

**Text: “COVID-19 and readjusting clinical trials”**

1. What is the main question discussed in the text? (2.0 pts)

Response: The main question discussed in the text is the disrupted of clinical trials worldwide due to the COVID-19 pandemic, with long-lasting effects on medical science.

2. What were the guidelines recommended to researchers and sponsors by the Food and Drug Administration (FDA) regarding patient participation in clinical trials during the COVID-19 pandemic? (2.0 pts)

Response: The FDA guidelines called on researchers and trial sponsors to “determine that the protection of a participant’s safety, welfare, and rights is best served by continuing a study participant in the trial as per the protocol or by discontinuing the administration or use of the investigational product or even participation in the trial.

3. What are the barriers (in many cases) in Kevin Sheth's view that prevent the broader incorporation of telemedicine technology both in clinical practice and in the world of research? (2.0 pts)

Response: In many cases, the barriers that prevent the incorporation of telemedicine technology more widely are largely administrative and bureaucratic, having to do with cost and reimbursement.

4. What were the tremendous disruptive effects pointed out by Michael Lauer in relation to biomedical research that is not directly related to COVID? (2.0 pts)

Response: According to Michael Lauer, “Laboratories are closed. Communications have been shut down, conferences have been cancelled, supply chains for equipment have been lost, resources have been lost. There have been widespread financial losses within academic medical centres that have had spillover effects on their research operations.”

5. The COVID-19 pandemic has brought negative effects to the world stage in terms of clinical research trials. According to the text, what are the lessons that remain for the future as examples of clinical trials developed with COVID-19? (2.0 pts)

Response: COVID-19 exposed ways to improve the design, conduct and reporting of clinical trials that are an essential tool in clinical research. The rapid design and launch of clinical trials designed to research COVID-19 has shown that certain aspects and practices of clinical trials can be improved, simplified or modernized in ways that would benefit patients, doctors and all research.