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Implementing AI to **Accelerate** the Next Era of RWD/RWE

SCOPE Summit
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Co-Host Real-World Wednesdays (RWW) Podcast

What is AI?

"AI is the new electricity"

Andrew Ng

Co-Founder , Chief Scientist

Google Brain DeepLearning.AI

Baidu 百度 coursera

"AI is not the new electricity; it's a new operating system."

Andrej Karpathy

Director, Educator, Communicator

TESLA OpenAI

What is AI?

"AI is technology that enables machines and computer systems to perform tasks that typically require human intelligence, such as learning, problem-solving, and decision-making."

Gemini

FDA/EMA: Guiding Principles of Good AI Practice in Drug Development

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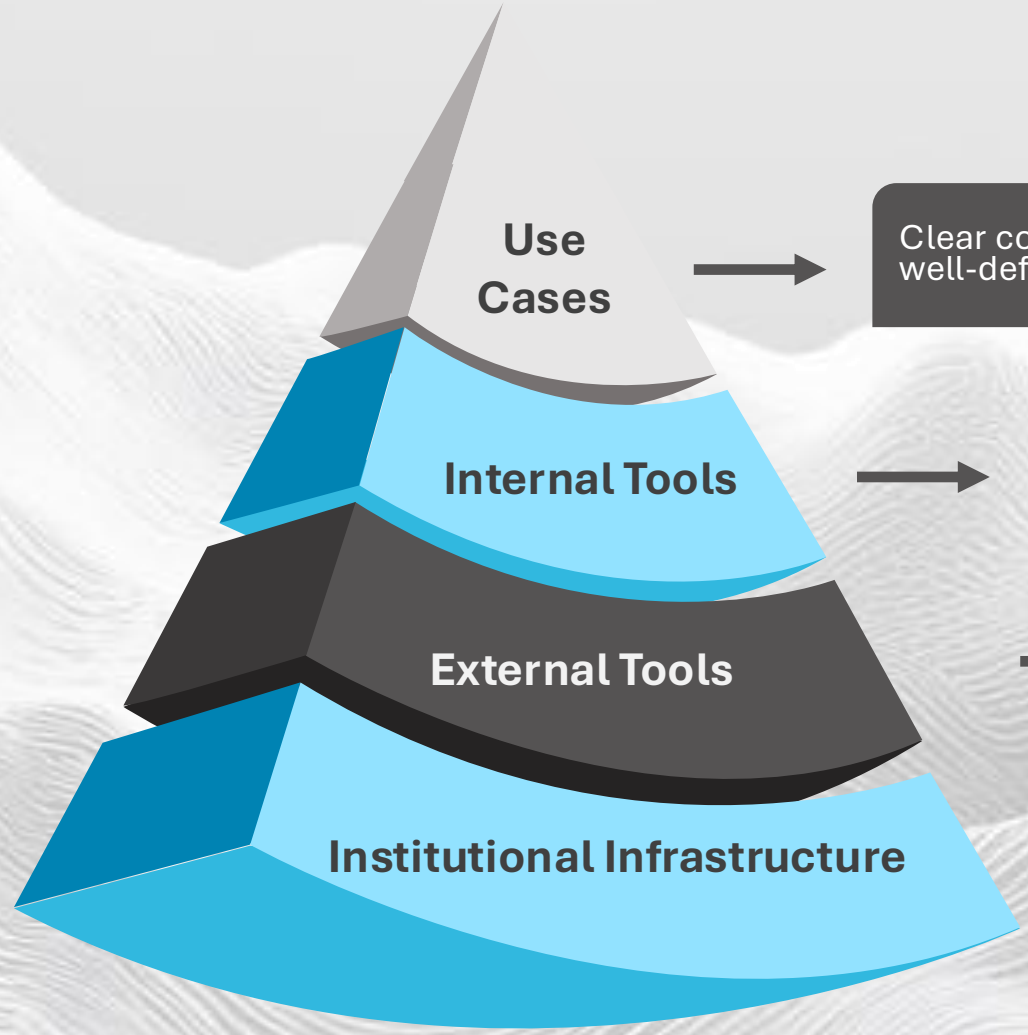
Principle	FDA/EMA Source Wording	Key Requirement	Regulatory Implication
1. Human-centric by design	The development and use of AI technologies align with ethical and human-centric values.	Ethical, human-centric values	AI serves patients and clinicians, not vice versa
2. Risk-based approach	The development and use of AI technologies follow a risk-based approach with proportionate validation, risk mitigation, and oversight based on the context of use and determined model risk.	Proportionate validation based on model risk	Higher-risk applications require more rigorous validation
3. Adherence to standards	AI technologies adhere to relevant legal, ethical, technical, scientific, cybersecurity, and regulatory standards, including Good Practices (GxP).	Compliance with GxP and other standards	AI doesn't exempt you from existing regulations
4. Clear context of use	AI technologies have a well-defined context of use (role and scope for why it is being used).	Well-defined role and scope	Must articulate exactly why/how AI is used
5. Multidisciplinary expertise	Multidisciplinary expertise covering both the AI technology and its context of use are integrated throughout the technology's life cycle.	Both AI and domain expertise	Need clinical/regulatory AND data science knowledge
6. Data governance and documentation	Data source provenance, processing steps, and analytical decisions are documented in a detailed, traceable, and verifiable manner, in line with GxP requirements. Appropriate governance, including privacy and protection for sensitive data, is maintained throughout the technology's life cycle.	Full traceability and documentation	Every data processing step must be documented
7. Model design and development practices	The development of AI technologies follows best practices in model and system design and software engineering and leverages data that is fit-for-use, considering interpretability, explainability, and predictive performance. Good model and system development promotes transparency, reliability, generalizability, and robustness for AI technologies contributing to patient safety.	Best practices, fit-for-use data	Consider interpretability, explainability, performance
8. Risk-based performance assessment	Risk-based performance assessments evaluate the complete system including human-AI interactions, using fit-for-use data and metrics appropriate for the intended context of use, supported by validation of predictive performance through appropriately designed testing and evaluation methods.	System-level validation including human-AI interaction	Test the complete workflow, not just the model
9. Life cycle management	Risk-based quality management systems are implemented throughout the AI technologies' life cycles, including to support capturing, assessing, and addressing issues. The AI technologies undergo scheduled monitoring and periodic re-evaluation to ensure adequate performance (e.g., to address data drift).	Ongoing monitoring for data drift	One-time validation isn't sufficient
10. Clear, essential information	Plain language is used to present clear, accessible, and contextually relevant information to the intended audience, including users and patients, regarding the AI technology's context of use, performance, limitations, underlying data, updates, and interpretability or explainability.	Plain language communication	Stakeholders must understand limitations and performance

Source: FDA/EMA. "Guiding Principles of Good AI Practice in Drug Development" Available: https://www.fda.gov/about-fda/artificial-intelligence-drug-development/guiding-principles-good-ai-practice-drug-development

AI Implementation Framework



Clear context of use; well-defined role and scope

Tailored to your unique needs and/or an external tool is not available

Suite of external tools:
- Broad-use tools
- Use-specific tools

Set of technologies, environments, policies & processes to support AI use across functions/depts

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AI in Practice: AI-*assisted* **Expert** Curation

01 → 02 → 03 → 04

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STUDY ELEMENTS

Extract / organize research study elements

Obese or **Overweight** with a **Comorbidity**

CODefs PRECISELY DEFINE...

- Eligibility Criteria
- Patient Characteristics
- Comorbid Diseases
- Treatment History

...and more

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CONCEPTUAL DEFINITION

Comprehensive list of relevant clinical concepts, described in clinical terms

Obesity
OR
Overweight
AND
Diagnosis of **hypertension**
OR
Diagnosis of **dyslipidemia**
OR
Diagnosis of **obstructive sleep apnea**
OR
Etc.

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OPERATIONAL DEFINITION

Specifies exact data, codes, timeframes and other relevant qualifiers

Body Mass Index ≥ 30 kg/m² within the **12 months prior to the index date** AND the most **proximal documented value** to the index date
OR
≥ 1 Diagnosis Record from Obesity Diagnoses within the **12 months prior to the index date** AND any **encounter type** AND **any diagnosis position** AND most **proximal documented value** to the index date
AND
Etc.

CODef

perplexity

Verification

Assisted by Perplexity,ai, an expert health informaticist verified the accuracy of the CODefs and associated code lists

Conclusion: AI accelerates an expert informaticist's ability to create and maintain CODefs (and code lists) **quickly** and **accurately**; which are compliant with *stakeholder / regulatory* expectations

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Conclusion

AI technology is real and works, but working AI isn't enough.

"Pharma's biggest barrier isn't accuracy or model quality, it's **change management**. The organizations you're selling into are governed by entrenched SOPs, regulatory risk aversion, and workflows designed decades ago. The successful startups won't just build great models. They'll help their customers realize the full value of AI by helping them **change their processes to capture its benefits**."

Source: Jeffrey Low MD. Averin Capital. "Why Pharma AI Startups Need to Be Integrators, Not Just Innovators" Available: https://www.averincapital.com/insights/why-pharma-ai-startups-need-to-be-integrators-not-just-innovators

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