significant study coordinator effort only on certain days)

3. **Billing/Accounting (if applicable)**

- **Special Invoicing Forms as applicable**
  - Time spent capturing budgeted invoice opportunities
  - Requires utilization and completion of appropriate invoice forms followed by submission to Accounting for generating invoices to study sponsors

4. **Pre-Printed Templates (if applicable)** – time spent creating original/initial trial management templates – *it is assumed these efforts will be necessary in Year 1 only*

- **Review with appropriate department** –
  - Time spent reviewing created documents with ancillary departments
- **Create Initial – Inpatient Order Care Set**
  - Time spent working with various departments to create inpatient order templates
- **Create Initial – Infusion Order Sheet / Pre-Printed Orders / Chemo Flow Sheet / CDM Audit**
  - Time spent working with various departments to create treatment order sheet(s)
- **Create Initial – Lab Kit Template**
  - Processing instructions, lab kit cover sheets, research Study Card meetings, etc.
- **Create Initial – Source Documents**
- Toxicity evaluation forms, Vital Signs and Blood Sample Collection flow sheets, Quick Reference Guides, Pill Diaries, etc.

5. **Case Report Form Completion including Data Abstraction (Per Patient, Per Visit)** – time spent abstracting data from the subjects medical record, obtaining study subject external records and entering data onto/into case report forms (CRF’s), paper and electronic

6. **Administrative (See Assumptions Tab – General Administrative Assumptions)**
   - General Administrative Duties
     - Provides a list of routine (but not necessarily all) trial administration duties required regardless of enrollment or accrual
   - Per Patient Administrative Duties
     - Provides a list of routine (but not necessarily all) administrative duties typically required for each patient enrolled

7. **Study Related Travel** – time spent away from the work unit attending study-related meetings (at Investigator meetings, Coordinator workshops, etc.). Includes time en route to meeting, time at meeting and travel time home

**Tab: Final Year: Study Close-Out Tasks** –

It is anticipated that most tasks required at close-out are accomplished throughout the life of the study (e.g. regulatory maintenance, query responses, data clean-up). Therefore, there should not be a need for large numbers of hours required for these tasks

1. **All Tasks Combined** – time spent performing tasks (such as coordinating return of unused study drug, assisting with IRB final closure reports, etc.) related to closing out a study

2. **Administrative (See Assumptions Tab – General Administrative Assumptions)**
   - General Administrative Duties
     - Provides a list of routine (but not necessarily all) trial administration duties required regardless of enrollment or accrual

**Tab: Summary: Estimated Coordinator Effort** –

Combines all hours accounted for in previous tabs to estimate the total Coordinator effort required per year and overall to manage a clinical trial

**Responsibilities – CRA**

1. **Task** – Obtain most current version of Time & Task tool for calculation of Coordinator effort
2. **Task** – Review assigned protocol with site Principle Investigator (PI) paying particular attention to the test schedule and all visits/tasks and effort in hours required to screen, enroll and manage study subjects
   
   o All required effort relates to face-to-face interactions between the coordinator and study subject
   o This may or may not include telephone interactions (e.g. management of interval labs, toxicity assessments, concurrent medication review or other study specific procedures as outlined in the study protocol )
   o Screening effort is defined as all coordinator effort occurring after subject informed consent is obtained and prior to study enrollment (NOTE: pre-screening and recruitment effort are captured as general administrative duties – see Assumptions Tab, Per Patient Administrative Duties

3. **Task** – Forward completed Time & Task tool to appropriate supervisory personnel for review and approval.

**Responsibilities – Supervisory Personnel**

1. **Task** – Review and approve (sign and date summary page and provide all applicable comments where indicated) completed Time & Task tool for appropriateness of effort
   
   o Complexity
   o Equivalent to the number of hours noted for Coordinator visits in the Year 1 tab

2. **Task** – Forward approved Time & Task tool to appropriate budget development personnel with copy to assigned CRA

**Responsibilities – Budget Development Personnel**

1. **Task** – Receive Time & Task tool and use to enter appropriate effort per year in budgeting system

**General Tips for Use of the Time & Task Tool:**

1. **FRONT LOAD** the greater percentage of anticipated enrollments in the early years of the study
   
   a. For example, if anticipating 20 subjects to be enrolled over 2 years, assume that 12-15 of those will be in year 1

2. Don’t be afraid to **OVERESTIMATE** the hours needed to complete tasks
   
   b. We frequently underestimate how long it will take to accomplish tasks, given our busy days and the demands on our time
3. **ALWAYS** round up the time needed to complete a task to the next whole hour

4. **AVERAGE** the hours necessary for Coordinator Visits

   a. Using the Assumption of Hours Per Visit on the Assumptions Tab, review the test schedule in the protocol with particular attention to the activities required in each given “visit” and tabulate the number of hours for each “visit” separately, including “visits” that will happen over the phone (e.g. interval labs, toxicity checks, etc.)

   b. Add all of these hours together

   c. Determine the number of Coordinator “visits” required

      - All required effort relates to face-to-face or verbal interactions between the coordinator and study subject
      - This may or may not include telephone interactions (e.g. management of interval labs, toxicity assessments, concurrent medication review or other study specific procedures as outlined in the study protocol)

   d. Divide the total number of hours for each “visit” by the total number of Coordinator “visits” to get the required number of Coordinator Visit Hours