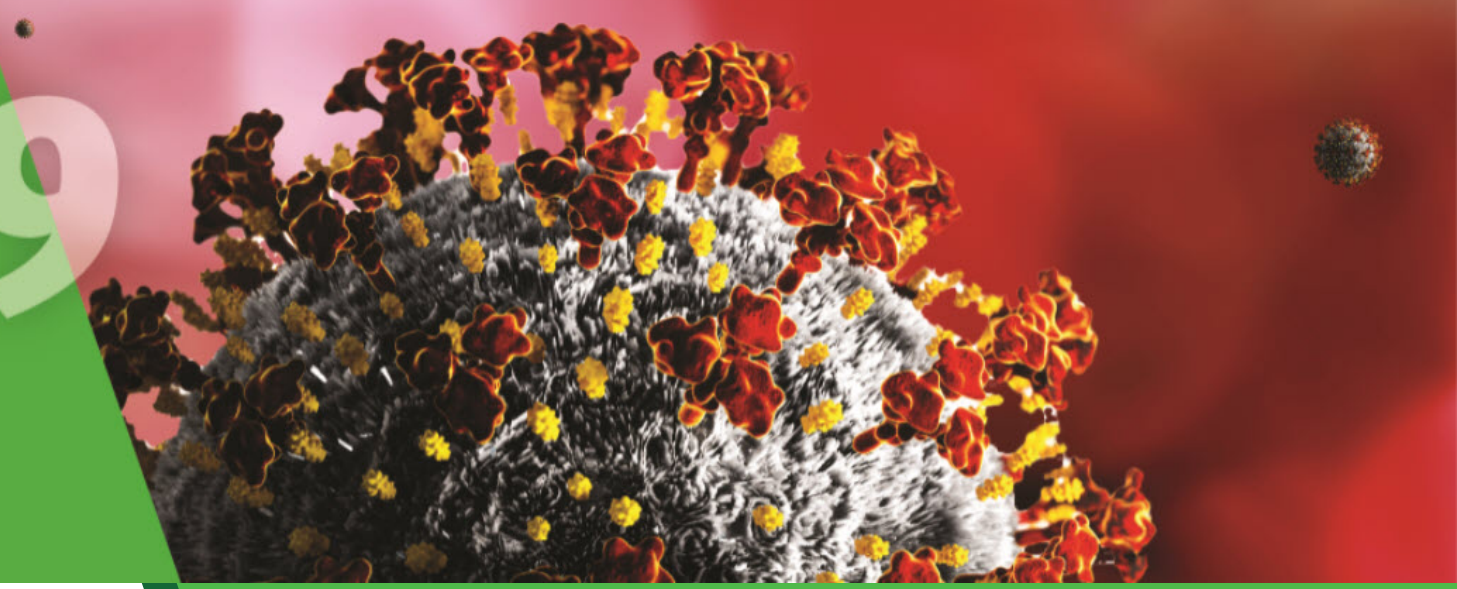
COVID-19

SPECIAL EDITION
PANDEMIC RESPONSE



Clinical Trials in the Era of COVID-19

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The session will begin at 2:00 ET

June 17, 2020

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Clinical Trials in the Time of COVID-19

June 17, 2020

Agenda

- Introduction on Current State of Clinical Trials During the Pandemic
- Current Regulatory Accommodations for Clinical Trials
- Regulatory Considerations for Initiating a Clinical Trial Related to COVID-19
- Practical Legal and Regulatory Considerations for Sponsors and Sites
- Perspectives on Clinical Trials in 2021 and Beyond
- Discussion and Q&A

Introduction on Current State of Clinical Trials During the Pandemic

Review of Regulatory Accommodations for Clinical Trials

FDA Guidance for Clinical Trials During the Pandemic

- Key points from the guidance:
  1. Assess new risks to subjects and the study itself in light of circumstances, including
     - the type of investigational product,
     - ability to conduct safety monitoring,
     - supply chain,
     - nature of the subjects' condition
  2. Develop appropriate measures that mitigate risks to subjects
  3. Document all deviations and mitigations!
     - In some cases, prior consultation with FDA is necessary

FDA Guidance for Clinical Trials During the Pandemic

- The Q&A appendix at the end of the guidance provides more detailed information on acceptable mitigations that comply with FDA regulations
  - FDA regularly updates the Q&A based on major issues and inquiries sent to Clinicaltrialconduct-COVID19@fda.hhs.gov
- Major topics include:
  - Performing remote "clinic visits" or site monitoring
  - Conducting clinical outcome assessments remotely
  - Options for obtaining informed consent
  - Shipping investigational products to HCPs
  - Using alternative laboratories or imaging centers
- FDA has made its COVID MyStudies app available as an option for obtaining informed consent electronically

FDA Policy on Remote Monitoring Devices Support Expanded Use of Telehealth

- Applies to specifically named devices, which may be connected to a wireless network to transmit data to HCPs:
  - *E.g.*, Clinical electronic thermometer, ECG, cardiac monitor, pulse oximeter, non-invasive blood pressure meters, respiratory rate monitors
- FDA states that it does not intend to bring enforcement action for limited modifications to such devices, such as:
  - Including claims or functionality relating to monitoring of COVID-19 patients
  - Changing indication to include home use
  - Hardware or software changes to increase remote monitoring capabilities

Any modifications must not create "undue risk" to patients!

Other Federal Agency Accommodations

- Federal agencies modified policies to blunt the impact of COVID-19 on clinical trial sponsors, sites, and human subjects:
  - OHRP issued guidance relating to the Common Rule and is directing researchers and sponsors to FDA resources
  - CTEP & NCORP issued interim guidance for patients in clinical trials
  - OCR relaxed enforcement of HIPAA Privacy Rule requirements for teleconferencing platforms
- All interim polices emphasize that patient safety is the primary consideration when implementing any mitigation relating to COVID-19

Accommodations for NIH Grants and the Common Rule

- The Office of Human Research Protections (OHRP) is offering flexibility to researchers and encouraging a "safety first" approach
- Per OHRP's April 8, 2020 Guidance on COVID-19:
  - "the research community is encouraged to prioritize public health and safety"
  - "OHRP will take into account the specific circumstances that institutions and investigators are experiencing, and use available flexibility in its decision making"
  - "investigators may implement changes to approved research prior to IRB review and approval if the changes are necessary to eliminate apparent, immediate hazards to subjects"
    - Note that such deviations for participant safety are already permitted under the Common Rule

Accommodations for NIH Grants and the Common Rule

- On March 12, NIH published a Notice announcing flexibility for applicants and recipients of federal funding. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html
  - "NIH will be doing our part to help you continue your research"
- On March 16, NIH published guidance for NIH-funded clinical trials affected by COVID-19
  - "Recipients will likely encounter delays to ongoing research based on the effects of COVID-19. … recipients may submit late financial and progress reports, if research is delayed due to COVID-19, and may carryover unobligated balances on active grants without requesting prior approval."
- NIH COVID-19 resources page: https://grants.nih.gov/policy/natural-disasters/corona-virus.htm
- OLAW has published information for institutional animal care and use programs coping with the pandemic: https://olaw.nih.gov/covid-19.htm

Considerations for Initiating a Clinical Trial Related to COVID-19

Considerations for Sponsors

- While many non-COVID clinical trials have paused, the number of clinical trials studying COVID-19 and possible treatments continue to grow:
  - Clinicaltrials.gov shows **2,200+ COVID-related trials**
  - WIRB-Copernicus Group reports there are **1,700+ clinical trials underway worldwide for potential COVID-19 treatments and vaccines**
- There are massive populations of patients who could benefit from investigational COVID-19 treatments or vaccines
- Consider subject risks and safety issues beforehand:
  - Informed consent process
  - Logistics of administering an investigational product
  - Conducting safety assessments
  - Study monitoring process

Considerations for Sites

- Considerations for taking on clinical trial responsibilities revolve around ensuring the safety of patients and HCPs
  - Benefits and risks of investigational product
  - Status of institution's IRB
  - Subject assessment and safety monitoring
  - Institution and investigator capacity to perform clinical trial
  - Protecting investigators
- Implement policies and procedures for engaging in and conducting new clinical trials
  - Make sure that the sponsor accepts safety procedures and that the protocol is compatible with them

Overview of Legal and Regulatory Considerations for Sponsors and Sites

Legal and Regulatory Considerations for Sponsors

- Sponsors should continue to:
  - Assess ongoing trials and determine (1) potential/actual risks and (2) necessary mitigations
  - Engage with sites and CROs to prevent exercise of early termination rights
  - Consider suspension as an option to termination
  - Establish and assess procedures for protecting study subjects and adjusting trial processes to account for COVID-19 disruptions
  - Determine whether usable data can still be collected
  - Document COVID-related disruption to your study, contingency measures, how human subject participation was affected and – most importantly – measures that have been taken to keep participants safe

Legal and Regulatory Considerations for Sites

- Sites should continue to:
  - Communicate with sponsors/CROs and responsible IRBs to discuss COVID-19 impacts on a trial and necessary deviations or modifications
  - Discuss all protocol and process changes with study subjects and make sure to obtain informed consent for any modifications requiring new or revised consent
  - Evaluate any alternatives that are implemented
  - Assess actual risks to study subjects and research personnel and consider terminating, if necessary

Perspectives on Clinical Trials in 2021 and Beyond

Discussion and Q&A

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THANK YOU!

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For ongoing coverage, visit Mintz's COVID-19 Insight Center at:
https://www.mintz.com/insights-center/coronavirus