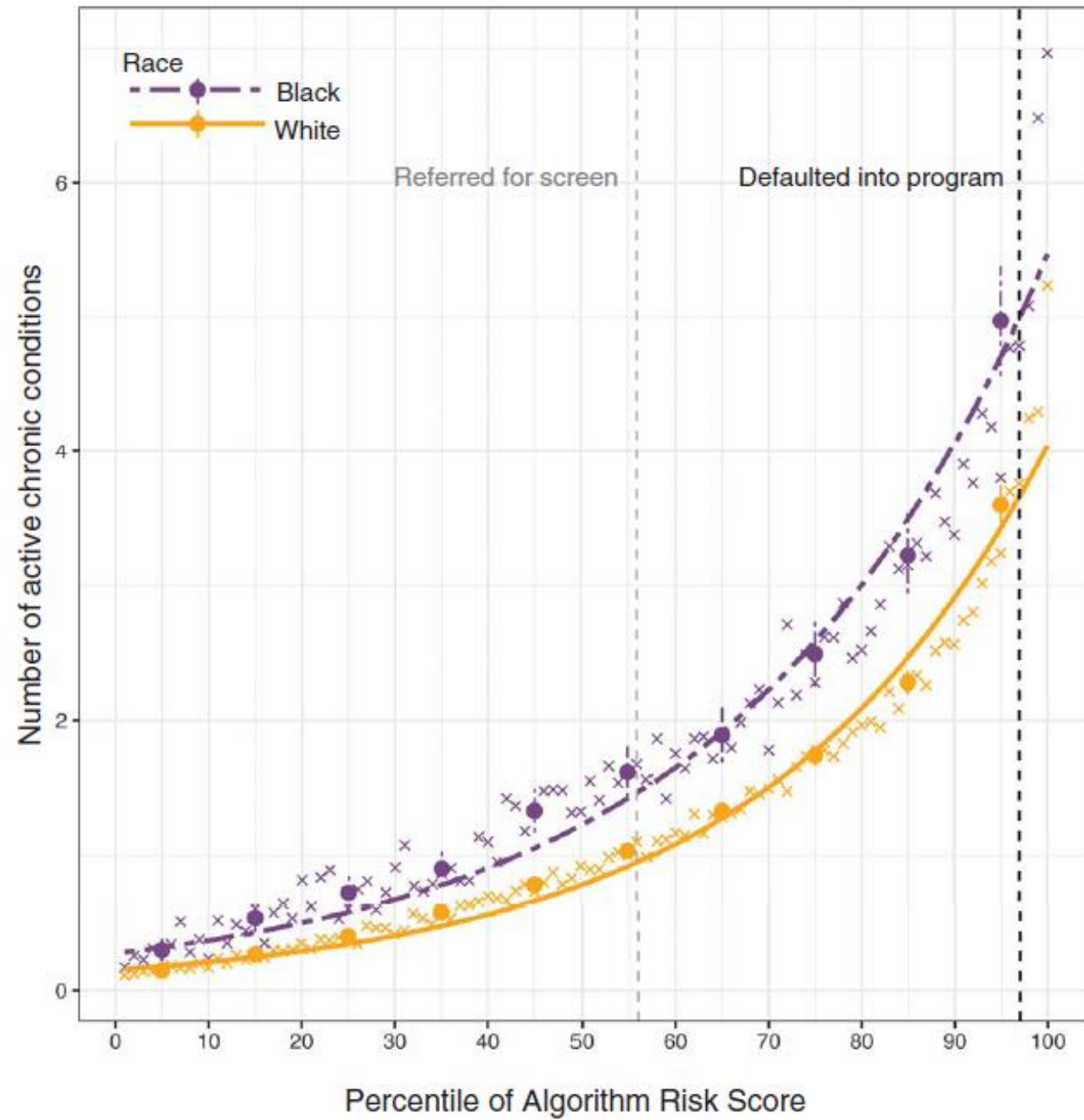


AI in Clinical Trials: striving for equitable healthcare through innovation

Melanie Poulin-Costello
Director Statistics
Roche





Artificial Intelligence



- The real future of AI is hard to see without dedicating time and effort to learning more about what it is
 - Amy Webb
- AI stresses me out
 - Elon Musk

Equitable Healthcare

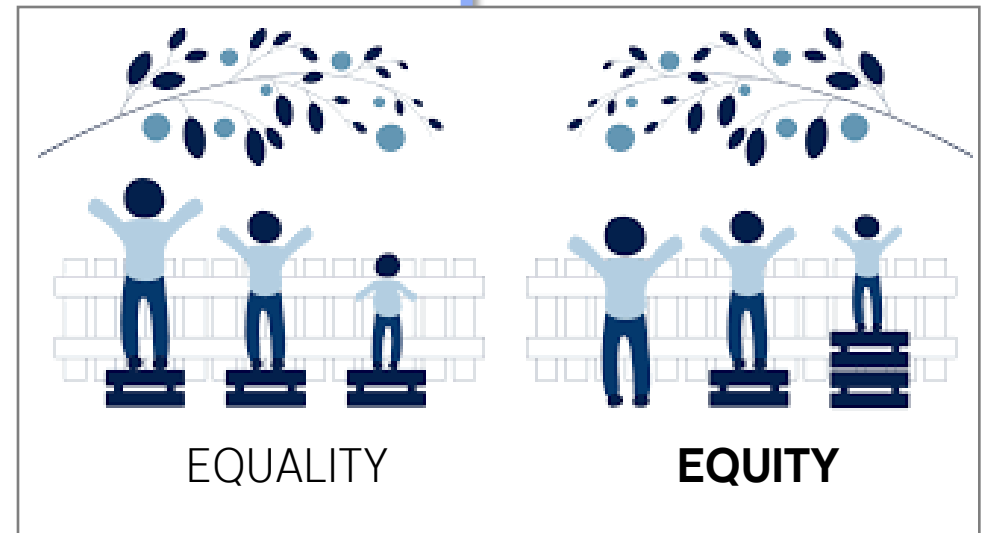
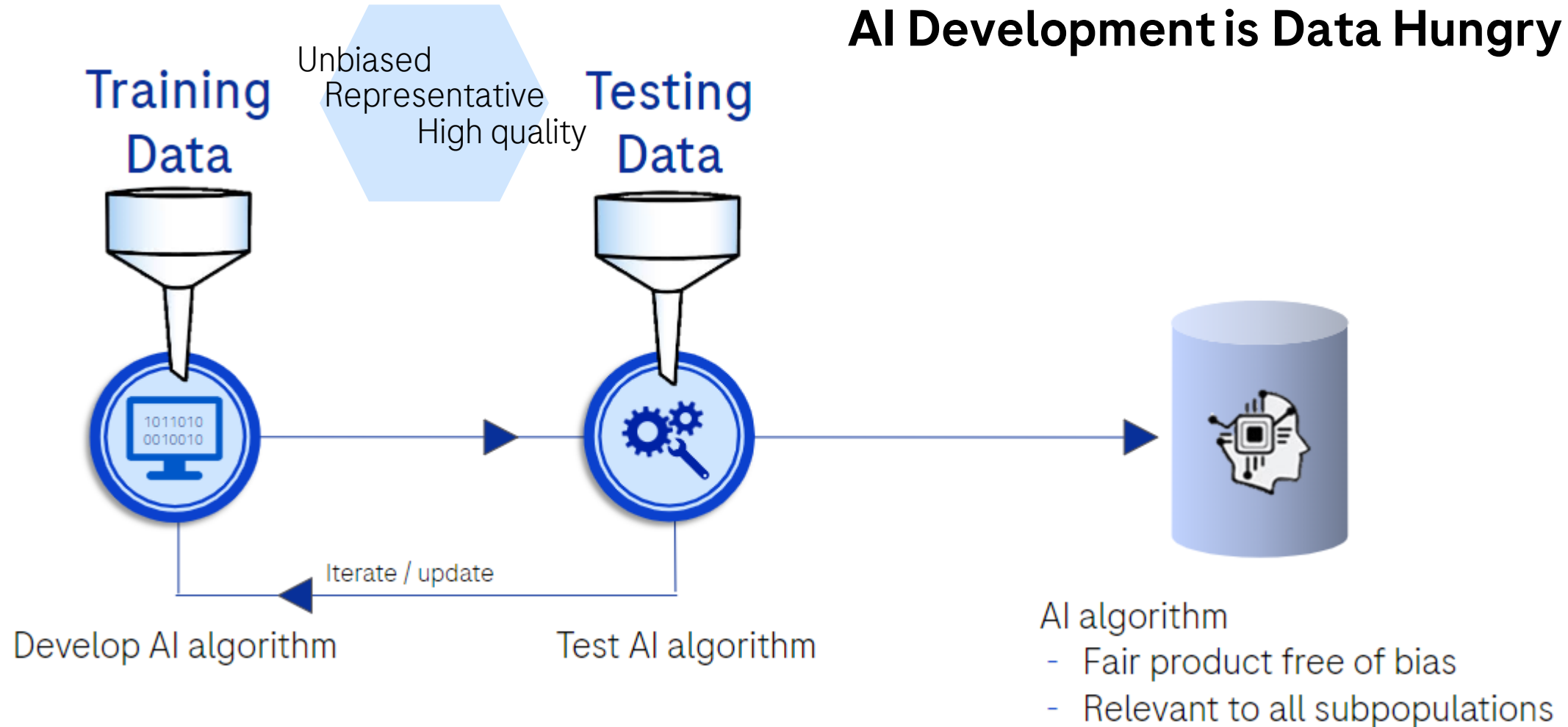


Table of contents

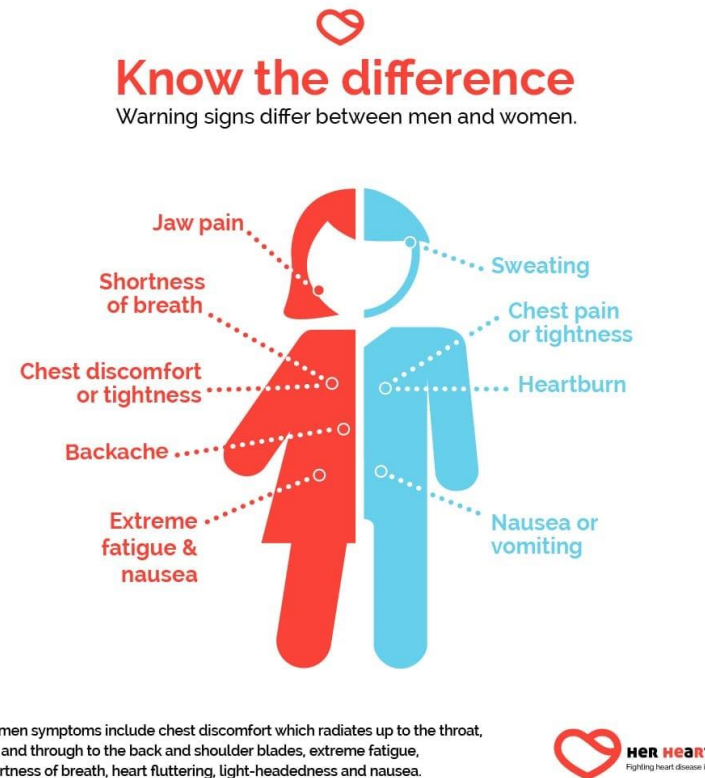
1. Using Data to Generate Equitable AI
2. Regulation of AI
3. Striving for AI and equitable healthcare

1.Using Data to Generate Equitable AI

AI Development is Data Hungry



Bias in test and training data lead to inequitable AI



Foster positive interpersonal relationships between people experiencing homelessness and healthcare providers

Include peer support workers and interprofessional team members to address the complex needs of people experiencing homelessness

Establish a welcoming and inclusive environment to encourage access to primary care and social connectedness

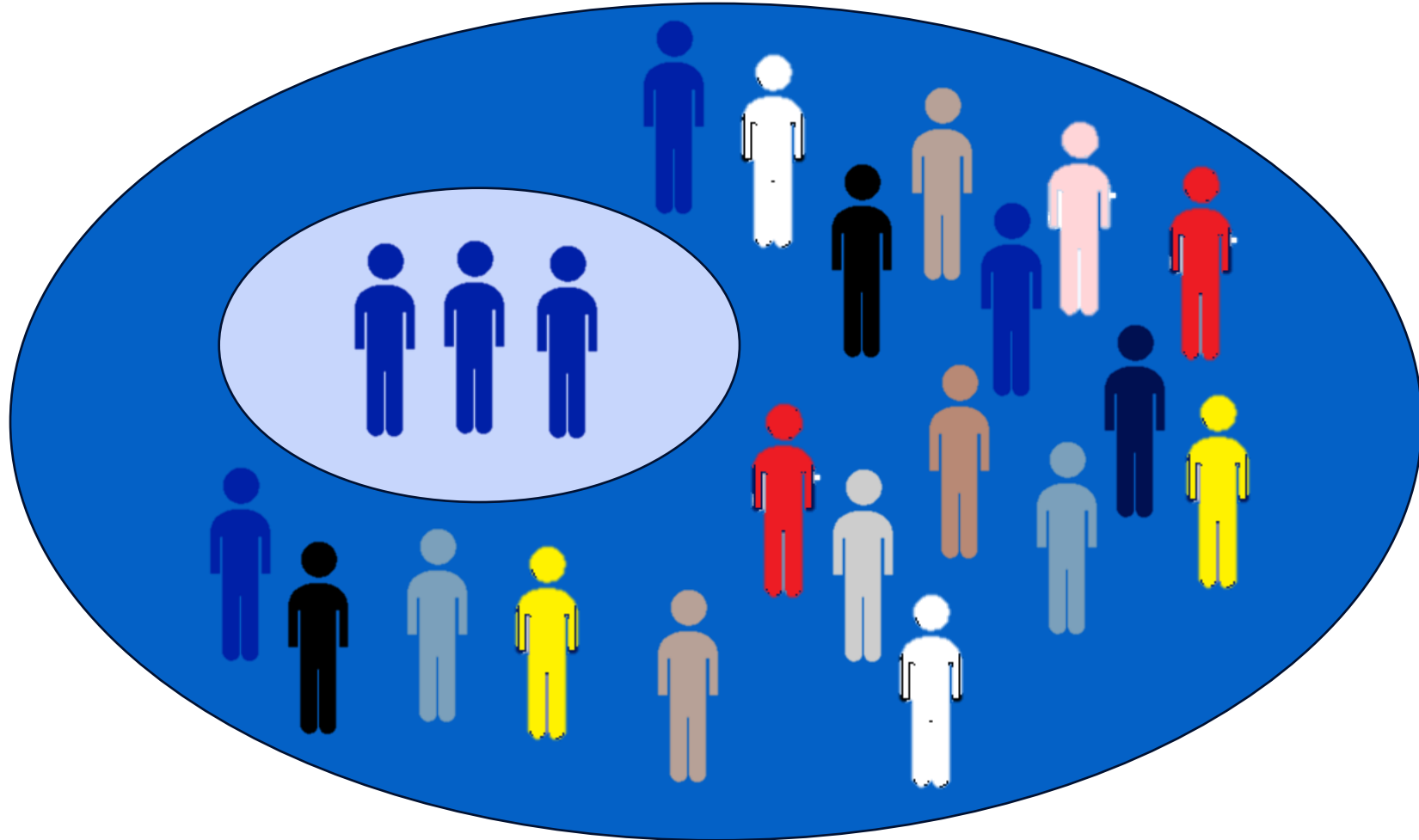
Support system navigation and build connections to mainstream care to help reduce barriers

Enable collection and sharing of health information to improve care continuity and support evaluation of primary care programs

Adopt sustainable and adaptive funding models

Unbiased
Representative
High quality

Data for testing/training should be representative



2. Regulation of AI

Regulation of AI

What will it look like?

Sam Altman's U Turn on EU AIA



Sam Altman: CEO of OpenAI calls for US to regulate artificial intelligence

17 May 2023



By James Clayton
North America technology reporter

The creator of advanced chatbot ChatGPT has called on US lawmakers to regulate artificial intelligence (AI).

Sam Altman, the CEO of OpenAI, the company behind ChatGPT, testified before a US Senate committee on Tuesday about the possibilities – and pitfalls – of the new technology.

17 May 2023



ChatGPT-maker warns it might leave EU over planned AI law

25 May 2023



By Shona McCann and Chris Vellante
Technology reporters

The boss of the company behind ChatGPT has said it might consider leaving the EU if it fails to comply with a planned law on artificial intelligence (AI).

The EU's planned legislation could be the first to specifically regulate AI.

25 May 2023



TECHNOLOGY | EUROPE
OpenAI CEO rolls back threat to quit Europe over regulation

Thursday

Sam Altman sparked criticism after accusing the European Union of "overregulating" artificial intelligence platforms. Having warned that ChatGPT may pull out of Europe, Altman now says his firm has "no plans to leave."

f t v

OpenAI – the company behind the popular artificial intelligence (AI) platform ChatGPT – has no plans to leave Europe, CEO Sam Altman said on Friday, reversing a threat made earlier this week.

"We are excited to continue to operate here and of course these are often the issues," Altman said in a

26 May 2023

ChatGPT boss wants HQ in Europe

OpenAI's Sam Altman tells POLITICO France is looking good, as he pledges to comply with EU rules.



31 May 2023

What does / will Regulation of AI look like?



中共中央网络安全和信息化委员会办公室
Office of the Central Cyberspace Affairs Commission

Draft AI regulation



**U.S. FOOD & DRUG
ADMINISTRATION**

Artificial Intelligence and Machine Learning (AI/ML) for Drug Development

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US, Europe Working on Voluntary AI Code of Conduct as Calls Grow for Regulation

The United States and Europe are drawing up a voluntary code of conduct for artificial intelligence, with a draft expected in weeks

By [Associated Press](#) | May 31, 2023, at 12:04 p.m.

[Save](#) [Comment](#) [f](#) [t](#) [v](#)

White House AI Bills of Rights

- five principles to prevent discrimination and protect user privacy and safety

<https://www.whitehouse.gov/ostp/ai-bill-of-rights>



EUROPEAN
COMMISSION

Brussels, 21.4.2021
COM(2021) 206 final

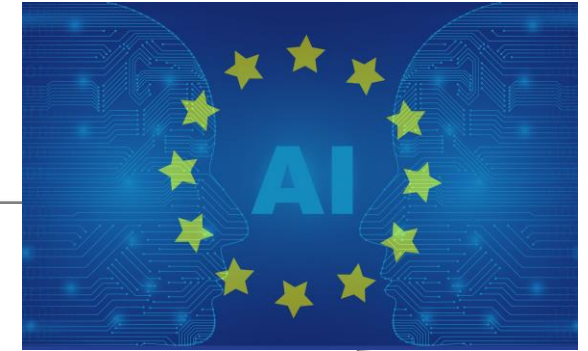
2021/0106 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE
(ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION
LEGISLATIVE ACTS

{SEC(2021) 167 final} - {SWD(2021) 84 final} - {SWD(2021) 85 final}



Artificial Intelligence and Data
Act (AIDA), as part of [Bill C-27](#).

2. Regulation of AI

Alarmed tech leaders call for AI research pause

As systems dazzle, researchers worry about lack of safeguards and regulation

11 APR 2023 • 2:50 PM

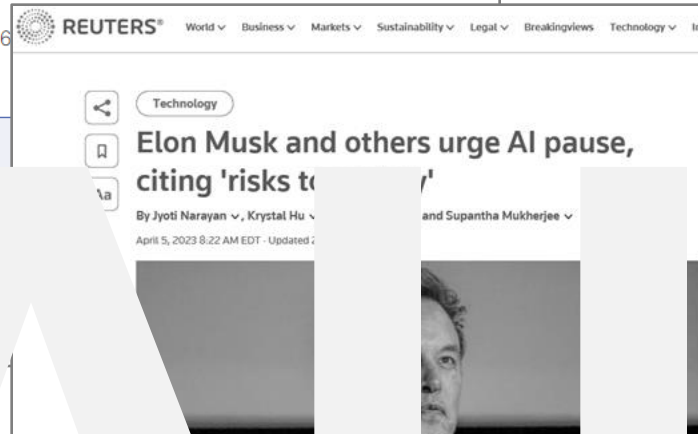
Pause Giant AI Experiments: An Open Letter

We call on all AI labs to immediately pause for at least 6 months any training of AI models more powerful than GPT-4.

Signatures

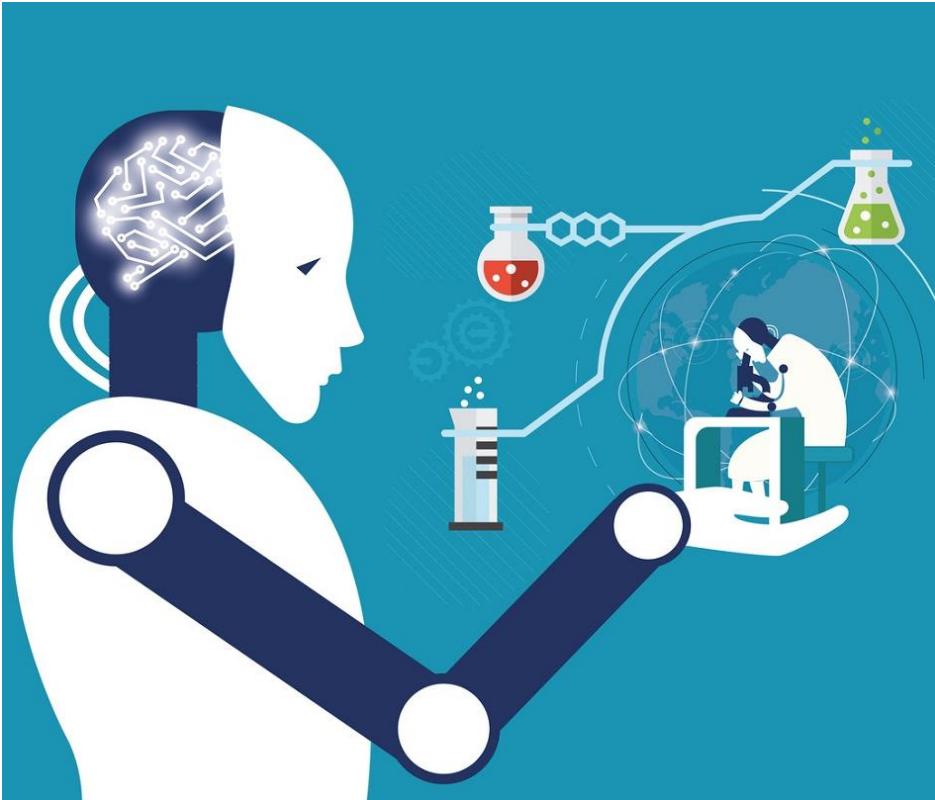
Add your signature

ISHED
ch 22, 2023



Statement on AI Risk

AI experts and public figures express their concern about AI risk.



What role do data scientists and statisticians play to ensure regulators address that AI tools perform as advertised, to provide equitable solutions in multiple-use settings?

3. Striving for AI tools for equitable healthcare

AI for Drug Discovery

nature chemical biology

Article

<https://doi.org/10.1038/s41589-023-01349-8>

Deep learning-guided discovery of an antibiotic targeting *Acinetobacter baumannii*

Received: 25 March 2022

Accepted: 25 April 2023

Published online: 25 May 2023

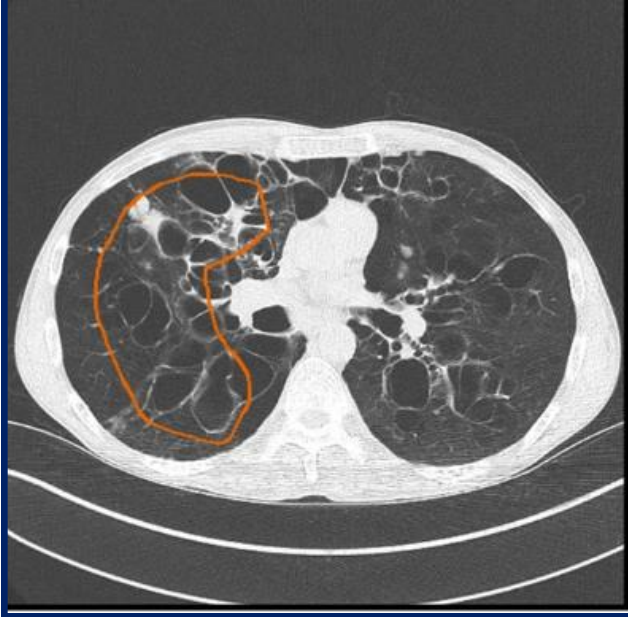
 Check for updates

Gary Liu^{1,10}, Denise B. Catacutan^{1,10}, Khushi Rathod^{1,10}, Kyle Swanson², Wengong Jin², Jody C. Mohammed¹, Anush Chiappino-Pepe^{3,4}, Saad A. Syed⁵, Meghan Fragis^{1,6}, Kenneth Rachwalski¹, Jakob Magolan^{1,6}, Michael G. Surette⁵, Brian K. Coombes¹, Tommi Jaakkola², Regina Barzilay^{2,7}, James J. Collins^{3,7,8,9}  & Jonathan M. Stokes¹ 

AI for Drug Development

Active space and lots to do

Reading Images



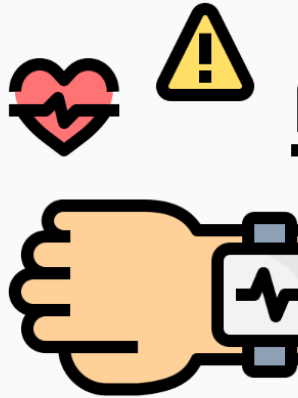
Patient Recruitment
- Diversity



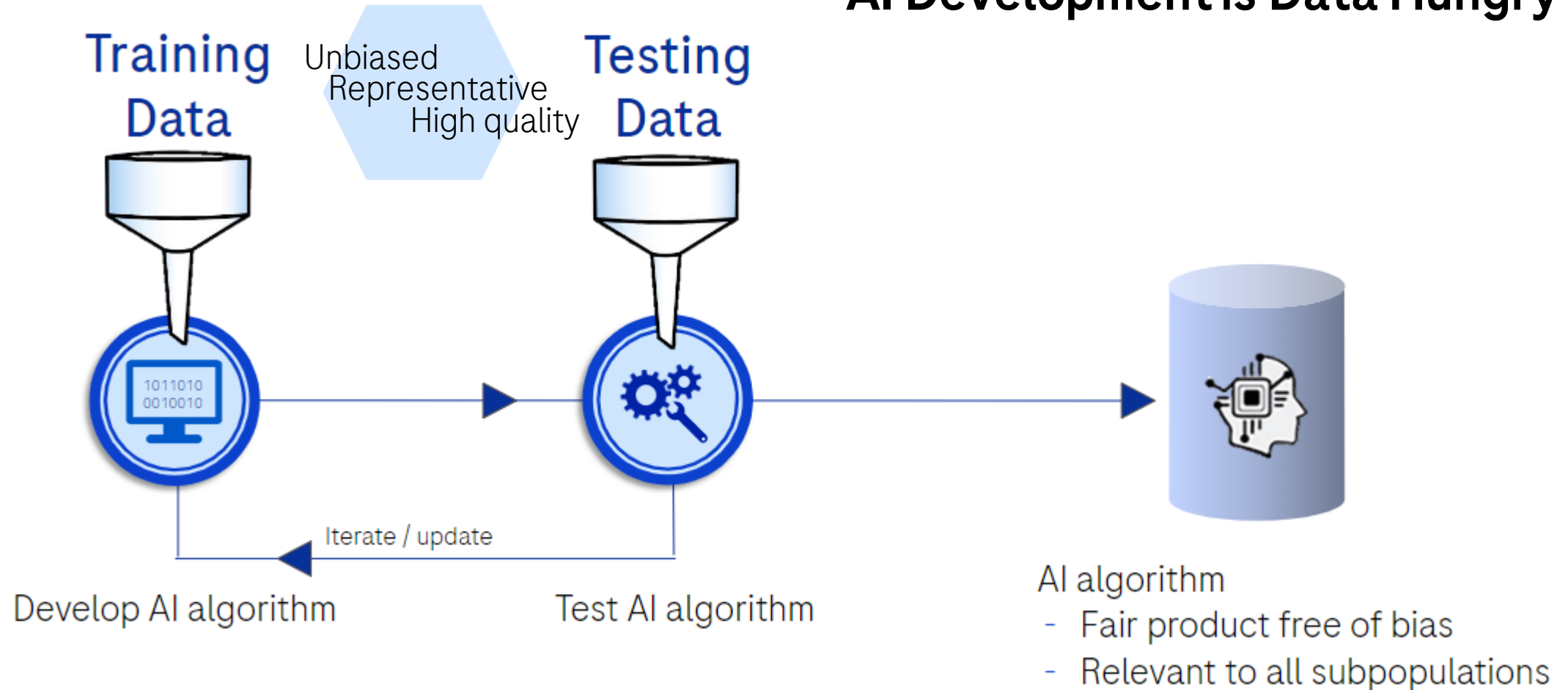
Automating analyses and
report writing



Wearables



AI Development is Data Hungry



Sources of Data

Data selection is essential for equitable AI

Electronic Health Records (EHR)

Registries

Commercial sources eg FlatIron

Clinical Trials (TransCelerate, Vivli.org)

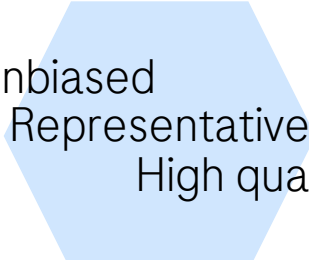
- Further Innovation:
 - synthetic data,
 - virtual human twin,
 - in silico trials solutions
- EU Health Data Space (EHDS)
- Canada's Health Transfer

BUT

Data sharing challenges:

Privacy (GDPR, PIPEDA)

Intellectual Property (IP)



Unbiased
Representative
High quality

Define QUALITY...

Elements to consider

Missingness

Correctness

Curation

Endpoints (eg PFS in RWD)

Objectivity

Provenance

?

Bias training/testing data → biased AI tools

- Explore data sources
- Explore the data

“Classifiers on race, socioeconomic status, or other social determinants of health are generally not present in datasets due to patient privacy laws”

Duke-Margolis White Paper

Innovative Solution

Synthetic data /sin'THedik dādə/

Artificial data generated by simulation to mimic complex clinical relationships and are clinically indistinguishable from real data, but contain no real patient's individual data

- Boost underrepresented groups
- Adjust for rare diseases
- Adjust for bias

Definitions: Chen 2021; Jordan, 2022; Kokosi, 2022; Myles 2022.

Generating AI for Drug Development

active space with opportunity for innovation

- Are we asking the right question / solving the right problem
- Check Algorithms
 - Bias auditing
 - Fairness assessments
 - Eg Google What If Tool, FairLearn
- Adjustments to statistical inference to ensure equity
- Human in the loop

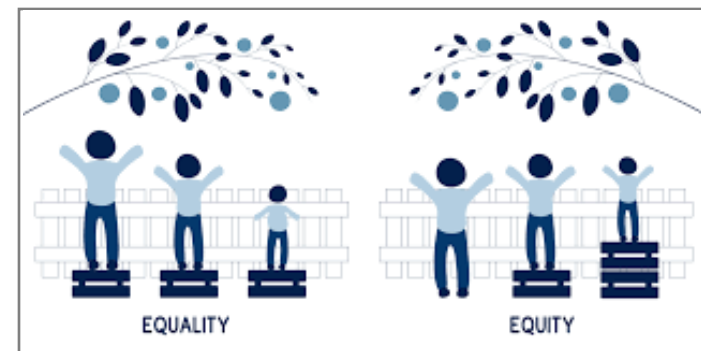
Future of innovation and AI



- AI Regulation will continue to evolve
- AI will continue to change drug discovery and development. Don't miss the opportunity
- As data scientists we have an obligation to generate AI for equitable outcomes
- Malicious intent or detrimental use of AI tools will only continue. Understanding and awareness is essential to know the difference and prevent mis-use

Strive for AI tools for Equitable Healthcare through innovation

1. Biased training and testing data can lead to biased AI solutions
2. Regulation of AI is coming (is here?). How do we respond?
3. Striving for equitable healthcare requires smart solutions to difficult problems (unbiased data, synthetic data, right questions, AI fairness assessment....)



Suggested Reading

- Locke T, Parker V, Thoumi A, Goldstein B, Silcox C (2022). Preventing Bias and Inequities in AI-enabled Health Tools. Washington, DC: Duke-Margolis Center for Health Policy.
- Haug, C. J., & Drazen, J. M. (2023). Artificial intelligence and machine learning in clinical medicine, 2023. New England Journal of Medicine, 388(13), 1201-1208.
- Webb, A. (2019). The big nine: How the tech titans and their thinking machines *could warp humanity*. Hachette UK.

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- Locke T, Parker V, Thoumi A, Goldstein B, Silcox C (2022). Preventing Bias and Inequities in AI-enabled Health Tools. Washington, DC: Duke-Margolis Center for Health Policy.
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- Webb, A. (2019). The big nine: How the tech titans and their thinking machines *could warp humanity*. Hachette UK.
- Generating Equitable AI Equitable Artificial Intelligence - a comparison of fairness libraries Authors: Marta Batlle, Finn Janson, Alicja Kocieniewska, Katie McGoldrick, Eric Shen, Finn Rea
- https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en
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- <https://www.reuters.com/technology/musk-experts-urge-pause-training-ai-systems-that-can-outperform-gpt-4-2023-03-29/>
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- <https://www.frontiersin.org/articles/10.3389/frai.2021.691626/full>
- Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. *Science*, 366(6464), 447-453.

Doing now what patients need next

Doing now what patients need next