Clinical Trials in a Virtual World: A Case Study Analysis of Compliance Risks in Decentralized Clinical Trials

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Laura Podolsky

Laura Podolsky is Senior Counsel at Nixon Gwilt Law. Prior to joining NGL, Laura was the founding General Counsel of Science 37, a leader in the decentralized clinical trial field. At Science 37, Laura led development of the legal and regulatory strategies underpinning the DCT model. Laura advises clients on matters related to clinical research, telemedicine, healthcare technology, and data privacy, as well as complex agreements and multiparty collaborations. Laura earned her J.D. and master's degree in public health from UCLA, and graduated magna cum laude from Duke University.

Bethany Corbin

Bethany A. Corbin, Esq., Senior Counsel at Nixon Gwilt Law, advises healthcare and pharmaceutical clients on matters relating to regulatory compliance, reimbursement, and customer and partner transactions.

One of the firm's healthcare privacy experts, Bethany earned a Health Care LL.M. with a Certificate in Compliance Studies from Loyola University Chicago School of Law. Her designation as a Certified Information Privacy Professional (CIPP/US), as well as certifications in Healthcare Compliance (CHC) and Healthcare Privacy Compliance (CHPC), increase the value of her privacy expertise for femtech, digital health, medtech, and life sciences clients who want to understand the nuances of overlapping state, federal and international privacy laws and close deals faster.

She is also the host of the Legally Femtech Podcast.

Agenda

- **Background: Explanation of Clinical Trials & DCTs, Evolution of DCTs, and Projected Growth/Future of DCTs**
- **Overview of the Foundational Principles of DCTs**
- **DCT Risks: Analysis Through Women's Health Case Studies**
- **Data Privacy and Security Concerns in DCTs**
- **DCT Risk Mitigation Strategies**
- **Conclusion and Q&A**

Part 1: Clinical Trial & DCT Background

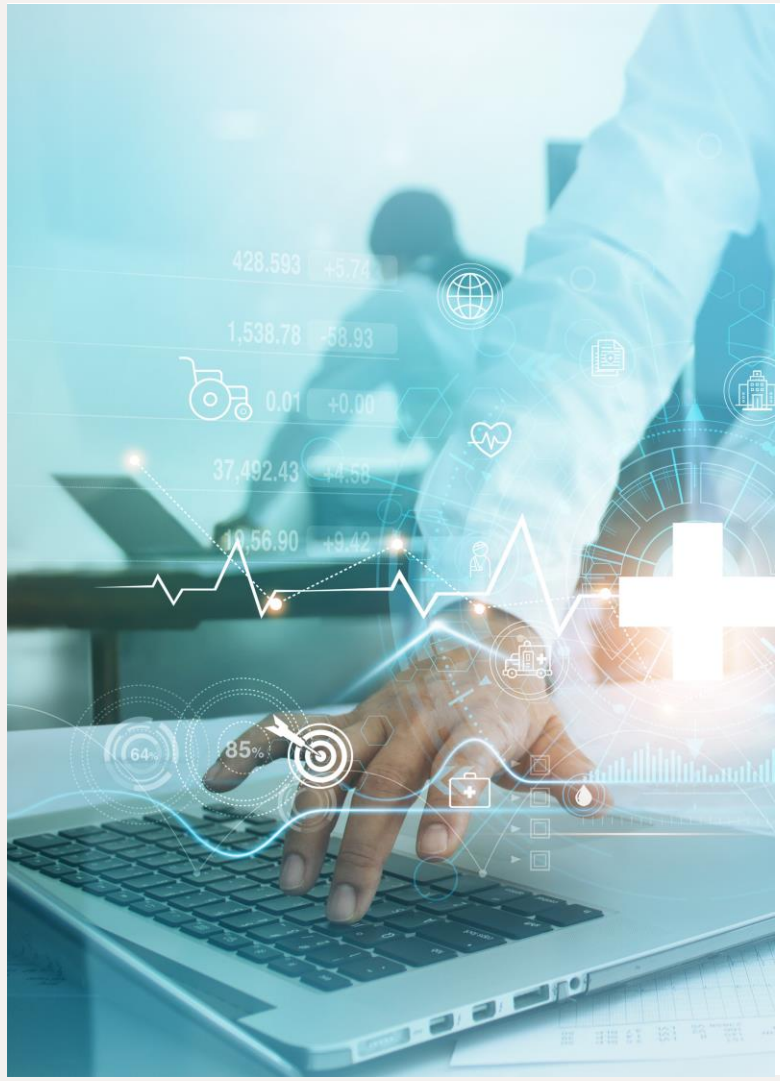
Clinical Trial Overview

- **What is a Clinical Trial?**
  - Research studies performed in people that evaluate a medical, surgical, or behavioral intervention.
  - Primary way to find out if a new treatment is safe and effective in people.
- **Types of Trials.**
  - Observational Studies.
  - Clinical Trials

- **Key Players in Clinical Trials.**
  - Food & Drug Administration (FDA)
  - Sponsor (or CRO)
  - IRB
  - Investigators (Sites)
  - Participants

Clinical Trial Overview

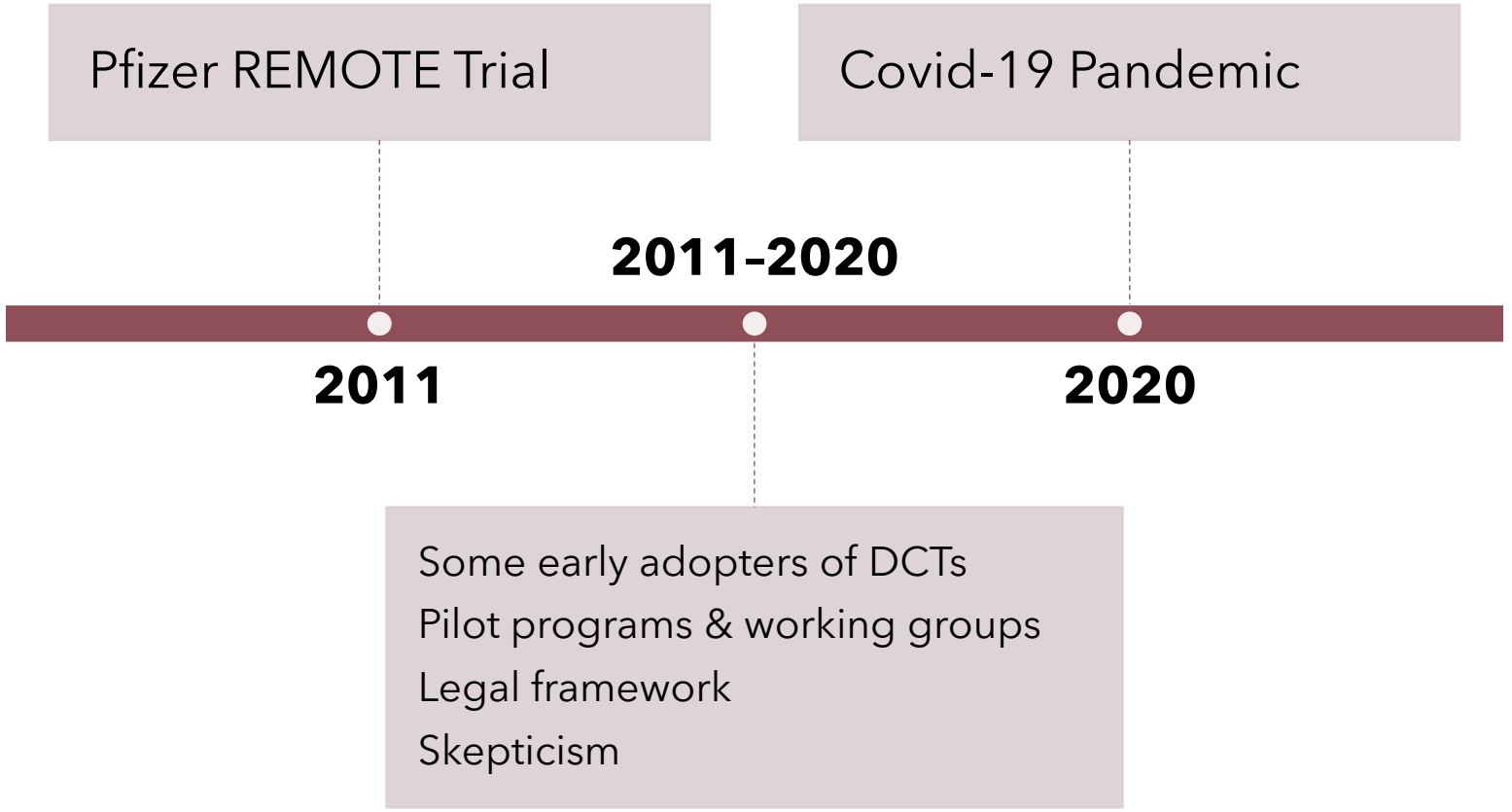
- **Regulatory Framework for Clinical Trials.**
  - FDA
  - Good Clinical Practices
  - International Conference on Harmonization of Technical Requirements for Pharmaceuticals in Human Use.



Decentralized Clinical Trials

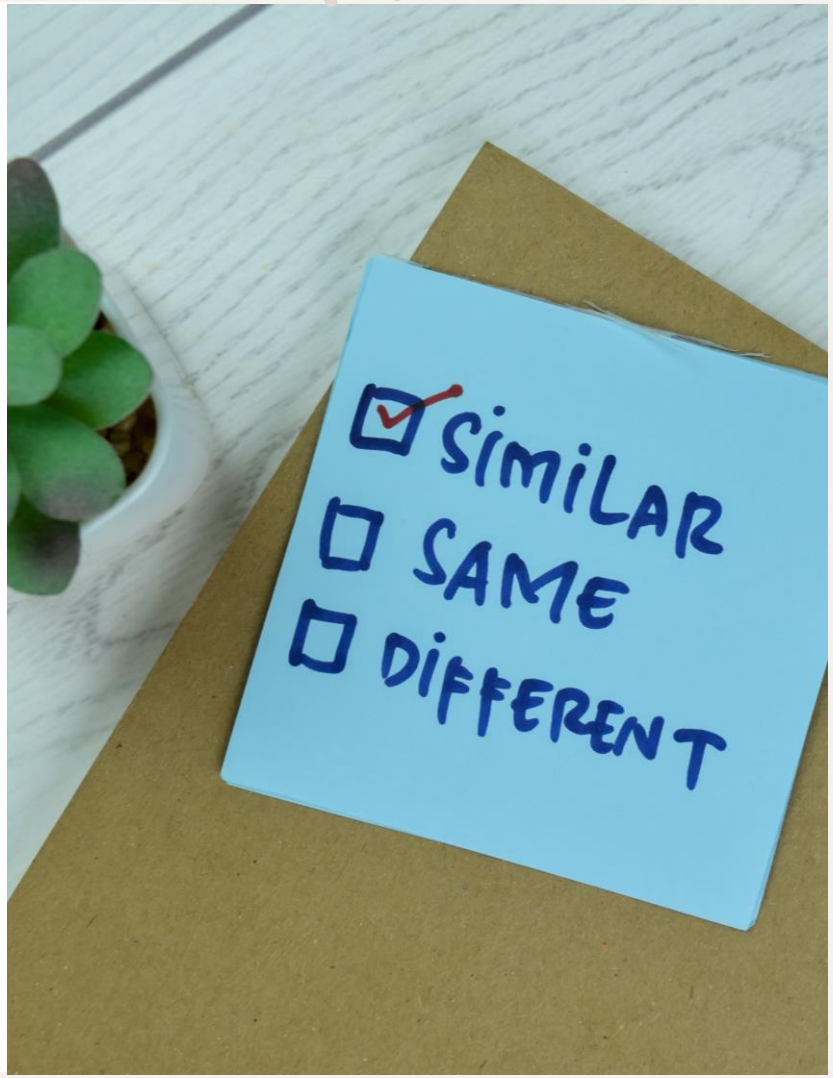
- **Defining Decentralized Clinical Trials (DCTs)**
  - Clinical trials centered around the patient.
  - Studies executed through remote data collection and local investigations.
  - Studies that make use of modern health technologies rather than specialized research facilities.
  - Delivery of care to the patient's home.

Evolution of DCTs



DCTs vs. In-Person Clinical Trials

- Similarities and Differences Between DCTs and In-Person Clinical Trials.
  - Quality and Compliance.
  - Protocols.
  - Technology.
  - Personnel.
  - Processes.

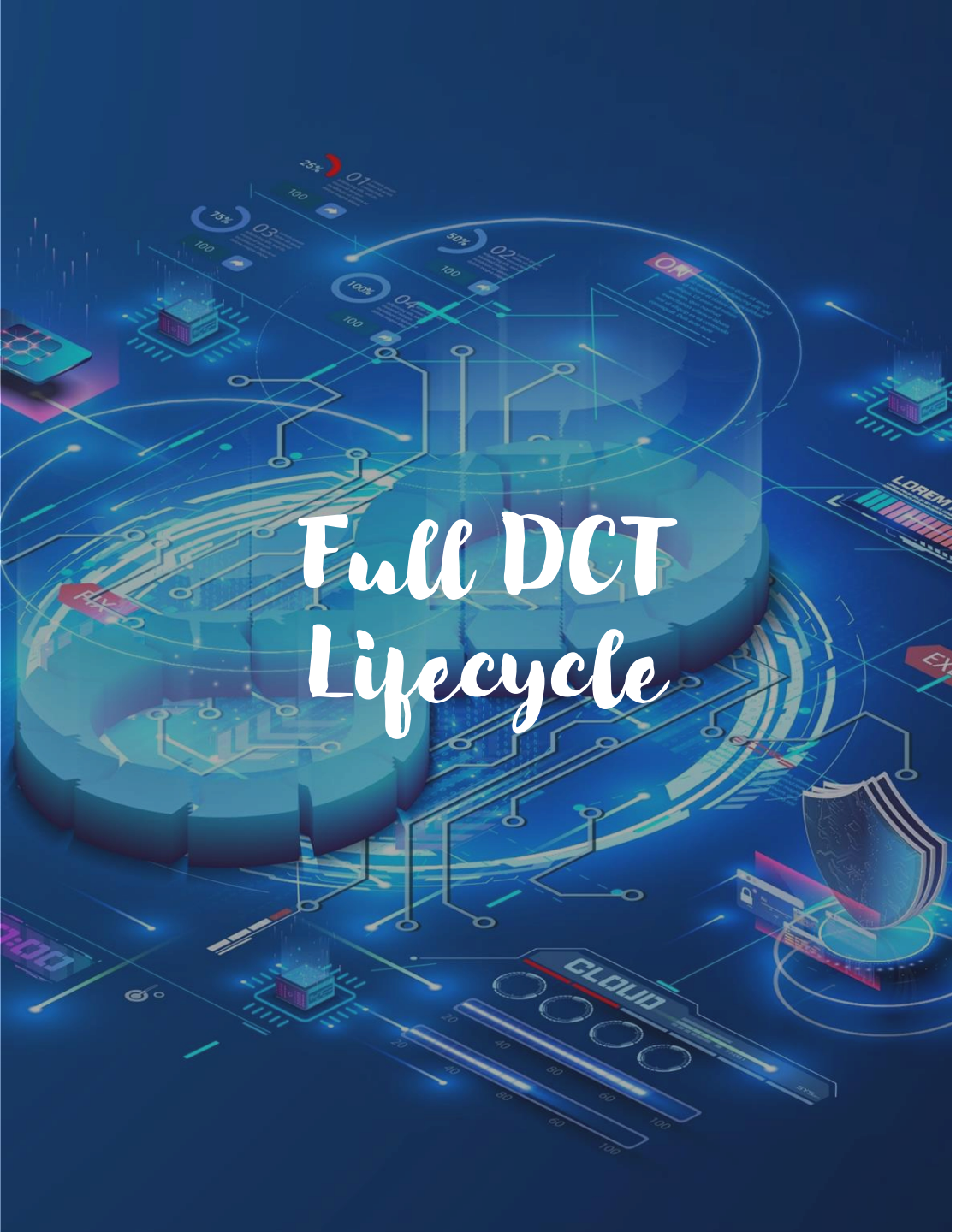


DCT Benefits

- **Advantages to the Patient**
  - Patient Convenience & Experience
  - Less Time-Consuming
- **Advantages for Sponsor/Investigator**
  - Faster Patient Recruitment
  - Access to Diverse Patients
  - Reduced Drop-Out Rates
  - Real-World Data

DCT Challenges

- **Challenges/Risks**
  - Technology Learning Curves
  - Data Quality
  - Data Overload
  - Changing Regulatory Guidance



Protocol Development → Contracting with CRO/Sites; Sponsor Audits

"Solutioning" – Vendors & Operational Plan → IRB Submission

Trial Tool Development → Train Study Team; Recruit Investigators

Site Initiation Visit → Start Study

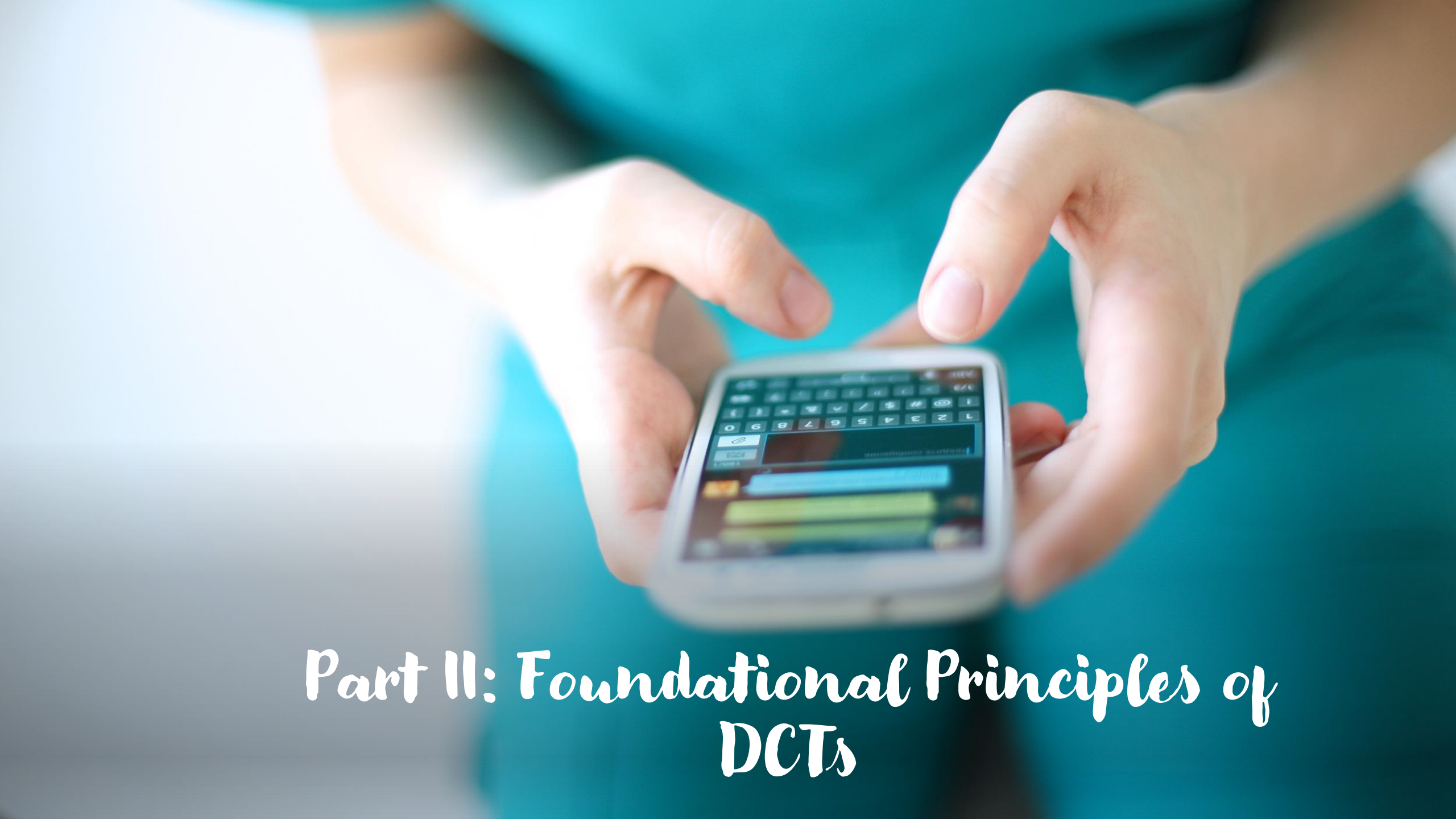
Full DCT Lifecycle (Cont'd)

- Patient Recruitment
- Study Conduct Period
- Data Management
- Transfer Data to Sponsor
- Study Close-Out

Current and Expected Growth of DCTs.

DCTs as the “standard” for the future.

Trends and Predictions.



Part II: Foundational Principles of DCTs

Foundational Principles of DCTs

- Patient Safety
- Data Integrity
- Provider Licensure
- Data Privacy and Security

Part III: DCT Risks: Analysis Through Women's Health Case Studies

Women's Health Clinical Trial: Case Study

General DCT Challenges

- Protocol Adjustment & Accidental Protocol Deviations
- Regulatory Acceptance
- Logistics
  - Vendors
  - Home Visits
  - Medication
  - Staffing

DCT Risks: Consent

- Identity Verification
- Legally Authorized Representative/Surrogate
- State Telemedicine Consent Requirements

DCT Risks: Physician & Nurse Licensure

- Ensure proper physician and nurse licensure.
- Medical boards do not distinguish between patient-provider relationships in clinical trial settings vs. traditional clinical settings.
- Investigator must be licensed where the patient is located.
- What if a patient moves around during the trial?
- Non-Licensed Staff (e.g., Phlebotomist)

DCT Risks: Physician & Nurse Licensure

- Licensure During and After the Public Health Emergency.
- Physician-Patient Relationship Without In-Person Visits?

DCT Risks: Medication

- Medication Delivery
  - Chain of Custody
  - Vendors
- Controlled Substances
- Rescue Medications
- Safe Storage & Disposal

Part IV: Data Privacy & Security Concerns in DCTs

Data Privacy Framework for DCTs

- Overview and Discussion of HIPAA
- HIPAA Privacy Requirements Applicable to Clinical Research
- HIPAA Authorization vs. Informed Consent
- Privacy and Security Risks for DCTs
- Risk Mitigation Tactics

What is HIPAA?

- Health Insurance Portability and Accountability Act ("HIPAA").
- Not originally created with privacy in mind.
- **HIPAA Privacy Rule**
  - Establishes national standards to protect individuals' medical records and other individually identifiable health information (i.e., protected health information).
  - Limited applicability – must determine whether HIPAA applies to the data at issue.

Does HIPAA Apply?

HIPAA applies only to:

- ***Covered entities*** – i.e., health plans, health care providers, and health care clearinghouses
- ***Business Associates***
- ***Protected Health Information*** (PHI)

NOTE: Researchers are generally not covered entities (with some exceptions).

Uses & Disclosures of PHI Under HIPAA

Basic Principle: A covered entity (or its business associate) may not use or disclose protected health information ("PHI") except:

- As the Privacy Rule permits or requires; or
- As the individual who is the subject of the information (or their personal representative) authorizes in writing.

Required Disclosures: A covered entity (or its business associate) must disclose PHI only in two situations:

- To individuals (or their personal representatives) when they request access to, or an accounting of disclosures of, their PHI; and
- To HHS when it is undertaking a compliance investigation or review or enforcement action.

Permissible Uses & Disclosures of PHI Under HIPAA for Research

Covered Entity or Business Associate is Permitted to Use or Disclose PHI for Research Under the Following Circumstances:

- Subject of the PHI has signed an Authorization.
- Reviews preparatory to research.
- Research on decedents' information.
- Appropriate documentation that an IRB or Privacy Board has granted a waiver of the Authorization requirement.
- PHI is de-identified.
- Information is released in the form of a limited data set.
- "Grandfathered" informed consent, IRB waiver of such informed consent, or Authorization or other express legal permission to use or disclose the information for research.
- Treatment, payment, and health care operations

Activities Preparatory to Research

- Identifying Research Participants.
- Contacting Research Participants.
- Provider Discussions of Patient Enrollment in Clinical Research.
- Call Centers for Research.

Privacy & Security Risks for DCTs

- Connected Ecosystem = Difficulty Securing Data Input Points, Trial Sites, Networks, Applications, and Patient Devices.
- Transition from Centralized to Decentralized Trials Means Sponsors May Not Have a Good Grasp of Moving Parts & Security Vulnerabilities.
- Data Authentication Concerns.

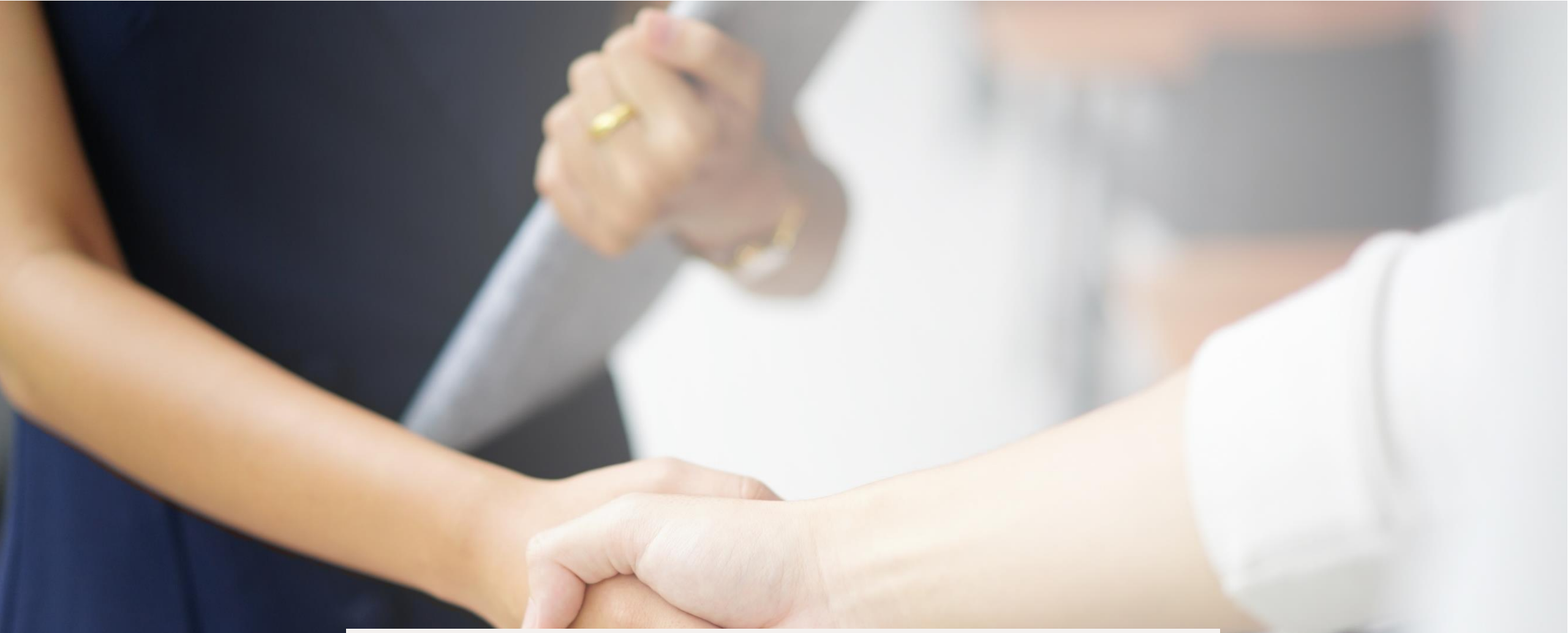
Privacy & Security Risks for DCTs

- Integrating New Technologies
- Data Reliability and Quality.
- Lack of Standard Approach to Data Transfer Controls.
- Data Breach or Security Incident.

Part V: DCT Risk Mitigation Strategies

DCT Risk Mitigation Strategies

#1 CULTURE OF COMPLIANCE



DCT Risk Mitigation Strategies

#2 VENDOR AUDITING, TRAINING & PARTNERSHIP

DCT Risk Mitigation Strategies

#3 PARTICIPANT & EMPLOYEE SATISFACTION

DCT Risk Mitigation Strategies

#4 TRACK LEGAL & REGULATORY CHANGES

DCT Risk Mitigation Strategies

#5 IMPLEMENT STRONG DATA PRIVACY & SECURITY CONTROLS

DCT Privacy & Security Risk Mitigation

- Proactive vs. Reactive Strategies
- Investment in strong IT infrastructure
- Access and authentication controls
- Encryption
- Continuous security testing
- Monitor system alerts & errors
- Network segmentation

DCT Privacy & Security Risk Mitigation

- Data and device inventory
- Patient & employee education and training
- Prepare incident response plans and teams
- Cyber risk assessments

Part VI: Question & Answer

FEEL FREE TO ASK ANY QUESTIONS