Clinical Research Education Series 2025

Presentation will begin at 12:00 PM (PT)

Artificial Intelligence in Clinical Research: Innovations, Challenges, and Future Directions

Presented by:

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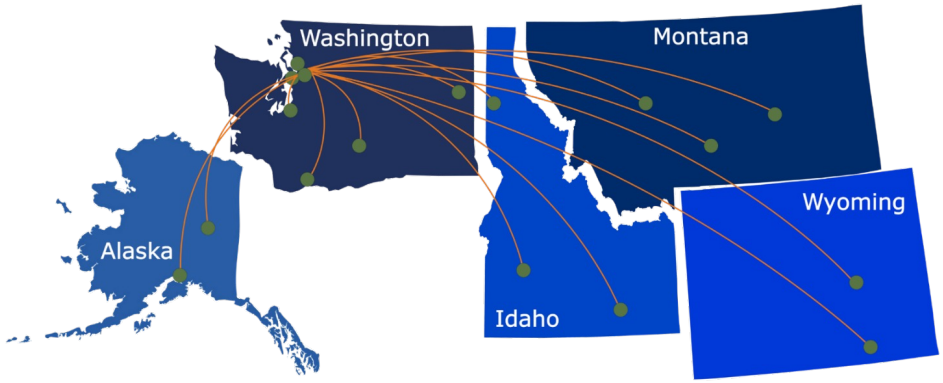

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Disclosures

I have no financial conflicts of interest to disclose.

I am not affiliated with nor compensated by any of the AI companies or platforms mentioned in this presentation.

Artificial Intelligence (AI) tools were used in the development of this presentation, including the generation of some visual content and draft text. All materials were reviewed and edited for accuracy and integrity.

The views and opinions expressed in this presentation are my own and do not necessarily reflect those of Fred Hutchinson Cancer Center.

 *"Ethically created with the help of AI tools."*

Learning Objectives

Understand AI Fundamentals

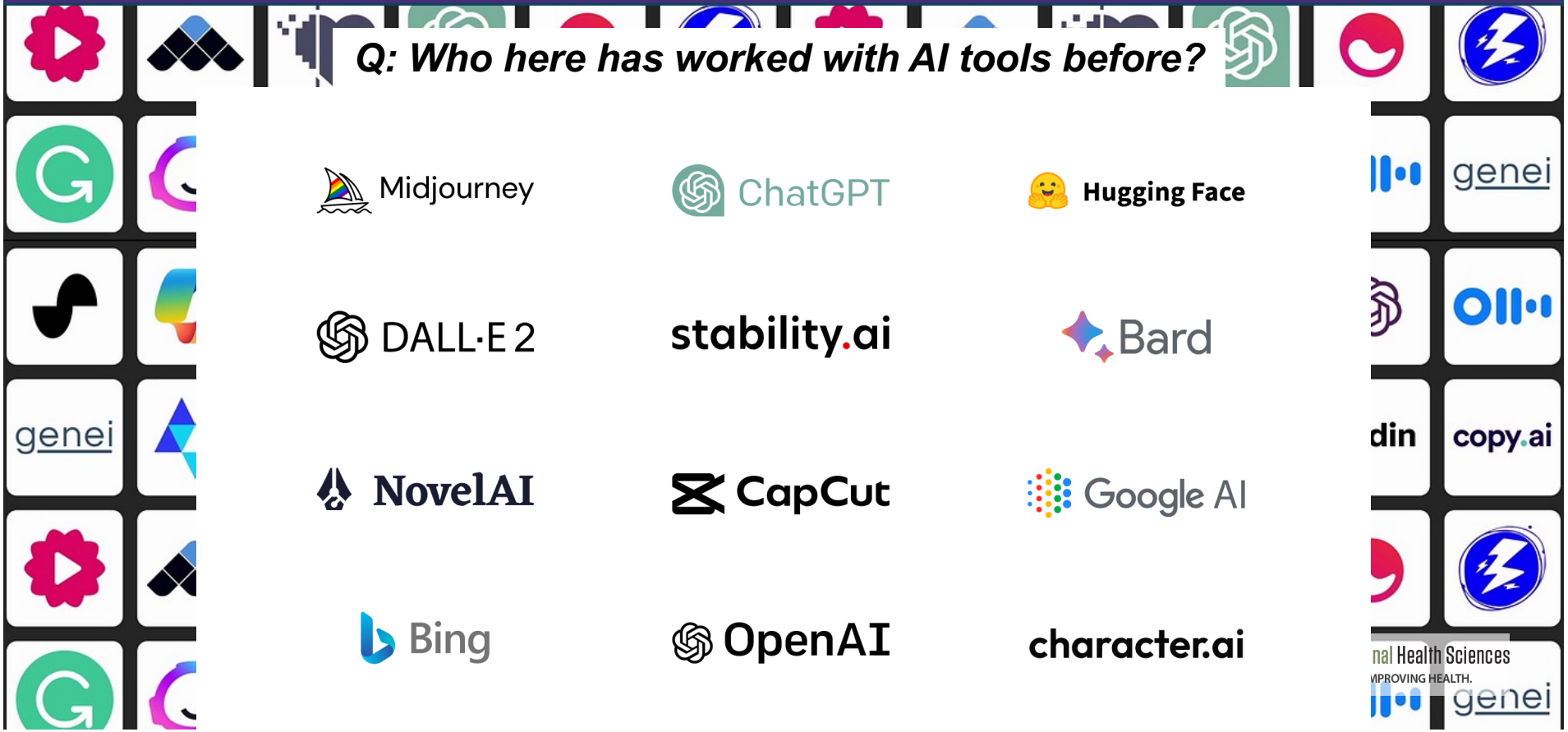
- Define Artificial Intelligence (AI), Machine Learning (ML), Deep Learning, Generative AI.
- Learn how these technologies are being applied within clinical research.

Critically Evaluate Research

- Examine key studies and data on demonstrating the effects of implanting AI in clinical research.
- Discuss both successes and limitations of AI in trials.

Introduction to AI in Clinical Research

Q: Who here has worked with AI tools before?



What is Artificial Intelligence (AI)?

Artificial Intelligence	• Making machines capable of performing intelligent tasks like human beings
Machine Learning	• A set of algorithms used by machines to learn from experience or data
Deep Learning	• A multi-layer Neural Network architecture to learn representations
Generative AI	• Using Deep Neural Networks, Such as Transformers, for, e/g/, human language tasks or for image, audio generation

What is Artificial Intelligence (AI)?

🧠 **Basic AI – Rule-Based Logic**
- Follows pre-programmed commands
- No learning or adaptation

"Hey Siri, what's the weather today?"

📊 **Machine Learning (ML) – Learns from Data**
- Improves with repeated use
- Recognizes patterns and preferences

"Hey Siri, call my wife." (Learns who "my wife" is over time)

🧠 **Deep Learning (DL) – Understands Context**
- Mimics how the human brain works
- Handles complex speech and intent

"Hey Siri, remind me to take my meds when I get home."

✨ **Generative AI – Creates Responses**
- Generates dynamic, human-like replies
- Future Siri: personalized conversations & planning

"Hey Siri, help me plan a 7-day trip to Japan under $2,000."

AI Integrations & Applications

AI in Healthcare & Clinical Research

Why AI is Important in Clinical Research

- Reduces trial costs & time.
- Improves patient recruitment & retention.
- Enhances data accuracy.
- Speeds up drug development.

Examples of AI in Healthcare

- AI-driven imaging for cancer detection.
- AI-powered personalized treatment plans.

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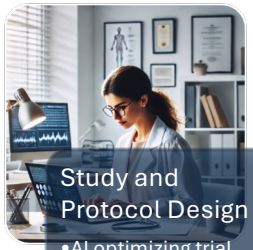
AI in the Clinical Trial Life Cycle

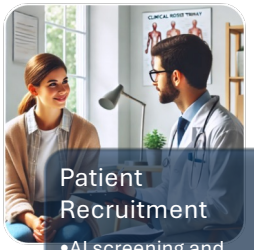


Study and Protocol Design

- AI optimizing trial protocols

Startup and Implementation

- AI calculates budgets
- AI improving operational efficiency

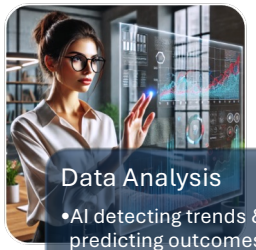


Patient Recruitment

- AI screening and matching participants

Data Collection and Monitoring

- Wearable tech
- Remote monitoring and AI QC



Data Analysis

- AI detecting trends & predicting outcomes

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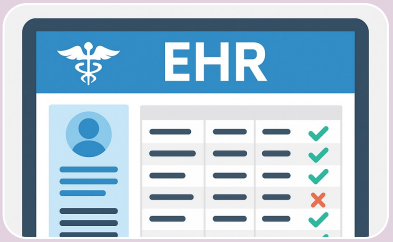
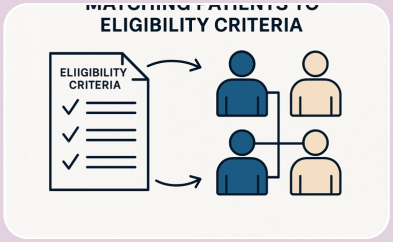
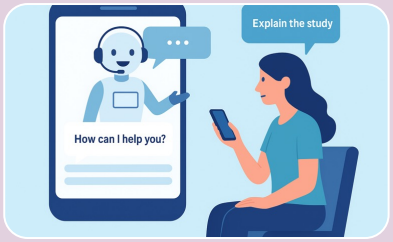
AI in Study Design & Optimization

Predictive Analytics Models	📊 *Forecast trial feasibility and success rates*
NLP (Natural Language Processing)	📄 *Scan past protocols & FDA letters to spot design risks*
Simulation Algorithms	🧬 *Run virtual trials using synthetic patient data*
ML-Based Site Selection	📌 *Identify top-performing sites based on historical data*

AI in Patient Recruitment & Retention







Machine Learning Algorithms: Screen EHR & claims data

NLP Models: Extract eligibility criteria & match patients

Conversational AI & Chatbots: Engage patients, explain studies

Predictive Models: Forecast drop-out risk

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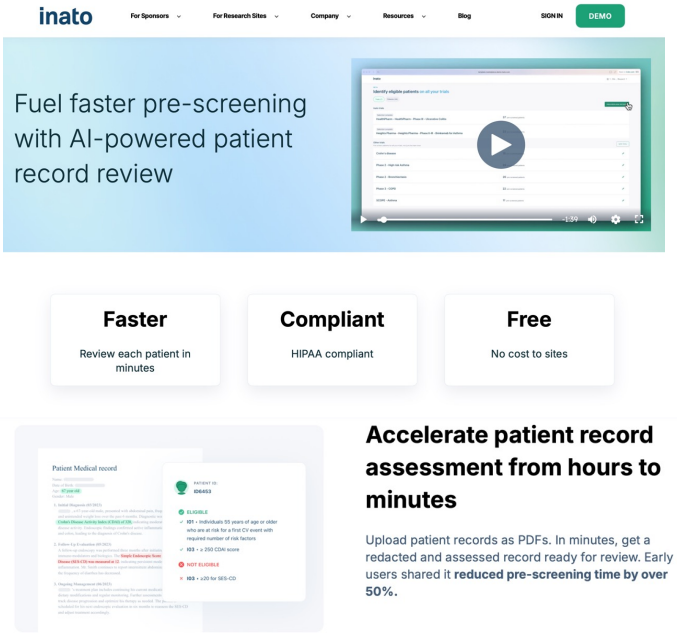
Case Study #1: AI-Powered Pre-Screening (Inato)

AI-Powered Patient Pre-Screening
Inato Platform, 2025

- **Objective:**
  Simplify & accelerate patient pre-screening at research sites
- **Approach:**
  AI analyzes patient PDFs & eligibility criteria. Results delivered in minutes
- **Results:**
  Pre-screening time reduced by 50–90%. Improved operational efficiency
- **Key Takeaway:**
  AI tools can ease recruitment burdens at the site level



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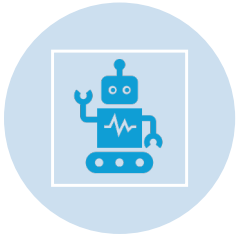
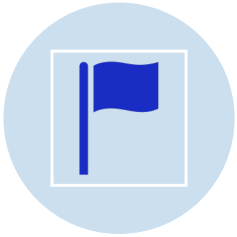
AI in Data Collection & Monitoring



AI-Powered Remote Monitoring Systems: Integrate data from wearables



ML-based Anomaly Detection: Flag protocol deviations in real time

NLP Tools: Clean & structure unstructured clinical data

Computer Vision Algorithms: Analyze imaging data remotely

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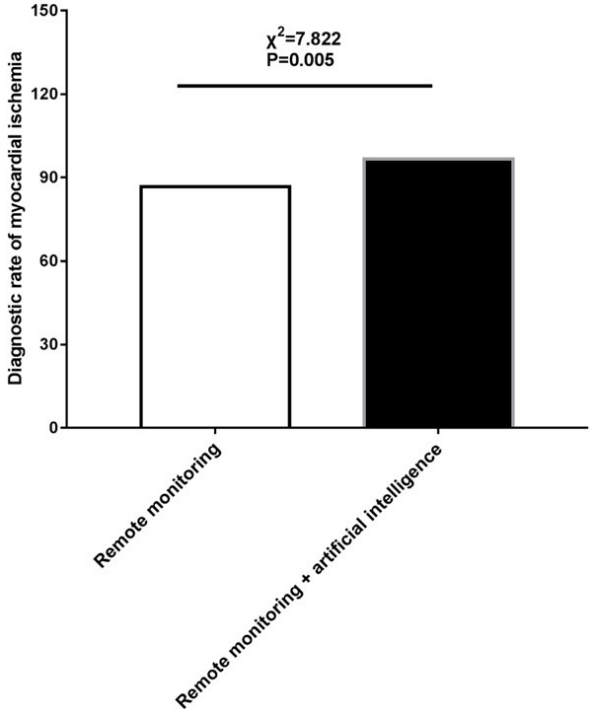
Case Study #2: AI-Enabled Remote Monitoring (Heart Failure Study)

AI-Enabled Remote Cardiac Monitoring
Heart Failure Trial, 2021

- **Objective:**
  Detect early signs of patient deterioration remotely
- **Approach:**
  AI-driven ECG monitoring system
  Continuous real-time analysis
- **Results:**
  Detected cardiac anomalies before symptoms appeared
  Enabled earlier clinical interventions
- **Key Takeaway:**
  AI improves real-time patient monitoring & safety



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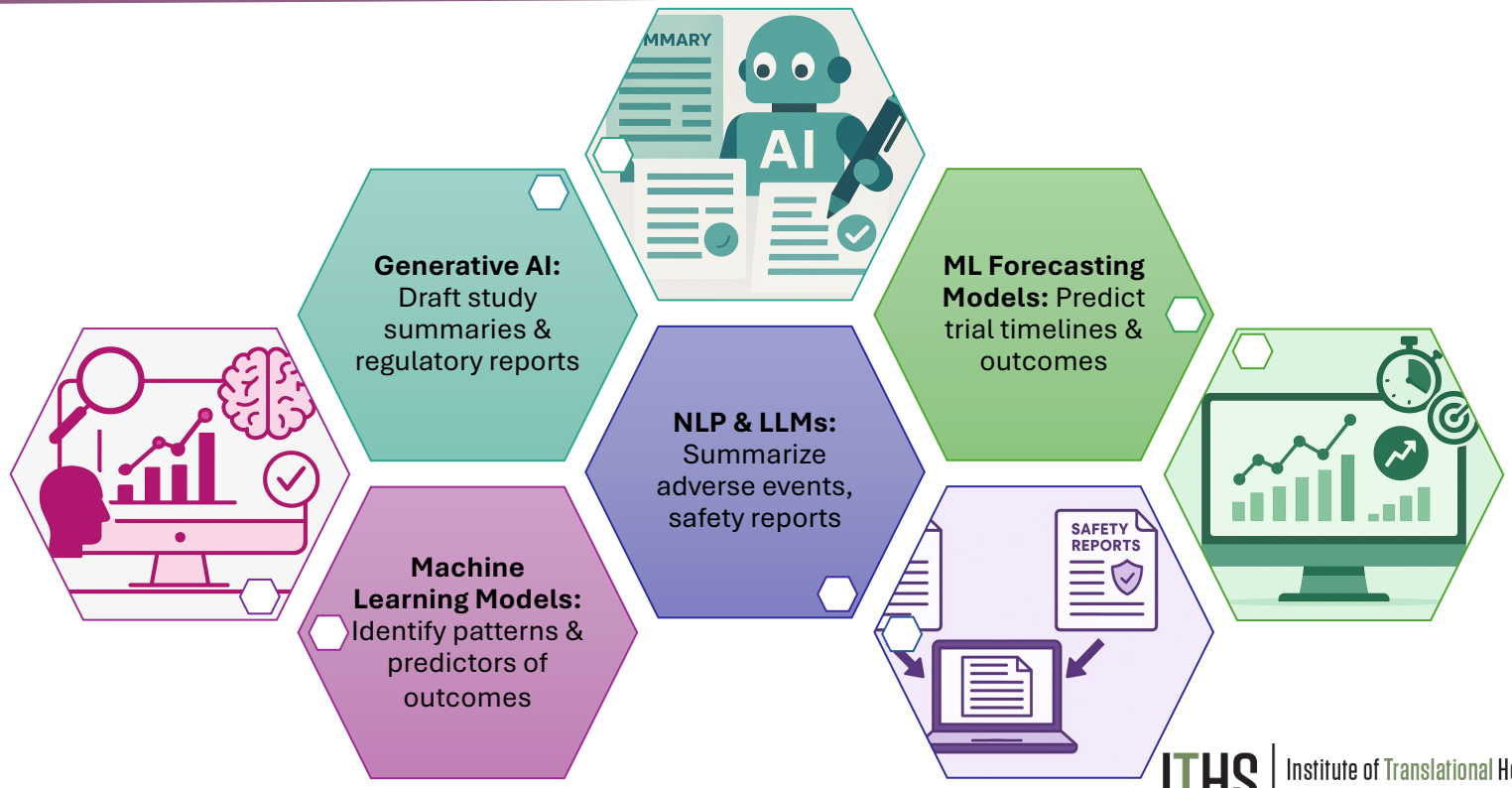
AI in Data Analysis & Insights



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Challenges & Ethical Considerations of AI in Clinical Research

⚖️ Algorithmic Bias & Fairness

- Risk of underrepresentation of minority populations

? Transparency & Explainability

- AI models often function as “black boxes”

🔒 Data Privacy & Security

- Sensitive patient data access & storage

📜 Regulatory & Compliance Gaps

- FDA & EMA guidance still evolving

🔍 Model Validation & Generalizability

- Many studies based on small-scale, early-phase data

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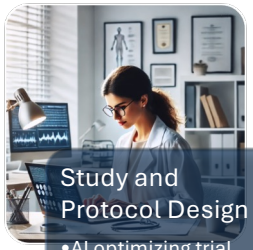

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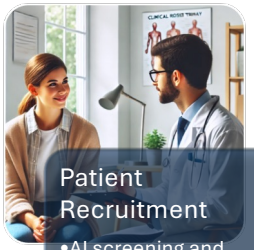

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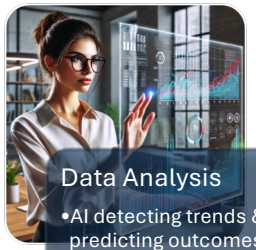

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Future of AI in Clinical Research

The Key Players of AI in Clinical Research

💊 **Pharmaceutical & Biotech Companies**	Pfizer, Novartis, Roche, Janssen investing in AI partnerships
🧬 **Tech & AI Startups**	Inato, TrialWire, Tempus, Deep 6 AI
🌐 **Academic & Research Institutions**	MIT, Stanford, NIH AI initiatives **Fred Hutch & Cancer AI Alliance (CAIA)**
🟫 **Regulatory Agencies & Consortia**	FDA's AI in Drug Development Framework EMA's AI Reflection Paper
🤝 **Public–Private Collaborations**	TransCelerate, CTTI, Alliance for AI in Healthcare

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The Game Plan:
Emerging Trends in AI & Clinical Trials

AI-Driven Adaptive Trial Designs

- Real-time protocol adjustments based on emerging data

Precision Medicine at Scale

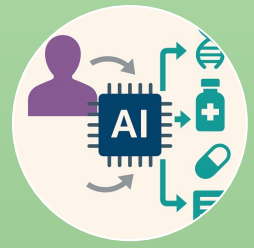
- AI matches patients to therapies using genomics, biomarkers, and clinical profiles

Deep Integration of Real-World Data (RWD)

- AI analyzes EHRs, claims, and wearable data to inform eligibility and endpoints

Enterprise-Scale Generative AI

- Drafting study documents, patient summaries & insights from structured/unstructured data



AI-Augmented Decision-Making

- AI-supported recommendations for dose selection, site choice, trial arms

The Path to Victory: What's Needed for Responsible AI Integration?

⚖️ **Ethical & Regulatory Frameworks**	FDA, EMA, and IRBs must align on AI use in trials
🔍 **Transparency & Explainability**	Reduce "black box" risk in patient care and decision-making
🧠 **AI Literacy & Training**	Equip CRCs, investigators, and ops teams with baseline AI understanding
🤝 **Cross-Sector Collaboration**	Pharma, tech, academia, and regulators working together
📈 **Robust Validation & Independent Evidence**	Large-scale, diverse studies needed to prove effectiveness and equity

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IN THIS SECTION: Center For Drug Evaluation And Research (CDER)

← Center for Drug Evaluation and Research (CDER)

Artificial Intelligence for Drug Development

What is Artificial Intelligence (AI)?

Artificial Intelligence (AI) refers to a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems (1) use machine- and human-based inputs to perceive real and virtual environments, (2) abstract such perceptions into models through analysis in an automated manner, and (3) use model inference to formulate options for information or action. A subset of AI that is commonly used in the drug product life cycle is machine learning (ML). ML refers to a set of techniques that can be used to train AI algorithms to improve performance at a task based on data.

What role is AI playing in drug development?

FDA recognizes the increased use of AI throughout the drug product life cycle and across a range of therapeutic areas. In fact, CDER has seen a significant increase in the number of drug application submissions using AI components over the past few years. These submissions traverse the drug product life cycle, which includes nonclinical, clinical, postmarketing, and manufacturing phases.

Additionally, AI is increasingly integrated in areas where CDER is actively engaged, including Digital Health Technologies (DHTs), and Real-World Data (RWD) analytics.

What is CDER's perspective on the use of AI in drug development?

CDER is committed to ensuring that drugs are safe and effective while facilitating innovations in their development. FDA published a draft guidance in 2025 titled, "Considerations for the Use of Artificial Intelligence to Support Regulatory Decision Making for Drug and Biological Products." This guidance provides recommendations to industry on the use of AI to produce information or data intended to

FDA Search Menu

IN THIS SECTION: Search For FDA Guidance Documents

← Search for FDA Guidance Documents

GUIDANCE DOCUMENT

Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products

Draft Guidance for Industry and Other Interested Parties

JANUARY 2025

Download the Draft Guidance Document | Read the Federal Register Notice

Draft | Level 1 Guidance

Not for implementation. Contains non-binding recommendations.

Search for FDA Guidance Documents

Docket Number: FDA-2024-D-4689

Issued by: Center for Veterinary Medicine
Office of Inspections and Investigations
Oncology Center of Excellence
Center for Biologics Evaluation and Research
Center for Devices and Radiological Health
Center for Drug Evaluation and Research
Office of the Commissioner, Office of the Chief Medical Officer, Office of Combination Products

This guidance provides recommendations to sponsors and other interested parties on the use of artificial intelligence (AI) to produce information or data intended to support regulatory decision-making regarding safety, effectiveness, or quality for drugs. Specifically, this guidance provides a risk-

The Path to Victory: What's Needed for Responsible AI Integration?

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Key Takeaways & Final Thoughts

What We Learned Today:

🚀 **AI is transforming clinical research operations**

- From protocol design to patient recruitment, data monitoring & analysis

📊 **Real-world case studies show measurable benefits**

- Improved recruitment efficiency & patient safety

⚖️ **Ethical & regulatory challenges remain**

- Bias, transparency, privacy & compliance must be addressed

🌍 **The future of AI in clinical research is collaborative**

- Requires academia, industry, regulators & research professionals working together

🔥 **Your role:**

- Stay informed, ask critical questions, and engage responsibly with AI

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Thank You!

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Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.

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