RFA-CA-15-501 Recommended Template 1: Clinical Research Activity Summary

# Fill out table for Lead Academic Organization (UM1 Grantee) and all affiliates included in UM1 supplement application. Add rows as needed.

#

RFA-CA-15-501 Recommended Template 2: Significant Completed or Ongoing Investigator-Initiated Phase 2 Clinical Trials 1/1/2010- present

List up to 10 of the most significant phase 2 clinical trials that have been completed during the time period and any ongoing clinical trials for which significant research findings are available. Include clinical trials that determined safety and efficacy for both single agents and investigational agent combinations. Enumerate total actual accrual by year for each clinical trial included. Add rows as needed.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| CancerSite | TrialPhase | Year(publication or other) | TrialNumber & Brief Title | ExperimentalAgent or Regimen | PrimaryEndpoint Result- indication | Manuscriptor Abstract Reference | Date TrialActivation | DateTrial Closure | TotalAccrual |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

# RFA-CA-15-501 Recommended Template 3: Other Significant Scientific Achievements in Cancer Clinical Trials

# 1/1/2010- present

#

Include important achievements that were reported only in the last 5 years. Add rows as needed.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Institution | Cancer Site | Trial Phase | Year (publication) | Trial Number& Brief Title | Experimental Agent or Regimen | Secondary Endpoint or Sub- Study Result | Manuscript or Abstract Reference | Description of Importance from Secondary Endpoint or Sub-study | Date Trial Activation | Date Trial Closure | Total Accrual |
|  |  |  |  |  |  |  |  |  |  |  |  |

# RFA-CA-15-501 Recommended Template 4: Summary of Biomarkers and Correlative Studies in Cancer Clinical Trials 1/1/2010- present

List Phase 2 biomarker assays and other correlative laboratory studies (other than PD/PK) performed on patient tissue during the previous 5 years by the LAO and all affiliates in phase 1 and phase 2 cancer clinical trials, especially those that included surgical or image-guided biopsies. Add rows as needed.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Trial Number& BriefTitle | Biomarker |  | # of Specimens |  | # of Specimens Requested | # of Specimens Acquired | # of Specimens Banked | # of Specimens Completed& Reported | # of Specimens Analyzed | Reference for Completed Specimens |
|  | Baseline | During Treatment | After Treatment, Off Study or at Progression |  |
|  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

#  RFA-CA-15-501 Recommended Template 5: List of Procedures and Policies

List the relevant Standard Operating Procedures (SOPs) and organization policies to be used by the Phase 2 Program for ETCTN clinical research activities. These items may include, but are not limited to: specimen acquisition and handling; tumor banking procedures and policy; Institutional Review Board (IRB) policies, Human Subjects Research Protections (HSRP) policies, safety, and pharmacovigilance procedures and policies, assay validation procedures, etc. If utilizing the ETCTN LAO's SOPs and policies, enter "Utilizing ETCTN LAO's SOPs and Policies" on the table and no further information is required. Do not submit the SOPs or policy documents. Add rows as needed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Procedure and Policies for: (specimen acquisition, CTSA, tumor banking, IRB, etc.) | Brief Title | Effective date | Issuance date | Applicable to: (institute wide, laboratory, pharmacy, etc.) | Expiration date |
| Standard Operating Procedures |
|  |  |  |  |  |  |
| Policy |
|  |  |  |  |  |  |