Strategic Planning Working Group 2024 Update

NIH NATIONAL CANCER INSTITUTE

November 6, 2024

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

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

Reviewed and addressed necessary clinical trials infrastructure

Developed 15 recommendations

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

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

CTAC Strategic Planning Working Group (SPWG) – 2024

- SPWG reconstituted in 2024 to:
  - Review the current status of the 2020 strategic plan initiatives
  - Determine if additional SPWG recommendations should be pursued at this time
  - Identify any new initiatives that should be considered

CTAC SPWG Update – 2024 Activities

- July 2024 Virtual Meeting
  1) Assessment of three of the 2020 SPWG recommendations not yet implemented
     - Statistical Issues: Use of External Controls
     - Patient Access: Modernize Informed Consent Process
     - Operational Burden: Refinement of Audit Process
  2) Recommended new SPWG initiative: Assessing Clinical Trial Activation Timelines
- September 2024
  - Input on urgency of implementing remaining 2020 SPWG recommendations not discussed in July

SPWG Implementation Report – July 2024 Meeting

Assessment of Three of the 2020 SPWG Recommendations Not Yet Implemented

Use of External Control Arms – 2020 Recommendation

- Investigate whether and in what situations data from previously completed clinical trials or contemporaneous clinical practice sources could be used as “synthetic” (external) control arms without jeopardizing trial validity
- Impetus for recommendation
  - Trials in rare diseases
  - Trials focused on specific patient subgroups

External Control Arms: SPWG 2024 Assessment

- Ongoing extramural interest in the potential value of external control arms to facilitate accrual and reduce costs, especially for trials in rare diseases
- Some statisticians remain skeptical of the feasibility of external control arms
- Expert group should be convened to:
  - Rigorously assess the feasibility of using external control arms
  - Identify clinical trial scenarios for which use of external control arms would be appropriate

Modernize Informed Consent Process – 2020 Recommendation

- Modernize the informed consent process by moving toward risk-based, modularized, dynamic consent forms and procedures
- Impetus for recommendation
  - Process remains burdensome for trial staff and participants
  - Many trial participants continue to find consent forms complex and difficult to understand and interpret
  - Consent language often not tailored to risk level of study protocol

Informed Consent Process: SPWG 2024 Assessment

- Extensive regulatory requirements limit NCI freedom to change the informed consent process
- CTEP should:
  - Continue its efforts to improve informed consent template within regulatory constraints
  - Monitor external efforts to improve communication with trial participants (e.g. videos, AI-based tools) to identify any approaches appropriate for adoption by CTEP and/or the NCTN Groups

Refinement of Audit Process – 2020 Recommendation

- Redesign the audit process to audit only data elements essential for determining safety, efficacy, and regulatory compliance
- Impetus for recommendation
  - Need to limit audited data elements to those essential for ensuring quality and meeting regulatory requirements
  - Need to take full advantage of FDA guidance on adaptive, risk-tailored auditing

Audit Process: SPWG 2024 Assessment

- Audit burden remains an important concern
- Retrospective analysis of past audit results should be conducted to help identify areas where changes to the audit process could most effectively reduce burden
- Continuing need for improved standardization and coordination of audit timing and frequency across NCTN
- Audit process revisions should be implemented in a way that preserves and enhances the collaborative educational and process improvement aspects of the audit process

Input on New Initiative to Assess Clinical Trial Activation Timelines

Potential New Initiative: Clinical Trial Activation Timelines

- Recommendations of CTAC Operational Efficiency Working Group Report (2010) led to implementation of standard timelines that reduced both median and outlier durations for trial activation steps
- Timeline performance perceived to have deteriorated in recent years
  - COVID pandemic impacts
  - Clinical trial staffing challenges
  - Complexity of precision medicine trials
  - Institutional/practice payment issues
  - Industry delays in supplying agents

Clinical Trial Activation Timelines: SPWG July 2024 Consensus

- Updated analysis of NCTN clinical trial activation timeline performance is warranted
- Analysis should:
  - Document which timeline components and milestones are under control of NCI, the NCTN Groups, Cancer Centers and other NCI clinical trial network participants, and pharmaceutical companies
  - Assess outliers as well as median values
  - Investigate the causes of any observed bottlenecks

Assessment of Urgency of Implementing Remaining SPWG 2020 Recommendations

Remaining Recommendations – Not Discussed in July

- Community Outreach
  - Increase interest in NCI clinical trial participation among community oncologists and health care institution leaders
- Workforce Training
  - Develop clinical trials training programs for community oncologists, oncology trainees, and local providers
- Statistician Involvement
  - Involve statisticians earlier in protocol design for correlative, early phase, and Cancer Center–led studies
- Mobile/Remote Device
  - Collect clinical trial data with mobile/remote devices

Community Outreach Recommendations – Urgency

- SPWG assessment of implementation urgency

Recommendation	Rating:	1	2	3	Mean
Outreach to encourage participation of community oncologists and staff in NCI trials		12	3	0	1.2
Outreach to healthcare institution leaders to encourage support for NCI trials		7	7	1	1.6

Rating scale: 1 = implement immediately, 2 = implement within 3 years, 3 = defer for now

SPWG Observations on Community Outreach

- Need
  - Outreach to community oncologists is of greater urgency than outreach to leaders of healthcare institutions
- Challenges
  - Low per-case funding
  - Lack of necessary support infrastructure in community settings

Workforce Training Recommendations – Urgency

- SPWG assessment of implementation urgency

Recommendation	Rating: 1	2	3	Mean
Clinical trial training for community oncologists	11	4	0	1.3
Clinical trial training for oncology residents/fellows	10	5	0	1.3
Training for physicians and other staff providing ancillary support for NCI clinical trials	10	5	0	1.3

Rating scale: 1 = implement immediately, 2 = implement within 3 years, 3 = defer for now

SPWG Observations on Clinical Trial Workforce Training

- Need
  - Training for clinical trial workforce participants judged to be of high urgency
- Challenge
  - Funding

Statistician Involvement Recommendation – Urgency

- SPWG assessment of implementation urgency

Recommendation	Rating:	1	2	3	Mean
Early involvement of statisticians in protocol design for correlative, early phase, and Cancer Center–led studies		8	5	2	1.6

Rating scale: 1 = implement immediately, 2 = implement within 3 years, 3 = defer for now

SPWG Observations on Early Involvement of Statisticians in protocol design for correlative, early phase, and Cancer Center–led studies

- Need
  - Early involvement of statisticians in protocol design for correlative, early phase, and Cancer Center–led studies judged to be less urgent than the recommendations on workforce training and outreach to community oncologists
- Challenges
  - Financial resources to support statistician involvement
  - Statistician availability currently extremely limited
  - Expansion of clinical trial statistician workforce difficult because of poor alignment of trial support activities with incentive structure for academic careers

Mobile/Remote Device Recommendation – Urgency

- SPWG assessment of implementation urgency

Recommendation	Rating:	1	2	3	Mean
Use of mobile/remote devices for data collection in NCI trials		5	6	4	1.9

Rating scale: 1 = implement immediately, 2 = implement within 3 years, 3 = defer for now

SPWG Observations on Use of Mobile / Remote Devices

- Need
  - Use of mobile/remote devices judged to be the least urgent of the remaining SPWG recommendations
- Challenges
  - Need to develop data standards and address analytic implications, data integration and security issues
  - Application in clinical trial context imposes incremental training requirements
  - Equitable access to these devices
  - Rapidly evolving technology makes for moving target

Summary of SPWG Assessment of Remaining 2020 SPWG Recommendations

- Highest urgency assigned to initiatives on:
  - Workforce training, including community oncologists, oncology residents/fellows, and physicians/staff providing ancillary support
  - Outreach to community oncologists to encourage participation
- Lesser urgency assigned to initiatives on:
  - Outreach to institutional leaders
  - Early involvement of statisticians in protocol design for correlative, early phase, and Cancer Center–led studies
  - Use of mobile/remote devices

www.cancer.gov

www.cancer.gov/espanol

Proposed Motion: Accept the Strategic Planning Working Group Implementation Report

(July 2024 Meeting)