NCI Clinical Trials Innovation Unit (CTIU)

NIH NATIONAL CANCER INSTITUTE

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CTAC Meeting, July 19th, 2023

Current State of Cancer Clinical Trials

- Complex and expensive
- Burdensome designs
- Data collection often in excess of what is used
- Slow and cumbersome activation process
- Delayed results to patients and providers
- Inequitable access to studies
- *Resulting in a model that is unsustainable*

NCI Strategic Vision for Clinical Trials: 2030 and Beyond

Develop **flexible**, **faster**, **simpler**, **less expensive**, **high-impact** clinical trials that seamlessly integrate with clinical practice

- Streamline processes for trial design and execution
- Focus on essential endpoints
- Decrease regulatory hurdles and broaden trial access
- Increase efficiency of data collection

CTAC Strategic Planning Working Group 2020 report:
https://deainfo.nci.nih.gov/advisory/ctac/1120/SPWGreport.pdf

Clinical Trials Innovation Unit (CTIU): A new initiative aligned with the NCI Strategic Vision

Aims to **radically transform** how clinical trials are conducted:

- Rapidly identify and test the most innovative approaches
- Preserve current infrastructure and trials already underway

CTIU: Overarching Goals

Rapidly design and activate trials that focus on innovative science, designs, data analysis, and collaborations

Promote equitable clinical trials participation

Complement the National Cancer Plan and Cancer Moonshot's goals to work with partners in government, industry, advocacy, and other organizations to modernize trials to bring results to patients faster

CTIU: An Interagency Platform

Provides a forum for NCI, FDA, and the extramural cancer clinical research community to advance clinical care and equitable clinical trials participation through innovative:

- Science,
- Trial designs, and
- Operational efficiencies

…for a few high priority clinical research studies

CTIU: Needed Expertise at the Same Table

Co-Directors/Facilitators: Michael Morris, Sheila Prindiville

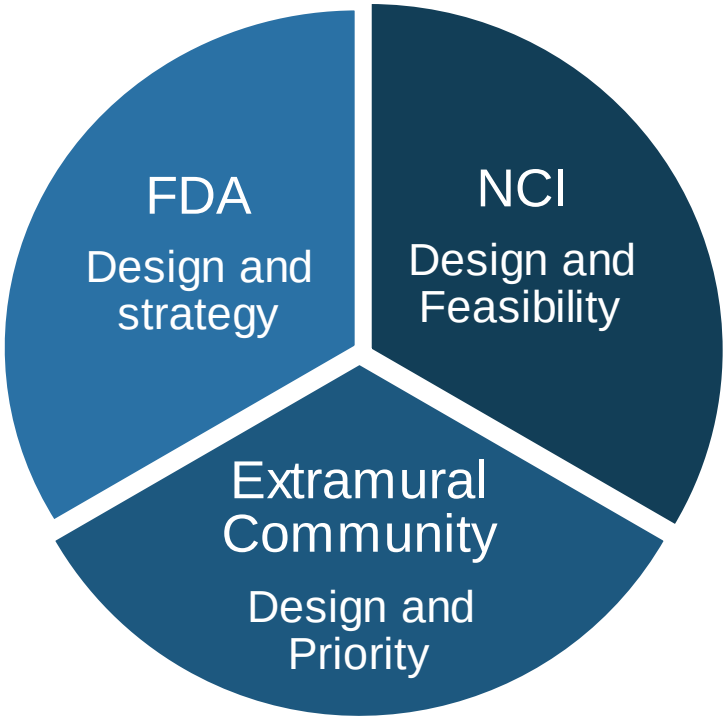
Coordinator: Iris Castro

CTIU: Collaboration from the first inception of ideas

Reservoirs of Ideas

- NCTN
- NCORP
- Industry
- Foundations

Multidisciplinary Expertise



What Studies are Appropriate for CTIU? What is Innovative?

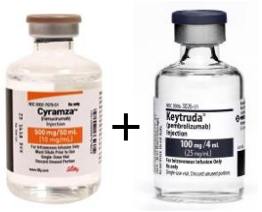
- Studies that “break the mold”
  - **Interventions** that non-incrementally alter standards of care
  - **Biomarkers** that will dramatically shorten trial endpoints (e.g., imaging, path, serum)
  - **Data extraction** and management that streamline trial conduct
  - **Collaborations** that conjoin expertise and resources
  - Built in: Novel evaluation, approval, and activation

CTIU: Collaboration from the first inception of ideas
Streamlined Clinical Trials: Real or Aspirational?
Pragmatica-Lung Study (S2302)

Designed to:

- **Eliminate potential barriers** to enrollment
- **Increase diversity and enrollment** in clinical trials
- **Streamline processes** for trial design and execution
- **Use focused endpoints and efficient data collection**

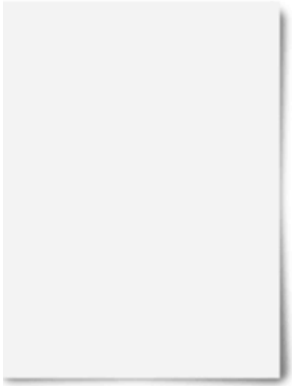
- **No protocol required disease assessments (CT, imaging)**
- **No protocol required lab tests**
- **No specimen collection**
- **Only report all Grade 5 and Unexpected Reportable Gr 3-4 AE**



Purpose: Evaluate whether ramucirumab + pembrolizumab combination therapy improves overall survival over standard treatment in people with advanced NSCLC.

CTIU's Submission Process: Focused proposals with rapid turnaround

1-2 page submission by investigator
(up to 4 per group)



Rapid vetting by CTIU of ideas

Selection of proposal to advance

Collaborative protocol development with execution in NCI networks

CTIU's first round of submissions:

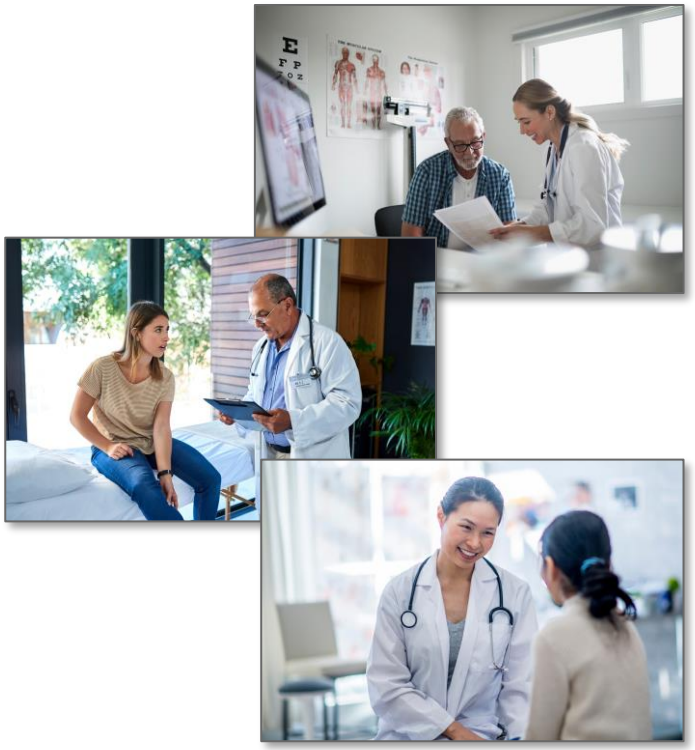
- **Interventions** that non-incrementally alter standards of care using simplified designs and pragmatic approaches
- **Biomarkers** that will dramatically shorten trial endpoints

  (imaging, path, serum)
- **Data extraction** and management that streamline trial conduct
- **Collaborations** that conjoin expertise and resources
- **Process**: Novel evaluation, approval, and activation
  - Rapid evaluation period
  - 2 weeks from submission to multiagency discussion of the proposals
  - Now preparing for final selection

CTIU progress to date

Event	Time
Inception	February 2023
Communication to NCTN investigators	May 2023
Submission of proposals	June 12, 2023
Evaluation of proposals	June 26, 2023
Notification of investigators	June 29, 2023
Selection of proposal(s)	July 2023

Clinical Trials Innovation Unit (CTIU) Summary



The CTIU will:

- **Select a few high-priority studies** for innovative study designs and operational procedures
- **Simplify and speed clinical testing to deliver new approaches** for diagnosis, treatment, and prevention of cancer
- **Solve problems** that face clinical trials with *innovative, inclusive, collaborative, and efficient solutions*

A collaboration between NCI, the FDA Oncology Center of Excellence, and the Extramural Community

With Appreciation …..

- Dr. Monica Bertagnolli
- NCI Colleagues
- FDA Oncology Center of Excellence
- Extramural partners

Questions? NCIClinicalTrialsInnovationUnit@nih.gov