Artificial Intelligence and innovation in medicines development

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Potential for AI in medicines development

Collaboration on innovation

Considerations for implementation

J&J

Exploding regulatory frameworks for artificial intelligence (AI)

1 13 July 2023
2 EMA/CHMP/CVMP/83833/2023
3 Committee for Medicinal Products for Human Use (CHMP)
4 Committee for Medicinal Products for Veterinary Use (CVMP)

5 Reflection paper on the use of Artificial Intelligence (AI) in
6 the medicinal product lifecycle
7 Draft

ICMRA

Informal Innovation Network

Horizon Scanning Assessment Report – Artificial Intelligence

6 August 2021

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European Parliament
2019-2024

Plenary sitting

cor01

19.4.2024

CORRIGENDUM

to the position of the European Parliament adopted at first reading on 13 March 2024 with a view to the adoption of Regulation (EU) 2024/ ..... of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)
P9_TA(2024)0138
(COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

Collection

AI Airlock: the regulatory sandbox for AIaMD

A proactive, collaborative, agile and the first of its kind approach to identifying and addressing the challenges faced by AI as a Medical Device (AIaMD).

From: Medicines and Healthcare products Regulatory Agency
Published 9 May 2024

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Why we are setting up AI Airlock

Hiroshima Process International Guiding Principles for Organizations Developing Advanced AI system

The International Guiding Principles for Organizations Developing Advanced AI Systems aims to promote safe, secure, and trustworthy AI worldwide and will provide guidance for organizations developing and using the most advanced AI systems, including the most advanced foundation models and generative AI systems (henceforth "advanced AI systems"). Organizations may include, among others, entities from academia, civil society, the private sector, and the public sector.

EMA/95098/2010 Rev.11

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology
(Revision 11)

KEYWORDS	*methodological standards, pharmacoepidemiology, pharmacovigilance, ENCePP, research, guidance, real-world data (RWD), real-world evidence (RWE)*

Consensus Statement | Open access | Published: 09 September 2020

Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension

Xiaoxuan Liu, Samantha Cruz Rivera, David Moher, Melanie J. Calvert, Alastair K. Denniston & The SPIRIT-AI and CONSORT-AI Working Group

Nature Medicine **26**, 1364–1374 (2020) | Cite this article

Abstract

The CONSORT 2010 statement provides minimum guidelines for reporting randomized

Recommendation of the Council on Artificial Intelligence

In force | Recommendation | Science and Technology

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

Federal Register
Vol. 88, No. 210
Wednesday, November 1, 2023

Presidential Documents

Title 3—
The President

Executive Order 14110 of October 30, 2023

Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* Artificial intelligence (AI) holds extraordinary potential for both promise and peril. Responsible AI use has the potential to help solve urgent challenges while making our world more prosperous, productive, innovative, and secure. At the same time, irresponsible use could exacerbate societal harms such as fraud, discrimination, bias, and disinformation; displace and disempower workers; stifle competition; and pose risks to national security. Harnessing AI for good and realizing its myriad benefits requires mitigating its substantial risks. This endeavor demands a society-wide effort that includes government, the private sector, academia, and civil society.

My Administration places the highest urgency on governing the development and use of AI safely and responsibly, and is therefore advancing a coordinated, Federal Government-wide approach to doing so. The rapid speed at which AI capabilities are advancing compels the United States to lead in this moment for the sake of our security, economy, and society.

Exploration of a vast number of applications for AI: A flavour

Drug discovery and non-clinical

- Better understanding disease
- Identify new targets
- Predict potential risks

Manufacturing

- Manage risks
- Process development

Clinical trials

- Identify novel biomarkers
- Facilitate patient recruitment

Post-authorisation

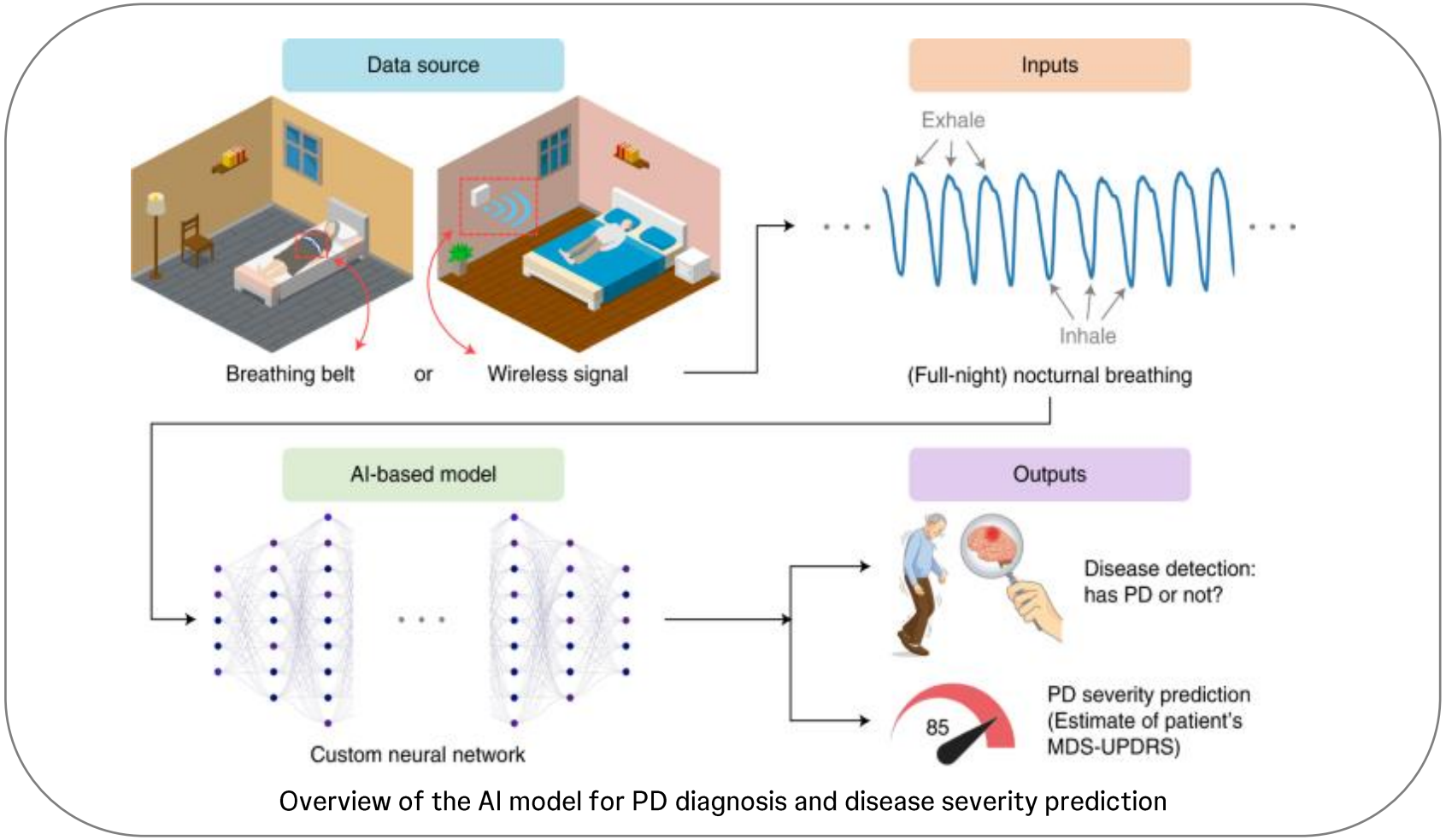
- Enhance signal detection
- Automate processing and workflow

Regulatory operations

- Facilitate interrogation of regulatory information sources
- Draft initial regulatory documents

AI facilitating detection and assessment of Parkinson's disease

Massachusetts Institute of Technology



Overview of the AI model for PD diagnosis and disease severity prediction

Yang, Y., Yuan, Y., Zhang, G. *et al.* Artificial intelligence-enabled detection and assessment of Parkinson's disease using nocturnal breathing signals. *Nat Med* **28**, 2207–2215 (2022). https://doi.org/10.1038/s41591-022-01932-x

Cross-stakeholder collaboration as an enabler for AI

IDERHA
Integration of heterogeneous data and evidence towards regulatory and HTA acceptance

DRAGON
Rapid and secure AI imaging-based diagnosis, stratification, follow-up and preparedness for coronavirus pandemics

LIVERAIM
Biomarker-based platform for early diagnosis of chronic liver disease to enable personalised therapy

innovative health initiative

innovative medicines initiative

Inno4VAac
Innovations to accelerate vaccine development and manufacture

PREDICTOM
Prediction of Alzheimer's disease using an AI driven screening platform

GRIPonMASH
Global research initiative for patient screening on MASH

iCARE4CVD
Individualised care from early risk of cardiovascular disease to established heart failure

COMBINE-CT
Combining diagnostic data and interventional approaches for futureproof cardiology care

MELLODDY
Machine learning ledger orchestration for drug discovery

HIPPOCRATES
Health initiatives in psoriasis and psoriatic arthritis consortium European states

CLAIMS
Clinical impact through AI-assisted MS care

PROMINENT
Precision medicine platform in neurodegenerative disease

BIGPICTURE
Central repository for digital pathology

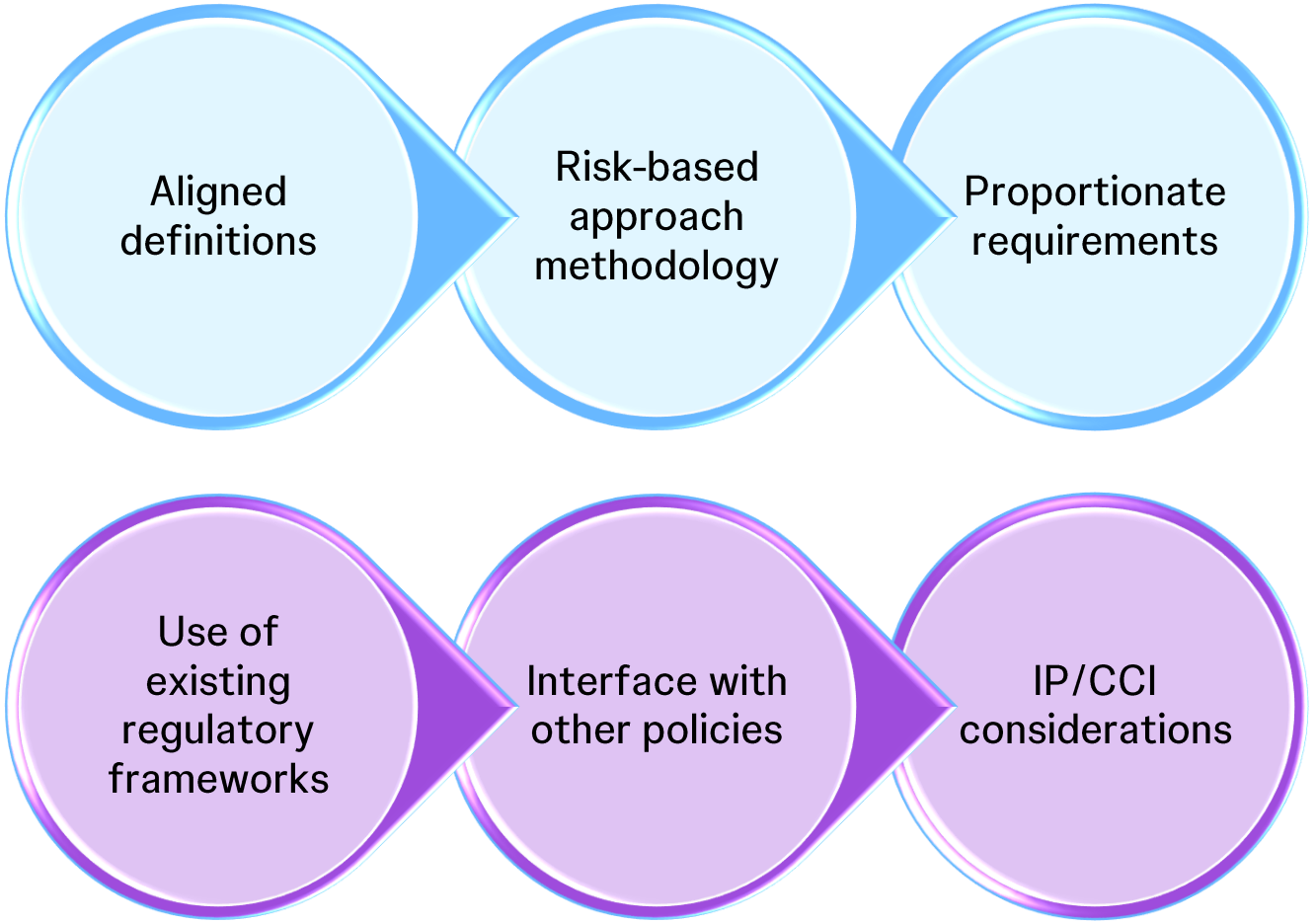
Screen4Care
Shortening the path to rare disease diagnosis by using newborn genetic screening and digital technologies

OPTIMA
Optimal treatment for patients with solid tumours in Europe through AI

https://www.ihi.europa.eu/projects-results/project-factsheets?tools=TR25, search term "artificial intelligence", extracted 14 May 2024.
Johnson & Johnson is a partner in IHI.

COCIR Advancing Healthcare · efpia · EuropaBio The European Association for Bioindustries · MedTech Europe from diagnosis to cure · Vaccines Europe · Co-funded by the European Union

Challenges and considerations for engagement



IP/CCI: Intellectual property/commercially confidential information

Summary

Potential opportunities to leverage AI in medicines development are wide ranging

Implementation needs to be navigated in the context of a complex regulatory environment.

Stakeholder collaboration is key to success.

Thank you

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