Session 5 Keynote: Accelerating Research to Practice

Douglas R. Lowy, M.D.
Deputy Director, National Cancer Institute

NCPF: Cancer Care and Cancer Research in the Context of the COVID-19 Pandemic
A Virtual Workshop on Lessons Learned, July 26-27, 2021

Disclosures

- None related to this presentation

Overview of improvements

- Shorten the time needed to develop and initiate clinical trials, to the extent feasible
- Bring the trial to the patient, rather than the patient to the trial, to the extent feasible
- Participation in a clinical trial should bring hope for people with cancer, rather than additional burdens for them, to the extent feasible
- Trials should be accessible for all, including patients in rural areas and underserved minorities

During the COVID-19 pandemic, has your site used the following modified clinical trials processes for ETCTN trials?

	Yes	No	Average Usefulness Rating Rated from 1 (not at all useful) to 5 (very useful)
Worked with local healthcare providers to provide continuity of care for patients on ETCTN trials	12	3	**3.9** (n=12)
Used virtual (telehealth / telephone) study visits	15	0	**4.5** (n=15)
Shipped oral IND agents directly to patients enrolled	13	1	**4.9** (n=14)
Used remote informed consent to enroll patients	6	7	**4.3** (n=7)
Underwent a remote audit	7	7	**3.9** (n=8)

Survey of 223 investigators, 94 unique responses (42% response rate); conducted July 2020

Some telehealth research needs

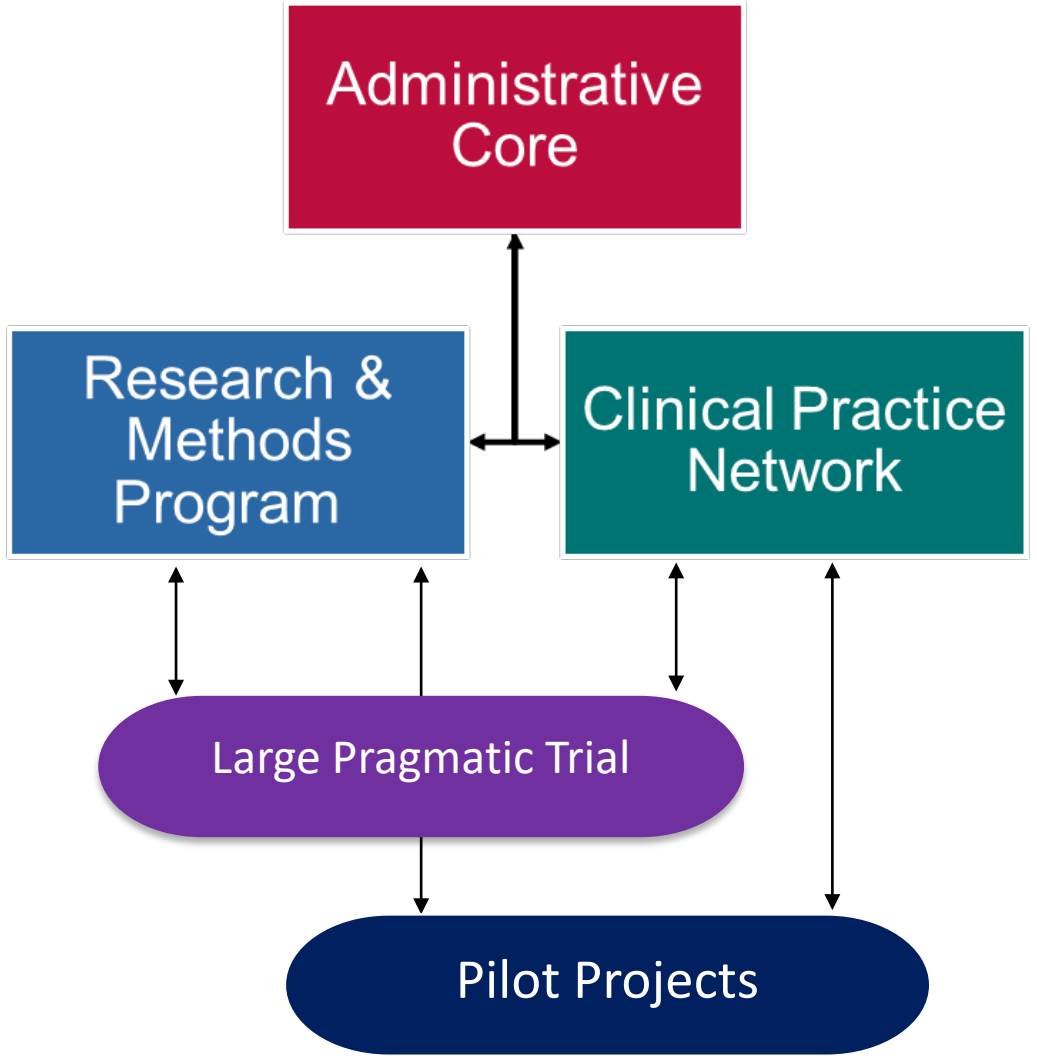
Support for telehealth research that:

- Identifies care contexts optimally suited to use of telehealth
- Tests innovative approaches to combining synchronous (real time) and asynchronous (sequential) communication
- Demonstrates how telehealth can reduce disparities and improve care access
- Yields scalable, transferable, and sustainable models of telehealth that improve quality of care, healthcare utilization and health outcomes

From Dr. Paul Jacobsen, NCI

Centers on Telehealth Research and Cancer-Related Care (RFA CA-21-029; Receipt date: 7/20/21)

- Create centers to advance a national cancer-focused telehealth research agenda in a changing healthcare environment
- Establish research infrastructures to facilitate testing of telehealth models of care in “real world” settings
- Promote development, evaluation, and dissemination of evidence-based models of telehealth



Current telehealth NOSI's from NCI

Activity Code	FOA Title	First Available Due Date	Expiration Date
R01	PAR-21-190: Modular R01s in Cancer Control and Population Sciences (R01 Clinical Trial Optional)	October 8, 2021	March 8, 2024
R01	PAR-21-035: Cancer Prevention and Control Clinical Trials Grant Program (R01 Clinical Trial Required)	June 5, 2021	January 8, 2024
R01	PAR-19-348: Innovative Approaches to Studying Cancer Communication in the New Information Ecosystem (R01 Clinical Trial Optional)	June 9, 2021	June 9, 2022
R21	PAR-19-350: Innovative Approaches to Studying Cancer Communication in the New Information Ecosystem (R21 Clinical Trial Optional)	June 9, 2021	June 9, 2022

See https://grants.nih.gov/grants/guide/notice-files/NOT-CA-21-043.html

Minority enrollment to NCI NCTN and NCORP clinical trials (all phases) did not decrease in 2020

	Enrollment 2017-2019	Enrollment 2020
Majority	**71%**	**64%**
Minority	**25%**	**34%**
Black	**11%**	**10%**
Hispanic	**10%**	**20%**
Other minority groups	**4%**	**4%**

Data from Dr. Worta McCaskill-Stevens, NCI

Some specific lessons from COVID-19

- Improve operational efficiency and reduce cost
  - Remote/electronic consenting; trial care visits close to home; drugs to the patient
  - New trial designs to reduce number of required data elements and/or testing that will decrease resource utilization
  - Enable rapid review of clinical trial documents
  - Add core infrastructure to facilitate electronic data capture from EHRs
- Modernize regulatory requirements
  - Stop collecting minor protocol deviations and reduce reporting of adverse events that have no impact on patient safety
  - Simplify study endpoints
- Bring trials to more patients; lower barriers to trial entry
  - Increase trial sites for the underserved
  - Re-evaluate co-morbidities that stifle accrual

See https://deainfo.nci.nih.gov/advisory/ctac/0721/Doroshow3.pdf