Table 1: Key Leadership Staffing

Provide information on key leadership staff and their role in the ET-CTN site. Add rows as needed.

Staffing Category	Member Designation	Member Name	Title	Institution	Length of Service in Position
Lead Academic Organization PI					
Integrated Component PI(s)					
Affiliated Organization PI(s)					
Lead Statistician(s)					
Pharmacy Leader(s)					
Administrative Coordination Component Leader					
Regulatory Leader					
QC/QA Leader					
Data Monitoring Leader					
Head Research Nurse(s)					
Lead Protocol Coordinator(s)					
Senior Clinical Research Associate(s)					

Template Table 2: Completed and Ongoing Phase I and Phase II Clinical Trials
MM/YYYY to MM/YYYY

Include phase 1 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. Phase II trial examples may be provided. Enumerate total actual accrual by year for each clinical trial described. Add rows as needed.

Cancer Site	Trial Phase	Year (publication or other)	Trial Number & Brief Title	Experimental Agent or Regimen	Primary Endpoint Result-indication	Manuscript or Abstract Reference	Incorporated into Practice Guidelines (Type Guidelines, Year)	FDA Approved Labeling Indication or other important impact (Describe)	Date Trial Activation	Date Trial Closure	Total Accrual

Template Table 3: Other Scientific Achievements for Clinical Trials
MM/YYYY to MM/YYYY

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

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

Template Table 4: List of PK/PD Assays and Molecular Characterizations Performed During Conduct of Early Phase Clinical Trials
MM/YYYY to MM/YYYY

Describe all PK and PD research contributions and accomplishments for PK and PD studies associated with early phase clinical trials over the past 5 years. Add rows as needed

Cancer Site	Year of Request	Trial Phase	Trial Number & Brief Title	Brief Description of Request	# and Type Samples Provided	Date Samples Provided	Reference to Publication Resulting from Approved Request or Other Result (or Pending Publication)

Template Table 5: Summary Accrual for Screened and Treated Patients on All Early Experimental Therapeutic Clinical Trials

Describe the number of patients screened and the number of patients treated on clinical trials that were/are led by the applicant or where the applicant accrued patients to a clinical trial but was not the lead on the protocol. Include accrual only over the past 5years.
Add rows as needed. S=Screened S&T = Screened and Treatment Tx = Treatment

Study Accrual Period (MM/YYYY) to MM/YYYY)	Pilot and/or Exploratory IND Studies (Phase 0) Tx Studies			Phase 1 Tx Studies			Phase 1 Combination Tx Studies (Includes phase ½ studies)			Phase 2 Tx Studies			Phase 2 Combination Tx Studies		
	S	S&T	Total	S	S & T	Total	S	S & T	Total	S	S & T	Total	S	S & T	Total
Study Title and Protocol Number #1															
Accrual **to Trial Led** by Applicant															
Accrual **to Trial NOT Led** by Applicant															
Study Title and Protocol Number #2															
Accrual **to Trial Led** by Applicant															
Accrual **to Trial NOT Led** by Applicant															
Total	Sum of Total **column**														
Grand Total (across all studies)	(Sum of all totals in "Total" **row**)														

Template Table 6: Summary of Letters of Intent (LOI) Submitted and Approved, and Protocols Submitted
MM/YYYY to MM/YYYY

List Phase 1 clinical trial protocol development activities during the last 5 years, including relevant dates and milestones for LOIs submitted, clinical trial protocols submitted, and clinical trials activated. Add rows as needed.

	LOI Number Designation	Date Submitted	Date Approved/ Disapproved	Date Protocol Submitted	Date Protocol Approved	Date Trial Activated	Date Trial Completed	Type of Novel Trial Design
Study Title #1								
Study Title #2								
	# of LOIs	# Submitted	#Approved	# Submitted	# Approved	# Activated	# Completed	
Total (across all studies)								

Template Table 7: Inclusion Enrollment Report

For the FOA submission, submit one summary table for total accrual for each completed trial over the past 5 years. For annual progress reports, submit one table for each individual protocol reported in the annual progress report for the ET-CTN sites. Do not modify the table.

Program Director/Principal Investigator (Last, First, Middle):

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title:

Total Enrollment: **Protocol Number:**

Grant Number:

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race					
Ethnic Category	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**	
Hispanic or Latino					**
Not Hispanic or Latino					
Unknown (individuals not reporting ethnicity)					
Ethnic Category: Total of All Subjects*					*
Racial Categories					
American Indian/Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of All Subjects*					*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)					
Racial Categories	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**	
American Indian or Alaska Native					
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More Than One Race					
Unknown or Not Reported					
Racial Categories: Total of Hispanics or Latinos**					**

* These totals must agree.
** These totals must agree.

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Template Table 8: 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. Include only trials open or submitted during the past 5 years. Add rows as needed.

IND Studies – Pilot and/or Exploratory IND Studies (Phase 0)

Cancer Site	LOI	Trial Number and Brief Title	Operational Efficiency Start Date	Date of LOI Approval	Date First Protocol Submission	Number Protocol Revisions	Date Protocol Approval	Date Study Open for Patient Accrual	Number of Days in Development	Comments

IND Studies – Phase 1

Cancer Site	LOI	Trial Number and Brief Title	Operational Efficiency Start Date	Date of LOI Approval	Date First Protocol Submission	Number Protocol Revisions	Date Protocol Approval	Date Study Open for Patient Accrual	Number of Days in Development	Comments

IND Studies – Phase 1 Combination

Cancer Site	LOI	Trial Number and Brief Title	Operational Efficiency Start Date	Date of LOI Approval	Date First Protocol Submission	Number Protocol Revisions	Date Protocol Approval	Date Study Open for Patient Accrual	Number of Days in Development	Comments

IND Studies – Phase 2

Cancer Site	LOI	Trial Number and Brief Title	Operational Efficiency Start Date	Date of LOI Approval	Date First Protocol Submission	Number Protocol Revisions	Date Protocol Approval	Date Study Open for Patient Accrual	Number of Days in Development	Comments

IND Studies – Phase 2 Combination

Cancer Site	LOI	Trial Number and Brief Title	Operational Efficiency Start Date	Date of LOI Approval	Date First Protocol Submission	Number Protocol Revisions	Date Protocol Approval	Date Study Open for Patient Accrual	Number of Days in Development	Comments

Template Table 9: Patient Accrual By Individual Clinical Trials
MM/YYYY to MM/YYYY

Describe actual timelines for specific steps in the clinical trial protocol development process, including accrual rate projected and achieved, total accrual, and study duration. Include only trials open during the past 5 years that are still accruing patients or that are temporarily closed to accrual and/or treatment. Tx = treatment Add rows as needed.

Cancer Site	Trial Phase	LOI	Trial Number & Brief Title	Date Study Open for Patient Accrual	Trial Status (Open or Temporarily Closed to Accrual and/or Tx)	Sample Size	Accrual to Date	Projected Monthly Accrual Rate	Estimated Study Closure Date (i.e. Closed to Accrual)	Anticipated Primary Completion Date	Average Actual Monthly Accrual	Average Actual Annual Accrual

Template Table 10: Summary of Biomarker and Correlative Studies
MM/YYYY to MM/YYYY

Describe biomarker assays and other correlative laboratory studies performed on patient tissue during the last 5 years, especially those that included surgical or image-guided biopsies. Add rows as needed.

Trial Number & Brief Title	Description of Study	# 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						

Template Table 11: List of Procedures and Policies

List the relevant Standard Operating Procedures and LAO policies including, but not limited to, specimen acquisition and handling; tumor banking procedures and policy; Institutional Review Board policies, Human Subject Research Protections policies, safety and pharmacovigilance procedures, assay validation, etc. 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					