**Template Table 1**

**Completed and Ongoing Early Phase Clinical Trials**

**MM/YYYY to MM/YYYY**

Include early phase clinical trials that have been completed during the last 5 years and any ongoing clinical trials for which significant research findings are available. Include first-in-human studies and trials that determined dose and schedule for both single and investigational agent combinations. Enumerate total actual cumulative accrual for each clinical trial described. Template may be duplicated for additional entries.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Protocol #: | Study Title: | | | |
| Experimental Agent or Regimen: | | | | |
| Cancer Site: | Trial Phase: | Date Trial Activation: | Date Trial Closure: | Actual Cumulative Accrual: |
| Primary Endpoint Result Indication: | | | | |
| Publication, Manuscript or Abstract Reference (include Year): | | | | |
| Incorporated into Practice Guidelines (Type Guidelines and Year): | | | | |
| FDA Approved Labeling Indication or description of other important impact: | | | | |

**Template Table 2**

**Other Scientific Achievements for Clinical Trials**

**MM/YYYY to MM/YYYY**

Include important achievements that were accomplished in the last 5 years. Template may be duplicated for additional entries.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Protocol #: | Study Title: | | | |
| Experimental Agent or Regimen: | | | | |
| Cancer Site: | Trial Phase: | Date Trial Activation: | Date Trial Closure: | Actual Cumulative Accrual: |
| Secondary Endpoint or Sub-Study Result: | | | | |
| Description of Importance from Secondary Endpoint or Sub-Study: | | | | |
| Publication, Manuscript or Abstract Reference (include Year): | | | | |

**Template Table 3**

**Summary of Biomarker and Correlative Studies Including Molecular Characterizations**

**Performed During Conduct of Early Phase Clinical Trials**

**MM/YYYY to MM/YYYY**

Describe biomarker assays, molecular characterization, and other correlative laboratory studies performed on patient tissue during the last 5 years, especially those that included surgical or image-guided biopsies. Template may be duplicated to include additional entries. Tx = treatment

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Protocol #: | | | Study Title: | | | | | |
| Description of Study: | | | | | | | | |
| Enter the Number of Specimens in the following Categories: | | | | | | | | |
| Baseline | During Tx | After Tx, Off Study, or at Progression | | Requested: | Acquired | Banked | Completed & Reported | Analyzed |
| Publication Reference, Pending Publication or Other Result: | | | | | | | | |
| Brief Description of Accomplishment or Contribution (include year): | | | | | | | | |

**Template Table 4**

**Summary Accrual for Screened and Treated Patients on Early Experimental Therapeutic Clinical Trials**

**MM/YYYY to MM/YYYY**

Describe the number of persons screened and the number of persons treated on clinical trials over the last 5 years that were/are led by the applicant or where the applicant accrued patients to an early phase clinical trial but was not the lead on the protocol. Template may be duplicated for additional entries.

|  |  |  |
| --- | --- | --- |
| Protocol #: | Study Title: | |
| Study Accrual Period (MM/YYYY to MM/YYYY): Trial Led by Applicant (Y/N): Trial Not Led by Applicant (Y/N): | | |
| Trial Phase: | Number of Persons Screened: | Number of Persons Treated: |

**Template Table 5**

**Operational Timelines for Activation of Clinical Trial Proposals**

**MM/YYYY to MM/YYYY**

Describe Operational Timelines for the LAO and any AOs (if applicable) for specific steps in the clinical trial protocol development process for IND studies. Include only trials open or submitted during the past 5 years. Template may be duplicated for additional entries.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Letter of Intent #: | Study Title: | | | |
| Single Agent or Combination Study (Y/N): | Days in Development: | | Trial Phase: | Number of Protocol Revisions: |
| Provide Dates for the Following: | | | | |
| Operational Efficiency Started: | | Study Open for Patient Accrual: | | |
| LOI Approval: | | First Patient on Study: | | |
| Protocol Approval: | | EMR Build Complete: | | |
| Comments: | | | | |