

# Strategic Planning Activities

*Introduction*

# 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

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## Themes:

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Trial Complexity and Cost

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Decentralized Trial Activities

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Promoting Accrual and Access

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New Data Collection Approaches

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PRO Data for Clinical Trials

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Operational Burden

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Statistical Issues

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Workforce Outreach and Training

# Focus of Initial Implementation Activities

- Streamlining Clinical Trials
  - Limiting Data Elements Collected
  - Using EHRs to Support Clinical Trials
- Decentralized Trial Activities
  - Local/remote Conduct of Study Procedures
  - Telehealth Use in Clinical Trials
- Patient Access to Trials
  - Broaden Eligibility Criteria
  - Conduct Trials that Support Minority and Underserved Patient Needs
- Workforce – Emerging issues

# Telehealth Initiative Update

# NCI Funding Announcements on Telemedicine in Cancer Care

- RFA-CA-21-029: Centers on Telehealth Research for Cancer-Related Care
  - P50 Centers to leverage clinical practice networks able to support multiple cancer-focused telehealth research studies, including two rapid-cycle pilot projects and one large-scale pragmatic randomized control trial
  - Focused on improving cancer-related care and outcomes across the cancer control continuum
  - Proposals currently under review, announcement expected spring 2022

# NCI Funding Announcements on Telemedicine in Cancer Care

- NOT-CA-21-043: Notice of Special Interest (NOSI) – Telehealth in Cancer Care
  - Solicits investigator-initiated applications for conducting research on the use of telehealth in cancer-related care
  - Broad scope encompassing both patient-provider and provider-provider interactions and any aspects of care across the continuum from prevention to end-of-life care
  - Expiration date March 8, 2024

# NCI DCCPS Webinar Series Telehealth and Cancer: Studying its Role in Cancer Control and Care Delivery

- Feb. 25: Introduction to Telehealth and Cancer Webinar Series
- Mar. 21: Patient-Provider Communication and Cancer-Related Telehealth
- Apr. 26: Telehealth Models of Cancer Care Delivery
- May 19: Telehealth Research to Address Cancer Disparities
- Jun. 21: Overview of NCI's Telehealth Research Centers of Excellence (TRACE)

Register for webinar series:

<https://healthcaredelivery.cancer.gov/telehealth/webinar-series.html>



# Decentralized Trial Activities: Recommendation

## Telehealth Use in Clinical Trials

**Rationale:** Convenience of telehealth can improve clinical trial access

**Recommendation:** Expand the use of telehealth in clinical trials

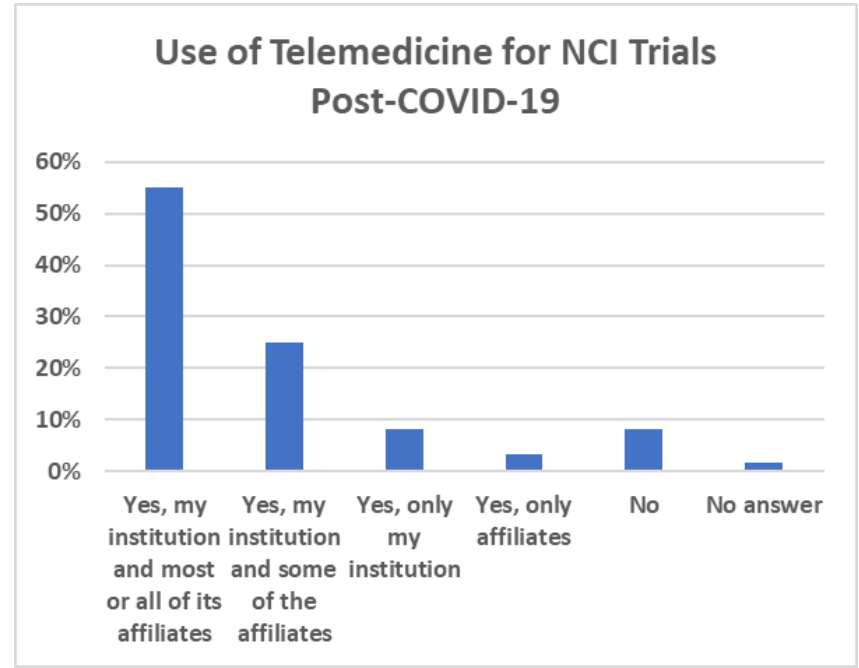
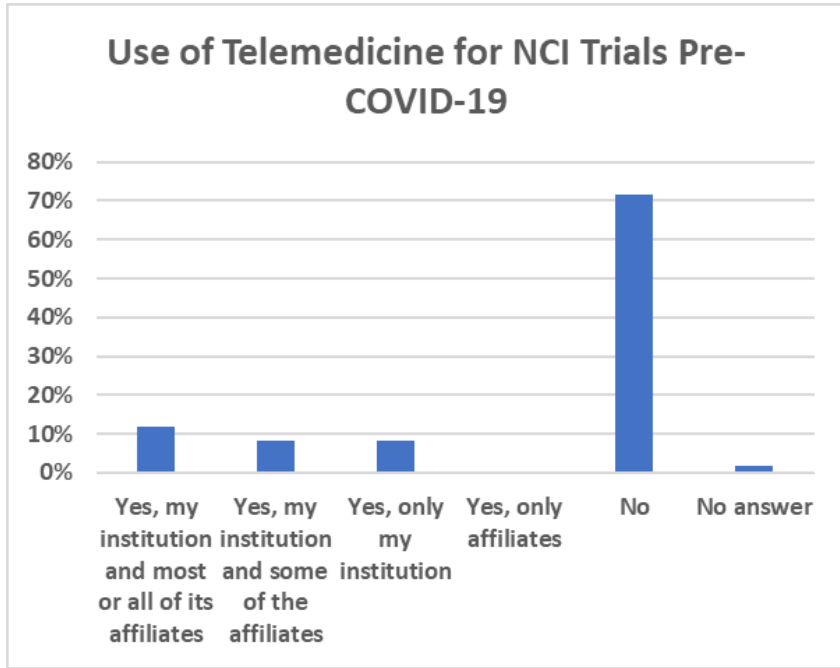
# Telehealth Use in Clinical Trials: Progress

- Conducted NCORP survey on telemedicine use during pandemic and community sentiment about continuation
  - Discussed findings with NCORP Research Bases and Sites
- Presentation and discussion of survey findings today
  - Soliciting CTAC input on specific activities or initiatives that NCI could undertake to facilitate use of telemedicine in NCI-sponsored clinical trials

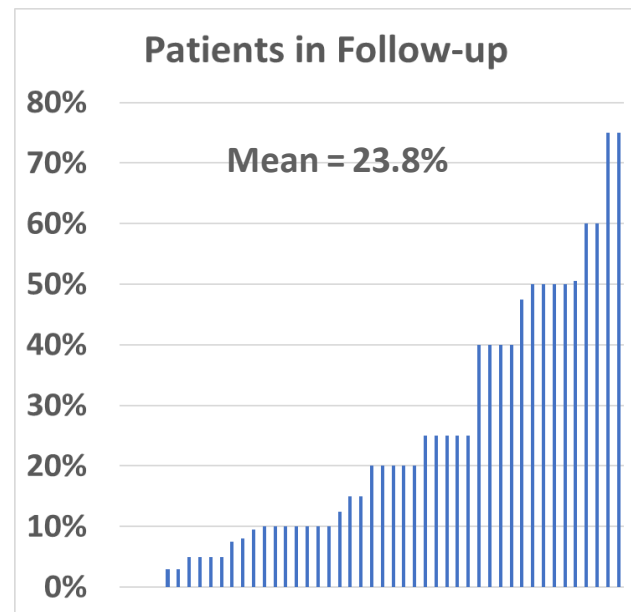
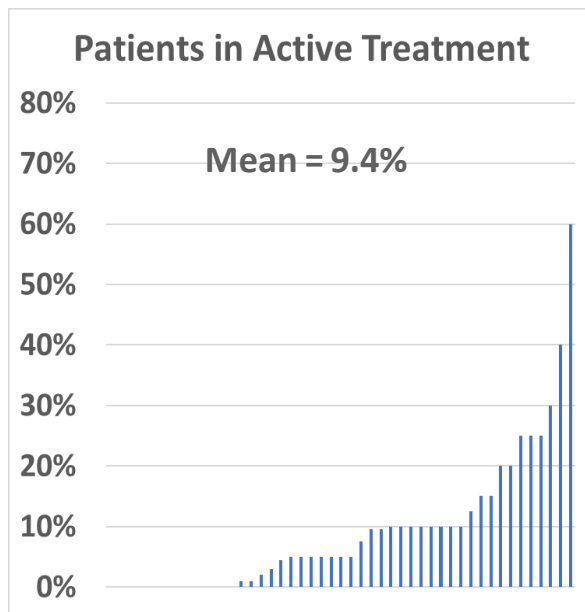
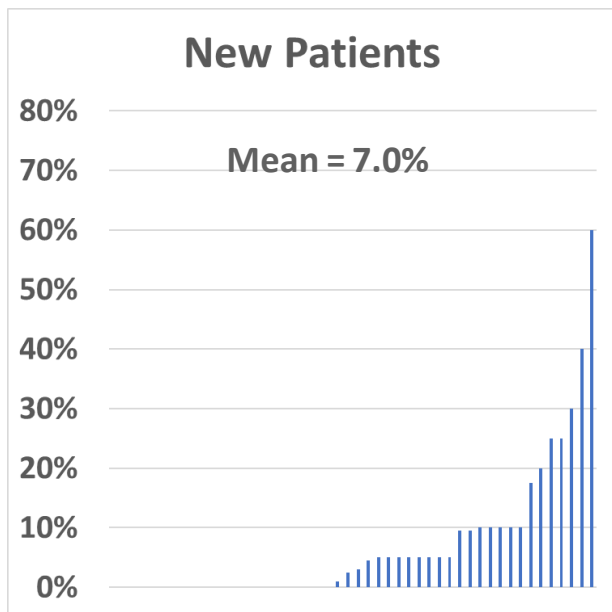
# NCORP Telemedicine Survey

- Administered online July 29 – August 27, 2021
- 61 responses received from 46 NCORPs
- Based on voluntary respondent self-identification, at least 1 response received from at least 44 of the 46 NCORPs
- Some respondents did not answer all questions
  - Reported percentages or mean ratings/rankings for each question calculated based on the non-null responses to that question

# Adoption of Telemedicine for NCI Trials

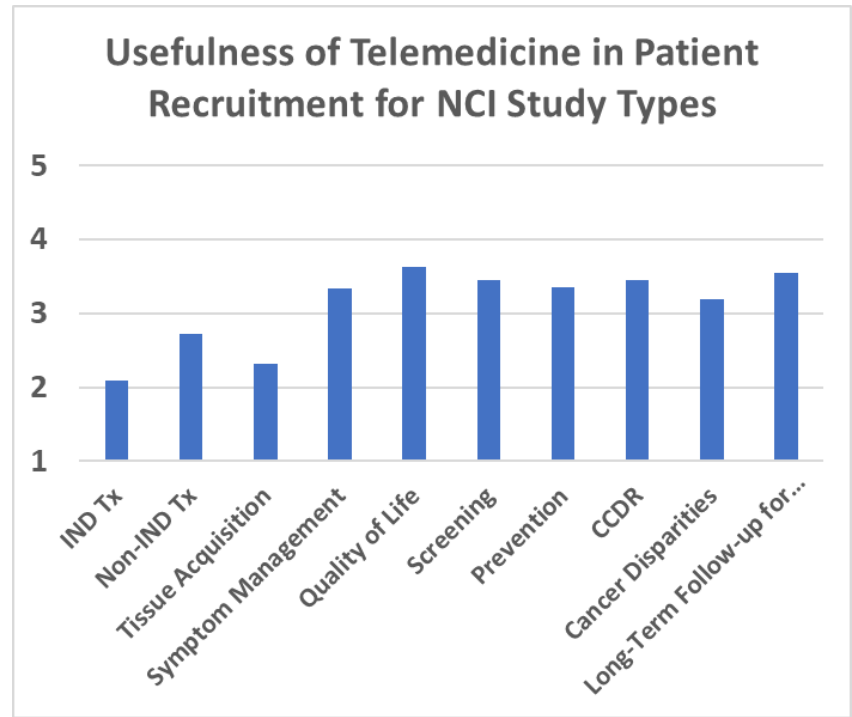
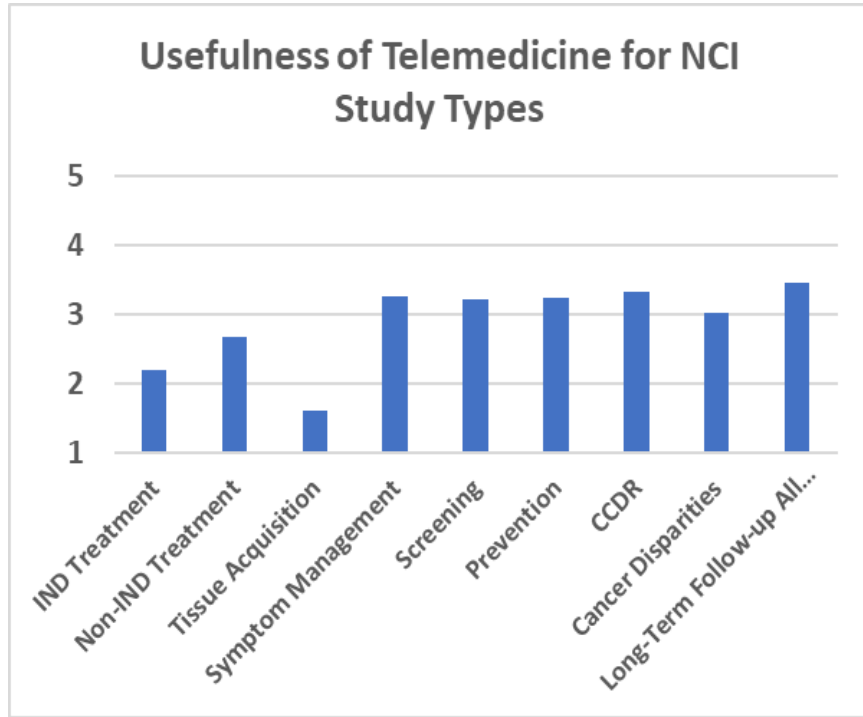


# Telemedicine Use at Different Stages of Trials



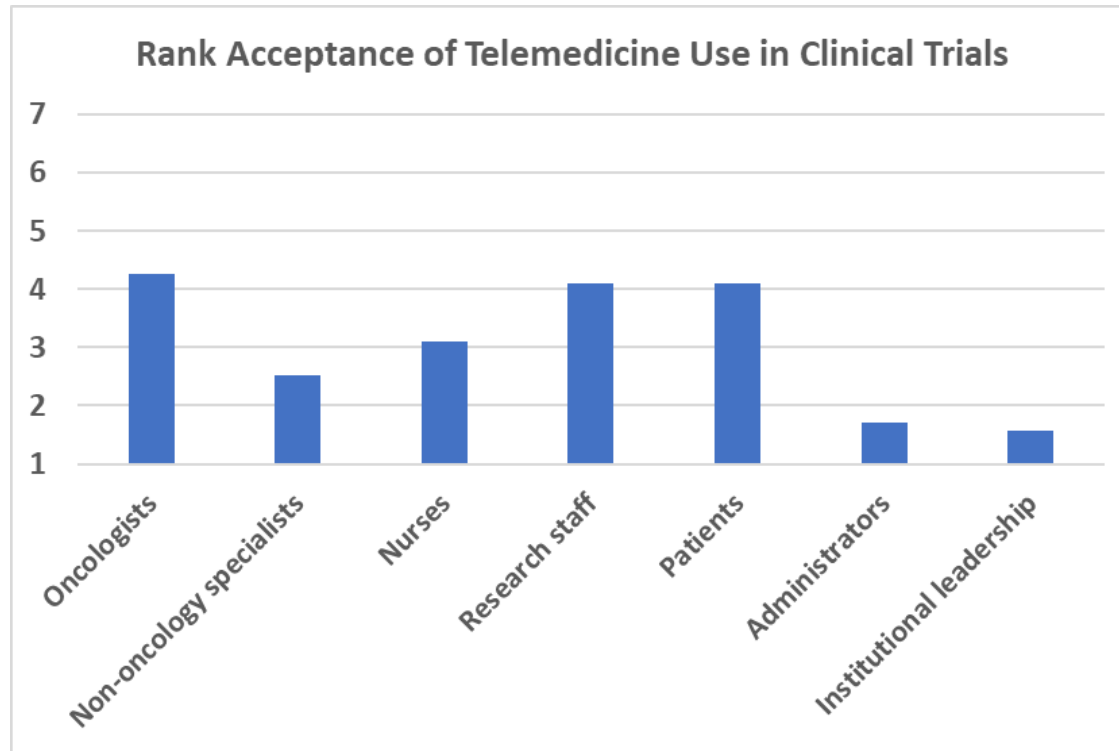
- X-axis is individual sites arranged in order of increasing proportion of patients seen via telemedicine
- Y-axis is percentage of patients seen via telemedicine at the site

# Usefulness of Telemedicine for NCI Trials



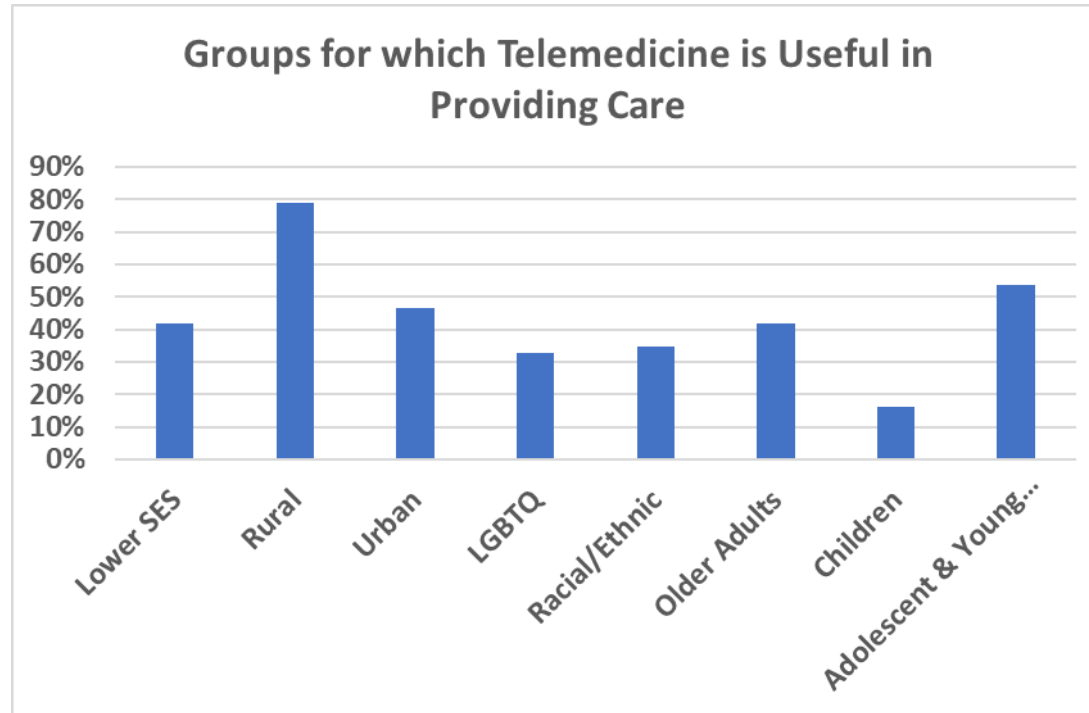
Scale: 5 = Very useful ... 1 = Not at all useful

# Acceptance of Telemedicine Use in Clinical Trials



7 = Most accepting  
1 = Least accepting

# Utility of Telemedicine for Different Patient Groups



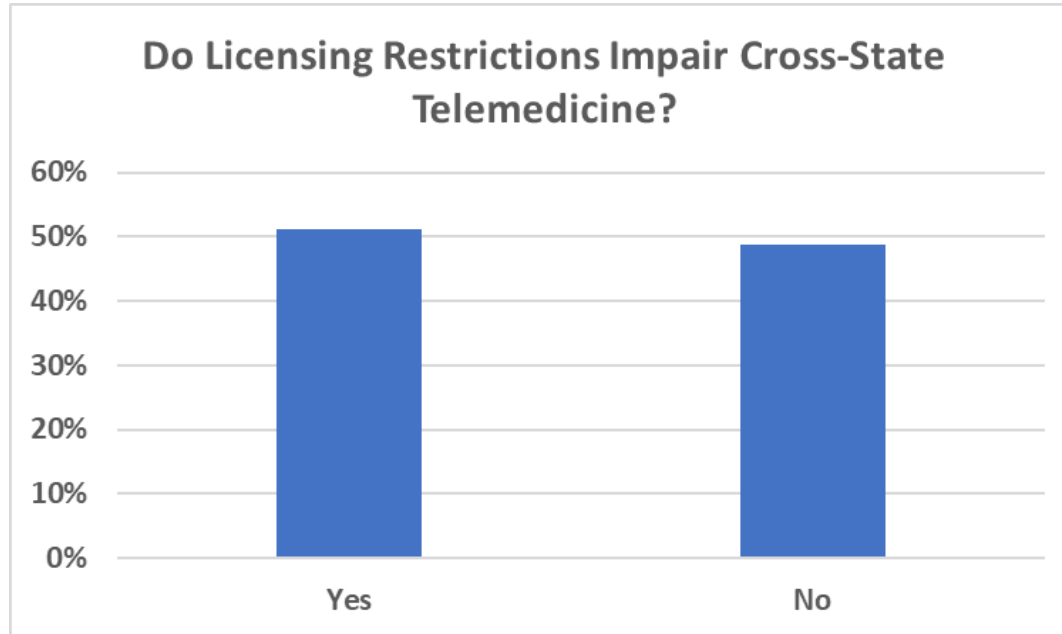
- Y-axis is proportion of respondents who addressed this question who identified the respective patient group as one for which telemedicine is useful
- Response options not mutually-exclusive – multiple choices allowed



# Observations on Telemedicine Impact Volunteered on Open-Ended Survey Questions

- Most commonly-noted benefits of telemedicine
  - Improves trial access – reduces patient visit burden, extends participation to more diverse and/or remotely-situated patients
  - Enables remote screening/consent and more flexible and tailored consent processes
- Three-quarters of respondents noted adverse impacts of telemedicine on “patient/provider component of care”
  - Most common concern was that certain clinical assessments must be done or are more informative in-person
  - Adverse impact on personal relationship between provider and patient also noted

# Impact of Licensing Restrictions



Commenters noted that this is a particular challenge for health systems with catchment areas that cross state lines

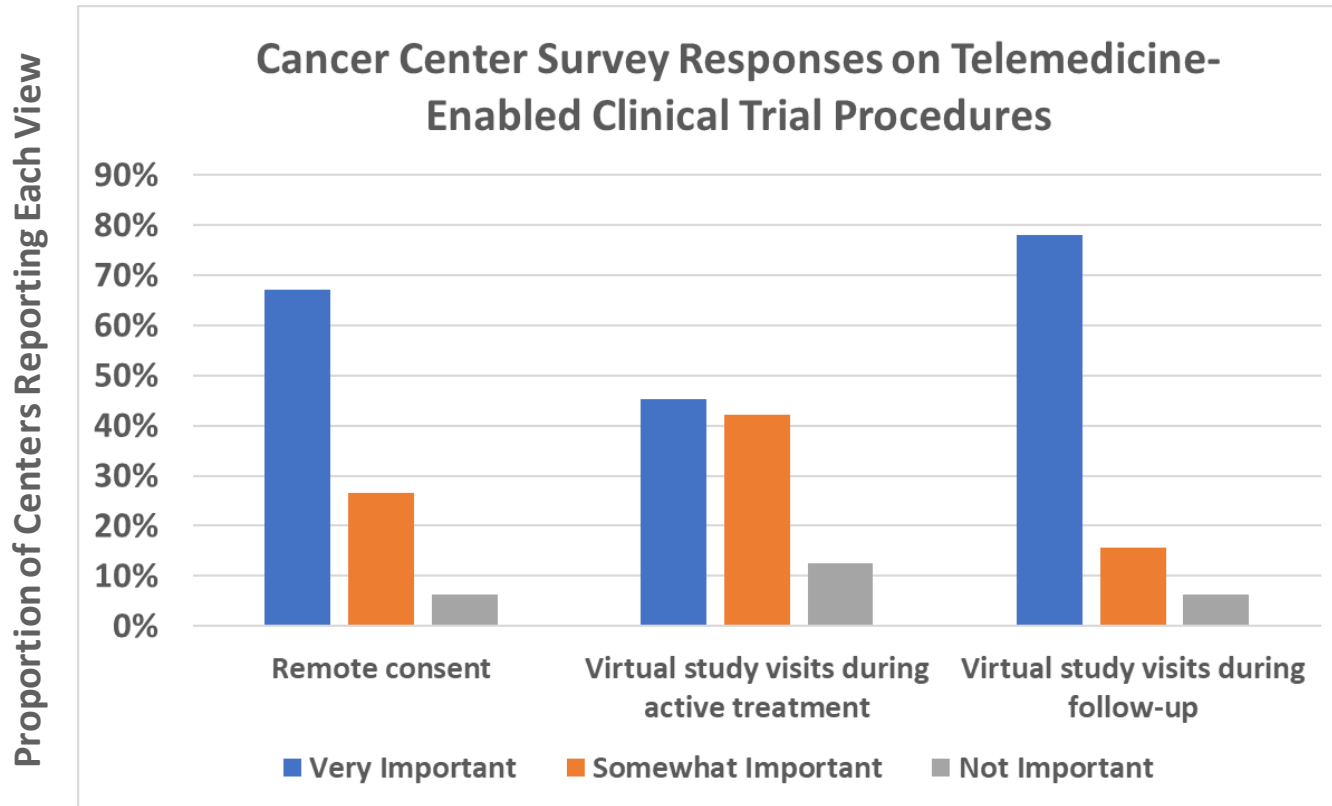
# Reimbursement Changes Needed to Facilitate Telemedicine in the Community Setting

- Most common response
  - Reimbursement at similar level to in-person visits
- Other responses
  - Clarity about reimbursement rates
  - Reimbursement reflecting clinician time and effort
  - Parity of reimbursement rates across different modalities (e.g. video vs telephone)
  - Appropriate level-of-care coding
  - Private insurance industry will follow if Medicare endorses

# Cancer Center Survey Overview

- Open from November 8-26, 2021
- Response rate 100% (64/64 clinical Cancer Centers)

# Cancer Center Survey Responses on Telemedicine-Enabled Clinical Trial Procedures



# Discussion Topics

Based on NCI's survey findings on telemedicine as well as your experiences and observations with telemedicine both before and during the COVID pandemic:

1. What are the obstacles to broader use of telemedicine in NCI-sponsored clinical trials?
2. What are specific activities or initiatives that NCI could undertake to address these obstacles or otherwise facilitate use of telemedicine in NCI-sponsored clinical trials?
3. Should there be controlled empirical studies of the utility of telemedicine procedures for NCI clinical trial conduct?
4. If so, what questions should those studies address?

# Challenges with the Clinical Trial Operations Workforce

# Workforce: Emerging Issues

## Analyze current issues for the oncology clinical trials workforce

### Staff attrition during COVID

- Conducted survey of Cancer Centers concerning the nature and persistence of COVID-era workforce recruitment and retention challenges
- Presentation and discussion of survey findings today
- Soliciting CTAC input on specific activities or initiatives that NCI could undertake to address the recruitment and retention challenges identified

### Demographic characterization of clinical trials leadership for NCI-sponsored trials

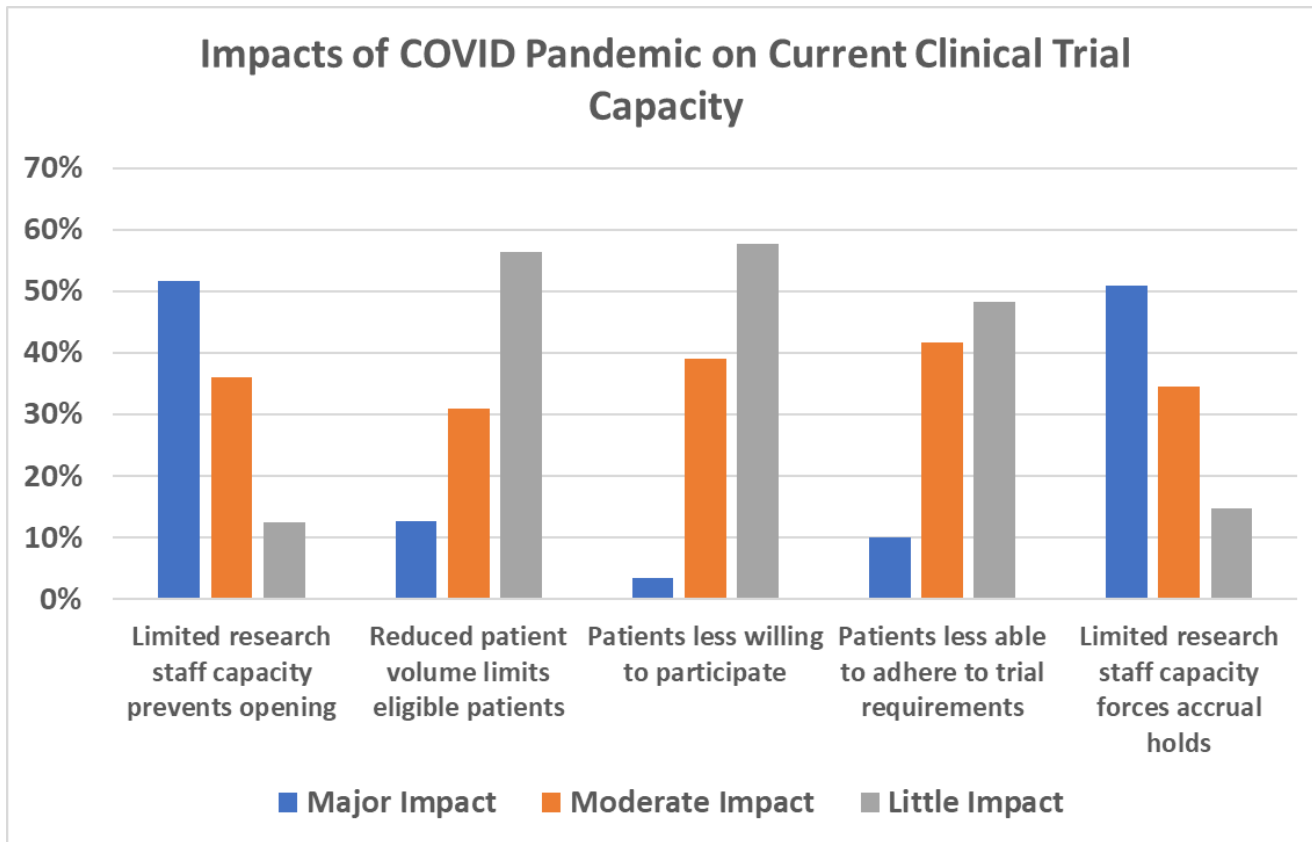
- Plan to collect data to inform efforts to increase clinical trials leadership diversity



# Cancer Center Survey

- Open from November 8-26, 2021
- Administered online
- Response rate 100% (64/64 clinical Cancer Centers)

Proportion of Centers Reporting Each View



Respondent group for this question: all 64 clinical Cancer Centers

# Additional Factors Affecting Cancer Center Clinical Trial Capacity During Pandemic (1)

- Staffing shortages in ancillary clinical services (number of respondents volunteering each item)
  - Pharmacy (1)
  - Pathology (4)
  - Blood (1)
  - Imaging (4)
  - Operating rooms (1)
  - General nursing staff (3)

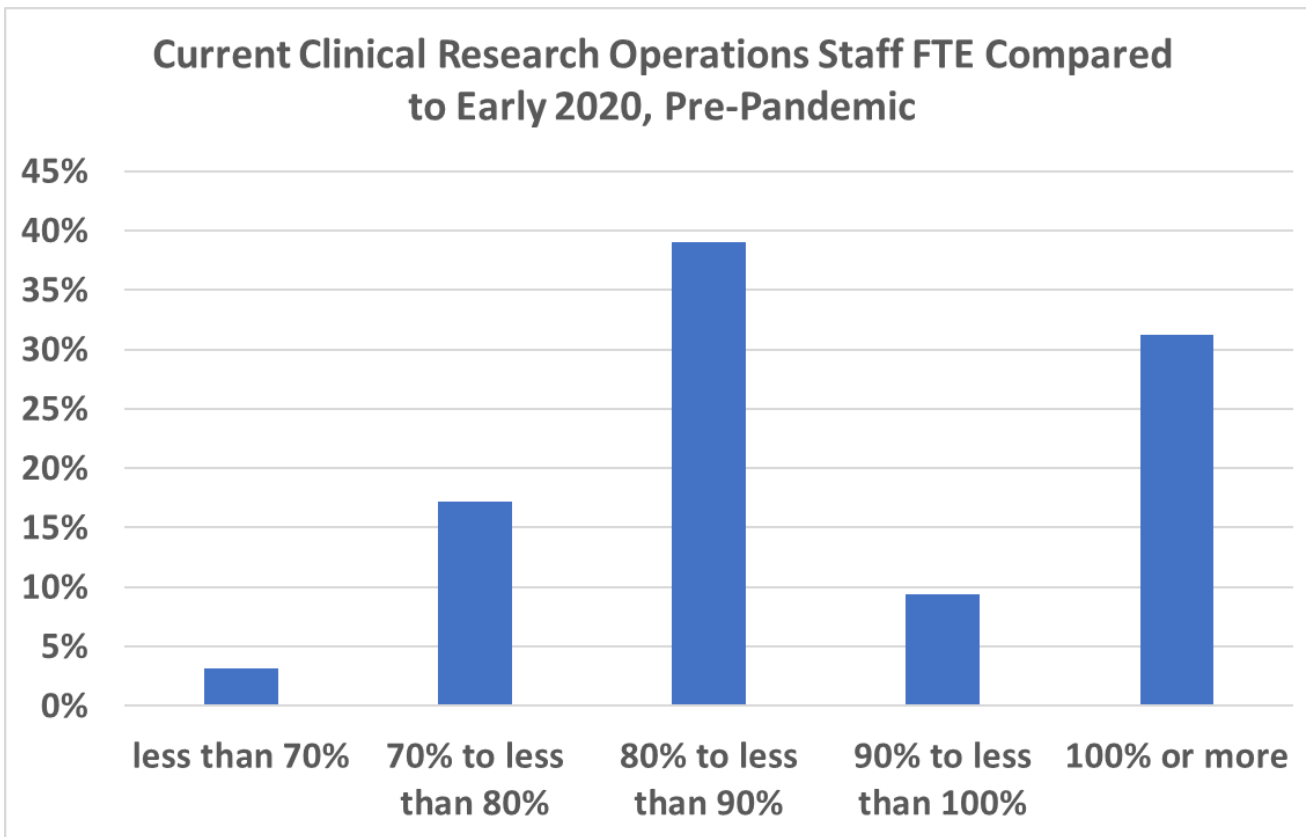
# Additional Factors Affecting Cancer Center Clinical Trial Capacity During Pandemic (2)

- Staffing shortages in university central services (number of respondents volunteering each item)
  - IRB (6)
  - Legal/contracting (7)
  - Coverage analysis (1)
  - HR (1)

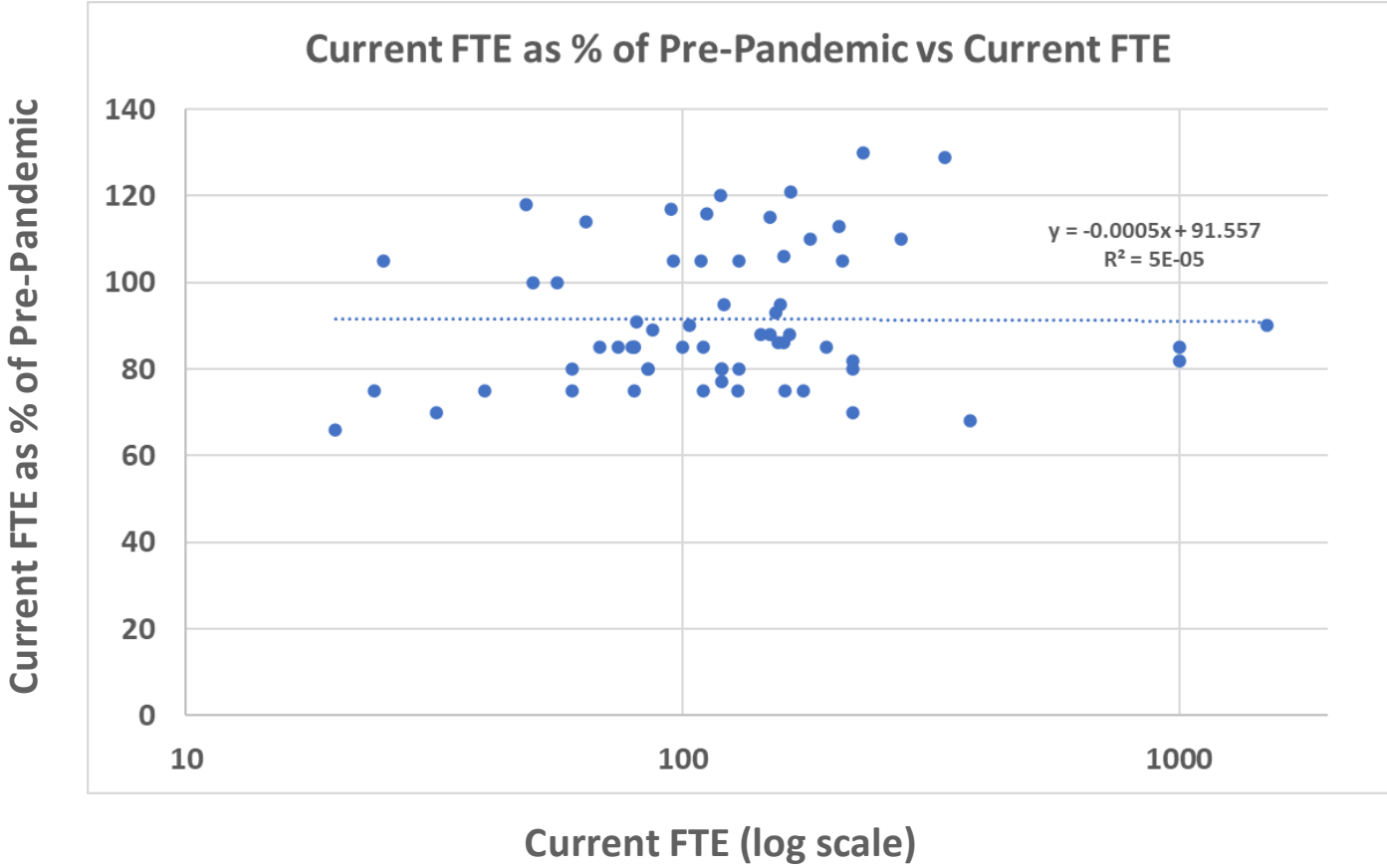
# Additional Factors Affecting Cancer Center Clinical Trial Capacity During Pandemic (3)

- Institutional policies (number of respondents volunteering each item)
  - Limits to number of new trials opened (3)
  - Social distancing requirements (1)
  - Remote work requirements (1)
  - Hiring freezes, new requirements for hiring sign-offs (2)
- State and local government policies (number of respondents volunteering each item)
  - Lockdowns – disproportionate impact on safety-net hospitals / minority accrual (1)

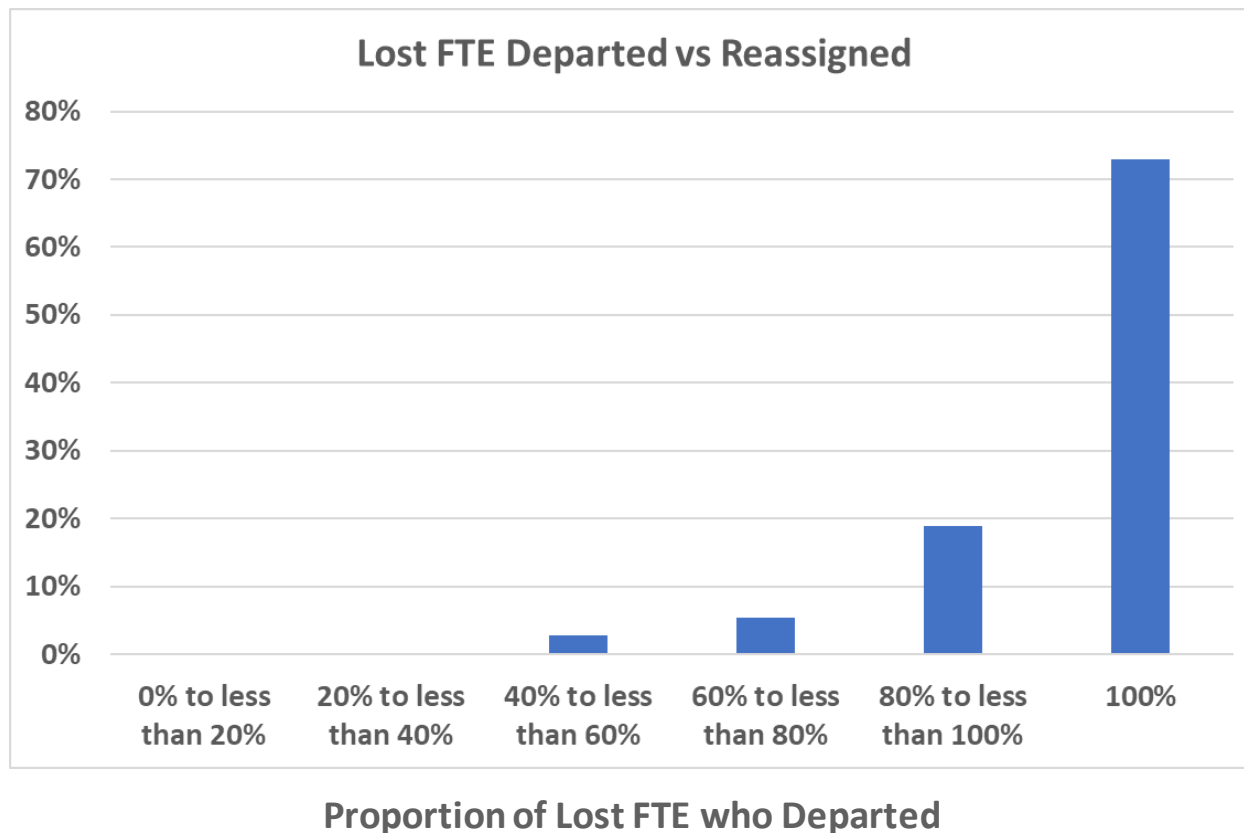
Proportion of Centers Reporting Values Within Each Range



Respondent group for this question: all 64 clinical Cancer Centers



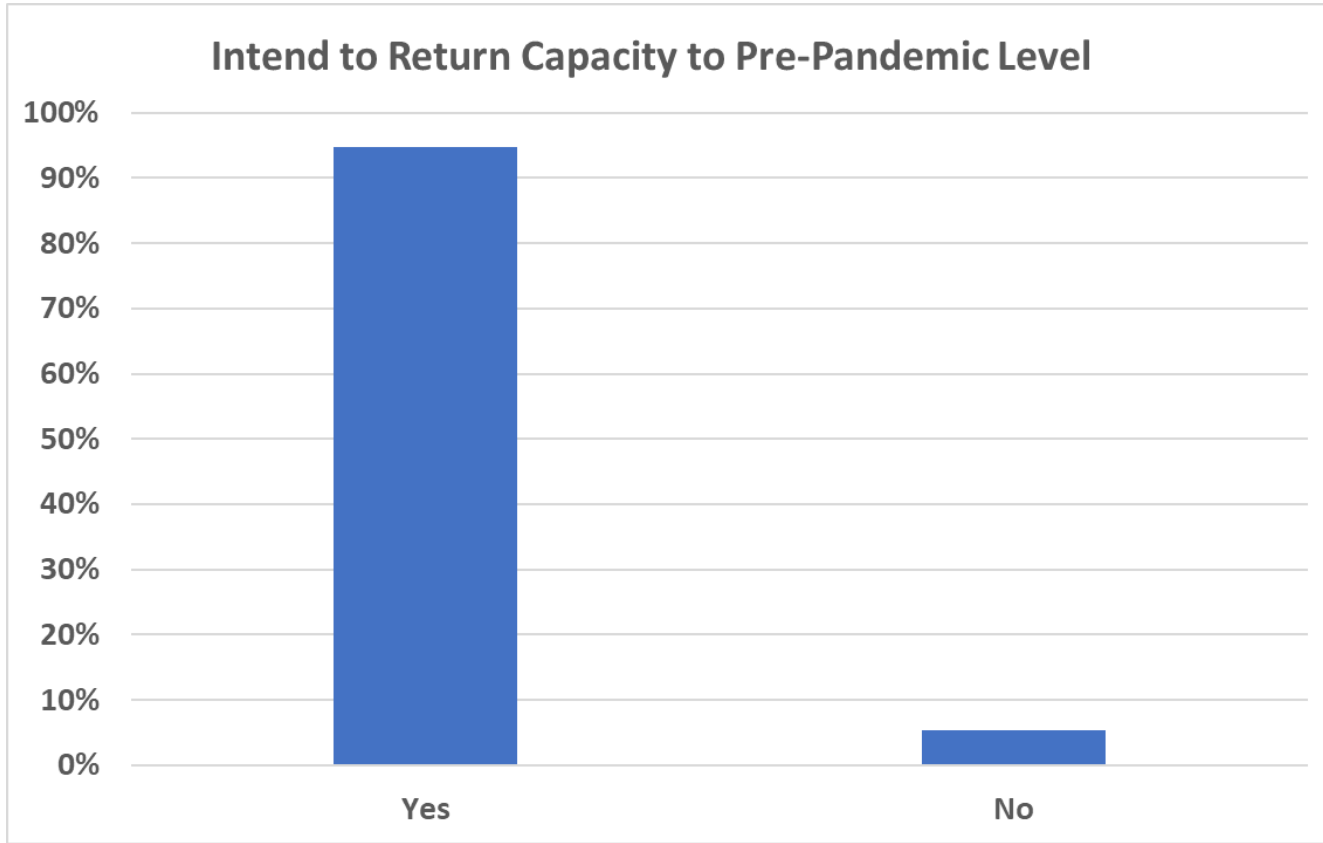
Proportion of Centers Reporting Values Within Each Range



Respondent group for this question: the 38 clinical Cancer Centers that reported <90% pre-pandemic clinical research operations staff FTE

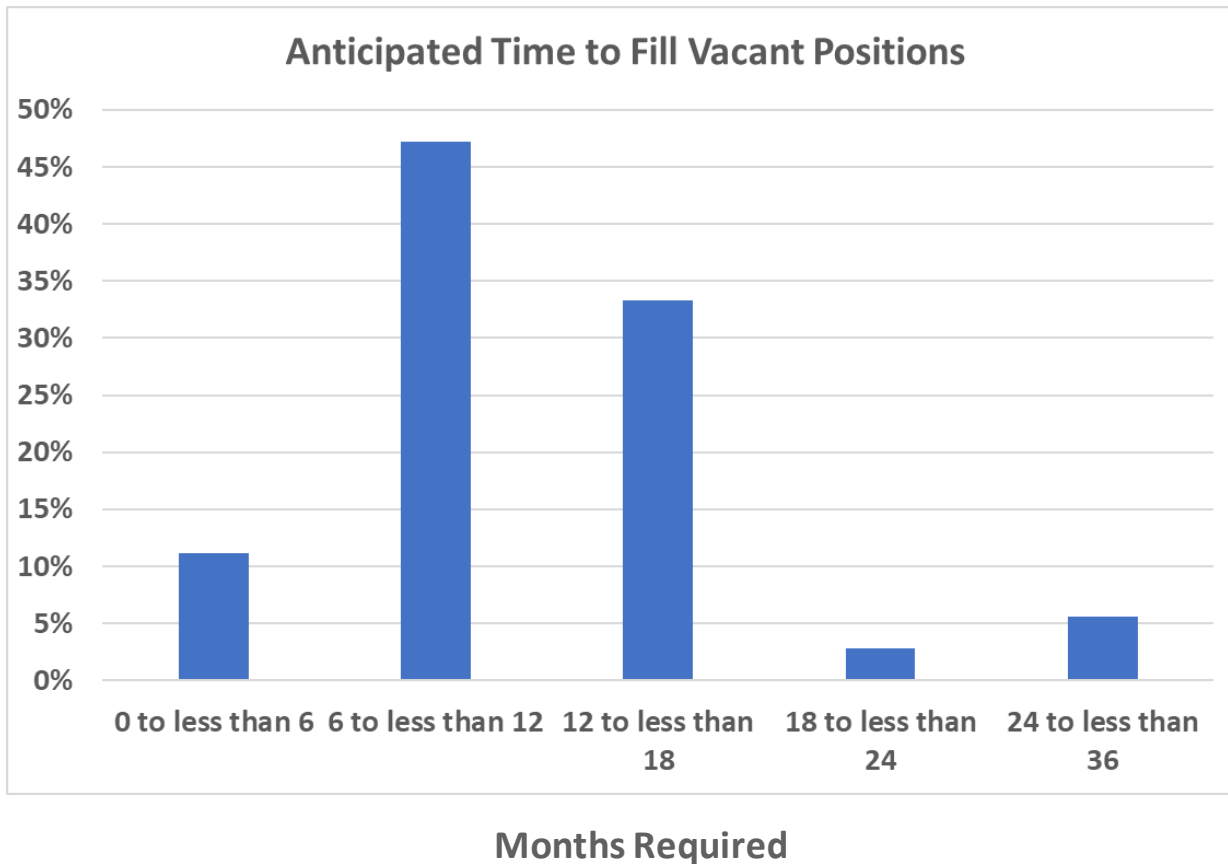


Proportion of Centers Providing Each Response



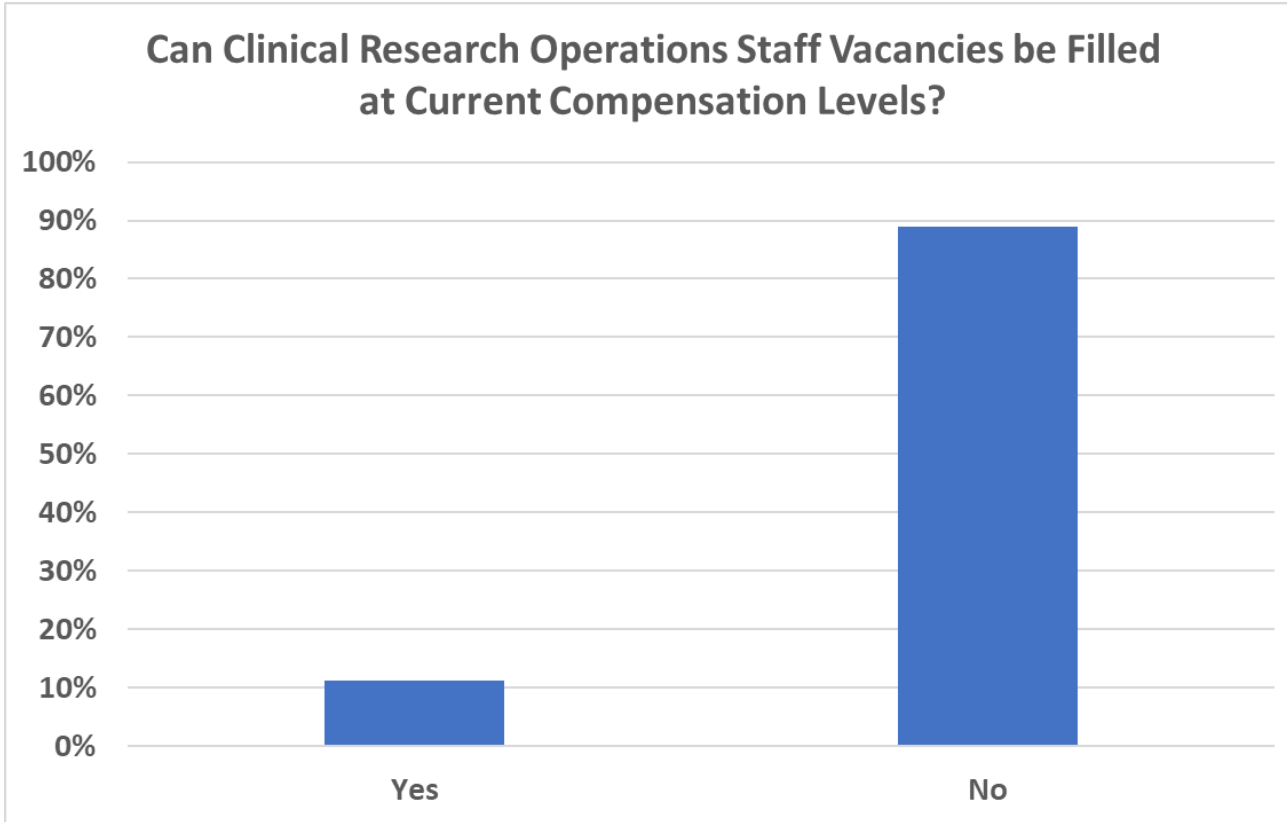
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Proportion of Centers Providing Each Response



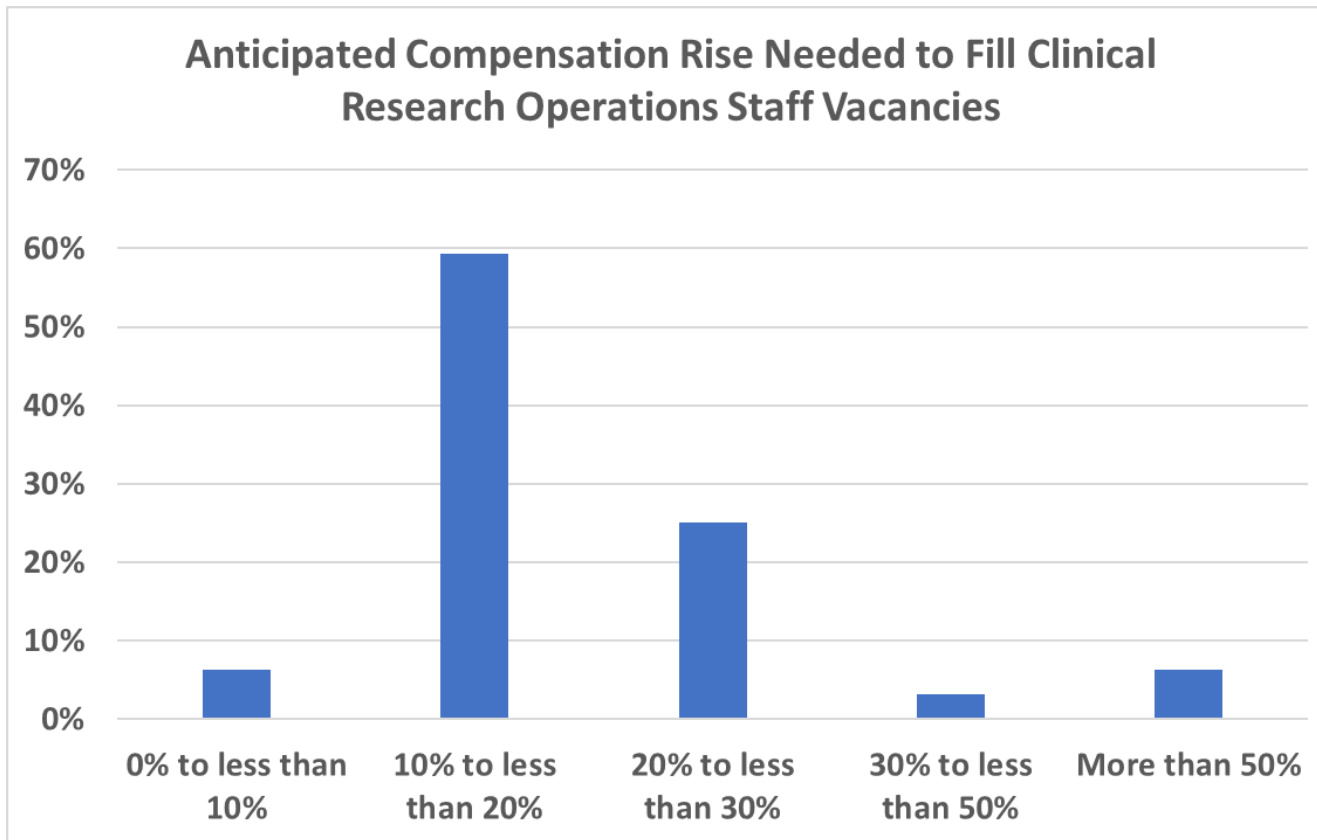
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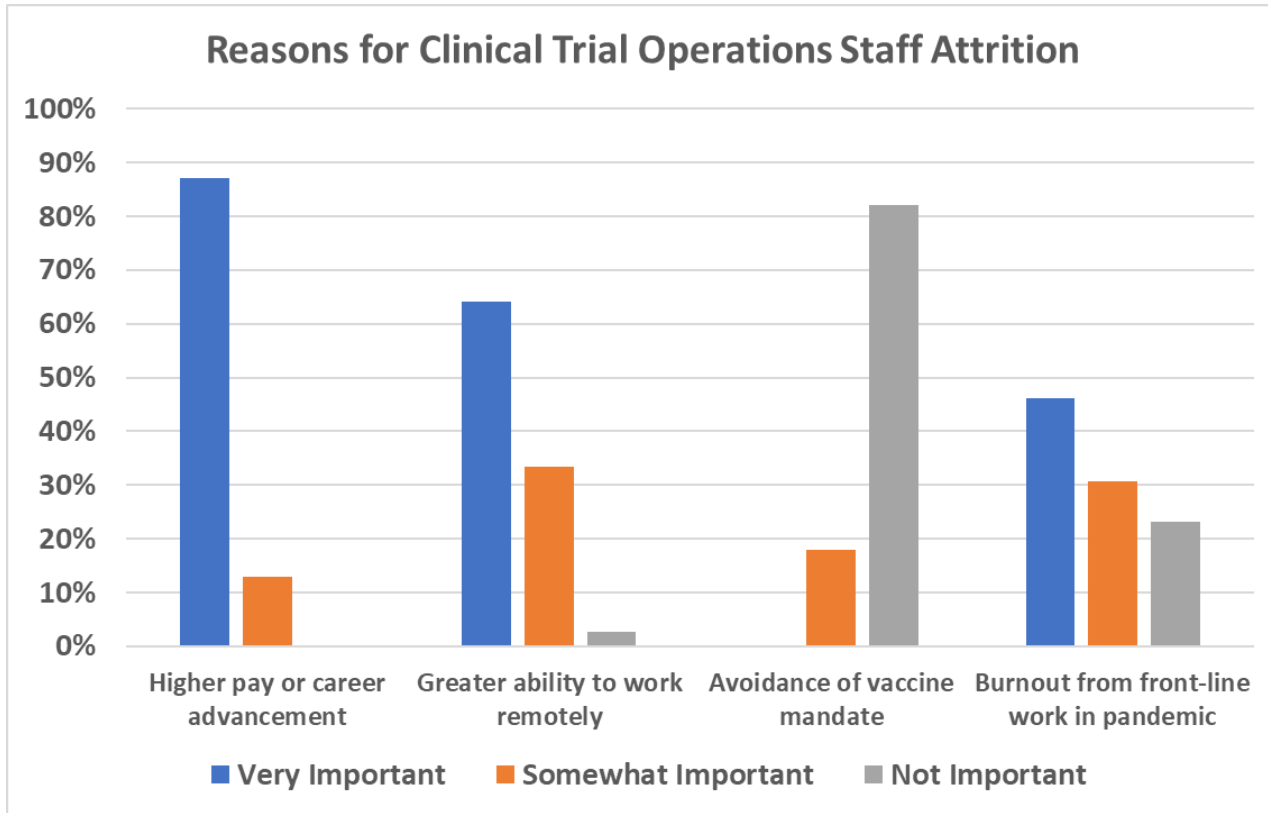
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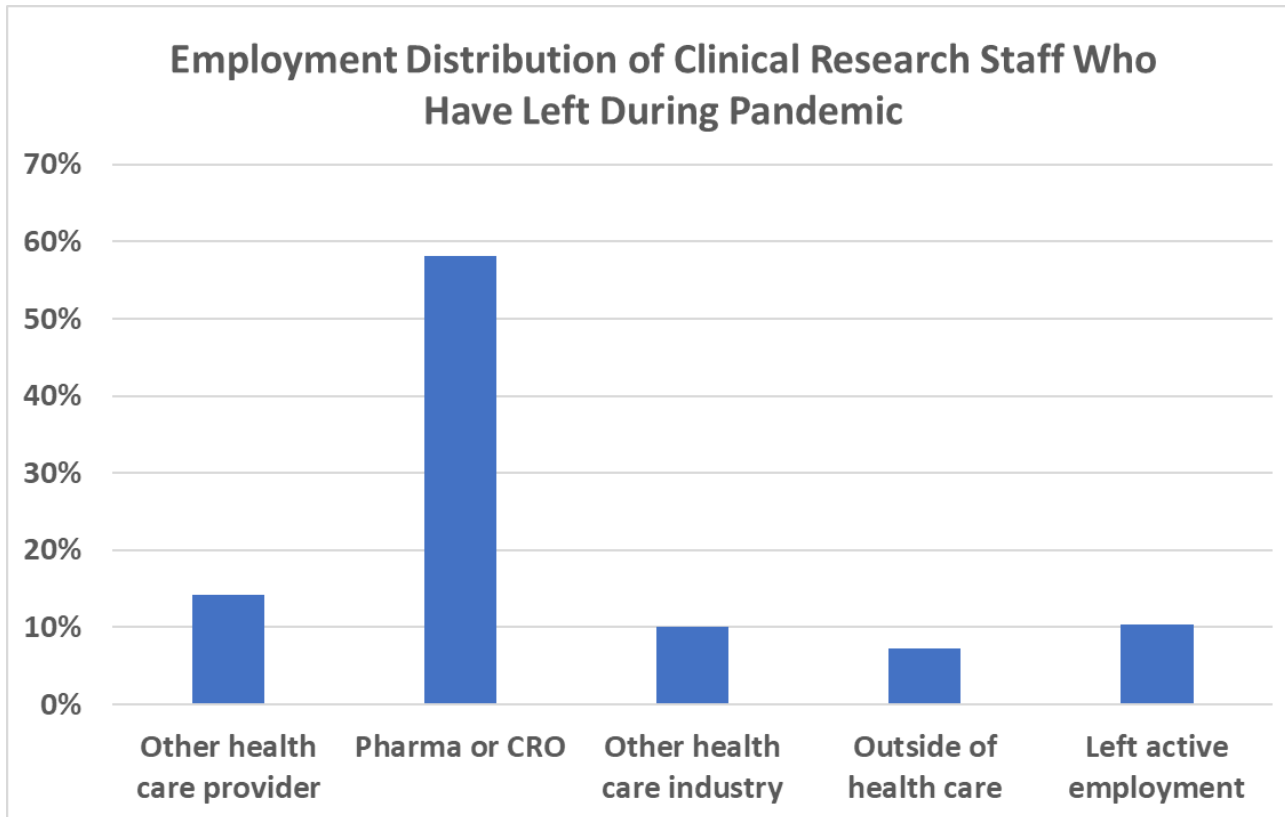


Respondent group for this question: the 38 clinical Cancer Centers that reported <90% pre-pandemic clinical research operations staff FTE

Proportion of Centers Reporting Each View



Respondent group for this question: the 38 clinical Cancer Centers that reported <90% pre-pandemic clinical research operations staff FTE



Respondent group for this question: the 38 clinical Cancer Centers that reported <90% pre-pandemic clinical research operations staff FTE

# Additional Observations on Clinical Research Staff Turnover (1)

- Almost half of the 64 clinical Cancer Centers volunteered substantive comments about the challenges posed by turnover of clinical research staff
- Commenters included 9 out of 20 Centers that have maintained at least 100% of pre-pandemic FTE – need to “run harder” even to maintain status quo
- Reported turnover rates varied widely, with a maximum of almost 50%
- Problem not limited to 2020 – has persisted in 2021

# Additional Observations on Clinical Research Staff Turnover (2)

- Effects of pharma/CRO “poaching”
  - Loss of staff, both senior and recently-trained
  - Smaller pool of qualified candidates for replacement hires
  - Higher compensation spurred by competition from pharma/CRO makes Centers less cost-effective for pharma/CRO work, threatens important income stream



## Discussion Topics

Based on NCI's survey findings on clinical trial workforce challenges as well as your experiences and observations concerning these challenges both before and during the COVID pandemic:

1. What specific actions could NCI take that would help mitigate these challenges?
2. Although retention appears to be the primary issue, would there be any value in expanding clinical trial workforce training to increase the workforce pool?
3. Would operational changes in NCI-sponsored clinical trials to reduce staff workloads help to improve retention?
4. If so, what are examples of changes that would be helpful?