ASCO Clinical Trial Site Survey on the Early Effects of COVID-19 on Clinical Trials

REPORT OF THE FINDINGS

May 12, 2020

This report is a companion to the manuscript: Early Impact of COVID-19 on the Conduct of Oncology Clinical Trials and Long-Term Opportunities for Transformation: Findings From an American Society of Clinical Oncology Survey. David M. Waterhouse, R. Donald Harvey, Patricia Hurley, Laura A. Levit, Edward S. Kim, Heidi D. Klepin, Kathryn Finch Mileham, Grzegorz Nowakowski, Caroline Schenkel, Courtney Davis, Suanna S. Bruinooge, and Richard L. Schilsky. JCO Oncology Practice DOI: 10.1200/OP.20.00275

Citation for this report:

American Society of Clinical Oncology. ASCO Clinical Trial Site Survey on the Early Effects of COVID-19 on Clinical Trials: Report of the Findings. May 2020.

For inquiries, contact researchcommunityforum@asco.org.

ASCO® CENTRA

ASCO® Research Community Forum

Contents

OVERVIEW OF REPORT

The coronavirus disease 2019 (COVID-19) pandemic has disrupted all aspects of oncology clinical care, including clinical trials. In March 2020, the American Society of Clinical Oncology conducted a survey of clinical research programs represented on its Cancer Research Committee and Research Community Forum Steering Group and taskforces. The objective was to learn about the types of changes and challenges experienced early in the COVID-19 pandemic.

This Report details the survey findings and includes summary tables and additional insights from respondents.

A Special Article[1] was published in the JCO Oncology Practice that summarizes the key findings from the survey, provides strategies for modifying the conduct of clinical trials during the pandemic, and identifies several long-term opportunities for transforming trials.

[1] David M. Waterhouse, R. Donald Harvey, Patricia Hurley, Laura A. Levit, Edward S. Kim, Heidi D. Klepin, Kathryn Finch Mileham, Grzegorz Nowakowski, Caroline Schenkel, Courtney Davis, Suanna S. Bruinooge, and Richard L. Schilsky. Early Impact of COVID-19 on the Conduct of Oncology Clinical Trials and Long-term Opportunities for Transformation: Findings from an American Society of Clinical Oncology Survey DOI: 10.1200/ OP.20.00275

SURVEY FINDINGS

SURVEY RESPONDENTS

On March 24, 2020, ASCO launched the survey of clinical programs represented on its Cancer Research Committee and Research Community Forum Steering Group and taskforces to learn about the types of challenges and changes to clinical trials that research programs were experiencing due to the COVID-19 pandemic. The survey was sent to 64 individuals at US-based research programs. There were 46 responses (71.9% response rate), 14 of which were substantially incomplete and excluded from analysis. Data from 32 surveys were included in this analysis. While duplicate responses from a single program are unlikely, survey results were submitted anonymously and thus uniqueness by program cannot be confirmed.

Table 1. Practice/Research Program Type	Frequency n (%)
Academic Research Center	14 (43.75)
Non-Academic Practice, Hospital, Health System, or Research Network	18 (56.25)
Non-Academic Research Network	*7 (21.87)*
Community Health System	*5 (15.62)*
Non-Academic Practice (with Academic-Affiliation)	*2 (6.25)*
Community Hospital	*2 (6.25)*
Non-Academic Practice	*2 (3.12)*

N=32

Table 2. Type of National Cancer Institute (NCI)-Funded Research Program	Frequency n (%)
Not Applicable	11 (34.38)
NCI-Designated Cancer Center	13 (40.63)
NCI Community Oncology Research Program Site/Research Base	9 (28.13)
NCI National Clinical Trial Network Group/Member/Institution/Practice	8 (25.00)

N=32

Table 3. Respondent Role at Site	Frequency n (%)
Research Director, Administrator, or Manager (Clinical and Non-Clinical)	15 (46.88)
Physician Investigator or Medical Director	14 (43.75)
Research Staff (Clinical and Non-Clinical)	3 (9.38)

N=32

Table 4. Institution Policy Specific to COVID-19 and Clinical Trials	Frequency n (%)
Yes, formal policy in place	20 (64.52)
No formal policy	11 (35.48)
N=31	

Institution COVID-19 Policies

Respondents elaborated on their institution policies in response to COVID-19, which were categorized into the following themes:

- Halting, limiting, and/or prioritizing screening and enrollment for new clinical trials
- Halting, limiting, and/or prioritizing screening and enrollment for ongoing clinical trials
- Preventing patient exposure to COVID-19
    - Telehealth where possible
    - Remote consenting
    - Patient review and report of symptoms and adverse events through patient portal, email, phone, video
    - Shipment of oral drugs directly to patients
    - Local lab testing
- Restricting outside visitors
    - No sponsor, contract research organization (CRO), monitor, vendor in person visits
    - Remote visits permitted for monitoring and site trial initiation
- Restricting staff exposure to COVID-19
    - Staff working remotely except for study visits that are not possible through telehealth
    - Staff travel prohibited

SITE CHANGES AND CHALLENGES SINCE COVID-19 OUTBREAK

Table 5. Changes to Conduct of Clinical Trials at Site Since COVID-19 Outbreak

Changes Made	Frequency n (%)
Remote patient reported review of symptoms (e.g., through patient portal, email, phone)	29 (90.62)
Initiated telehealth visits for participants, where possible	28 (87.50)
Research staff mandated to work remotely	24 (75.00)
Remote monitoring by sponsors and/or CROs	23 (71.87)
Remote site initiation visits	21 (65.62)
Ceased research-only visits except those providing cancer treatment	19 (59.37)
Halted screening and/or enrollment for non-therapeutic trials	19 (59.37)
Prioritized enrollment for certain clinical trials (e.g., certain agents, easier schedules, shorter infusions, fewer pharmacokinetic testing, safety profiles)	17 (53.12)
Ceased research-only blood and/or tissue collections	16 (50.00)
Physician investigators taking on new and/or additional clinical responsibilities	13 (40.62)
Research staff taking on new and/or additional clinical responsibilities	12 (37.50)
Implemented remote safety lab collections	11 (34.37)
Halted screening and/or enrollment for all clinical trials	8 (25.00)
Ceased opening any new clinical trials	8 (25.00)
Other*	6 (18.75)

N=31; *included staffing strategies to reduce exposure (schedule rotations, reduced patient encounters, redeployment)

Table 6. Changes Initiated to Conduct of Clinical Trials at Site Since COVID-19 Outbreak

Changes Made	Change Initiated By*		
	Site n (%)	Industry or CRO n (%)	Federal Sponsor n (%)
Remote patient reported review of symptoms	27 (93.10)	8 (27.59)	8 (27.59)
Initiated telehealth visits for participants, where possible	24 (85.71)	6 (21.43)	6 (21.43)
Research staff mandated to work remotely	22 (91.67)	4 (16.67)	4 (16.67)
Remote monitoring by sponsors and/or CROs	18 (78.26)	8 (34.78)	4 (17.39)
Remote site initiation visits	18 (85.71)	7 (33.33)	3 (14.29)
Ceased research-only visits except those providing treatment	16 (84.21)	5 (26.32)	4 (21.05)
Halted screening and/or enrollment for non-therapeutic trials	14 (73.68)	6 (31.58)	7 (36.84)
Prioritized enrollment for certain clinical trials	14 (82.35)	4 (23.53)	4 (23.53)
Ceased research-only blood and/or tissue collections	13 (81.25)	5 (31.25)	5 (31.25)
Physicians taking on new/additional responsibilities	12 (92.31)	1 (7.69)	3 (23.08)
Research staff taking on new/additional responsibilities	10 (83.33)	1 (8.33)	3 (25.00)
Implemented remote safety lab collections	7 (63.64)	3 (27.27)	3 (27.27)
Halted screening and/or enrollment for all clinical trials	5 (62.50)	5 (62.50)	3 (37.50)
Ceased opening any new clinical trials	5 (62.50)	4 (50.00)	4 (50.00)

*Respondents could choose more than 1; N=31

Table 7. Greatest Challenges for Conducting Clinical Trials Since Outbreak	Frequency n (%)
Decrease in patient ability/willingness to come to site	17 (54.84)
Time spent organizing/conducting telehealth visits	17 (54.84)
Time spent in discussion with sponsors/Institutional Review Boards (IRBs) about modifying trial procedures	16 (51.61)
Limited other ancillary services available (radiology, surgery, cardiology, ophthalmology, dermatology, etc.)	16 (51.61)
Reduction in available staff	14 (45.16)
Protocol compliance	12 (38.71)
Delays in scheduling/providing routine services	12 (38.71)
Time spent screening patients for COVID-19 symptoms prior to scheduled appointments	11 (35.48)
Decrease in patient interest/willingness to enroll	6 (19.35)
Limited supplies available	6 (19.35)
Limited laboratories available	5 (16.13)
Other*	5 (16.13)
Decrease in eligible patients	4 (12.90)
Reduction in available physician investigators	3 (9.68)

N=31

*Other responses were categorized into the following themes:

- Concerns about financial burden that “downtime” will place on organization
- Struggles with remote monitoring with staff working remotely
- Insufficient technology for essential job functions for staff who normally do not work from home
- Limited drug and other study supplies
- Inconsistent prioritization of research by some physicians and/or staff
- Staff anxiety

STRATEGIES FOR SITES DURING THE COVID-19 PANDEMIC

Respondents shared the following strategies for trial sites to adapt during the COVID-19 pandemic.

- Ensure Open Communication
  - Keep participants informed about changes to trials and their care and remind participants to alert their research team about changes to their health
  - Organize daily staff "huddles", videoconferencing, and/or email to provide updates and discuss operational challenges and patient management
  - Communicate any changes or concerns about existing trials to IRBs
- Implement Formal COVID-19 Standard Operating Procedures
  - Develop and execute formal COVID-19 standard operating procedures (SOPs) for clinical trials that could be
    - Develop frequently asked questions (FAQs) to provide to monitors and sponsors
    - SOPs can be repurposed with other disease outbreaks
  - Establish a system for prioritizing clinical trial resource allocation (e.g., determine which trials to maintain screening and enrollment)
  - Ensure thorough documentation of changes to procedures and modifications to or deviations from protocols, and use a "COVID-19" tag to facilitate searching after the pandemic
- Simplify and Leverage Technology
  - Use e-signatures for informed consent and other study documents
  - Promote telehealth visits for patients
  - Implement patient review of symptoms and adverse events (e.g., through patient portal, email, phone, video)
  - Require remote study initiation visits and monitoring from trial sponsors and CROs
  - Use remote safety lab collections, where feasible
  - Ship oral drugs directly to patients

OPPORTUNITIES TO IMPROVE CLINICAL TRIALS ENTERPRISE POST COVID-19

Table 8. Opportunities to Improve Clinical Trials	Frequency n (%)
Telehealth visits for participants	28 (90.32)
Remote patient reported review of symptoms	24 (77.42)
Remote site initiation visits	22 (70.97)
Remote monitoring by sponsors/CROs	20 (64.52)
Remote safety lab collections	14 (45.16)
Other*	9 (29.03)

*Other responses were categorized into the following themes:

- "Smarter trials"
  - Remote consenting
  - Remote adverse event assessments
  - Less collection of "unnecessary" data
  - Modifications to procedures (e.g., drug distribution and shipments, altered documentation for transportation receipts, specimen management)
- Teleworking at least part time will address facility space limitations and provides potential increase in job satisfaction and staff retention
- Improved IRB communications and responses
- Prioritization of trials in various stages including long term follow-up

ACKNOWLEDGEMENTS

The authors thank the ASCO Cancer Research Committee members and Research Community Forum Steering Group and taskforce members who completed the survey. These individuals provided invaluable insights into the current impact of COVID-19 on the conduct of cancer clinical trials during a very challenging time.