



AI in Drug Development

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Disclaimer

I am a current employee of Johnson & Johnson.

The information and content of this presentation are my own, for educational purposes, and do not reflect the views of the Johnson & Johnson company.

**What can we do with technology
today that we were not doing 5
years ago?**

Challenges in Clinical Trial Image Reviews

Challenges

- Time consuming
- Subjective
- Increase variability
- Potential introduction of bias

Opportunity

- AI / ML Models
- Standard measurements

Question

- How do you create a broad multi-anatomy, multi-tumor model?

Pre-competitive Consortia

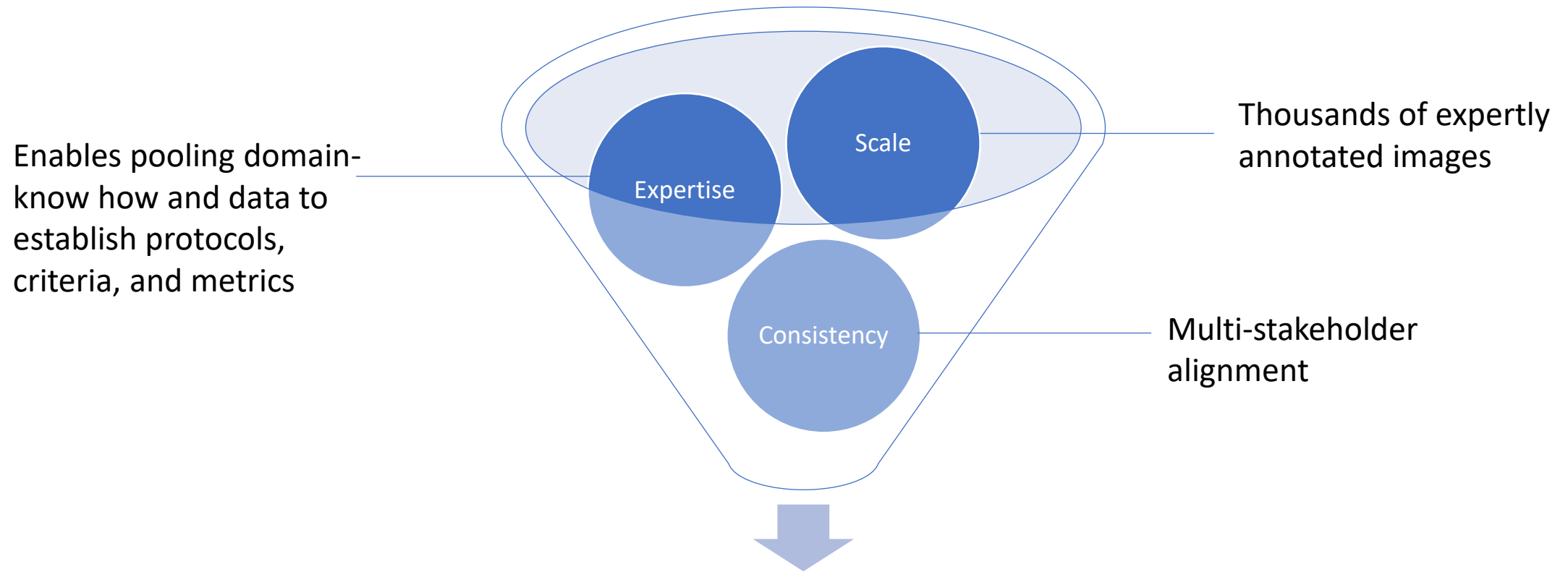
FDA: “...allow for multiple stakeholders to work collectively to achieve shared outcomes and address shared challenges...”

-[Establishing and Maintaining Collaborative Communities](#), CDRH



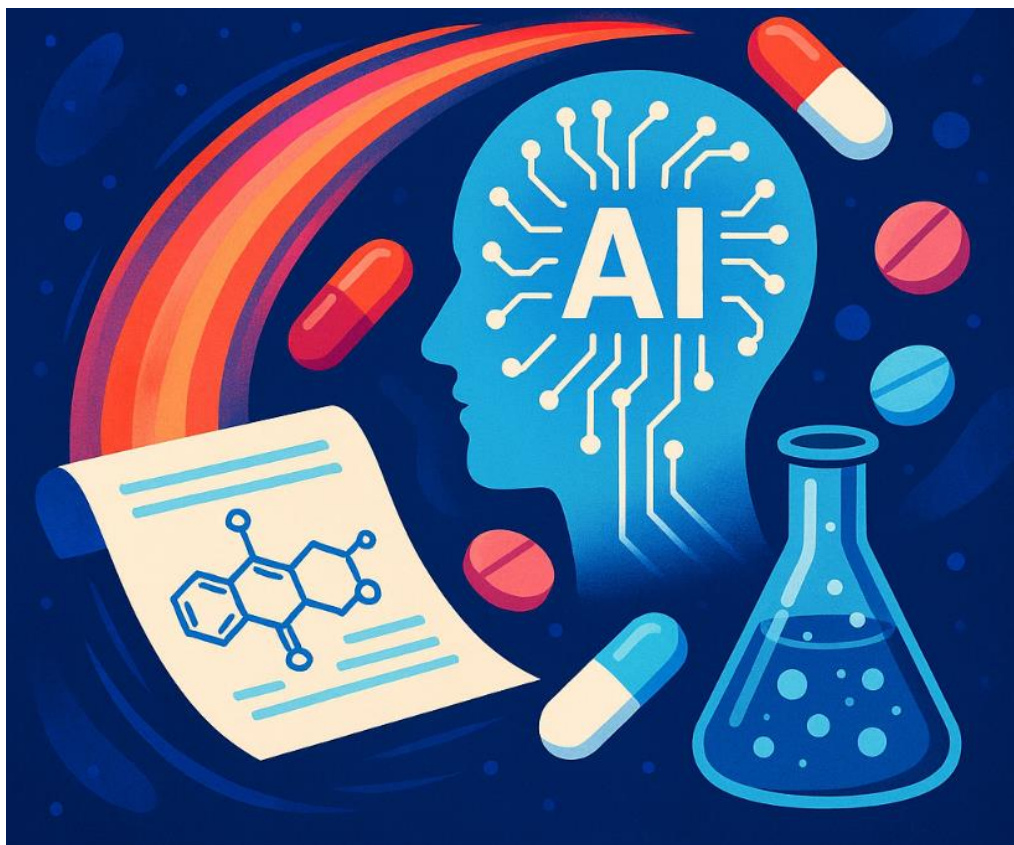
Diagram illustrating the organisation of the Pistoia Alliance and how its various constituents interface with each other

Why consortia for AI imaging?



Shared Vision for Development

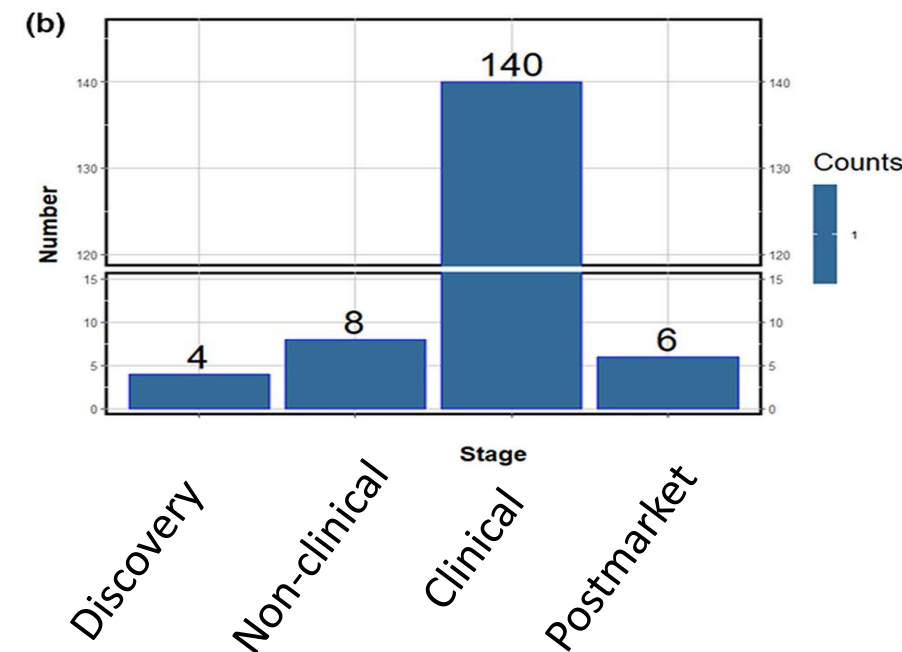
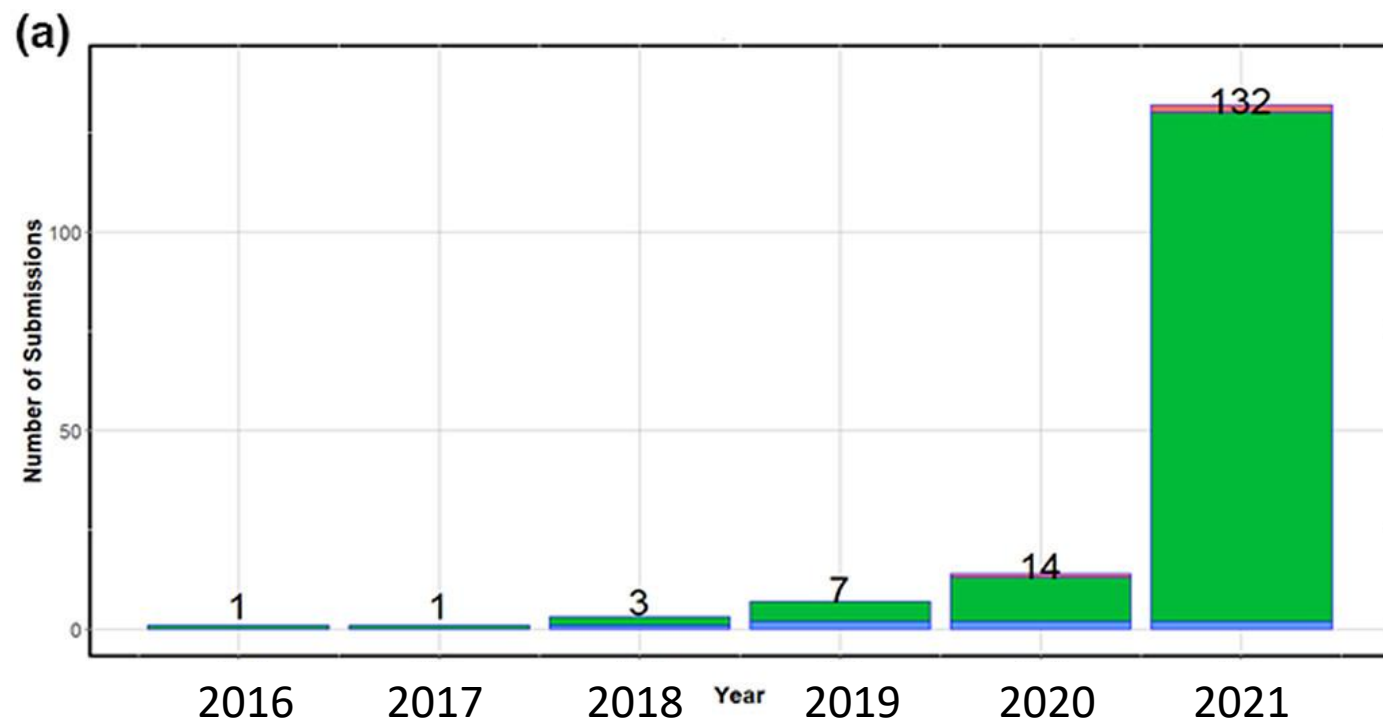
Momentum is building for AI in drug development



ChatGPT, 4o



AI/ML is increasingly used in drug clinical development



EMA Reflection Paper

- Structured framework on incorporating human-centric principles
- Where does AI fit in the current EU regulatory landscape?
- Risk-based oversight for use of AI in medicinal product lifecycle



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 September 2024
EMA/CHMP/CVMP/83833/2023
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle

Draft agreed by Committee for Medicinal Products for Human Use (CHMP) Methodology Working Party	July 2023
Draft adopted by CVMP for release for consultation	13 July 2023
Draft adopted by CHMP for release for consultation	10 July 2023
Start of public consultation	19 July 2023
End of consultation (<i>deadline for comments</i>)	31 December 2023
Final version agreed by MWP	6 September 2024
Final version adopted by CHMP	9 September 2024
Final version adopted by CVMP	11 September 2024

Keywords	Artificial intelligence, AI, machine learning, ML, regulatory, medicine, human medicinal product, veterinary medicinal product
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FDA Draft Guidance

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

Guidance for Industry and Other Interested Parties

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Tala Fakhouri, 301-837-7407; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Digital Health Center of Excellence, digitalhealth@fda.hhs.gov.

U.S. Department of Health and Human Services
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Center for Devices and Radiological Health (CDRH)
Center for Veterinary Medicine (CVM)
Oncology Center of Excellence (OCE)
Office of Combination Products (OCP)
Office of Inspections and Investigations (OII)

January 2025
Artificial Intelligence

- Defines context of use – AI's role and how it is involved in decisions
- Risk assessment – Impact on safety and efficacy decisions
- Credibility plan – Detail model design, training, performance, and testing

Tools to Support Drug Development



Deliberate AI's acceptance into FDA ISTAND program for a tool intended to automate anxiety and depression scoring with performance equivalent to a trained physician.



EMA CHMP Qualification Opinion enables data from the locked model to be accepted as scientifically valid. The model reduces variability and increases reproducibility and repeatability.

Building Confidence in AI

