



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)¹
2. FDA Draft Guidance [Decentralized Clinical Trials for Drugs, Biological Products, and Devices](#) (May 2023)²
3. FDA Draft Guidance [Digital Health Technologies for Remote Data Acquisition in Clinical Investigations](#) (December 2021)²
4. FDA / Califf R [Lessons Learned from COVID-19 Are Informing Preparation for Future Public Health Emergencies](#) (May 2023)
5. FDA [COVID-19 Pandemic Recovery and Preparedness Plan \(PREPP\) Initiative: Summary Report](#) (January 2021)
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)
7. Draft ICH Guideline: [E6\(R3\) Good Clinical Practice \(GCP\) Guideline](#) (May 2023)
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)

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, Stem 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)
8. Balevic SJ, Singler L, Randell R, et al. [Bringing research directly to families in the era of COVID-19](#). *Pediatr Res* 89, 404–406 (2021). doi.org/10.1038/s41390-020-01260-1
9. Barnes B, Stansbury N, Brown D, et al. [Risk-Based Monitoring in Clinical Trials: Past, Present, and Future](#). *Ther Innov Regul Sci* 55, 899–906 (2021). doi.org/10.1007/s43441-021-00295-8
10. CISCPR (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)
13. CTTI [Adapting Clinical Trials during COVID-19: Solutions for Switching to Remote & Virtual Visits](#) (November 2020)
14. CTTI [Best Practices for Conducting Clinical Trials during COVID-19](#) (July 2021)
15. de Jong AJ, Grupstra RJ, Santa-Ana-Tellez Y, et al. [Which decentralised trial activities are reported in clinical trial protocols of drug trials initiated in 2019-2020? A cross-sectional study in ClinicalTrials.gov](#). *BMJ Open*. 2022;12(8):e063236. Published 2022 Aug 29. doi:10.1136/bmjopen-2022-063236
16. Dorsey ER, Kluger B, Lipset CH (2020), [The New Normal in Clinical Trials: Decentralized Studies](#). *Ann Neurol*, 88: 863-866. doi.org/10.1002/ana.25892



17. Flaherty KT, Doroshow JH, Galbraith S, et al. [Rethinking Cancer Clinical Trial Conduct Induced by COVID-19: An Academic Center, Industry, Government, and Regulatory Agency Perspective](#). *Cancer Discov.* 2021;11(8):1881-1885. doi:10.1158/2159-8290.CD-21-0850
18. Informa Connect [Decentralized Clinical Trials in 2020: A Global Survey](#) (November 2020)
19. IQVIA / Lesley Freese [Best Practices for Site Communications During COVID-19](#) (July 2021)
20. Medidata [COVID 19 and Clinical Trials: The Medidata Perspective](#) (March 2020)
21. Medidata [Modernizing Clinical Trial Oversight: The Path to Clinical Operations Excellence](#) (July 2021)
22. Milken Institute / Krofah E, Schneeman K [Lessons Learned From COVID-19: Are There Silver Linings for Biomedical Innovation?](#) (January 2021)
23. Mitchell EJ, Ahmed K, Breeman S, et al. [It is unprecedented: trial management during the COVID-19 pandemic and beyond](#). *Trials* 21, 784 (2020). doi.org/10.1186/s13063-020-04711-6
24. O'Brien EC, Sugarman J, Weinfurt KP, et al. [The impact of COVID-19 on pragmatic clinical trials: lessons learned from the NIH Health Care Systems Research Collaboratory](#). *Trials* 23, 424 (2022). doi.org/10.1186/s13063-022-06385-8
25. Oracle Health Sciences [The Accelerated Evolution of Clinical Trials in a Pandemic Environment](#) (November 2020)
26. Parexel [Managing Continuity in Clinical Trials in the COVID-19 environment: The Decentralized Option and Regulatory Flexibility](#) (Undated)
27. Pennell NA, Dillmon M, Levit LA, et al. [American Society of Clinical Oncology Road to Recovery Report: Learning From the COVID-19 Experience to Improve Clinical Research and Cancer Care](#). *J Clin Oncol.* 2021;39(2):155-169. doi:10.1200/JCO.20.02953
28. PPD [2021-2022 Decentralized Clinical Trials Industry Report](#) (September 2022)
29. PPD [2022 Decentralized Clinical Trials Sites Survey Report](#) (September 2022)
30. Rametta SC, Fridinger SE, Gonzalez AK, et al. [Analyzing 2,589 child neurology telehealth encounters necessitated by the COVID-19 pandemic](#). *Neurology* Sep 2020, 95 (9) e1257-e1266; DOI: 10.1212/WNL.0000000000010010
31. Sathian B, Asim M, Banerjee I, et al. [Impact of COVID-19 on clinical trials and clinical research: A systematic review](#). *Nepal J Epidemiol.* 2020;10(3):878-887. Published 2020 Sep 30. doi:10.3126/nje.v10i3.31622
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)
36. Tan AC, David MA, Mustafa, K [Adapting to a Pandemic — Conducting Oncology Trials during the SARS-CoV-2 Pandemic](#). *Clin Cancer Res* 1 July 2020; 26 (13): 3100–3103. doi.org/10.1158/1078-0432.CCR-20-1364
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)
38. Tolaney SM, Lydon CA, Li T, et al. [The Impact of COVID-19 on Clinical Trial Execution at the Dana-Farber Cancer Institute](#), *JNCI: Journal of the National Cancer Institute*, Volume 113, Issue 11, November 2021, doi.org/10.1093/jnci/djaa144
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)
44. Vogl DT, Sallée V, Hendricks MC, et al. [A unique window of opportunity for practical reform of cancer clinical trials](#). *Cancer*. 2021. doi.org/10.1002/cnrc.33585
45. Wall Street Journal [What Covid-19 Taught Us About Telemedicine](#) (March 2021)
46. Waterhouse DM, Harvey RD, Hurley P, et al. [Early Impact of COVID-19 on the Conduct of Oncology Clinical Trials and Long-Term Opportunities for Transformation: Findings From an American Society of Clinical Oncology Survey](#). *JCO Oncol Pract*. 2020;16(7):417-421. doi:10.1200/OP.20.00275
47. Weinberg MS, Patrick RE, Schwab NA, et al. [Clinical Trials and Tribulations in the COVID-19 Era](#). *The American Journal of Geriatric Psychiatry*, Volume 28, Issue 9, 2020. doi.org/10.1016/j.jagp.2020.05.016
48. Yprime [Optimizing Decentralized Clinical Trial Strategy and Technologies](#) (Undated)