Mitigating Clinical Study Disruptions During Disasters and Public Health Emergencies

A public meeting to fulfill FDORA Section 3605 requirements and to address the need for advanced planning for clinical study disruptions

October 18-19, 2023 | 10:00 a.m.—1:30 p.m. EDT

Resource List

Federal Resources

1. FDA Final Guidance Considerations for the Conduct of Clinical Trials of Medical Products During Major Disruptions Due to Disasters and Public Health Emergencies (September 2023)

2. FDA Draft Guidance Decentralized Clinical Trials for Drugs, Biological Products, and Devices (May 2023)

3. FDA Draft Guidance Digital Health Technologies for Remote Data Acquisition in Clinical Investigations (December 2021)

4. FDA / Califf R Lessons Learned from COVID-19 Are Informing Preparation for Future Public Health Emergencies (May 2023)


6. Final ICH Guideline: E19 A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-Approval or Post-Approval Clinical Trials (April 2019)


8. NIH National Cancer Institute CTEP Guidances during COVID-19 Pandemic (January 2022)

9. NIH National Center for Advancing Translational Sciences Trial Innovation Network Toolkit (Various dates)

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1 FDA guidances are updated periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/.

2 When final, this guidance will represent FDA’s current thinking on this topic.
### Additional Resources

1. AAMC / Boyle P [Five ways that clinical trials might change for good](May 2021)
2. ACRO [Bringing the Trial to the Patient: A Quality-by-Design Manual for Decentralized Clinical Trials](September 2020)
3. ACRO [Quality By-Design Manual for Decentralized Trials and Template for Risk Assessment Considerations](September 2020)
4. ACRP / Ochuma A [The Impact of COVID-19 on Clinical Trial Activities and the Research Environment](August 2020)
5. ACRP / Clements M, Stern K [The Modernization of Clinical Trials: COVID-19’s Lasting Impact](April 2021)
6. ACRP [Risk-Based Monitoring of Clinical Trials: COVID-19 and Paving the Road to the Future](September 2020)
7. Applied Clinical Trials Online [COVID-19 and Its Impact on the Future of Clinical Trial Execution: Findings from a Tufts study examining the effects of COVID-19 on clinical trials](October 2020)
10. CISCeR (Center for Information and Study on Clinical Research Participation) [2020 Pediatric Perceptions & Insights Study](April 2020)
11. Cleveland Clinic [COVID-19 Response Digital Health Playbook](April 2020)
12. Clinical Leader / Thermo Fischer Scientific [No Place Like Home: How To Make Decentralized Clinical Trials A Win For Patients, Sponsors & Investigators](Undated)


19. IQVIA / Lesley Freese *Best Practices for Site Communications During COVID-19* (July 2021)


26. Parexel *Managing Continuity in Clinical Trials in the COVID-19 environment: The Decentralized Option and Regulatory Flexibility* (Undated)


28. PPD *2021-2022 Decentralized Clinical Trials Industry Report* (September 2022)

29. PPD *2022 Decentralized Clinical Trials Sites Survey Report* (September 2022)


32. SCRS *Impact Assessment of Decentralized Clinical Trials (DCT) Awareness in the Clinical Research Industry* (May 2020)

33. SCRS *Patient Centricity and Virtualizing Technologies in a COVID-19 World* (December 2020)

34. SCRS *Sites Speak Out on Clinical Trial Technology Overload: An SCRS Survey* (July 2020)
35. STAT *Rapid advances in remote patient monitoring* (April 2021)


37. The Avoca Group *COVID-19 Rapid Response Working Group Meeting Highlights Topic: Taking a Deeper Dive into Successful Approaches to SDR/SDV During Times When There is Inability to be On-Site* (April 2020)


39. TransCelerate *Beyond COVID-19: Modernizing Clinical Trial Conduct* (September 2020)

40. TransCelerate *Continuity Solution Case Studies* (July 2020)

41. TransCelerate *Modernizing Clinical Trial Conduct Workshop Findings* (September 2020)

42. Trials@Home / Innovative Medicines Initiative (IMI) Best practices in RDCT’s (Remote DCTs): *D1.1 First set of recommendations for RDCTs (to be implemented in the pan-EU pilot RDCT)* and *D1.2 Criteria for selection of appropriate trials*. (August 2020)

43. Veeva *Digital Clinical Trials Survey Report* (2020)


48. Yprime *Optimizing Decentralized Clinical Trial Strategy and Technologies* (Undated)