Implementation of CTAC Strategic Planning Working Group (SPWG) Recommendations for the NCI Clinical Trials System

NIH NATIONAL CANCER INSTITUTE

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July 14, 2021

Overview

- Effect of COVID-19 on NCI-Supported Clinical Trials
- NCI's 2030 Strategic Vision for Clinical Trials
  - Recap of the CTAC Strategic Planning Working Group Report
- Initial Implementation Plan
  - Activities Underway

Effect of COVID-19 on NCI-Supported Clinical Trials

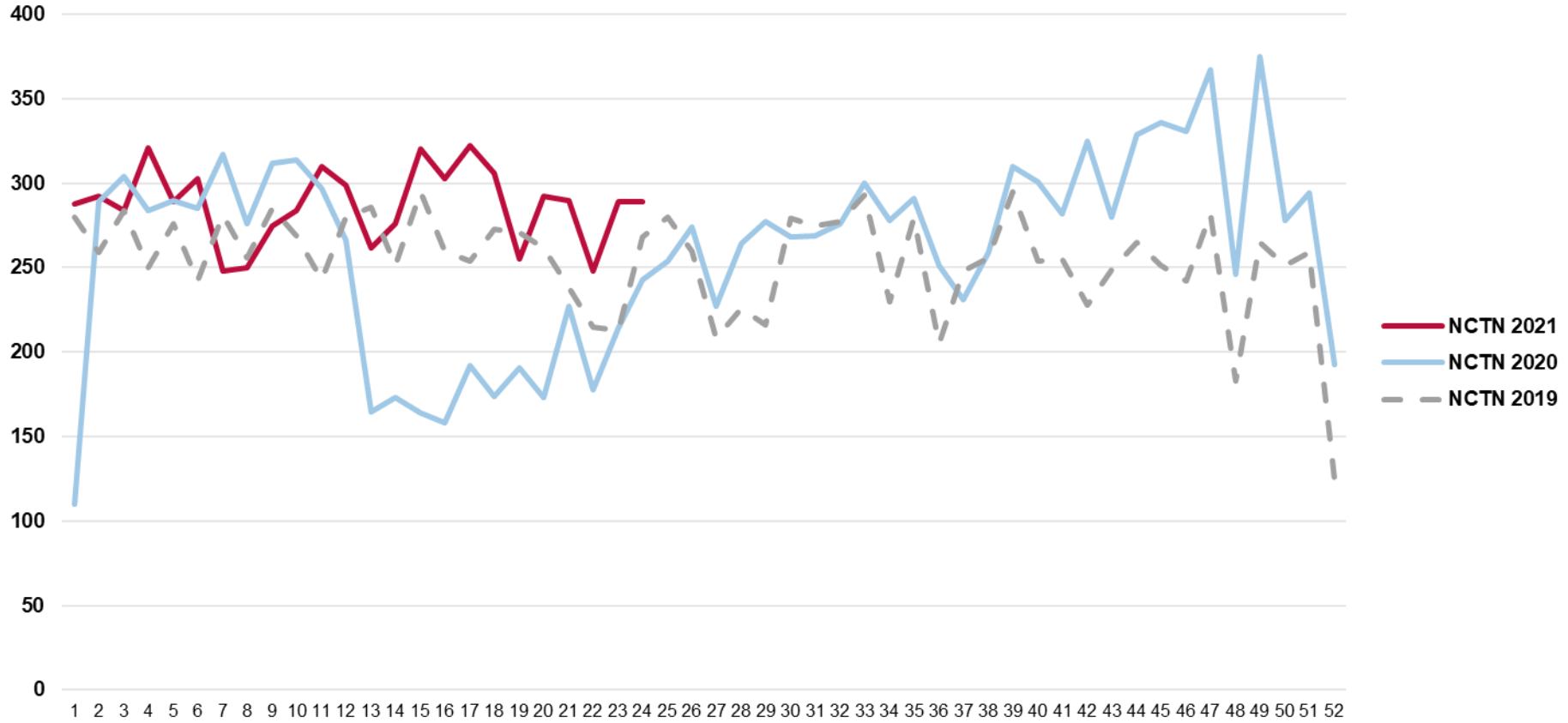
COVID-19-related Roadblocks to Clinical Trial Accrual

- In-person study activities
  - informed consent
  - visits to receive investigational study drug
  - assessments of patient safety and study adherence
- Exclusive use of imaging and laboratory facilities specified by trial documents and for the collection of abundant test data of limited importance
- Requirement to collect low grade adverse events despite potential lack of clinical relevance to study endpoints
- Limited access to cancer care personnel/facilities, and reprogramming of clinical research resources to clinical care
  - Further diminished availability of trials for underserved populations

NCI's Clinical Trials Programs: Rapid Response to Pandemic

- Changed to use of electronic consenting
- Provided oral investigational agents directly to patients
- Initiated electronic, rather than in person, study audits
- Facilitated use of telemedicine for study visits
- Limited impact of minor study deviations on trial conduct/evaluation
- Implemented decentralized testing for required lab and imaging studies
- Developed new strategic plan for NCI's clinical trials programs

NCTN Weekly Intervention Accrual in 2019 - 2021

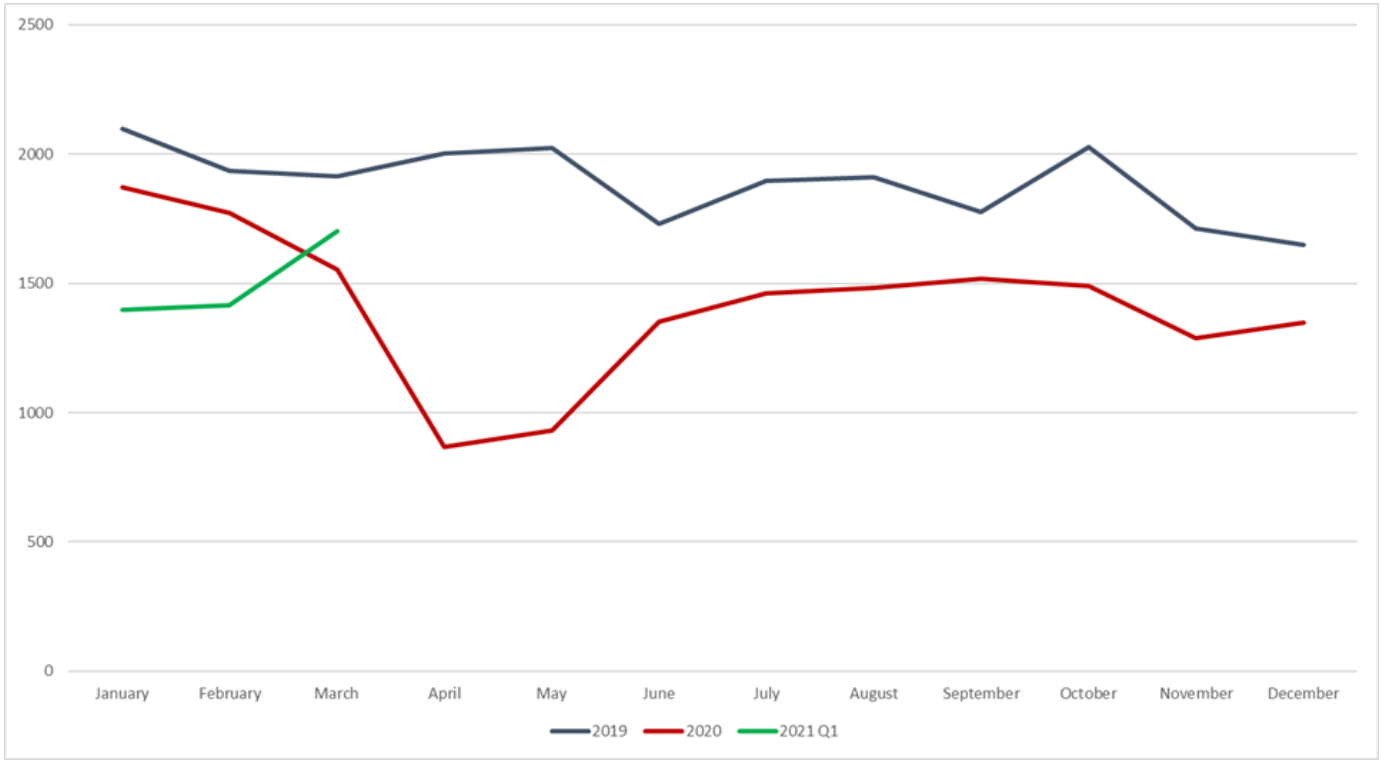


Data source: CTEP

NCI-Designated Cancer Center Monthly Accrual *2019 – 2021*

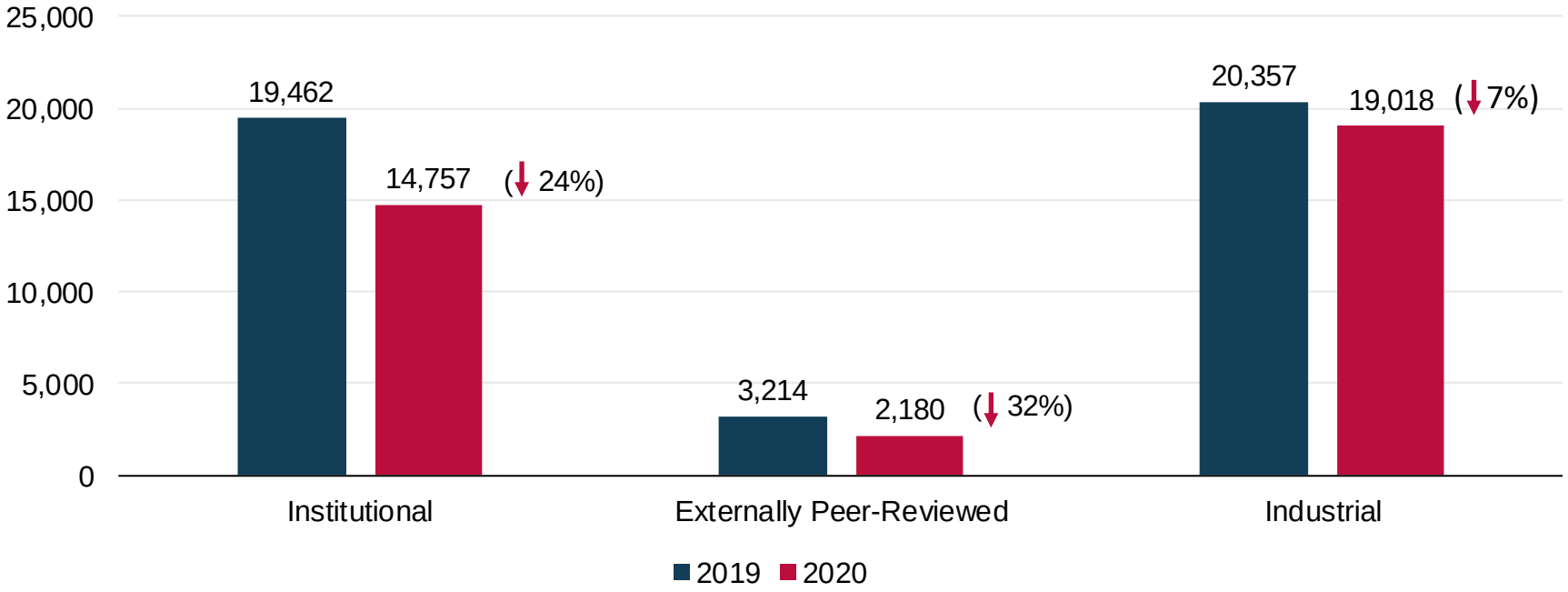
Institutional and Externally Peer-Reviewed Treatment Trials

(Excludes NCTN and Industrial Trials)



Data source: NCI's Clinical Trials Reporting Program (CTRP)

NCI-Designated Cancer Center Reported Annual Accrual 2019 - 2020
Interventional Treatment Trials (Excludes NCTN)



Summary

- There was a major impact in Q2/Q3 of 2020 on treatment trial accrual for NCTN studies as well as investigator-initiated and externally peer-reviewed trials conducted at NCI-Designated Cancer Centers
- NCTN trial accrual appears to have recovered
- NCI-Designated Cancer Center institutional and externally peer-reviewed trial accrual appears to have recovered, but only in part to date
- **Path Forward:** Implementation of NCI's Clinical Trials Strategic Planning Working Group Recommendations for 2030 and beyond

NCI's 2030 Vision for Clinical Trials

Recap of the CTAC Strategic Planning Working Group Report

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

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

Re-assess strategic vision for clinical trials system 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

Initial Implementation Plan

Focus of Recommendations Selected for Initial Implementation

- Streamlining Clinical Trials
- Decentralized Trial Activities
- Patient Access to Trials

Streamlining Clinical Trials

Limiting Data Elements Collected

Rationale: Logistical complexity and data collection burden of NCI clinical trials increases costs and disincentivizes site participation

Recommendation: Limit clinical trial data collection in late phase trials to essential data elements

Streamlining Clinical Trials

Using EHRs to Support Clinical Trials

Rationale: Manually building and validating study-specific documents in local EHR and CTMS systems results in duplicative, burdensome, expensive, and nonproductive activity

Recommendation 1: Engage EHR and CTMS vendors to create mechanisms for automatically integrating study-specific documents into local implementations of their products

Rationale: Lack of EHR data element standardization and interoperability with clinical trial systems complicates extraction of clinical trial data from EHRs

Recommendation 2: Resolve the logistical and data quality challenges of extracting clinical trial data from electronic health records

Decentralized Trial Activities

Local/Remote Conduct of Study Procedures

Rationale: Local or remote conduct of select study procedures would increase trial efficiency and patient convenience

Recommendation: Identify study procedures modified due to COVID-19 to be performed locally or remotely that can be adopted as standard clinical trial practice

Telehealth Use in Clinical Trials

Rationale: Convenience of telehealth can improve clinical trial access

Recommendation: Expand the use of telehealth in clinical trials

Patient Access to Trials

Broaden Eligibility Criteria

Rationale: Higher rates of chronic comorbidities in minority and underserved populations limit their participation in clinical trials

Recommendation: Broaden eligibility criteria to address distinctive medical problems experienced by minority and underserved patients

Conduct Trials that Support Minority and Underserved Patient Needs

Rationale: Clinical trials often do not adequately address cancer treatment needs of minority and underserved populations

Recommendation: Address the distinctive medical problems experienced by minority and underserved patients during cancer treatment

Implementation Activity Timeline

Project	Information Gathering (June – October 2021)	Convening Experts (October 2021 – Onward)
Limiting Data Elements Collected	Analyze sample of treatment trials, review findings, analyze previous efforts	Review findings, identify additional analyses, develop consensus on guidance
Using EHRs to support clinical trials	Review Cancer Center supplements, clarify status of mCODE initiative, gather information on ongoing clinical trials	
Local/Remote Conduct of Study Procedures	Determine status of remote informed consent and auditing, analyze investigator experience and sample of impact for remote/local trials	Review findings, identify procedures that should be standard practice

Implementation Activity Timeline

Project	Information Gathering June – October 2021	Convening Experts October 2021 – Onward
Telehealth Use in Clinical Trials	Clarify focus and status of NCI activities, gather information on telehealth use in NCI clinical trials	Review findings, identify standard practice procedures, establish dialogue with FDA, OHRP, CMS. ? New funding
Broaden Eligibility Criteria	Assess applicability of ASCO-Friends recommendations, identify opportunities for revised criteria	
Conduct Trials that Support Minority and Underserved Patient Needs	Identify barriers to participation and aspects of cancer treatment specifically concerning minority groups	Review findings, identify trial questions that address specific concerns

Implementation Activities Underway

Implementation Activities Underway

- CTEP is assessing which trial modifications due to the pandemic can be continued or transitioned to a full-time option
- Administrative Supplements to P30 CCSG grants awarded to assess feasibility of automatically integrating study-specific documents into local CTMS and EHR systems
  - MD Anderson Cancer Center consortium
  - Big 10 Cancer Consortium (IUSCCC)
- NCI is conducting a survey and analysis to evaluate telemedicine usage in NCI clinical trials before and after COVID-19
- Initial analysis of the utilization of the ASCO/Friends of Cancer Research broadened eligibility criteria among CTEP sponsored clinical trials presented at ASCO 2021(Denicoff et al., Abstract #6518)
- Communicating with other professional societies such as ASCO to complement and leverage efforts for related activities

Updates on activities underway planned for November 10, 2021 CTAC meeting

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