NCI Clinical Trials and Translational Research Advisory Committee (CTAC)

Strategic Planning Working Group Report

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NIH NATIONAL CANCER INSTITUTE

Today's Topics

- Introduction
- Themes and Highlights of Working Group Recommendations and Implementation Actions
- Conclusions and Next Steps

Introduction

Working Group Mission

Assess NCI's strategic vision for its clinical trials system for 2030 and beyond and make recommendations to achieve that vision

Working Group Focus and Process

- Focus on treatment trials although many topics and issues may apply to other types of trials (prevention, symptom science etc.)

- ***Six thematic subgroups established***
  - Operational Trial Design (Chair: Charles Blanke)
  - Data Collection (Co-Chairs: Neal Meropol & Mia Levy)
  - Patient Access (Chair: Augusto Ochoa)
  - Regulatory Issues (Co-Chairs: Julie Vose & Victor Santana)
  - Statistical Design (Co-Chairs: Sumithra Mandrekar & Michael LeBlanc)
  - Workforce (Co-Chairs: Nancy Davidson & Lynn Matrisian)

Working Group Timeline

- ***November 2019 plenary meeting:*** Priority areas of strategic concern identified and topics selected for more in-depth consideration
- ***Spring-Summer 2020:*** Subgroup webinars to develop and refine recommendations and implementation actions
- ***July and September 2020:*** Online plenary meetings to review subgroup output and develop consensus on definitive recommendations and implementation actions
- ***October 2020:*** Final report drafting and review

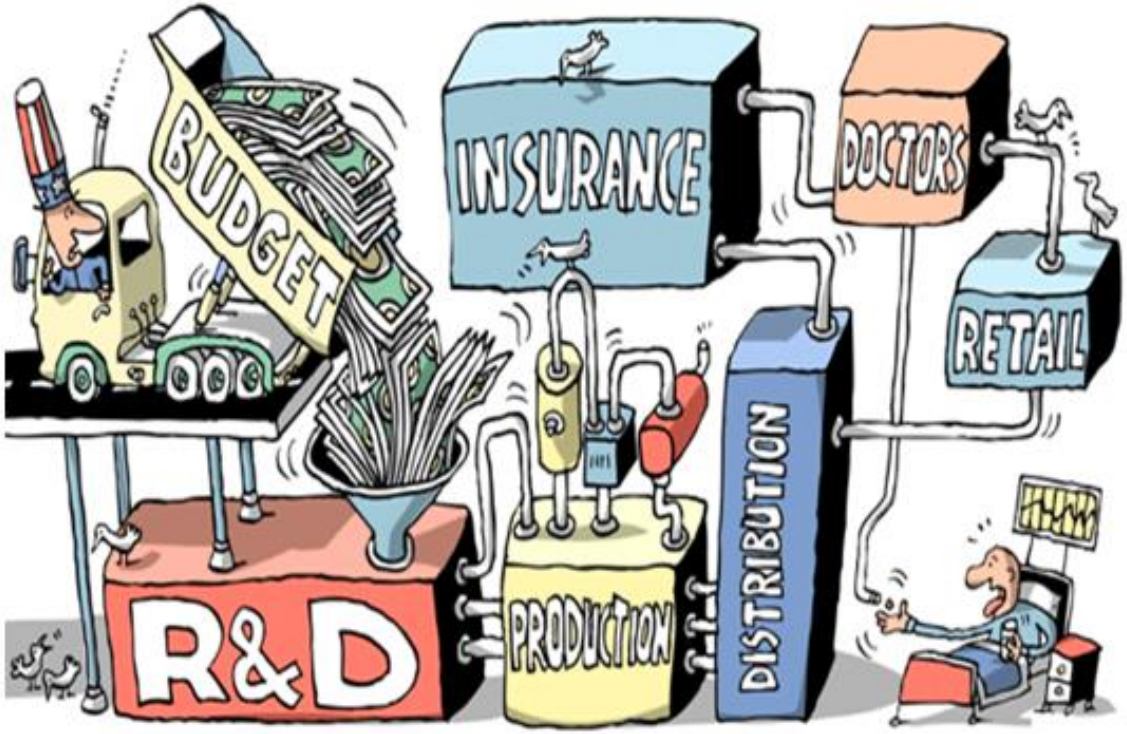
Context for Working Group Deliberations

- As scientific opportunities continue to expand, resources available for NCI clinical trials remain constrained, while institutions and investigators face increasing pressure to prioritize clinical productivity over research
- The COVID-19 pandemic has exacerbated resource pressures on healthcare institutions while simultaneously impeding clinical research
- The pandemic has also motivated NCI, regulatory authorities and clinicians to modify trial procedures in ways that provide proof of concept for process changes that could be of long-term benefit
- Events of 2020 have also stimulated a broader national conversation on disparities, providing additional motivation for NCI's long-standing efforts to address the greater burden of cancer on minority and underserved populations and expand their opportunities to participate in clinical trials

Strategic Vision for 2030 and Beyond

- *The exponential growth in complexity and expense associated with cancer clinical trials threatens the entire enterprise.*
- *We must urgently strive for a new normal that dramatically decreases regulatory hurdles, streamlines processes for trial design and execution, focuses on essential endpoints and increases the efficiency of data collection.*
- *The goal is flexible, faster, simpler, less expensive, high impact trials that seamlessly integrate with clinical practice.*

Optimizing Access to Cancer Clinical Trials



Where is the patient?

Themes

15 Recommendations across 8 Themes

Themes

Trial Complexity and Cost

- Limit NCI clinical trial data collection to reduce burdens on clinicians, clinical research staff, data managers, statisticians and patients

Decentralized Trial Activities

- Assess whether performing study procedures locally or remotely, including via telehealth, should become standard practice for NCI clinical trials

Promoting Accrual and Access

- Improve access, recruitment and retention to NCI trials, especially of minority and underserved populations

New Data Collection Approaches

- Advance the ability to extract NCI clinical trial data from electronic health records and through mobile and other remote technology devices

Themes (2)

PRO Data for Clinical Trials

- Establish standards and operational support to facilitate collection of patient reported outcome (PRO) data for NCI clinical trials

Operational Burden

- Facilitate automated integration of study documents into EHR and CTMS systems and refine audit processes to reduce site burden

Statistical Issues

- Further extend early involvement of statisticians in NCI clinical trial design and assess the feasibility and utility of “synthetic” control arms

Workforce Outreach and Training

- Refine approaches to cultivate interest in NCI trial participation and enhance training for the full range of participants in the clinical trials workforce

Highlights of Working Group Recommendations and Implementation Actions

Trial Complexity and Cost

Limit data collection to data elements essential for primary/secondary trial objectives

- Determine value of data elements versus collection burden
- Compare clinical trial data requirements with standard of care
- Determine data elements most important for FDA approvals
- Assess balance between scientific value of data for understanding biomarkers and mechanisms of action and for design of future trials versus collection burden
- Develop guidance for limiting data collection to data elements essential for primary/secondary trial objectives
- Consider value of trial designs than collect more data from early versus late enrollees

Decentralized Trial Activities

Identify study procedures that can be performed locally or remotely without affecting trial validity

- Survey clinical investigators, sites and patients on the advantages and disadvantages of performing study procedures locally or remotely during the COVID-19 crisis
- Collect data on trial quality for patients with study procedures performed locally or remotely versus those with study procedures performed at the clinical trial site
- Identify study procedures where local/remote performance was sufficiently beneficial to be adopted as standard NCI clinical trial practice
- Engage with regulators, payors and industry partners to identify actions necessary to implement local/remote procedures as standard NCI clinical trial practice and address any barriers to adoption

Decentralized Trial Activities (2)

Expand use of telehealth in clinical trials

- Determine extent of telehealth usage in NCI clinical trials before and after COVID-19
- Identify procedures conducted via telehealth that are sufficiently beneficial to be adopted as standard NCI clinical trial practice
- Engage with regulators, payors and industry partners to identify actions necessary to implement telehealth procedures as standard NCI clinical trial practice and address any barriers to adoption

Promoting Accrual and Access

Improve access, recruitment and retention to NCI trials, especially of minority and underserved populations

- Support ongoing efforts to broaden eligibility criteria, especially with regard to comorbidities which have higher rates in minority and underserved populations
- Conduct trials investigating areas of specific concern for minority and underserved patients during cancer treatment such as management of chronic comorbidities and cancer care differences in safety-net hospitals versus academic and other cancer care settings
- Identify ways to expand dissemination of tactics that have been shown to improve patient recruitment and retention, including for minority and underserved patients
- Identify and pilot new tactics that have high potential to improve patient recruitment and retention, including for minority and underserved patients
- Modernize the informed consent process by moving toward risk-based, modularized, dynamic consent forms and procedures

New Data Collection Approaches

Advance the ability to extract clinical trial data from electronic health records (EHRs) and through mobile and other remote technology devices

- Assess existing initiatives for collecting clinical trial data from EHRs and identify any opportunities for NCI to productively complement these efforts
- Encourage advocacy efforts to incorporate into EHRs interface standards, data models and data standards that facilitate use of EHR data for clinical trials
- Assess the status of physiologic data collection from mobile and other remote technology devices
- Identify data elements that could be collected remotely without affecting quality
- Determine whether a NCI centralized support service and/or standardized “platform protocols” should be established to facilitate clinical trial data collection from mobile or other remote technology devices

PRO Data for Clinical Trials

Establish standards and operational support to facilitate collection of PRO data for NCI clinical trials

- Assess existing PRO data collection software products
- Determine if NCI should endorse one or more products for use in NCI clinical trials and/or establish standards and features for such products
- Establish a downstream data model and supporting standards to provide a framework for interoperability with commercial and institutional PRO data collection software
- Establish a centralized service to provide operational support for PRO data collection and analysis in NCI trials and to facilitate a standard approach to the analysis of PRO endpoints
- Investigate approaches for providing PRO clinical trial data to patient care teams
- Determine whether an RFP should be issued for PRO collection technologies meeting key functional criteria

Operational Burden

Facilitate automated integration of study documents into EHR and CTMS systems and refine audit processes to reduce site burden

- Assess existing efforts to automate the integration of study documents into local EHR and CTMS systems
- Identify barriers to developing technologies for automated integration of study documents and potential solutions to those barriers
- Encourage advocacy efforts to convince EHR and CTMS vendors to develop technologies for automated integration of study documents into local implementations of their products
- Conduct a retrospective analysis of audit results to determine whether data elements not essential for evaluating safety, efficacy or regulatory compliance are audited
- Propose an updated approach to auditing limited to data elements essential for evaluating safety, efficacy or regulatory compliance

Statistical Issues

Further extend early involvement of statisticians in study design and assess the feasibility and utility of "synthetic" control arms

- Issue formal NCI guidance on
  - Early statistician involvement in protocol design for correlative, early-phase and Cancer Center-led studies
  - Improved communication among clinical investigators, correlative study specialists and statisticians
- Encourage Cancer Center biostatistics cores to include expertise in design and analysis of biomarker studies
- Assess results of prior studies on the use of control data from completed clinical trials or contemporaneous clinical practice sources
- Conduct prospective, methodologically-rigorous proof-of-principle studies assessing whether control data from completed clinical trials or contemporaneous clinical practice sources can be used without jeopardizing trial validity

Workforce Outreach and Training

Refine approaches to cultivate interest in NCI trial participation and enhance training for the full range of participants in the clinical trials workforce

- Assess current outreach efforts to increase interest of community oncologists and their staff in NCI trial participation and propose new approaches if needed
- Assess current outreach efforts to increase support by leaders of healthcare institutions for NCI trial participation and propose new approaches if needed
- Assess training needs for
  - Community oncologists who would like to participate as NCI clinical trial investigators
  - Oncology residents and fellows
  - Physicians, allied health practitioners and information technology personnel who conduct ancillary procedures in support of NCI clinical trials
- Support the development of additional training materials as needed

Recommended NCI Operational Initiatives

Recommended NCI Operational Initiatives*

1) Develop a single CTEP point of contact to provide information and assistance on the regulatory procedures required for international site participation in NCI trials
2) Provide NCI CIRB guidance on local context assessments/local noncompliance responses and simplify the NCI CIRB electronic infrastructure
3) Assess the statistical consequences of patient-level data collection deviations and incremental morbidity and mortality due to COVID-19

*Initiatives that are feasible for NCI to implement without fundamental policy changes or substantial non-NCI input

Conclusions and Next Steps

Strategic Planning Working Group Conclusions

- *These recommendations and NCI operational initiatives will accelerate progress toward an NCI clinical trials system that is faster, simpler, less expensive, and focused on outcomes that matter as well as being more flexible, responsive, accessible and equitable*

- *Expeditious implementation of the actions proposed in this report is of utmost urgency so that NCI can continue to take advantage of the most compelling new scientific opportunities while assuring that the benefits achieved will be available to all Americans and that a foundation is laid for integrating clinical trials more seamlessly with clinical practice*

Next Steps

- Develop a ten-year implementation road map which prioritizes the recommended actions and provides goals and milestones
- Implementation will involve:
  - Information gathering and analysis of current status/activities in certain topic areas
  - Surveys of NCI clinical trial stakeholders relevant to certain topic areas
  - Convening of expert groups in certain topic areas; activities could include:
    - Review current status, activities and survey results
    - Design and oversee targeted analyses to further clarify issues
    - Propose specific initiatives to achieve goals of the recommendation
  - Design and conduct of pilot projects and proof-of-principle studies
  - Encouragement of advocacy efforts beyond NCI to achieve goals of recommendations
  - New NCI guidance documents and operational improvements
- CTAC will oversee and advise on implementation over the next decade

Working Group Members, Liaisons, and Facilitators

Chair
Patrick Loehrer, Sr.

Members
David Arons
Debra Barton
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Janet Dancey
Nancy Davidson
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Questions?

Proposed Motion: Accept the Strategic Planning Working Group Report