Effect of COVID-19 on NCI-Supported Clinical Trials

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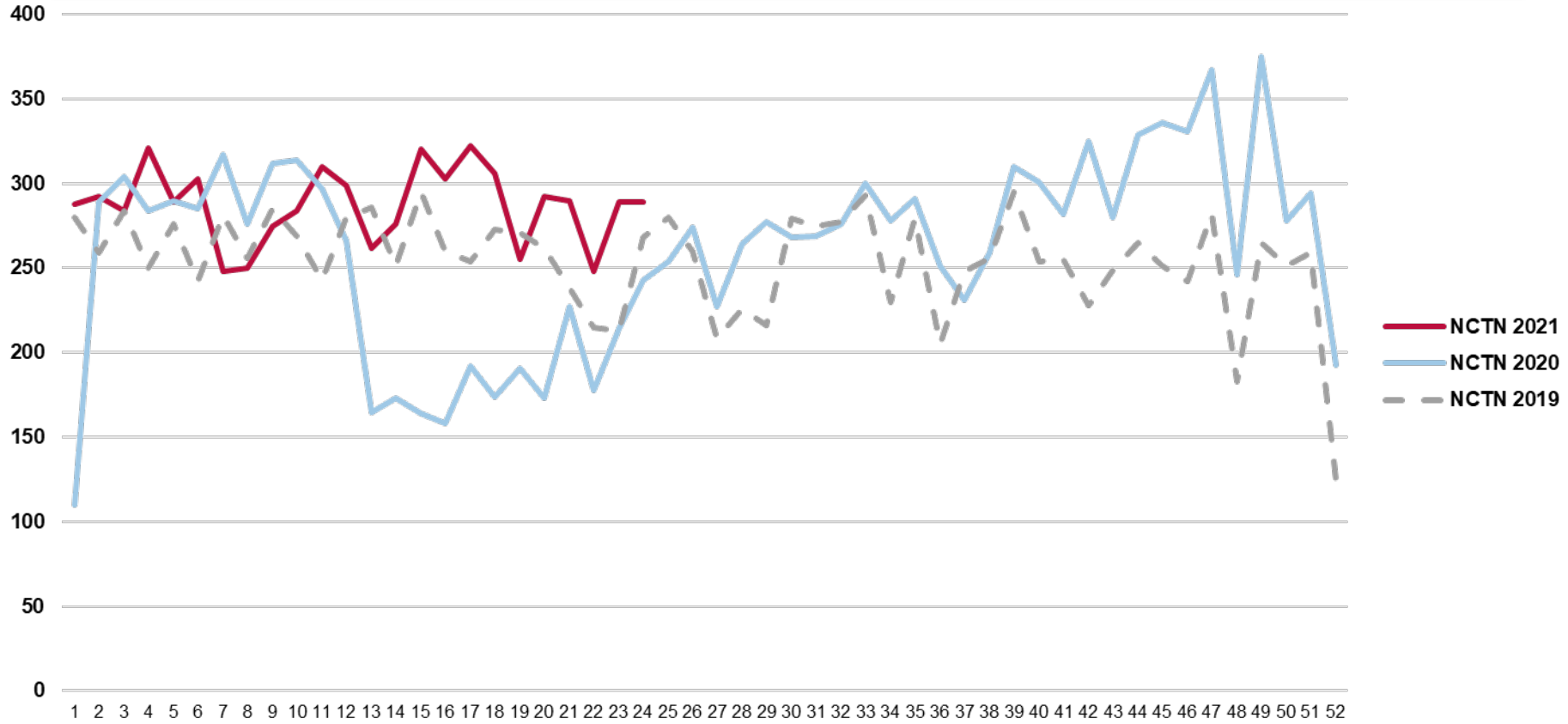
COVID-19-related Roadblocks to Clinical Trial Accrual

- Requirement for in-person informed consent
- Requirement for in-person visits to receive investigational study drugs
- Requirement for in-person assessments of patient safety and study adherence
- Requirement for 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
- Limited access further diminished availability of trials for underserved populations

NCI's Clinical Trials Programs: Rapid Response to Pandemic

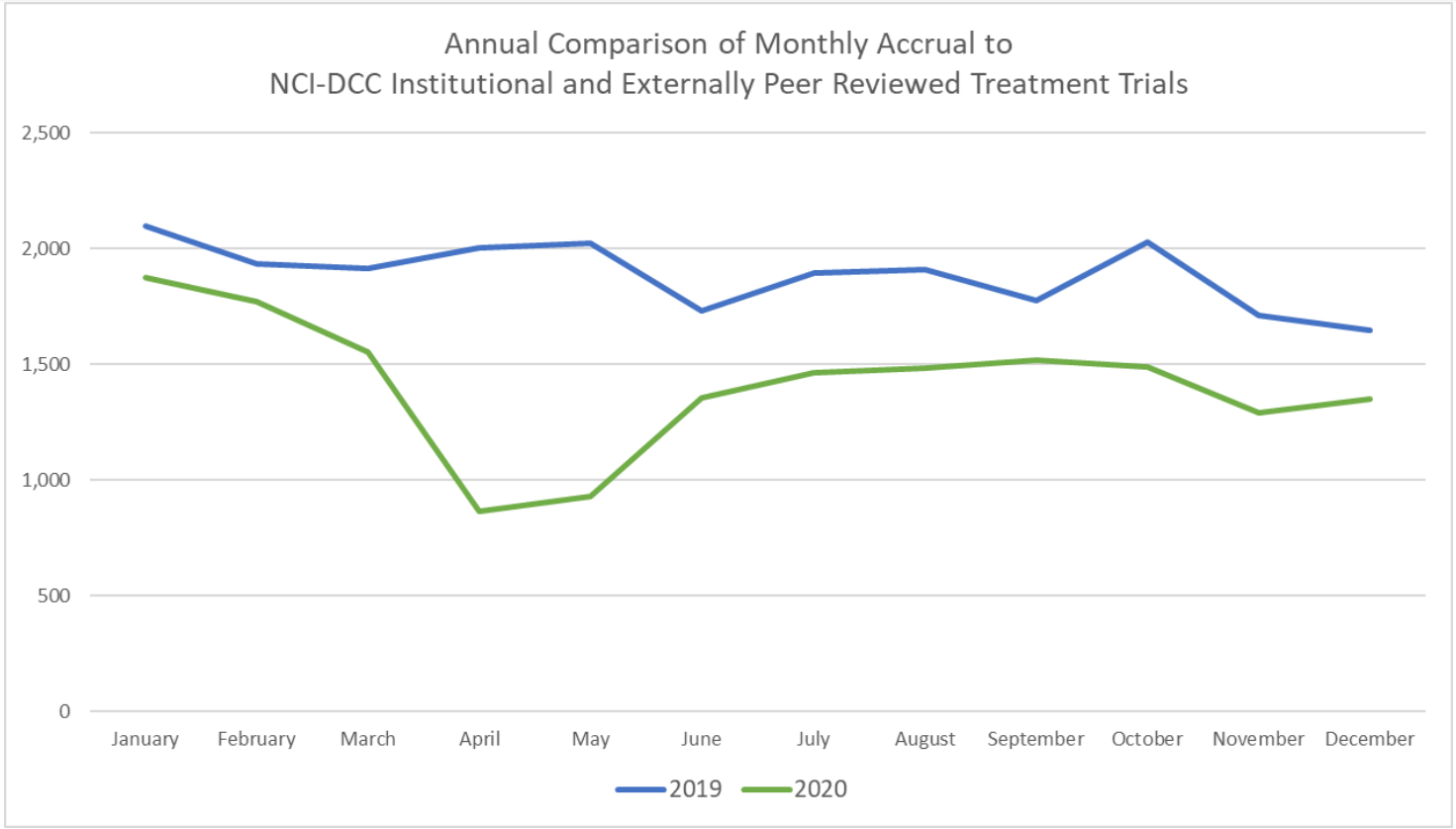
- Changed to use of electronic consenting
- Provided oral investigational agents directly to patients
- Initiated electronic, rather than in person, study audits
- Facilitated use of telemedicine for study visits
- Limited impact of minor study deviations on trial conduct/evaluation
- Implemented decentralized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

Weekly Intervention Accrual in 2019, 2020, and 2021 in the NCTN



NCI-Designated Cancer Center Reported Accrual *2019 – 2020*

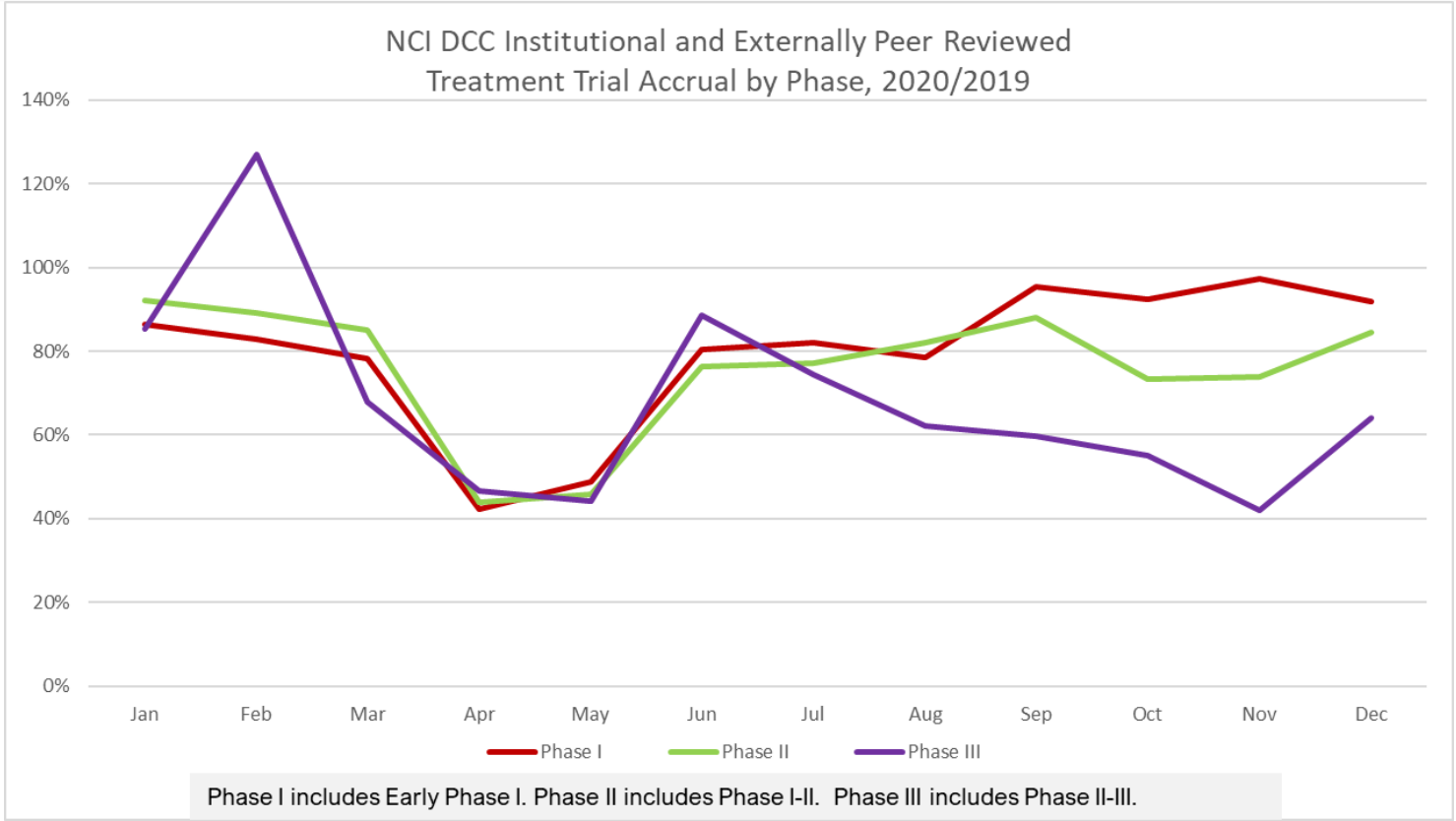
Interventional, Treatment trials (Excludes Industrial), n = 39,613



Monthly NCI-Designated Cancer Center Treatment Accrual

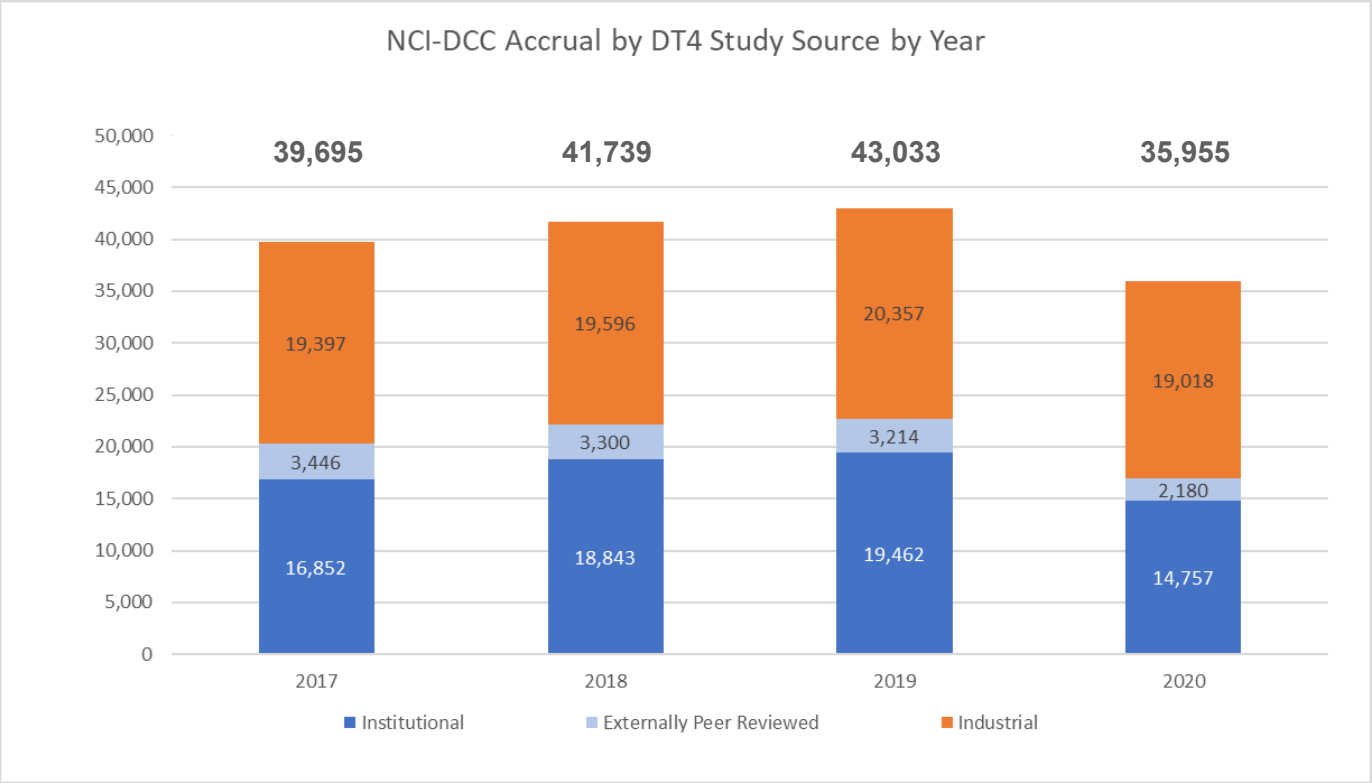
2020 Accrual as a % of 2019 Accrual –Excludes Industrial

Comparison by Phase, n = 37,349*



***Excludes Phase NA, n = 2,264: 39,613-2,264=37,349**

NCI-Designated Cancer Center Reported Annual Accrual 2017 - 2020 Interventional Treatment Trials



Conclusions

- There was a major impact in Q2/Q3 of 2020 on treatment trial accrual for NCTN studies as well as investigator-initiated, grant-funded, and industrially-sponsored trials conducted at NCI Designated Cancer Centers
- NCTN trial accrual appears to have recovered
- NCI Designated Cancer Center trial accrual appears to have recovered, but only in part
- Accrual to Pharma-sponsored trials at NCI Designated Cancer Centers was also adversely affected

Path Forward: NCI Clinical Trials 2030 Strategic Plan Initial Implementation Objectives

- Streamlining Clinical Trials
  - Limit clinical trial data collection in late phase trials to data elements essential for the primary and secondary objectives of the trial
  - Resolve the logistical and data quality challenges of extracting clinical trial data from electronic health records
- Distributed Trial Activities
  - Identify study procedures, including informed consent and auditing, modified due to COVID-19 to be performed locally or remotely that are sufficiently beneficial to be adopted as standard clinical trial practice
  - Expand the use of telehealth in clinical trials including for enrollment, consent, and study visits
- Patient Access to Trials
  - Broaden eligibility criteria for late phase NCI clinical trials as much as possible, especially with regard to comorbidities, while still achieving the trials' primary and secondary objectives
  - Conduct trials investigating areas of specific concern for minority and underserved patients during cancer treatment

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