Managing Clinical and Translational Research During COVID-19

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INTERNATIONAL ASSOCIATION FOR THE STUDY OF LUNG CANCER Conquering Thoracic Cancers Worldwide

Managing Clinical and Translational Research During COVID-19

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Housekeeping Notes

- An email will be sent after the meeting with instructions on how to claim CME credit
- Please submit all questions through the Zoom Q and A function at the bottom of the screen
 - > You can use the chat for other discussions
 - > We will NOT be using the raise hands function
- Staff will track your questions and share them during the live Q&A at the end of the session

Disclosures



- Antoinette Wozniak, MD, FACP, FASCO discloses she is a consultant for Regeneron, Epizyme, Lilly, Bristol Meyer Squibb, Novocure and GlaxoSmithKline and on a DSMB for Odonate, HUYA and BeyondSpring.
- Jyoti Patel, MD, FASCO discloses she is a consultant for AbbVie, AstraZeneca and Takeda.
- > M. Catherine Pietanza, MD discloses she has ownership/stock interest in Merck and Co, Inc. and is also an employee of Merck and Co, Inc.
- > Buerkley Rose, MSN, RN, HPE has no financial relationships to disclose.
- Amy C. Moore, PhD discloses she is on an advisory board for Guardant and receives grant support from Genentech and Bristol Meyers Squibb.
- Christian Rolfo, MD, PhD, MBA, Dr.hc. discloses he is on an advisory board for Mylan and Oncompass, receives honorarium from MSD and GuardantHealth and has research grants from OncoDNA, Biomark and GuardantHealth.

All relevant financial relationships have been mitigated.

Managing Clinical Research During the COVID Pandemic

Antoinette J. Wozniak, MD, FACP, FASCO Associate Director for Clinical Research

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UPMC HILLMAN CANCER CENTER

- NCI-Designated Comprehensive Cancer Center
- Hub and satellites encompassing 200 mi (320 km) around Pittsburgh
- 350 faculty members, 180 affiliated Oncologists
- 'State of the Art' cancer care
- 36,000 pts per year
- Over 200 Clinical Research staff
- Nearly 500 active clinical trials
- 2000 accruals to interventional trials with >1000 accruals to therapeutic trials per year



UPMC Clinical Trial Accruals in 2020





Stratifying and Managing Risk during the Pandemic



UPM

CANCER CENTER

Tier 1 – Studies with High Direct Benefit to Research Participants or High Public Health Priority:

Tier 1 Studies provide the potential for direct benefit to participants (e.g., therapeutic clinical intervention trials); may lead to serious or immediate harm to research participants if stopped (e.g., some investigational drug or vaccine trials with safety assessments); or investigate diseases with high public health impact (e.g., COVID-19 research).

Examples: All Oncology treatment trials

INSIGNA : A Randomized, Phase III Study of Firstline Immunotherapy Alone or in Combination With Chemotherapy in Induction/Maintenance or Postprogression in Advanced Nonsquamous Non-Small Cell Lung Cancer (NSCLC) With Immunobiomarker SIGNature-Driven Analysis (SWOG / NCI)



Stratifying and Managing Risk during the Pandemic

Tier 2 – Studies with Moderate Direct Benefit

Protocols that, if stopped, may pose a risk to research participants (e.g., studies in which a research intervention and clinical care are interrelated); studies in high risk diseases where delays in clinical discovery can adversely impact patient outcomes or slow critical advances for a field of medicine.

Example:

A randomized non-inferiority trial evaluating the length of treatment with PD-1/PDL1 inhibitors in patients with advanced solid tumors (Wozniak, Hillman Investigator Initiated Trial)





Stratifying and Managing Risk during the Pandemic

Tier 3 – Low Direct Benefit

Studies such as cohort and natural history studies where delays in data collection have limited impact

Example:

Outcome and QOL collection of patients receiving External beam radiochemotherapy and MRI based adaptive BRAchytherapy in locally advanced CErvical cancer (BRACE)



CTEP and FDA guidance



NCI Cancer Therapy Evaluation Program (CTEP) and FDA have provided various accommodations to promote patient and staff safety but still allow continuation of clinical trials.

- Visit schedules (delaying, telemedicine)
- Lab and imaging (delaying, continuing on study despite missing some of these tests/images)
- Treatment delays at the discretion of responsible investigator
- Biospecimen collection delays, alterations in processing are allowed
- Protocol amendments or CAPA are not necessary if major deviations are due to public health emergency
- Remote monitoring in lieu of on-site monitoring
- Remote consent during COVID is not a major deviation

Clinical and Research Staff Safety

- Reduced onsite staffing (flex schedules)
- Provided IT resources to support work from home (WFH)
- Alternate parking arrangements and shuttles for those who no longer want to take the bus

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- Management is available on-site on a rotational schedule (2-3 days WFH)
- Non-nursing staff are on-site on rotating basis and for few hours a day
- All regulatory staff worked from home
- Maintained tracking of 'at risk employees' through management huddle*
- Increased testing based on CDC guidelines through Employee Health*

Patient Safety

- Converted all non-essential visits to virtual visits (telemedicine)
- Staff screening and PPE during visits
- Stopped all visitors (patients only in clinical areas)
- Pre-visit calls for COVID screening
- COVID screening and thermal scanners at the entrance
- Social distancing in waiting rooms





Adapting to the Pandemic



- Prioritization of clinical trials
- Stopped all on-site monitoring
- Implemented new remote monitoring agreements and EMR remote access
- Adjusting staffing and managing new consents based on local guidelines
- Telemedicine as necessary
- Protocol Review committees and Data Safety Monitoring committee business as usual via ZOOM/TEAMS meetings



The 'FUTURE': Research in post pandemic world

- Remote EMR access and monitoring as a standard
 - Standard in protocol contracts
- eConsent for Tier-2 and Tier-3 trials
- Remote data collection
- Clinical trial prioritization
- Writing clinical trials that are less restrictive and "can work" during a pandemic/emergency
- Standard Operating Procedures that protect staff and patients

BE PREPARED!

IPMO

Managing Research During COVID: Translational Focus

Jyoti D. Patel, MD FASCO

Professor of Medicine Assoc Vice Chair of Clinical Research, Dept of Medicine

Northwestern University, Feinberg School of Medicine Lurie Cancer Center Chicago, IL



Clinical Research Impact from the Pandemic



3 Key Questions for Investigators



What can we do as a research community to address the COVID-19 pandemic and impact on cancer care and delivery?



What should we do with the ongoing research that millions of people are participating in currently?



How can we learn from this crisis to be better the next time (e.g. learning health system)?

What should we do with the ongoing research that millions of people are participating in currently?

What happens here?



Total Number of Trials

Millions of individuals answering important questions



Benefits and Risks

Providing access for patients to protocols when alternatives don't exist

Limiting risk

To potential participants To research staff Propagating community exposure



Essential: High/Moderate potential direct benefit to research participants

Non-Essential: Primarily observational, behavioral studies without potential direct benefit

These trials can benefit thousands of individuals with disease even after the current pandemic



Collateral Damage

Disruption of All Biomedical Research



Research Guidance

- Compliant and congruent with university, city, and state policies
- PIs are ultimately responsible—space, personnel (2-3/500 sf)





Salaries & Stipends

If unable to work on grant or training activities, salaries and stipends may be charged to NIH grants

Ensure that your organization's policy allows such charges from federal and non-federal funds

Prior approval is not required to divert faculty from research to clinical work related to COVID-19 until the end of the public health emergency period.

Learn more: <u>NOT-OD-20-086</u> FAQs: <u>grants.nih.gov/faqs#/covid-19.htm</u>



Accommodations for Loss of Research Time

Extensions for early stage investigator eligibility due to COVID-19-related disruptions will be considered NIH will be flexible with extending time constraints for fellowship, career development, and training awards, including phased awards

FAQs: grants.nih.gov/faqs#/covid-19.htm



Transformation of Clinical Research



Decentralized Patient Centered Collaborative Agile—follows the best science The best, most innovative care



Industry Perspective

M. Catherine Pietanza, MD

Associate Vice President of Clinical Research Sub-Section Head of Thoracic Malignancies

> Merck & Co, Inc. Kenilworth, New Jersey, USA





Moving Forward with Research during the COVID-19 Pandemic

- Continue enrollment on clinical trials
- Ensure supply chain of investigational agents
- Allow for implementation of trial procedures through alternative methods if necessary
 - Imaging off-site (investigators to provide guidance on image acquisition as per protocol)
 - Laboratory assessments at different facilities (investigators to provide support and oversight)
 - Telemedicine visits (in compliance with local regulations and site processes)
 - Home health visits (e.g. home infusion of study intervention)
 - Shipment of oral investigational products (dependent on country regulations)
- Encourage investigators to maintain study conduct
 - Investigators to assess risks and benefits of continuing participants in trials, and utilize best practices as issues arise
 - Refer physicians to guidance drafted by FDA, EMA and organizations such as ASCO
- Reinforce safety monitoring as per standard AE/SAE reporting

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Impact of COVID-19 on Ongoing Trials

- Enrollment of participants to studies has slowed from original projections
- Patients have developed COVID-19 infections (Grade 1 to Grade 5 events)
 - Investigators encouraged to evaluate risks and benefits of continuing, interrupting or discontinuing study intervention
- Treatment delays and interruptions, as well as delays in assessments, due to travel restrictions, site closures and/or COVID-19 infections
 - Encourage use of windows allowed in trial, as well as ongoing discussions with Sponsors
- Deviations from protocol specified procedures (e.g. safety assessments, imaging, study visits)
 - Documentation of all COVID-19 related protocol deviations using prefix "COVID-19"
- Monitoring of sites has continued, occasionally variable due to regional outbreaks of infection
 - Remote monitoring performed in accordance with local laws, when adequately discussed with sites and with oversight from managers

Moving Forward in the Midst of the COVID-19 Pandemic



- Processes in place for COVID-19 reporting of infections, severity of disease, study interruptions/discontinuations, and deviations
 - Statistical guidance available for treatment lapses and deaths due to COVID-19
 - FDA and EMA guidance in place to assist
- In instances where patients discontinued from study intervention, every effort should be made to keep patients on trial and followed for key safety and efficacy endpoints
- As new trials are being planned, trial procedures and study intervention closely considered as the COVID-19 pandemic continues

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Clinical Trials During COVID-19: A Nursing Perspective

Buerkley Rose MSN, RN, HPE

Oncology Nurse Navigator Department of Medicine, Section of Hematology/Oncology The University of Chicago Medicine & Biological Sciences Member, Board of Directors, Mesothelioma Applied Research Foundation





Oncology Nursing During COVID-19

- > Nurses are the largest health care professional group providing front-line care
 - > Globally, 20.7 million out of 43.5 million health care workers are nurses
- > Nurses' role and contribution is more relevant than ever before:
 - > The cornerstone of health services in the front-line setting
 - In leadership and education, developing and implementing new policies on standards of care
- Cancer patients have 3.5 times higher risk of severe COVID-19 disease than other patient groups
 - This creates pressure on healthcare systems to meet demands of the pandemic while addressing the needs of the oncology patient population

Patterson et al., Semin Oncol Nursing, 2020

COVID-19: Oncology Nursing Challenges



- > Adapting to new information and frequently changing regulations
- > Need to reallocate resources (human and budget)
- Cancellation or postponement of non-curative chemotherapy and elective surgeries
- Challenges obtaining and communicating while wearing personal protective equipment (PPE)
- > Social distancing requirements result in fewer staff helping on site
- > Need to communicate via telehealth instead of in person
- > Visitor restrictions result in less family support for patients
- Psychological impact of social isolation on patients requires enhanced supportive care resources

Patterson et al., 2020

Impact of the COVID-19 pandemic on clinical trials and participation in research



- Clinical trials are key to improving the management and developing potential cures for multiple malignancies
- Drug, device, and biological product trials immediately impacted by the pandemic
- > Many potential barriers:
 - > Facility closures, quarantines, and travel restrictions
 - > Patient and staff concerns about infection

Patterson et al., 2020



Clinical Trials Nursing During COVID-19

- Communication with principal investigators, study sponsors, regulatory staff, research coordinators/data management on new processes and workflow
- Prioritizing necessary clinical trial safety monitoring of patients and integrating COVID-19 protocols
- Overcoming barriers for screening and enrollment and creating new logistical workflows when many staff work remotely
- > Utilizing telehealth for toxicity management
- Working with study sponsors on adjusting protocol requirements, and allowing shipment of oral investigational drugs
- Practicing diligent nursing documentation via telehealth for optimal data collection and monitoring

Caring for Patients on Clinical Trials During COVID-19



- Communicating with patients on new policies and procedures such as masking, social distancing requirements while on campus
- Educating patients on safe masking, hand hygiene, and social distancing practices to prevent COVID-19
- Monitoring patients for any potential symptoms of COVID-19 and advising testing when appropriate
- Utilizing telehealth resources to accommodate patient safety and allow for appropriate monitoring of patients on trial
- > Enhancing telehealth nursing skills
- > Educating patients on telehealth and resources
- Building on already established relationships within the oncology community to help accommodate patients

References



 Paterson C, et al. Oncology Nursing During a Pandemic: Critical Reflections in the Context of COVID-19. Semin Oncol Nurs.
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Amy C. Moore, PhD Director of Science & Research GO2 Foundation for Lung Cancer



Lung cancer patient advocacy groups in the US have IASLC come together to address the needs of the community



Empower Everyone. Ignore No One.









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COVID-19 Advocacy Timeline



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Top patient needs and concerns reflect the complexity of the pandemic



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Evolution of patient concerns over time

First wave of the pandemic

- General info about the virus
- Risks of everyday activities / how to stay safe
- Fears of triage*

Post-Shelter in Place

- Navigating cancer care
- Fears of exposure when visiting medical facilities
- Logistics of care transportation

Winter surge/Pandemic Year Two

- Old fears (triage) resurface
- Vaccinations risks/benefits, safety, timing, should I get one?
- Long-term implications for patients with cancer
- How long will "normal life" be on hold?





Age:

- <60 concerned about impacts on research/care
- >60 concerned with still being able to access their provider; technology challenges

Geography:

- Living in a COVID hotspot vs not living in a COVID hotspot
- Urban vs rural, access to care facilities
- Digital divide is real

Patient-specific factors:

- Diagnosis
- Stage
- Tx (chemo vs IO vs targeted therapy)



Call to prioritize patients with cancer for vaccination against COVID-19





Inside information on cancer research and drug development

publication date: Jan. 8, 2021

Cancer groups urge CDC to prioritize cancer patients for COVID-19 vaccination

By Matthew Bin Han Ong











GOOD SCIENCE BETTER MEDICINE BEST PRACTICE



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Thank you!

