Optimizing Public-Private Partnerships for Clinical Cancer Research: A Workshop

Session 3: Regulatory and Policy Considerations for PPP for Clinical Cancer Research

S. Gail Eckhardt MD FASCO
Associate Dean, Experimental Therapeutics
Baylor College of Medicine
Associate Director, Translational Research
Dan L Duncan comprehensive Cancer Center

Disclosure: I am an academic medical oncologist and committed mentor of junior faculty

NCI's Experimental Therapeutics Clinical Trial Network (ETCTN): Opportunities for clinical investigators in academia

Historical perspective: Prior to the explosion in oncology drug development, academic clinical investigators often worked collaboratively with industry to develop protocols and development pathways which provided critical exposure to many steps of the process.

Currently, since so many drugs are on a critical path to approval even in Phase I, it has been difficult for early career investigators to participate in the development process with industry.

The ETCTN mechanism:

- Is a PPP that enables academic clinical investigators to participate in the bench-to-bedside process of early drug development
- Provides centralized services that may not be readily available to faculty pursuing investigator-initiated clinical trials
- Focuses on the development of multidisciplinary drug development teams that pursue hypothesis-driven early phase trials
- Emphasizes mentorship of junior faculty in developing concepts

NCI's Experimental Therapeutics Clinical Trial Network (ETCTN):
Opportunities for early career investigators in academia

ETCTN
Experimental Therapeutics Clinical Trials Network
Team Driven. Cancer Therapy Focused.
National Cancer Institute at the National Institutes of Health

Overview/Objectives

The National Cancer Institute (NCI) has formed **partnerships** in the pharmaceutical industry, academic institutions, and individual investigators for the early clinical evaluation of innovative cancer therapies. The Experimental Therapeutics Clinical Trials Network (ETCTN) was created to evaluate these therapies using a **coordinated, collaborative, and inclusive team-based** approach to early phase experimental therapeutic clinical trials.

<u>The objectives of the ETCTN are to:</u>

- Conduct early clinical trials of NCI-IND agents in high priority areas of unmet medical needs
- Ensure efficient and timely activation and conduct of these clinical trials
- Integrate preclinical findings using clinical samples for biomarker analysis
- Promote collaboration among institutions and investigators
- Integrate molecular characterization, pharmacology, cancer biology, and imaging into clinical trials

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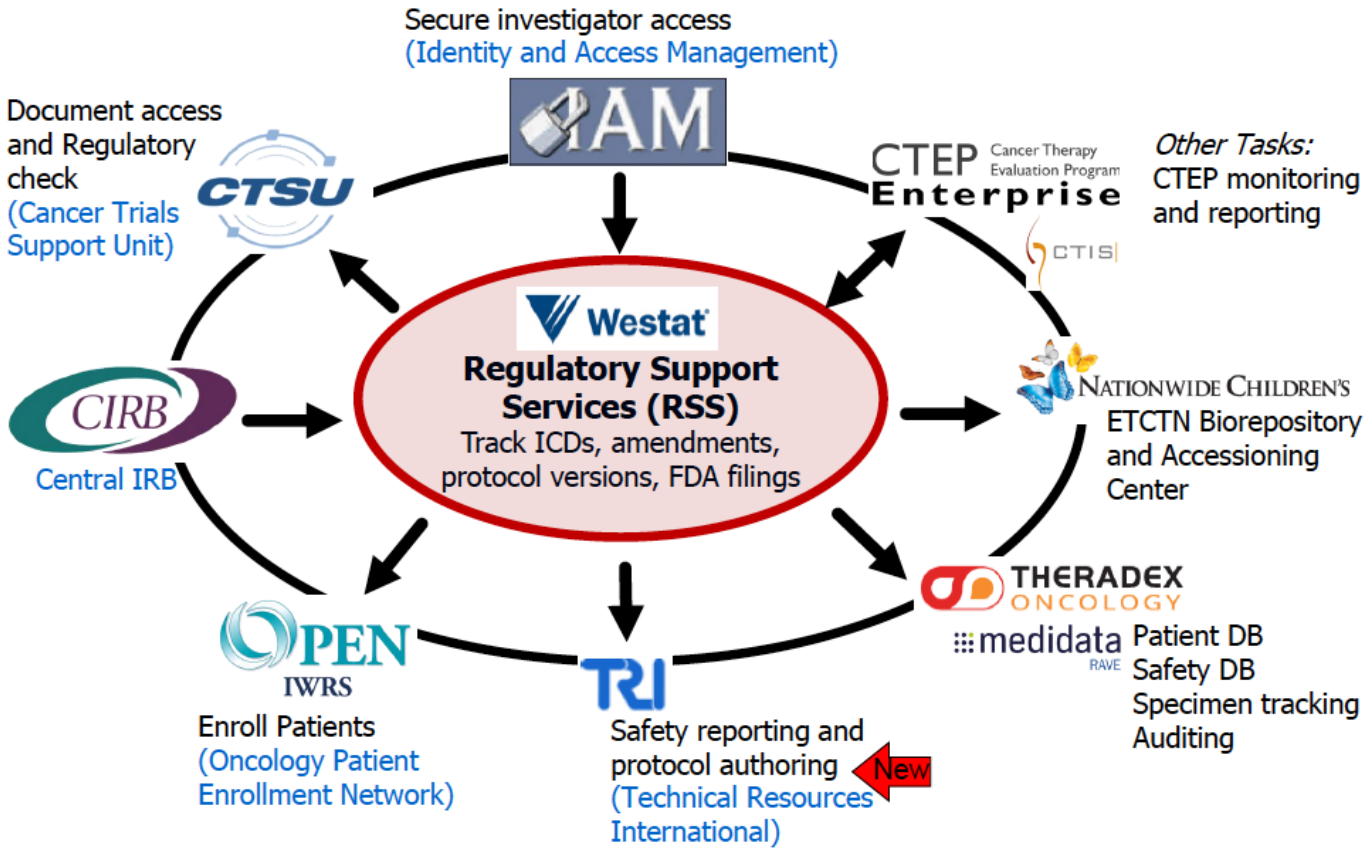
NCI's Experimental Therapeutics Clinical Trial Network (ETCTN):
Centralized services available to clinical investigators

NCI Designated Comprehensive Cancer Center

ETCTN central infrastructure support



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Career Enhancement and Development for Early Career Investigators (03.2014-01.2018)	
Activity	**Number of LOIs (% of total)**
LOIs from Project Teams with early career PI's	45 (90)
Unsolicited/pre-solicitation LOIs with early career PI	60 (31)
Activated or transitioned ETCTN protocol with early career PI	44 (60)

NCI's Experimental Therapeutics Clinical Trial Network (ETCTN): Opportunities to improve this historically successful PPP

Next Gen V 2.0 ETCTN PPP: to enhance opportunities for clinical investigators:

- Not all academic institutions have access to the ETCTN; what about community sites?
- Strengthen collaborations with industry to ensure more reliable access to drugs
- More efficient development and deployment of drug development teams (which may decrease drug attrition)
- Increase private/other public funding base; efficiency of teams is hampered by lack of staff! (foundations, state agencies)
- Joint clinical research training opportunities; scale up/diversify
- More collaboration among academic sites; disease expertise, preclinical capabilities
- Provide access to mentorship outside home institution, leadership training
- Rotations to FDA, industry, foundations; grants to provide funding