



# Clinical Trials Amid COVID-19

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# Webcast Outline

- ACCC Clinical Trials Focus
- COVID-19 Impact
- Clinical Trials Responses



# Community Oncology Can Close the Gap in Cancer Research: Here's How

- Imbalance between patients needing trials in communities and trials that do not meet accrual goals
- Address challenges that programs face in providing clinical trial access
- Draw on member experience
- Provide new resources



# ACCC Support for Members Addressing Unmet Oncology Needs in Our Communities

- Care and access for traditionally underserved people
- Awareness and understanding of special considerations and needs in geriatric oncology
- Need for molecular diagnostics expertise that guides precision medicine
- New models of care that address value, efficiency, and workforce resources



# COVID-19 Impact on Healthcare Operations

- Decreased access to services for patients
- COVID-19 exposure is a risk that changes or overwhelms every paradigm
- Staff availability



# What are ACCC Members Seeing in Their Programs?

- Clinical coordinators not allowed on campus
- All new trials halted
- No new accruals
- Staff redeployed or otherwise occupied
- Not a top priority now

Adapted from ACCC Post-03.27.2020 Webcast Survey



# What Clinical Trials Guidance Has Been Provided So Far?

- Food & Drug Administration (FDA)
- NCI Cancer Therapy Evaluation Program (CTEP)
- NCI Community Oncology Research Program (NCORP)
- NCI Central Institutional Review Board (CIRB)
- Cooperative Groups
- Industry Sponsors
- Internal Organizational Guidance



# What Topics Have Been Addressed?

## Trial Conduct and Protocol Deviations

- Patient misses visit/monitoring milestone
- Medication not available
- Protocol approved provider or service provider not available

## Local Amendments Submitted for Review

## Study Patient Develops—or is Suspected of—COVID-19





# Unchanged Clinical Trials Principles

- Ensuring safety of study participants is paramount
- Continue treatment trial when possible
- Maintain good clinical practices (GCP)
- Consult sponsor and IRB
- Determine alternates for patient contact, monitoring, drug access
- Document, document, document



# Trials Trends in Response to COVID-19

- New trials have decreased
- Some trials being cancelled
- Decreased accruals to existing trials
- Delays in completion of existing trials
- Stronger focus on continuing essential treatment trials
- New COVID-focused trials are accelerated
- Audits, on-site visits, travel, meetings suspended
- Streamlined approaches and recording of deviations
- Solutions include remote work and use of telemedicine



# What to Do if an On-Trial Patient Develops—or is Suspected of—COVID-19

- Stop trial drug
- Report as Adverse Event (AE)
  - “Infection, Other”
  - “Confirmed COVID-19”
  - “Suspected COVID-19 Infection”
    - Amend if confirmed
- Treat as appropriate
- Document
- Database development



# What You Can Do

- Stay safe and well
- Protect your patients and your staff
- Maintain focus on clinical trial safety
- Solve problems with your sponsor and your IRB
- Document
- Take this opportunity to look forward





# ACCC COVID-19 Resource Center & Listserv

- Weekly Webcast Series
- CANCER BUZZ Mini-Podcasts [COVID-19 Self-Care]
- Evidence-Based Guidelines & Information; Blog Posts
- Member Discussions & Resources on ACCCExchange

**[acc-cancer.org/COVID-19](https://acc-cancer.org/COVID-19)**