Artificial Intelligence Challenges for Regulating Vaccine Development

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Informal Communication Disclaimer

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

Artificial Intelligence (AI) Challenges

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- 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
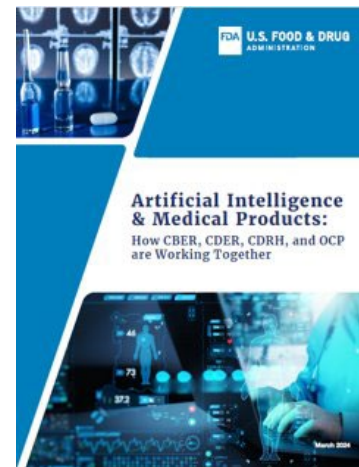
GP: Executive Order 14110

- 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

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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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Foster Collaboration to Safeguard Public Health

Advance the Development of Regulatory Approaches that Support Innovation

Area of Focus

Promote the Development of Harmonized Standards, Guidelines, Best Practices, and Tools

Support Research Related to the Evaluation and Monitoring of AI Performance

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

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

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Challenge Question #1

Executive Oder 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

Questions?

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Closing Thought

AI and its use in vaccine applications is evolving

Engage the FDA early