Clinical Trials Amid COVID-19

Friday, April 3, 2020

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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

accc-cancer.org/COVID-19