The Era of COVID-19 and Beyond

Lessons Learned from COVID-19: FDA Perspective

Harpreet Singh, FDA

Infectious Disease Perspective

John Powers, George Washington

Telehealth/Physician Perspective

Erica Ramsdale, University of Rochester

Digitization of medicine

Eric Topol, Scripps Research Translational Institute

Patient Perspective

Beverly Canin, Patient Advocate, Cancer & Aging Research Group

Clinical Trial Conduct in the COVID-19 Era: Implications for Drug Development in Older Adults

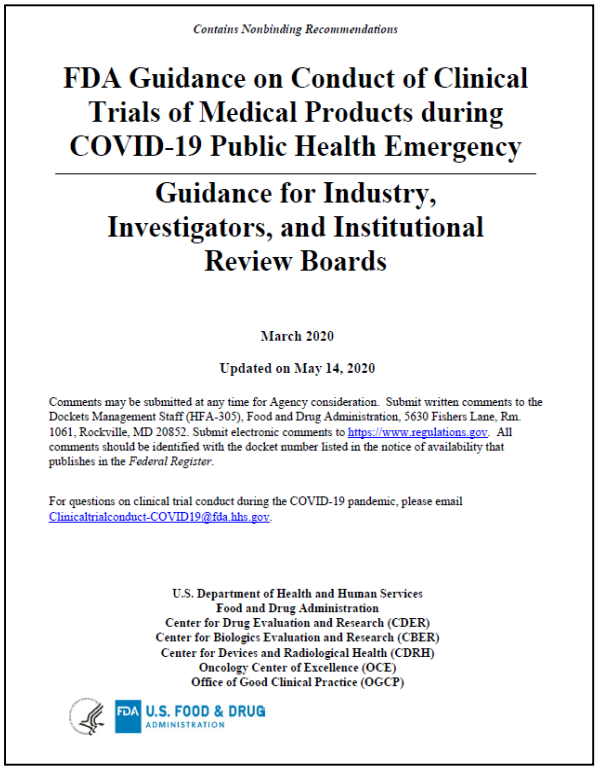
Harpreet Singh, MD
Associate Director (Acting), Cancer in Older Adults and Special Populations
Oncology Center of Excellence
Director, Division of Oncology 2
Office of Oncologic Disease

- I have no financial relationships to disclose

FDA Guidances Related to COVID-19

- FDA has issued multiple guidances related to COVID-19 on a variety of topics:*
  - Conduct of clinical trials
  - Statistical considerations for clinical trials
  - Alternative procedures for blood and blood components
  - Conduct and review of drug development for animals
  - Facilitation of veterinary telemedicine
  - Enforcement policies for personal protective equipment (PPE), sterilizers and disinfectant, respirators and ventilators
  - Manufacture of alcohol-based hand sanitizers
  - Nutrition labeling, food product packaging, food supplier audit requirements
  - REMS reporting requirements
  - Remote monitoring of patient-monitoring devices
- All FDA guidances can be accessed at https://www.fda.gov/regulatory-information/search-fda-guidance-documents

COVID Guidances- Rapid Dissemination of Information



Contains Nonbinding Recommendations

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

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicaltrialconduct-COVID19@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)
Office of Good Clinical Practice (OGCP)

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

- Initial release date: March 19, 2020
- Multiple updates:
  - Most Recent July 2, 2020

COVID-19 Guidances are **Expedited**

- Released without Public Comment

Guiding Principles

- Places the safety of trial participants at the center of the recommendations

"Ensuring the safety of trial participants is paramount"

- Provides guidance on the most common issues
- For specific questions that depend on factors such as the patient population, type of drug, or trial endpoint, FDA encourages sponsors to contact the appropriate FDA review division

Considerations for Ongoing Trials

- **Safety is paramount**- Modifications to trials should assure safety
- **Engage with IRB/IEC** on continued accrual, drug administration and trial participation
- **Alternative offsite methods** for safety assessments and site monitoring
  - Technology to facilitate remote data collection and monitoring
- **Alternative secure delivery methods of IP** can be explored
- **Clarifies Reporting Requirements and Interactions with FDA and IRBs**
  - **COVID-19 screening as a part of health care** does not need to be reported as a protocol amendment unless data is part of the research objective(s)
  - **Protocol modifications to protect life and well-being may be implemented before IRB/FDA approval.** (reporting required afterward)
  - **Document COVID-19 Contingency Measures**

Barriers to Clinical Trial Participation

- Geographic/logistical barriers
  - Clinical trials are not conducted where older adults live (rural US)
  - If the clinical trial site is local, older adults often require assistance in getting to their appointments
  - Clinical trials typically require more healthcare interactions than standard of care
- Caregiver support often required for transportation and advocacy
- Desire for treatment with “home” physician
  - There may be preference for treatment with known, community based physician

Basche M, Barón AE, Eckhardt SG, et al. Barriers to enrollment of elderly adults in early-phase cancer clinical trials. *J Oncol Pract*. 2008;4(4):162-168. doi:10.1200/JOP.0842001

Potential Lessons “Silver Linings” from COVID-19

- Calls to make clinical trials more patient centered pre-dated COVID-19 → FDA’s efforts and support longstanding
  - “Decentralize” Clinical Trials
    - Bring trial assessments to where patients live
    - Take Advantage of Digital Health Technology
  - Learn from “Real-World” Data → Older adults heavily impacted by COVID-19

COVID-19 Evidence Accelerator

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

FRIENDS of CANCER RESEARCH

SPEECH

Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making

JANUARY 28, 2019

To take one example: Pragmatic and hybrid clinical trials, including decentralized trials that are conducted at the point of care – and that incorporate real world evidence (RWE) -- can help clinical trials become more agile and efficient by reducing administrative burdens on sponsors and those conducting trials, and can allow patients to receive treatments from community providers without compromising the quality of the trial or the integrity of the data that's being collected.

FDA Puts Spotlight on Decentralized Clinical Trials

Blog - February 5, 2020

FDA Affirms Interest in Promoting Decentralized Clinical Trials

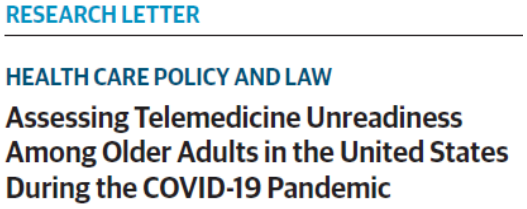
Blog - August 12, 2019

Elements of Decentralized Trials Which Address Current Barriers

- Alternative off-site methods for safety assessments and monitoring → local labs, local imaging
- Technology to facilitate remote data collection and monitoring → telemedicine visits (phone/video) and ePRO Wearables
- Alternative secure delivery methods of investigational products → shipping oral drugs, administering IV drugs locally where feasible
- Obtaining remote consent

Thoughts for the Panel

- Can we leverage clinical trials conducted during COVID to understand the implications of remote assessments and decentralized trial procedures for older adults?
- What are the challenges and opportunities for utilization of telemedicine to provide care for older adults?
- What are the practical lessons we can take from increased digitization and use of technology in clinical trials, as it relates to older adults?


RESEARCH LETTER

HEALTH CARE POLICY AND LAW

Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic

Acknowledgments

- Several slides on the COVID-19 Clinical Trial Guidance and Decentralization of Trials were provided by Khair ElZarrad from the FDA Office of Medical Policy, and Paul Kluetz, Oncology Center of Excellence

- For up to date information on FDA's response to COVID-19, please visit the following website:

- https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19