

# Artificial Intelligence Challenges for Regulating Vaccine Development

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# Informal Communication Disclaimer



My comments are an informal communication and represent my own best judgement. These comments do not bind or obligate FDA.

# Artificial Intelligence (AI) Challenges



- One word – *'Evolving'*
  - Like the technology itself, regulatory science is evolving
- Where are we today?



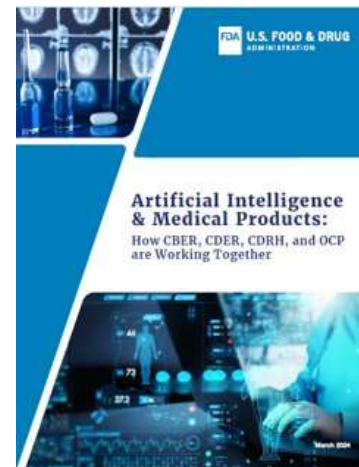
# Learning Objectives

- To appreciate and describe the current approach to AI challenges in regulatory oversight of vaccines.

# Guiding Principles (GP)



- [Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products](#) (May 11, 2023)
  - Discussion Paper requesting Feedback from Stakeholders on Uses and Regulation of AI
- [Executive Order 14110 – Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence](#) (October 30, 2023)
  - To advance and govern the development and use of AI in accordance with **eight guiding principles and priorities**
- [Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together](#) (March 15, 2024)
  - To advance responsible innovation and to foster the **safe, secure, and ethical** deployment and use of AI in medical product development and medical products



# GP: Executive Order 14110



- Eight guiding principles and priorities:
  - AI must be safe and secure
  - Promotion allowing U.S to lead in AI
  - Development and use supports American workers
  - AI policies consistent with equity and civil rights
  - Interests of Americans must be protected
  - Privacy and civil liberties must be protected
  - Manage the risks from Governmental use
  - Federal government should lead the way

# GP: AI and Medical Products



Figure 1. Four areas of focus regarding the development and use of AI across the medical product lifecycle.

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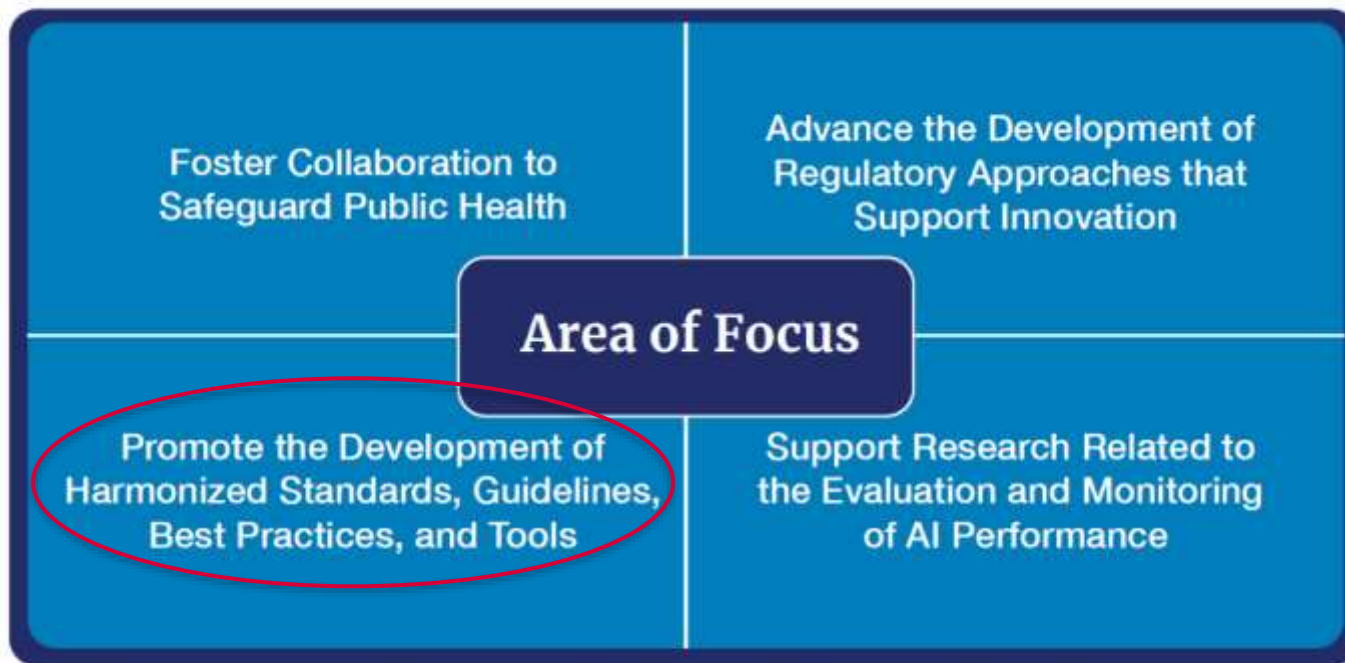


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# Artificial Intelligence Coordinating Committee (AICC)



- Staff education, communications, landscaping, review, use of AI
- Aligning AI strategy within FDA
- IND submission (2016 – 2023) identified 60+ submissions involving AI
  - Use of AI in INDs is growing each year
  - Mostly Oncology and Infectious Disease Product Areas
  - Prediction, classification, clustering, anomaly detection

# Regulatory Review AI Subcommittee (RRAIS)



- Exploring review approaches to AI-containing submissions
- Applying framework and standards as appropriate
- Using a risk-based review approach

# Engaging with CBER



- **FDA Web Site:** [Focus Area: Artificial Intelligence | FDA](#)
- **CBER Web Site:**
  - [Artificial Intelligence and Machine Learning \(AI/ML\) for Biological and Other Products Regulated by CBER | FDA](#)
  - [Artificial Intelligence and Medical Products | FDA](#)
- **For specific uses** in regulatory submissions: Contact assigned RPM or Office with product responsibility *well in advance of intended use* - [Request a formal meeting](#)
- **For broader application** in manufacturing, or novel products:
  - [CBER Advanced Technologies Team \(CATT\)](#)
- **For general AI inquiries:**
  - [OCOD@fda.hhs.gov](mailto:OCOD@fda.hhs.gov)

# Challenge Question #1



**Executive Order 14110 – Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence included the following guiding priority:**

- A. Development and use supports global usage
- B. AI policies consistent with market forces
- C. Privacy and civil liberties must be protected
- D. Industry sponsors should lead the way

# Challenge Question #2



Which of the following statements is **NOT** true?

- A. Use of Artificial Intelligence in vaccine development and production was found to be growing every year in a recent analysis.
- B. Uses of Artificial Intelligence was primarily found to be growing in neurology and pediatric diseases vaccine development.
- C. A recent 2016 – 2023 analysis of IND submissions found that there were around 60 submissions involving Artificial Intelligence.
- D. Artificial Intelligence use in vaccine development is growing faster than regulatory science can accommodate guidance documents to assist Sponsors in their product development.

# Summary

- Most AI regulatory activity within CBER has been a relatively recent occurrence
- We would like Sponsors to engage the Agency early in the process to assure success
- Working together, AI can be a powerful and useful tool to speed availability of biologics





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# Questions?

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# Closing Thought

AI and its use in vaccine applications is evolving

Engage the FDA early