

Cardiovascular Clinical Research in the COVID-19 Era ACC Heart House Roundtable

The Immediate Impact of COVID-19 on Clinical Research

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Entire spectrum of clinical research *People and Process*

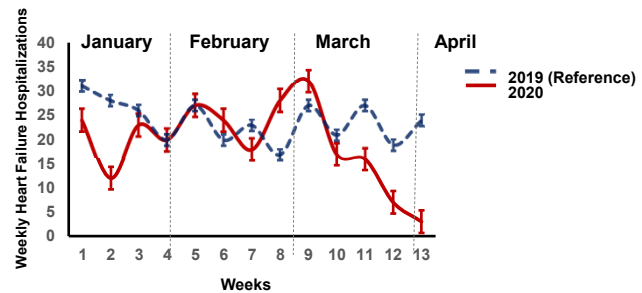
- Trial Participants
- Healthcare Professional
 - Site investigators
- Research Staff
- Hospitals and Sites
 - Local rules and guidance
 - PPE and supplies
 - Reassignment of duties
- Ethics Committee and IRB
 - Amendments
 - COVID research
- Sponsors
- Manufacturers and IP
- ARO / CRO
- Steering Committee
- Coordinating Centers
- Regulatory Agencies
- Core Laboratories
- Home Health / Local Sites / Local Businesses

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Entire spectrum of clinical research

Phases and Types

- Clinical Trials
 - New
 - Pre-enrollment
 - Early
 - Middle
 - Late
 - End
 - Analysis
 - Event rates
 - Adjudication
 - Data
 - Out of hospital events
- Non-Clinical Trials Research
 - Observational, quality, translational, clinical
- Intervention Type - Drugs, Devices, Others



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Goals and Objectives

Many


- Safety – patients and staff
- Compliance with ICH Good Clinical Practice guidelines
- Maintaining trial integrity
 - Continuing worthwhile?
 - Maintain intervention
 - IP supply?
 - Intervention requires contact?
 - Collecting relevant data reliably
 - Endpoints
 - Honoring social contact
- Preserving time, effort, resources
- Following local mandates and rules
- COVID related data

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FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020
Updated on May 14, 2020




ESC
European Society of Cardiology
European Heart Journal (2020) 00, 1–8
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CURRENT OPINION
Heart failure/cardiomyopathy

Conducting clinical trials in heart failure during (and after) the COVID-19 pandemic: an Expert Consensus Position Paper from the Heart Failure Association (HFA) of the European Society of Cardiology (ESC)

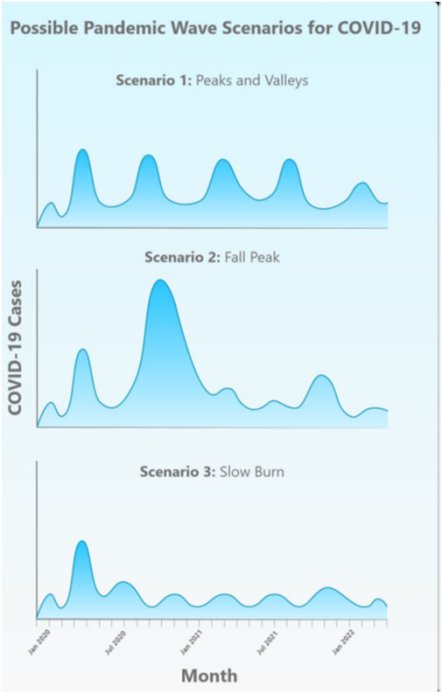
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CIDRAP
Center for Infectious Disease Research and Policy

Possible Pandemic Wave Scenarios for COVID-19



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