

# Emerging Best Practices and Future Directions in Data Privacy and Security

Virtual Expert Workshop  
February 7-8, 2023

## Agenda

### Background and Workshop Objectives

Interest in and reliance upon digital data and new technologies to support clinical research continues to increase. With the evolving clinical research landscape, new and enduring data privacy issues may arise with uses of sensitive personal information. Stakeholders from within and outside of the clinical research space can shed light on existing approaches and practices for managing data privacy and security challenges as well as how practices could be adapted to support clinical research now and in the near future.

This workshop will facilitate a shared learning of practices that can address or mitigate risks that may arise from the use of personal health information used in or generated from emergent technologies and methodologies in clinical research. The workshop will bring together a range of stakeholders, including industry representatives, clinical researchers, patient voices, and data privacy experts, to discuss and assess existing tools and practices that may be applied to new and emerging data privacy and security challenges arising in the clinical research space. Stakeholders will also discuss implementation of best practices and explore potential paths forward that meet data privacy needs while preserving data utility.

### Virtual Day 1: Key Considerations for Data Privacy and Security Practices for Clinical Research

February 7, 2023  
1:00 pm – 4:45 pm ET

**1:00 pm**      **Welcome and Overview**

**1:05 pm**      **Opening Remarks from FDA**

**1:15 pm**      **Background Presentation**

**1:30 pm**      **Session 1: Existing Laws Impacting Data Privacy and Security Practices for Clinical Research**

*Objective:* This session will include a review of key existing laws in the U.S. and a brief review of select laws outside of the U.S. (such as the European Union’s General Data Protection Regulation (GDPR)) that require or impact data privacy and security practices relevant to clinical research. Through this session, participants will gain an understanding of how legal obligations shape practices in the clinical research space today.

**2:30 pm**     **Session 2: Stakeholder Roles and Expectations toward Data Privacy and Security**  
*Objective:* This session will focus on characterizing stakeholders in clinical research and understanding how roles and expectations may differ between stakeholder groups. Participants will discuss how different patient needs may shape patient expectations around data privacy practices and risk mitigation and how expectations may differ, depending on the clinical research context. This session will also include discussion of patient attitudes toward data privacy and security.

**3:30 pm**     **Break**

**3:45 pm**     **Session 3: Data Privacy and Security Technical Considerations and Challenges in Clinical Research**  
*Objective:* This session will focus on how digital data sets flow through the clinical research process (i.e., from data collection/generation through use in product application) and what data privacy and security considerations arise during that process. Stakeholders will highlight and discuss pain points along the paths that data flow.

**4:40 pm**     **Closing Remarks**

**4:45 pm**     **Adjournment**

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### Virtual Day 2: Data Privacy and Security Practices and Future Directions

February 8, 2023  
1:00 pm – 4:45 pm ET

- 1:00 pm**      **Welcome, Recap of Day One and Overview of Day Two**
- 1:15 pm**      **Session 4: Lessons from Existing Data Privacy Practices Across Sectors**  
*Objective:* This session will cover data privacy practices and practices that ensure appropriately limited access to and use of an individual’s personal data. Discussion will include characterization of existing practices within and outside of the clinical research space as well as identification of gaps in these practices.
- 2:30 pm**      **Session 5: Lessons from Existing Data Security Practices Across Sectors**  
*Objective:* This session will cover data security practices and practices that prevent or minimize opportunities for malicious access to or disclosure of an individual’s personal data. Discussion will include data security needs and practices that flow from data privacy needs and support identified best data privacy practices, with a focus on practices that minimize risk while maintaining data utility.
- 3:25 pm**      **Break**
- 3:40 pm**      **Session 6: Charting a Path Forward for Data Privacy and Security**  
*Objective:* This session will focus on how stakeholders can chart a path forward to improve upon existing practices or design new ones that rise to the challenges of the evolving clinical research landscape. Discussion will include how stakeholder perspectives, particularly patient viewpoints, can be efficiently gathered and used to inform future efforts around data privacy and security.
- 4:40 pm**      **Closing Remarks**
- 4:45 pm**      **Adjournment**

### Funding Acknowledgement

*This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award U01FD006807 totaling \$2,575,023 with 100 percent funded by FDA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.*