MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Deploying Digital Twins and Synthetic Data in Evidence Generation

DATE

March 19, 2026

TIME

1pm-2pm ET

Disclaimer

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We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center and its directors retain responsibility and final control of the content of any products, results, and deliverables.

Welcome~

Thank you for joining this webinar today!

Tips for today's session:

- Please use the Q&A for questions. We will do our best to answer live.
- Feel free to use the Closed Captioning available on the Zoom toolbar.
- Most of the links in our presentations will be shared in the Chat.

This meeting is being recorded.

The recording, slides, and any additional materials will be available next week. If you registered, you will receive an email about their availability and a notification about future webinars in this series.

The Multi-Regional Clinical Trials Center (MRCT Center)

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

AI and Clinical Research

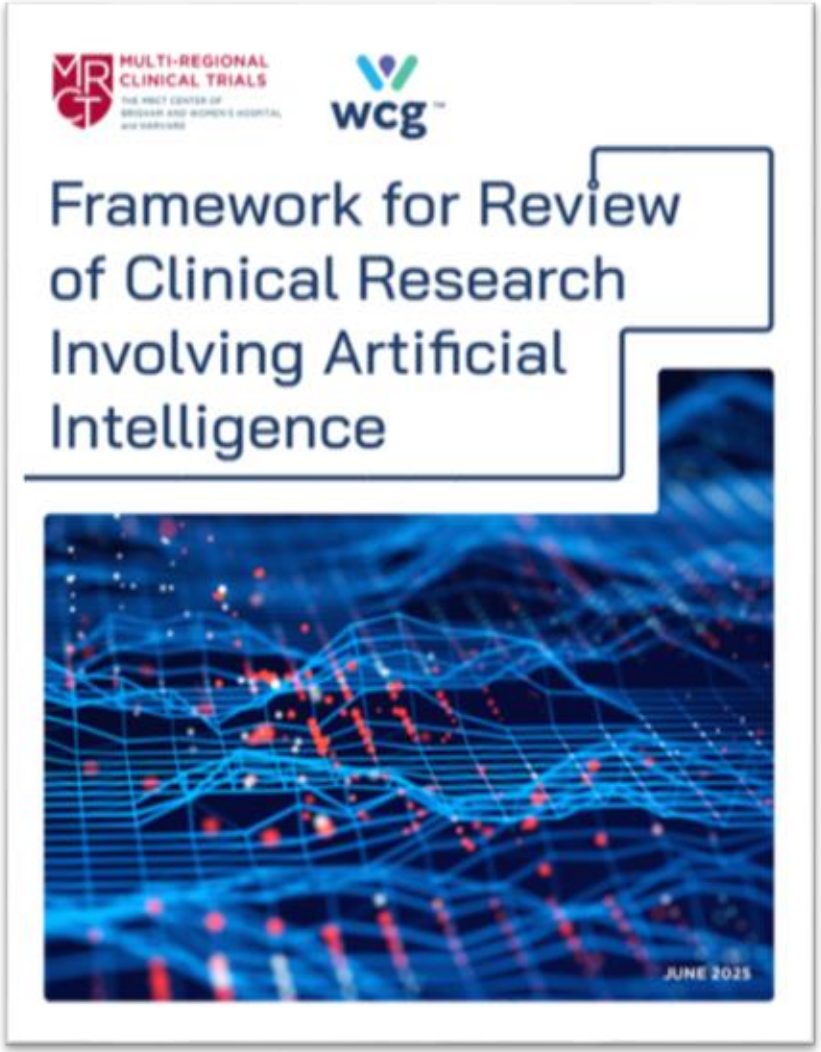
https://mrctcenter.org/project/ethics-ai/

The **Framework for Review of Clinical Research Involving AI** offers IRB and other oversight bodies a structured, practical approach to evaluating protocols that involve AI in research with human participants.

Available to download

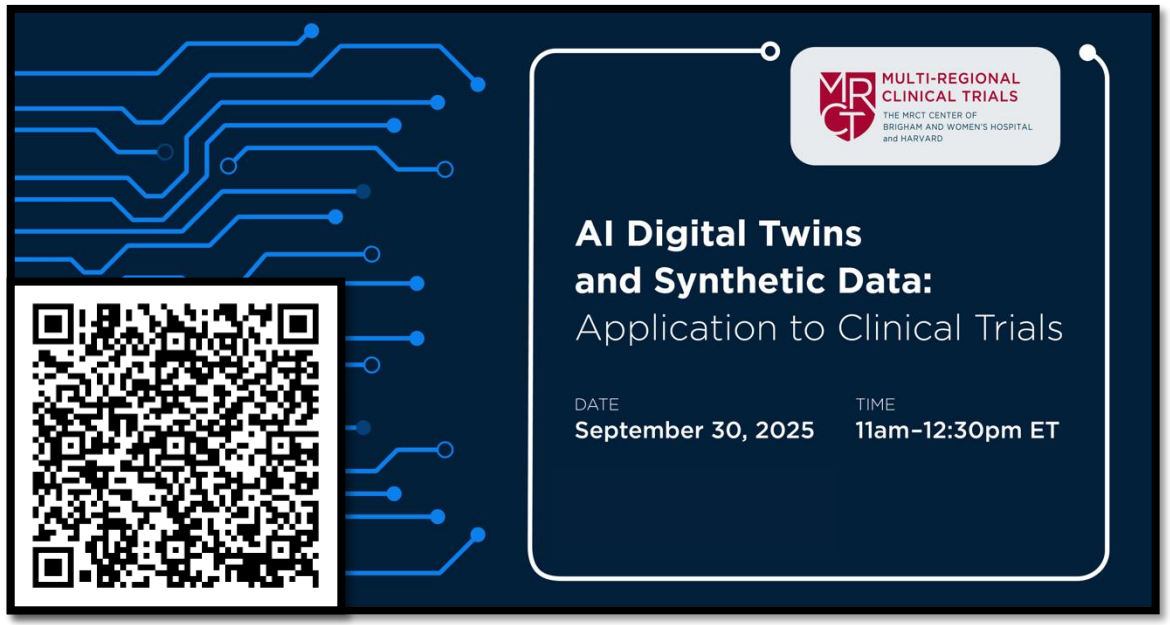
Ethical considerations during IRB review:

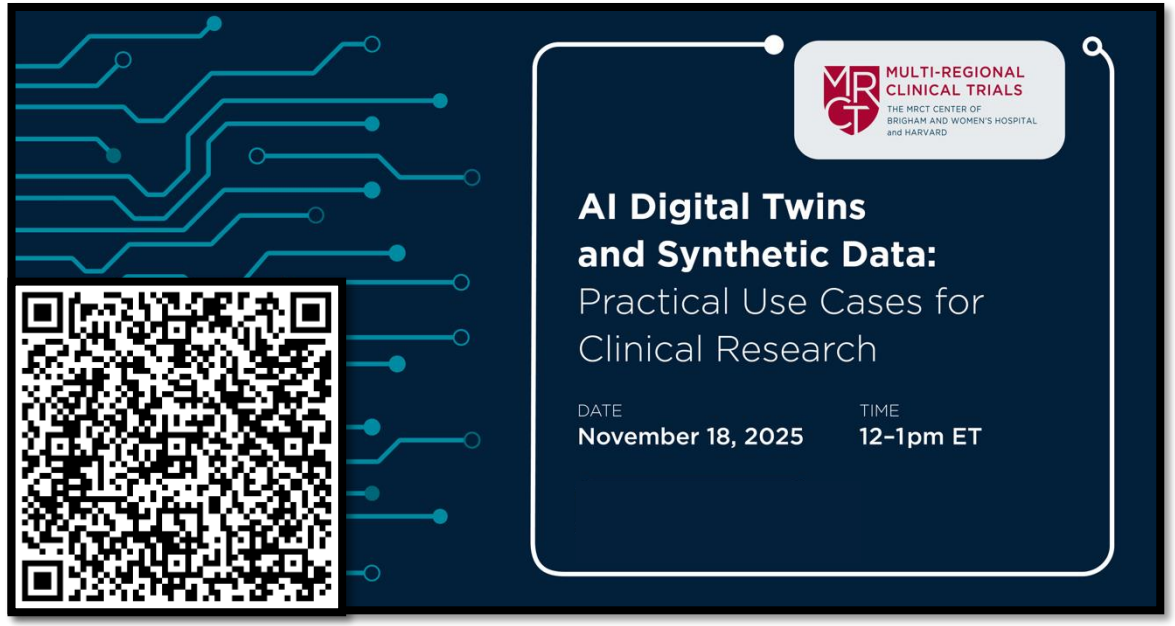
- Human Agency and Oversight
- Technical Robustness and Safety
- Privacy, Confidentiality, and Data Governance
- Transparency
- Representativeness and Fairness
- Informed Consent



Now: AI in the Administration of Research

AI Digital Twins and Synthetic Data Webinar Series





- Today's session is the third in the MRCT Center's AI Digital Twins and Synthetic Data webinar series
- The first two sessions covered:
  - An introduction to digital twins and how they are built for clinical research
  - Specific use cases for clinical research of digital twins and synthetic data
- On-demand recordings and slides are available on the MRCT Center's website

Deploying Digital Twins and Synthetic Data in Evidence Generation

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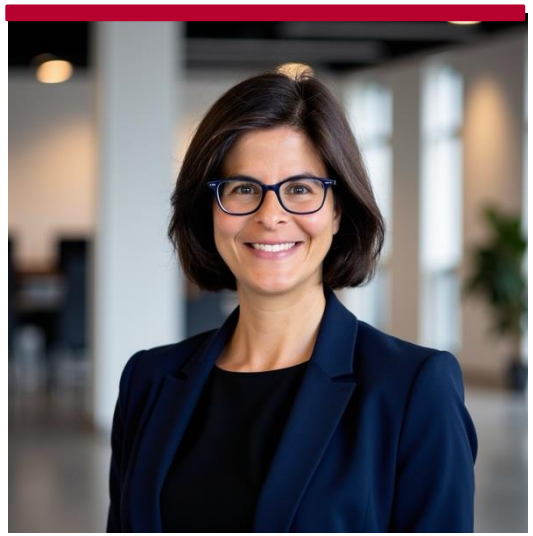

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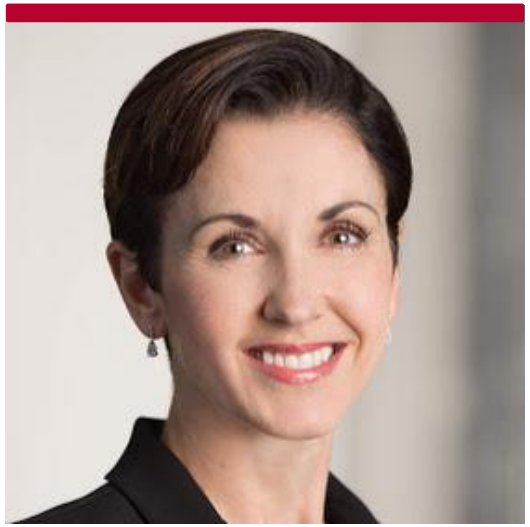

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https://mrctcenter.org/resource/ai-digital-twins-and-synthetic-data-practical-use-cases-for-clinical-research/

Digital Twins

A digital twin of a patient is a computational model of disease progression that **represents a specific subject** and predicts their expected clinical trajectory under defined conditions (e.g., standard of care).

- The twin is typically linked to the real patient through bidirectional information flow: patient characteristics are used to generate the twin's predictions, which can subsequently be compared with the patient's observed outcomes.
- AI-generated digital twins are typically produced using machine learning models trained on historical clinical data, rather than purely mechanistic models.

Key Properties

- Individual-level counterfactual:* corresponds to a specific trial participant
- Predictive: Estimates outcomes for that patient under alternative scenarios

* relating to or expressing what has not happened or is not the case.

Example Use Cases

- **In Clinical Trials:**
  - Improving trial efficiency (e.g., increasing statistical power or reducing sample size
  - Creating synthetic control arms in trials without a randomized control group
- **Outside clinical trials:**
  - Individualized medicine applications, like guiding treatment choices. But we won't cover these use cases

Synthetic Data

Synthetic clinical data are artificially generated patient records designed to reproduce the statistical properties of real datasets, but that **do not correspond to specific real individuals.**

Key Properties

- No one-to-one linkage to real patients: synthetic records represent population-level patterns rather than predictions for specific individuals
- Static generation: there is no direct dynamic interaction between synthetic records and real-world patients.

Example Use Cases

- **In Clinical Trials:**
  - Simulate and optimize different trial designs
- **Outside clinical trials:**
  - Generating privacy-preserving datasets for research and data sharing
  - Augmenting datasets used to train machine learning models