NCI Experimental Therapeutics Clinical Trials Network (ETCTN) Clinical UM1 and U24 PK Resource

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Interventional Radiology ETCTN Network  
Cancer Imaging Program  
Division of Cancer Treatment and Diagnosis

**Kim Witherspoon, MBA, MS**  
Grants and Administrative Officer  
Investigational Drug Branch  
Cancer Therapy Evaluation Program
Experimental Therapeutics Clinical Trials Network: Lead Academic (12) and Affiliated Organizations (41); Experimental Drug Development Opportunities Program (15)
Goals and Objectives of Experimental Therapeutics Clinical Trials Network

Research, development and improvement of cancer treatments

• Advance the clinical development of NCI-IND agents with early phase studies
  ❖ Complementary collaboration with pharma partners
• Determine dose, schedule and sequence for NCI-IND agents and combination regimens
• Perform disease-specific activity studies of NCI-IND-agents and combinations
  ❖ Prioritize cancers and cancer subsets where industry is not investing

Biomarker and cancer biology-driven studies using patient derived specimens

• Acquire high quality patient tumor specimens for correlative studies
• Incorporate fit-for-purpose PD/biomarker assays into ETCTN trials

Career enhancement for early career investigators

• Experience leading clinical trials in the ETCTN
• Play a significant role on the drug development Project Teams
Proposed updates/changes to ETCTN Network

- Affiliated organizations
- New ETCTN initiatives
- ETCTN biorepository (U10)
- Early drug development opportunities programs in NCI CCs (EDDOP) for accrual and leadership

≈ 41 enrolling North American sites
ETCTN – Transformation to a Network Structure

• Collaborative approach to clinical trial development and implementation
  – Moved from mass solicitations to extramural project teams early in clinical development planning
  – Involve disease-specific clinical expertise from all sites
  – Enhance study participation across the network

• Assuring Reproducible Translational Science
  – Transformed the approach to biomarkers from laboratory developed tests (LDTs) to analytically validated, fit for purpose bioassays

• Site Re-Organization and Infrastructure Support
  – Moved from siloed sites to a unified trials network with centralized infrastructure support
  – Further enhanced GCP principles in all aspects of ETCTN trials
  – Addition of protocol authoring service, recently
  – Interventional Radiology Working Group
Accrual Network: Year 1 to Year 4
External review of Agents and Trials in the ETCTN

- **All agents come from the NExT (NCI Experimental Therapeutics) Pipeline**
  Review of applications by external experts
  (https://next.cancer.gov/)

- **All trials proposed by drug development project teams are reviewed by Investigational Drug Steering Committee**
  - IDSC is composed of ETCTN PIs, external experts and NCTN members
Parallel processes not shown include: Biomarker and assay development and review
Regulatory agreement development and sign-off (e.g. CRADA)
Additional levels of internal review
ETCTN drug development project teams

Drug development project teams (14):
- AT13387 (onalespib) (HSP90i)
- Osimertinib (AZD9291, T790M EGFRi)
- M3814 (DNA-PKcs i)
- VX970 (ATRi)
- Durvalumab (PD-L1i)
- Atezolizumab (PD-L1i)
- T-VEC (Talimogene laherparepvec, oncolytic virus)
- AMG-232 (mdm2i)
- Anetumab ravtansine (BAY 94-9343, anti-mesothelin)
- Copanlisib (BAY 80-6946, PI3Ki)
- CB839 (glutaminase i)
- Ixazomib (proteasome i)
- Pevonedistat (NEDD8i)
- M3814 (DNA-PK-i)
- 3 others starting

- Extensive extramural involvement
- Reflects heavy emphasis on early career development
- Drug development and CRADA negotiations occur in parallel
- Unsolicited LOIs accepted after Project Team deliberations

Clinical
NCI/External Drug Development Project Team
Cancer Biology

Translational
High priority targets and DCTD/CTEP agents
Increasing Number of ETCTN Studies

- Activated Cumulative Studies
- Closed Studies Cumulative
Quarterly ETCTN Accrual (Limited, Wide, Legacy and Total) Q2 2014 – Q1 2018
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<tr>
<th>Activity</th>
<th>Number of LOIs (% of total)</th>
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<tr>
<td>LOIs from Project Teams with early career PI’s</td>
<td>45 (90)</td>
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<tr>
<td>Unsolicited/pre-solicitation LOIs with early career PI</td>
<td>60 (31)</td>
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<tr>
<td>Activated or transitioned ETCTN protocol with early career PI</td>
<td>44 (60)</td>
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Duration of Award

- The duration of the ETCTN UM1 and U24 PK awards has been extended to **6 years**.

- **Q & A** regarding the FOAs will be posted on the CTEP website in the section related to the Experimental Therapeutics Clinical Trials Network.

- Due on **May 22, 2019, by 5:00 PM local time** of applicant organization
ETCTN transformation during the 2020-2025 award period: 
Leveraging NCI resources 
to enhance drug development & productivity

1. Address the need to find rare or uncommon, molecularly defined subsets of patients – a challenge for phase 2 studies

2. Enhance requirements for high quality biopsy material for correlative studies

3. Improve ability to perform validated biomarker assays to characterize and monitor molecularly defined subsets of common or uncommon tumors (validation of integral/integrated biomarkers)
1. Recruit rare or uncommon, molecularly defined subsets of patients

- **Lead and Affiliate Organizations will apply as teams**
  - Encourage multiple PI applications
  - LAOs to have a minimum of **one Phase 1 investigator**
  - LAOs and AOs to have a minimum number of identified disease focused clinical investigators (DFCI) responsible for accrual
    - 4 distinct disease-specific investigators for each LAO
    - 2 distinct disease-specific investigators for each AO
  - Award will provide **partial salary support** for each team member- NCI can provide academic credit through grant salary support
  - Funded co-investigators will have **performance criteria outlined in Terms of Award** for performance in opening studies and accrual
1. Recruit rare or uncommon, molecularly defined subsets of patients (cont.)

Levels of Effort

- Each individual designated as a PD/PI (LAO and AO(s) PD/PI must commit a minimum of 1.2 person-months/calendar months of effort per year. This minimal effort level must be maintained throughout the entire project period.

- The designated DFCIs, Translational Scientist(s), Interventional Radiologist(s) and Research Pathologist(s) are expected to commit a minimum of 0.6 person-months/calendar months of effort each per year.
1. Recruit rare or uncommon, molecularly defined subsets of patients (cont.)

- **Disease Focused Clinical Investigators (DFCIs)**

  - Disease-Focused Clinical Investigators (DFCIs) should be either the site Clinical Trial PI or Co-Investigator.

  - LAO PD/PIs and AO site PD/PIs may serve also as Disease-Focused Clinical Investigators.

  - Disease-Focused Clinical Investigators may be early career clinical investigators with senior mentorship support.
1. Recruit rare or uncommon, molecularly defined subsets of patients (cont.)

- **Site Staff**

  - Each LAO is required to have at least one Translational Scientist, one Interventional Radiologist, one Research Pathologist, and four Disease-Focused Clinical Investigators.

  - Each AO is required to have one Interventional Radiologist and two Disease-Focused Clinical Investigators.

  - The LAO and/or its AO(s) should identify at least one statistician with the skill and expertise in the design and monitoring of early phase clinical trials including adaptive and other designs for phase 1 and 2 trials to support the clinical activities of the site or consortium.
Level of Effort for Required Personnel

0.6 Calendar months equal 5% effort
NIH salary cap = $189,600
Assume 3 AOs per UM1 application

Each LAO is required to have one Translational Scientist (TS), one Interventional Radiologist (IR), one Research Pathologist (RP), and four Disease-Focused Clinical Investigators (DFCI) with a minimum of 0.6 person-months/calendar months of effort each per year.

4 DFCI + TS + IR + RP = 7 staff X 0.6CM (5% effort) = 35% effort
$189,600 X 35% = $66,360 + fringe benefits

Each AO is required to have one Interventional Radiologist (IR) and two Disease-Focused Clinical Investigators (DFCI) with a minimum of 0.6 person-months/calendar months of effort each per year.

IR + 2 DFCI = 3 staff per AO X 0.6 CM (5% effort) = 15% effort
$189,600 X 15% = $28,440 per AO X 3 AOs = $85,320 + fringe benefits

Total for LAO with 3 AOs = $66,360 + $85,320 = $151,680 + fringe benefits
2. Improve the quality of biopsy specimens

- Organize ETCTN-wide initiatives with ETCTN-funded investigators to improve biopsy quality
  - Partial salary support for these team members will be provided
  - Funded investigators will have performance criteria in the Terms of Award

- Lead academic organization (LAO) teams to include:
  - An Interventional Radiologist and Research Pathologist for acquisition of high quality specimens

- Each Affiliate (AO) team to include
  - An Interventional Radiologist for acquisition of high quality specimens; Research Pathologist optional
3. Enhance the use of biomarker assays to achieve precision medicine goals

- Increase use of biomarker assay resources developed through NCI resources coordinated through the National Clinical Laboratory Network (NCLN)
  - Pharmacodynamic Assay Development and Implementation Section (PADIS) lab and network
  - Cancer Immune Monitoring and Analysis Centers (CIMACs) for Immuno-Oncology (IO) studies
  - Molecular Characterization (MoCha) lab for genomic and transcriptomic evaluation
  - ETCTN biorepository and accessioning center

- Scale back UM1 Biomarker Assay Development administrative supplements

- Consolidate ETCTN PK activities
  - Two U24-funded PK consortia
  - Remove funding for PK assays from core ETCTN UM1 awards
Additional goals for the ETCTN 2020-2025

- **Use of Moonshot℠ networks/centers** for preclinical work in support of clinical trials (e.g., Patient Derived Xenografts Network (PDXNet), Drug Resistance and Sensitivity Network (DRSN))

- **Broaden classes of agents** under NCI development (e.g., radiopharmaceuticals, cellular therapies, antibody drug conjugates (ADCs))

- Include **ePRO’s** in early phase ETCTN studies for safety and tolerability determinations

- Further development of **risk-based monitoring approaches**

- **Adoption of the ASCO/Friends broadened eligibility criteria:** age, viral, prior malignancy, organ function, brain metastasis
ASCO/Friends Broadening Eligibility

Does your LOI apply to YIA patients?

Include:


• Clearly list the one responsible ETCTN Group on the LOI.
   → List “champions” or vice-chairs from other groups, such as COG

• Consider both groups (for example ETCTN and COG) to project accrual

• Approval from the corresponding PI at the time of LOI or concept submission

• The protocol title should reflect the target population

• Explanation of selection of eligibility age range
ASC0/Friends Broadening Eligibility

Does your LOI apply to YIA patients?

Consider at this stage:

• Assent: will be reviewed by the NCI Early Phase CIRB

• Coordination between COG sites and ETCTN sites

• Not an excuse to prolong OEWG timelines

• Address any known safety/toxicity data obtained in patients < 18-yo (or if there are none available)

• Include dosing guidelines for patients < 18-yo

• Address age-appropriate dose modifications, supportive care and toxicity monitoring
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<tr>
<th>Activity</th>
<th>Description</th>
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<tr>
<td>Corrective Action Plans (CAPs)</td>
<td>Study chairs of slow accruing trials provide reasons for slow accrual and propose strategies to improve within 6 months; -Including 6 month OEWG re-review; -3-month follow-up to track progress of CAP</td>
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<tr>
<td>Champion Surveys</td>
<td>UM1 award PIs are asked to identify disease-specific site champions for recently activated trials</td>
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<tr>
<td>Slow Accrual Surveys</td>
<td>Send online queries to ETCTN PIs asking to report potential reasons why a trial is slow accruing</td>
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<td>Disease-specific Newsletters</td>
<td>Monthly newsletters sent to ETCTN PIs based on their disease specialty, to provide update and easy access to each disease portfolio of trials</td>
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<tr>
<td>Monthly Review of Portfolio Accrual</td>
<td>Categories of trials' progress based on accrual increase, number of activated sites, and time open; trials flagged as ‘red’ are addressed at CTEP IDB meeting every 6 weeks to develop strategy to improve accrual</td>
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<td>Trial-specific Materials</td>
<td>Develop CIRB-approved patient materials for trials, and physician fact sheets</td>
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<td>Trial promotion</td>
<td>On Twitter and other platforms</td>
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Monthly disease-specific email newsletters

- Breast Cancer clinical trial portfolio in the ETCTN

- Active Breast Cancer trials & recent amendments
- Top accruing sites to Breast Cancer trials
- Breast Cancer protocols activating soon
- Breast Cancer protocols in development
- Notes/Updates from NCI CTEP

Click here to see all ETCTN trials by disease type

Active Breast Cancer Trials & Recent Amendments

- Document Title: (9076) Phase 1b Study of HSP90 Inhibitor, AT13387 in Combination with Paclitaxel in Patients with Advanced, Triple Negative Breast Cancer

- Accrual Goal: 24
- Planned Accrual Rate: 2/mo
- Current Accrual: 15
- Principal Investigator: Viscidi, Robert
- Principal Investigator Email: Robert.Viscidi@Vcu.Vcu.edu
- Lead Organization Name: Virginia Commonwealth University

Top Accruing Sites to Breast Cancer Trials

- Ohio State University Comprehensive Cancer Center
- University of Pittsburgh Cancer Institute (UPCI)
- Washington University School of Medicine
- Dana-Farber/Harvard Cancer Center
- Mayo Clinic in Arizona

A big thank you to our top accruing sites across active Breast Cancer trials!

Breast Cancer Protocols Activating Soon

None scheduled

Breast Cancer Protocols in Development

- Document Title: (10146) Randomized Phase 2 Clinical Trial of Nab-Paclitaxel + Durvalumab + Neoadjuvant Vaccine Versus Nab-Paclitaxel + Durvalumab in Patients with Metastatic Triple Negative Breast Cancer

- Expected Activation Date: 5/18/2018
- Principal Investigator: Gillanders, William E.
- Principal Investigator Email: Gillanders.Bill@nih.gov
- Lead Organization Name: Duke University - Duke Cancer Institute
- LAO (LAO-MD010)

- Document Title: (10195) A Phase 2 Study of Copanlisib (BAY 80-6946) in Combination with Fulvestrant in Women with Metastatic Breast Cancer Progressing After Aromatase Inhibitor Plus CDK 4/6 Inhibitor

- Expected Activation Date: 10/12/2018
- Principal Investigator: Desai, Elizabeth Claire
- Principal Investigator Email: Elizabeth.Desai@ncln.clinic
- Lead Organization Name: Duke University - Duke Cancer Institute
- LAO (LAO-MD010)

Notes/Updates from NCI CTEP

- Announcement: Supplements to U1U1 grants for NCI’s Early Therapeutics Clinical Trials Network (ETCTN) to support biomarker assay development for incorporation into ETCTN studies.
- Resource: ETCTN Publication Policy Link

- Interested in receiving newsletters for other types of cancer clinical trials? Click here.

Questions or feedback? Email us at ET-CTN@mail.nih.gov

NATIONAL CANCER INSTITUTE
Human Subjects System (HSS)
Instructional Videos

Overview: https://www.youtube.com/watch?v=8s7xRT9mW10

Human Subjects and Clinical Trials Forms Walkthrough:
https://www.youtube.com/watch?v=nz9NWFhYOG8

Accessing the Human Subjects System:
https://www.youtube.com/watch?v=laBXeNqglto

You can also search YouTube using the phrase: “NIH Human Subjects System”
The Experimental Therapeutics Clinical Trials Network (ETCTN) Pharmacokinetic Resource Laboratories U24
Consolidation of Pharmacokinetics Research and Development in the ETCTN (PK)

What’s new?

- Up to two U24-funded PK consortia in FY2020
  $750,000 total funds; direct costs limited to $320,000/year

- Core ETCTN UM1 awards no longer include funding for PK
This FOA seeks U24 cooperative agreement applications from multidisciplinary groups that will conduct all pharmacokinetic studies for ETCTN early phase clinical trials filed to the IND applications in DCTD/CTEP (NCI).
Pharmacokinetics

- Absorption
- Distribution
- Metabolism
- Excretion

Parameters include but are not limited to:

- area under the curve (AUC)
- maximum agent concentration (Cmax)
- clearance (CL),
- half-life,
- volume of distribution

PK assay development

- All drugs and biologics show inter- and intra-individual variability in PK measures and parameters. (See FDA clinical pharmacology guidance: https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/ucm064982.htm)
Goals

• To advance the clinical development of NCI-IND agents through achieving comprehensive understanding of pharmacokinetic behavior of these agents studied in ETCTN protocols.

• To create Pharmacokinetics Resource Laboratories (PK Laboratories) that will support the Experimental Therapeutics Clinical Trials Network (ETCTN)

• To organize specimen collection and subsequent analysis of pharmacokinetic endpoints, drug-drug interactions, cytochromes P450 (CYP) interactions, and food effects

• To assure the availability of physicians, clinical pharmacologists, nurses and scientists who have the appropriate expertise in pharmacokinetic studies for early drug development and translational research

   The intent is for the PK experts to be an integral part of a collaborative drug development group
Area(s) of expertise

• Technical and clinical evaluation of assays for study drug(s) PK that are quality assured/quality controlled and standardized for use in plasma and/or tumor tissue

• Evaluation of drug-drug interaction risk for each drug and its active metabolites in relationship to other therapeutics and concomitant medications

• Definition of PK sampling strategies, limited sampling strategies and population PK

• Evaluation of PK in plasma and tissue

• Timely reporting to the study team and to NCI of the results of PK analyses.
Expectations

- **Infrastructure** to support PK studies for ETCTN clinical trials from trial initiation through clinical development of NCI-IND agents

- **Engagement** of multidisciplinary clinical and pharmacology experts

- Ability to perform biostatistical/computational **data analysis**, interpretation, and compartment modeling for PK studies

- Extensive experience in PK studies **for early phase clinical trials**

- Specific capabilities:
  - Performing PK analysis in high quality specimens in the context of clinical trials
  - Established Standard Operating Procedures (**SOPs for data quality and laboratory quality**) control, including institute quality control for reagents and technologies for ETCTN PK studies
  - Conducting PK studies according to Good Laboratory Practice (**GLP principles**)
  - Providing **preliminary data** to inform the design and conduct of PK studies for investigational drugs;
  - Evaluating PK data from early phase experimental therapeutic clinical trials using single or combinations of novel NCI CTEP IND agents;
  - Serving as **PK resource centers within the ETCTN** for collaborative validation studies, statistical and computational analyses, data management, and coordination of ETCTN pharmacokinetic studies; and
  - Providing technical and scientific expertise to **CTEP Project Teams** related to PK activities in the drug development plan
  - Ability to **accept and transfer specimens** from clinical trials both nationally and internationally
PD(s)/PI(s) Responsibilities

• Overseeing **all the activities** of the ETCTN PK laboratory

• Determining overall **research strategy** for ETCTN pharmacokinetic studies for early phase clinical trials

• Ensuring **timely** completion of PK analyses and reporting their results

• Ensuring **timely** preparation, presentation, and publication of PK results and research findings

• Ensuring **compliance** with the applicable rules for the conduct of clinical research
Due on **May 22, 2019, by 5:00 PM local time** of applicant organization
The Experimental Therapeutics Clinical Trials Network (ETCTN)

Interventional Radiology Working Group (IRWG)
**ETCTN Interventional Radiology Working Group (IRWG)**

- **Purpose:** Maximize the efficient acquisition of IR-guided biopsy samples that are sufficient for molecular analysis.

- **Members to Date:**
  - Meet via telecon as needed

- **All ETCTN sites welcome**

- **For more information**
  - [ETCTN@mail.nih.gov](mailto:ETCTN@mail.nih.gov)

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Backup Slides
Reasons for LOI disapproval

- Insufficient Preclinical Data: 27
- Insufficient Rationale and Background: 26
- Biomarker/correlative design or assay issues: 23
- Dose/schedule/regimen issue: 18
- Insufficient Clinical Data: 17
- Study Eligibility/Patient Population Issues: 17
- Combination Study Agent Problems: 16
- Endpoint design issue/Objectives: 14
- Company/Pharm/Manufacturer Issues: 13
- Hypothesis Issues: 13
- Duplicative/Competing study: 12
- Other Study Design Questions: 12
- Statistical design issue: 12
- Toxicity/Safety issues: 11
- Disease Questions: 10
- Concerns with Accrual Rate: 9
- Mechanism of Action or Resistance questions: 6
- Standard of Care (SOC) available: 4
- Funding: 4
- Imaging Issues: 3
- modality: 3
- Lack of Disease Expertise by Site/Consortium: 1
Protocol authoring decision: Triangulation of evidence

Grant PI interviews

- Many PIs are early career investigators
  - Inexperienced in writing protocols
  - Extremely busy schedules

PROTOCOL AUTHORIZATION

Objective: Assist PIs with writing protocols <60 days
- Increase quality, consistency
- Reduce errors

OEWG timeline analysis

- Long activation delays due to multiple revisions post-PRC (median=4 rounds)

CIRB data review

- 50% of protocols required multiple CIRB reviews
- Median of 26 stipulations/protocol
  - Poorly written
  - Inconsistent w/ templates
ETCTN External Program Review

- Reviewers were recruited from government and pharma, both nationally and internationally in January 2018
  - Greg Reaman, FDA, USA  
  - Janet Dancey, NCIC & ORI, Canada  
  - Eric Rubin, Merck & Co., USA  
  - Ian Walker, CRUK, UK

- Review questions included:
  - Have **phase 1 /2 trials opened** at an adequate rate?
  - Are trials answering **important questions and optimally designed**?
  - Were steps taken to adapt to cancer **precision medicine** challenges?
  - Does the program conform to **GCP standards**?
  - Is **team science** promoted? Is this a collaborative, interactive research network?
  - Are adequate clinical research opportunities provided for **early career investigators**?

- Reviewers **responded positively to all questions**, thought the program **achieved its goals and objectives**, and provided additional **input for future endeavors**.
I'm worried about you, sweetie. You're too old to have imaginary friends.

It's called "Facebook," Dad.