NCI Clinical Trials Innovation Unit (CTIU)

NIH NATIONAL CANCER INSTITUTE

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Today's Talk

- NCI's Strategic Vision for Clinical Trials
- Clinical Trials Innovation Unit

Current State of Cancer Clinical Trials

- Complex and expensive studies
- Slow and cumbersome activation process
- Delayed results
- Burdensome designs
- Inequitable access to studies
- Data collection often in excess of what is used

Resulting in a model that is unsustainable

NCI Clinical Trials and Translational Research Advisory Committee Strategic Planning Working Group Overview

Assess NCI's strategic vision for clinical trials for 2030 and beyond

Review and address necessary clinical trials infrastructure

Developed 15 recommendations and 3 operational initiatives

Themes:

- Trial Complexity and Cost
- Decentralized Trial Activities
- Promoting Accrual and Access
- New Data Collection Approaches
- PRO Data for Clinical Trials
- Operational Burden
- Statistical Issues
- Workforce Outreach and Training

Full November 2020 report: https://deainfo.nci.nih.gov/advisory/ctac/1120/SPWGreport.pdf

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

Examples of Actions to Achieve Strategic Vision for Clinical Trials

Focus on Essential Data

- Data Collection Standards for NCTN IND-Exempt Trials
- Pragmatica-Lung Study (S2302)

Decentralized Trials

- Adopting Local/Remote Study Procedures
- Telehealth Research Centers of Excellence (TRACE)

Patient Access to Trials

- Broaden Eligibility Criteria
- Connecting Underrepresented Populations to Clinical Trials (CUSP2CT)

Clinical Trials Innovation Unit (CTIU): Need

To **radically transform** how clinical trials are conducted, a new platform is needed to:

- Rapidly identify and test the most innovative approaches
- Without causing disruption to current processes, infrastructure, and trials already underway

CTIU: Overarching Goals

Reduce complexity through new models of scientific partnerships and collaborations for innovative science

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

What is CTIU?

An interagency platform 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: The needed expertise, at the same table

Co-Directors/Facilitators: Michael Morris, Sheila Prindiville

Coordinator: Iris Castro

CTIU: Extramural Community Partners

- NCTN
- NCORP
- Industry
- Advocacy

CTIU: Deliverables

- Develop impactful and transformative:
  - Therapeutic agents
  - Preventive strategies
  - Imaging and biological markers
- Produce high-impact actionable results
- Streamlined trial designs and data collection
- Rapidly conduct innovative studies in existing NCI networks

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

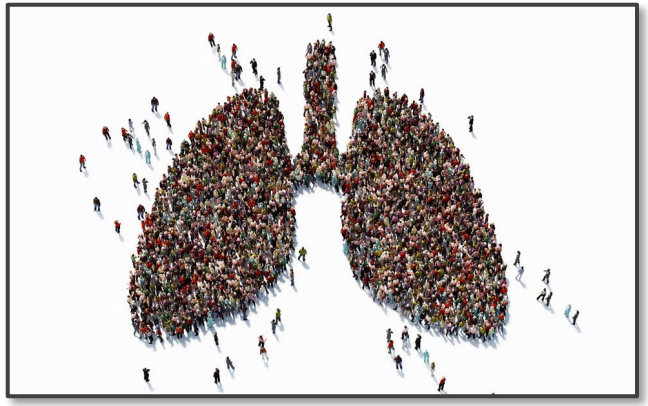
    (e.g., imaging, path, serum)
  - **Data extraction** and management that streamline trial conduct
  - **Collaborations** that conjoin expertise and resources
  - Built in: Novel evaluation, approval, and activation

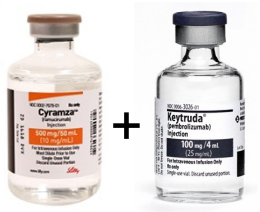
Streamlined Clinical Trials: Real or Aspirational?
Pragmatica-Lung Study (S2302)

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**
- Complete enrollment of 700 participants, by 2025

Led by SWOG Cancer Research Network, in collaboration with the Alliance for Clinical Trials in Oncology





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

Study Calendar: Pragmatica-Lung S2302

— Per Institution Standard and FDA-approved package insert(s)

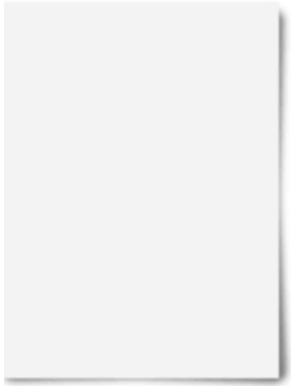
REQUIRED	Cycle Length (+/- 3 days)					At Off Tx	Off Tx FU
	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Subsequent		
PHYSICAL							
Vital Status Assessment							X
SAE Assessment							X (q 3 mos. until 3 years from date of randomization).
LABORATORY							
Participants must be able to … pembrolizumab described in … discretion, and institutional g…							…amucirumab plus …eating investigator's
TREATMENT							
Arm A: Investigator's Choice of Standard of Care (SoC)							
Chosen SoC drug(s) should be administered according to the current FDA-approved package insert(s). Arm A cycle length may vary.							
Arm B: Ramucirumab plus Pembrolizumab (21-day cycle)							
Ramucirumab	X	X	X	X	X		
Pembrolizumab	X	X	X	X	X (up to 35 cycles)		

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

Courtesy of Dr. Konstantin Dragnev

CTIU Roadmap for Trial Evaluation and Activation

1-2 page submission by investigator



Rapid vetting by CTIU for selection and go/no-go to protocol development

Collaborative protocol development with execution in NCI networks

How do Innovative Ideas come to CTIU?

Pilot phase – Limited to NCTN

Proposals due June 12

Clinical Trials Innovation Unit: Summary

A collaboration between NCI, the FDA Oncology Center of Excellence and **extramural partners that will:**

- **Select a few high-priority studies** for new study designs and operational procedures
- **Help speed clinical testing to deliver new approaches** for diagnosis, treatment, and prevention of cancer
- **Accept inputs** from the extramural research community

With Appreciation …..

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

Questions? NCIClinicalTrialsInnovationUnit@nih.gov