

Data Privacy Considerations for Clinical Systems

eLearning Course Outline

Course Description: In clinical research, everyone who has access to personally identifiable information needs to understand the importance of data privacy. This course is designed to provide a thorough understanding of how to protect and ensure the privacy of this sensitive and confidential information.

Approximate Duration¹: ~50 min

| Module | Topic |
|--|--|
| Introduction to Data Privacy (9 min) | Objectives |
| | Roles in Privacy Compliance |
| | What is Data Privacy? |
| | Personal Identifiable Information |
| | Data Privacy in Clinical Research |
| | Data Privacy Terms |
| | Data Privacy Triad |
| | Inline Assessment |
| | Responsibilities of Data Controllers |
| | Responsibilities of Data Processors |
| | Inline Assessment |
| | Summary |
| US Data Privacy Laws (15 min) | Objectives |
| | Privacy Laws in the US |
| | The Privacy Act |
| | The Gramm-Leach-Bliley Act |
| | The Children's Online Privacy Protection Act |
| | HIPAA |
| | Case Study: Pharmatrak Privacy Litigation |

| Module | Topic |
|---|--|
| | Role of the First Circuit in Pharmatrak Litigation |
| | US State Laws |
| | General E-Mail Privacy |
| | Inline Assessment |
| | Summary |
| International Data Privacy (23 min) | Objectives |
| | Global Data Privacy Regulations |
| | International Data Privacy Model |
| | Privacy Around the Globe |
| | Privacy Violation Penalties |
| | Data Protection Principles |
| | Data Protection Act Schedule 2 |
| | Data Protection Act Schedule 3 |
| | Seventh Principle of Good Information Handling |
| | Eighth Principle of Good Information Handling |
| | Transfer of Personal Data to a Third Country |
| | Adequate Level of Protection |
| | Safe Harbor Program |
| | Safe Harbor Principles |
| | Assessing Adequacy |
| | Adequate Safeguards |
| | Derogations to the Eight Principle |
| | Inline Assessment |
| | Summary |
| Data Privacy Program (3 min) | Features of a Good Data Privacy Program |
| | Assembling a Data Privacy Program |
| Post Assessment | Post Assessment |

¹ Duration listed is approximated, and does not reflect activities, simulations or assessments