PIcc Project Updates

PIcc Regulatory Landscape Survey

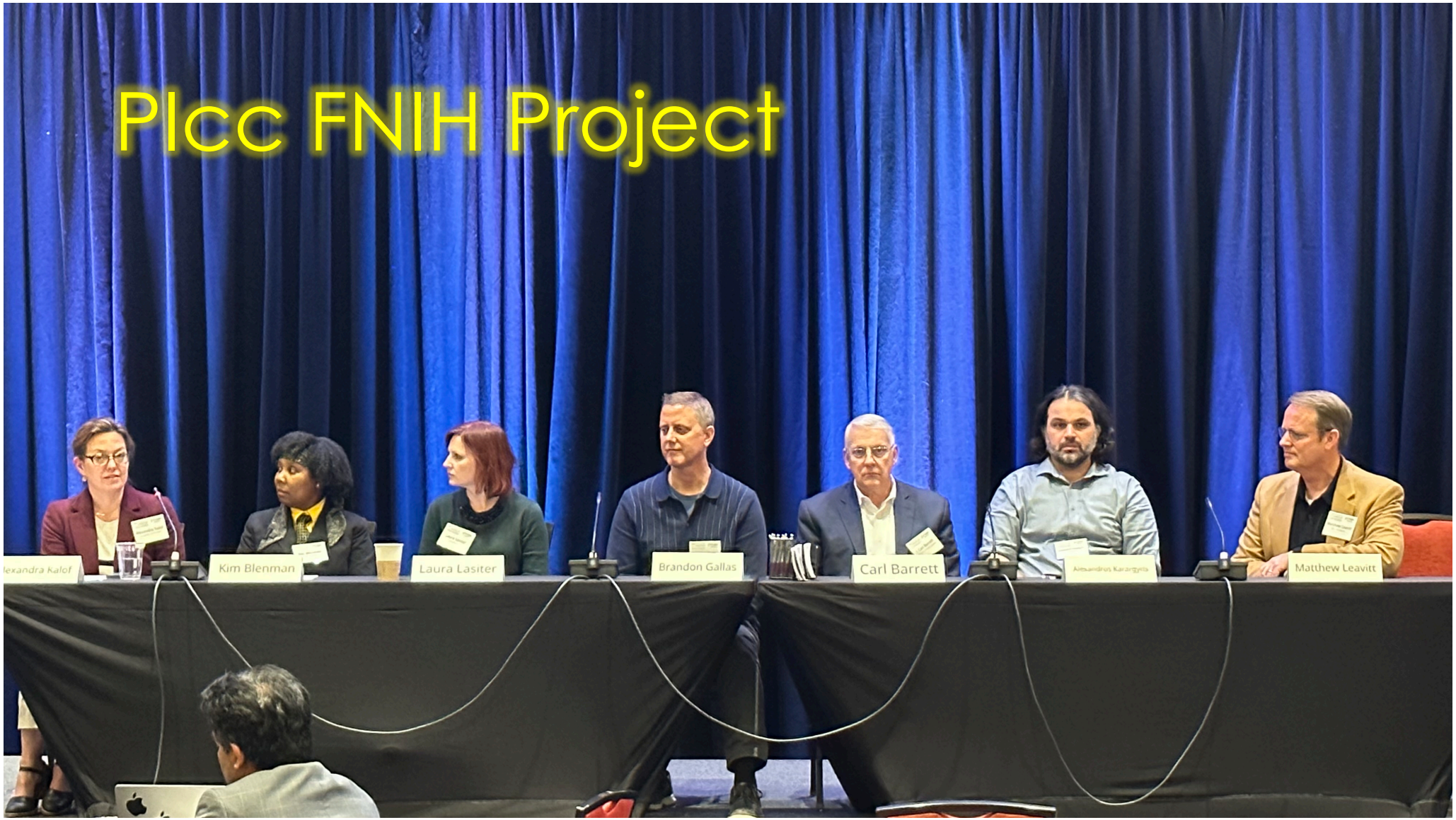
This survey aims to capture broad insights from stakeholders across academia, industry, healthcare providers, patients, and advocacy groups to identify and prioritize key regulatory hurdles in these emerging fields.

When providing input, please consider that we are looking for **statements and questions that can be addressed using regulatory science**.

For example, we are not looking for generic statements about the field (“AI should be implemented faster”). The survey aims to collect elements that can be addressed using regulatory science methods (“There is a lack of standardized protocols and guidelines for integrating AI decision support tools in digital pathology”). Collecting your input will help shape collaborative efforts to address these challenges through regulatory science methods, ultimately advancing the safety, effectiveness, and timely delivery of innovative pathology solutions to patients.

Participation is voluntary, and the results of this survey will be published on the PIcc website.

Please feel free to share the survey with your colleagues.


Plcc FNIH Project
Kim Blenman
Laura Lasiter
Brandon Gallas
Carl Barrett
Matthew Leavitt

Follow-up

Event

Multi Stakeholder Presentation

Friends of Cancer Research

New powerful stakeholders

Project Proposal MDDT

Presentation at FNIH

Topic 2

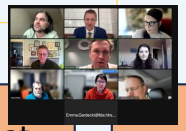
Preparation and discussion with FNIH

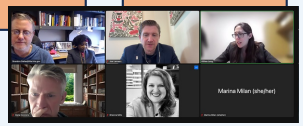
Plan and coordinate presentation at CSC

Present at CSC FNIH

Follow-up

Phase 1
Phase 2
Join?





Aug 2023

Oct 2023

Nov 14th, 2023

Dec 7th, 2023
Jan 2024
Feb 2024

Mar 2024

PIcc FNIH Proposal drafting phase

Introduction

The imperative to advance cancer diagnostics and treatment is underscored by the millions of lives lost annually. Despite the reliance on tissue-based diagnostics, **the adoption of digital pathology solutions has been slow** due to technical, regulatory, and workflow challenges. Meanwhile, AI tools offer significant promise in analyzing vast datasets, disease detection and prognosis, deciphering disease mechanisms, predicting treatment outcomes, facilitating drug discovery, and ultimately managing patient care. Crucially, these AI tools promise to enable risk assessment and performance evaluation, positioning them as pivotal elements in this endeavor.

Balancing Innovation and Regulation

Innovators argue that regulatory frameworks impede innovation by slowing down the development and deployment of new healthcare technologies. They advocate for more flexible regulations to adapt to the rapid pace of technological advancements, enabling quicker responses to emerging healthcare needs. Conversely, regulators stress the necessity of risk- and science-based transparent oversight to mitigate discovery bias and protect public health. Finally, **health providers and patients** want the best devices to support patient care and expect that the devices work as advertised. While innovation is crucial for addressing medical challenges, regulatory oversight is vital for safeguarding patient welfare and maintaining public trust. Balancing innovation with regulation is essential to foster progress while minimizing risks in healthcare innovation. This was the reason for starting PIcc.

Pathology Innovation Collaborative Community (PIcc): Harmonizing Approaches

The PIcc initiative, convened by the Medical Device Innovation Consortium (MDIC), serves as a open forum for stakeholders to collaborate on regulatory science questions and advance pathology innovation. With participation by the FDA, PIcc promotes pre-competitive collaboration to accelerate the delivery of safe and effective medical devices to patients. The community has worked on many projects and in November 2023 a set of stakeholders (represented by the authors) was invited to give a presentation to FNIH.

Starting Points: Problem, Pathway, and Preliminary Work.

Problem: Regulatory Readiness – A Missing Piece

The regulation of AI models poses challenges, particularly in establishing robust, regulatory-ready data-collection protocols. While real-world data (RWD) and real-world evidence (RWE) programs exist, the pathway to establish these datasets for AI performance and risk assessment remains unclear, especially in the field of pathology and diagnostics.

Two-Phase Approach for Implementation

The proposed implementation plan comprises two phases: review, optimization, and submission of the MDDT proposal, followed by the actual data collection. The context is TILs in breast cancer.

A. Phase 1 – Create a robust data-collection protocol to propose to the MDDT program
   a) Publication of the initial feedback from the MDDT program.
      Feedback publication as a tangible deliverable for emphasizing the relevance of the pathway and the FDA's thinking on requirements to make the data ready for a regulatory submission.
   b) Feedback incorporation into the MDDT submission (proposal phase)
   c) Outlining the scope, data collection protocols, data collection effort, statistical analysis plan, size, and cost
   d) Revision and planning of the qualification plan (proposal phase)
   e) Submission of the revised MDDT proposal

Estimated timeline: 1 year (May 2024 to May 2025)
Budget: TBD
FTE: TBD

B. Phase 2 – Collect and annotate digital H&E biopsies and patient metadata
   a) Establishing centers and a governance structure (executing the proposal)
   b) Deploying the data collection protocols (designed in Phase A)
   c) Data collection (across the US)
   d) Centralized review (ML Commons + Precision FDA + ARPA-H Marketplace)
   e) Summary of the analytical qualification plan + MDDT submission
   f) Delivery. Dataset available + approach publicized to serve as a blueprint for other

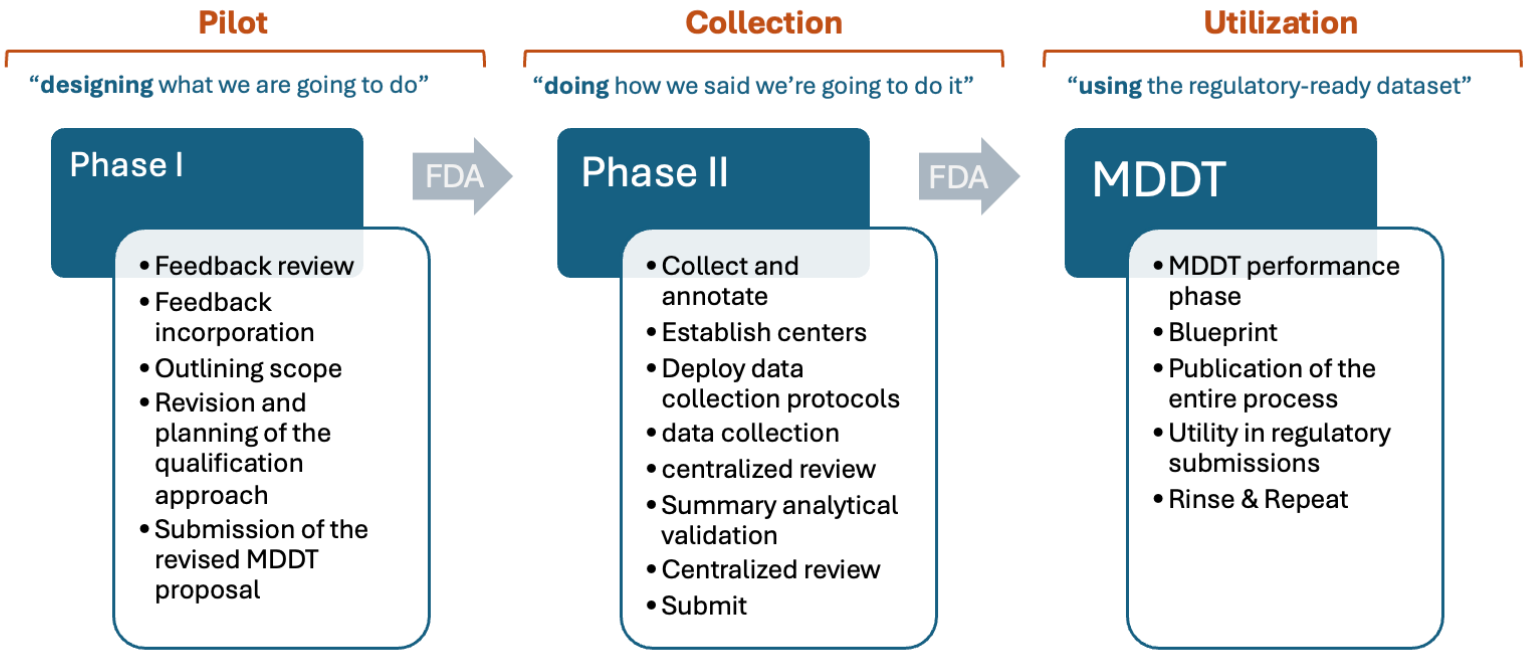
Estimated timeline: 2 years (May 2025 to May 2027)
Budget: TBD
FTE: TBD

Conclusion

The convergence of digital pathology and AI presents unprecedented opportunities to enhance cancer diagnostics and drug development. Through collaborative efforts, regulatory readiness, and innovative initiatives like the HTT project and PIcc, stakeholders aim to accelerate progress toward achieving reliable and effective diagnostic solutions. With a clear roadmap outlined, including defined milestones, the journey towards improved cancer care and treatment efficacy is underway.

If you want to join – please let us know

FNIH proposal (drafting phase)
Building Regulatory-Ready, Real World Datasets:
A Collaborative Approach for Validating AI Models in Breast Cancer Diagnosis



MDIC
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ENABLING DIGITAL PATHOLOGY WITH ARTIFICIAL INTELLIGENCE

1:40 Chairperson's Remarks

Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium

1:45 Advancing the AI in Diagnostics and Healthcare: Role of the Public-Private Partnership Model

Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium

Novel technologies including AI promise to revolutionize healthcare, from earlier diagnosis to better treatments and improved clinical care. Some of the perpetual concerns are the scarcity of data and the uncertainty in the regulatory frameworks. In addition, many of the stakeholders in the fast-moving space are working in silos. This presentation will highlight a few concrete examples of how public-private partnerships such as MDIC are bringing together stakeholders.

2:15 PANEL DISCUSSION: Unlocking the Potential of Digital Pathology and Artificial Intelligence (AI) through Regulatory Science

Moderator: Jithesh Veetil, PhD, Senior Program Director, Digital Health & Technology, Medical Device Innovation Consortium

Industry and regulatory leaders will discuss advances in digital pathology and AI as well as progress and hurdles in the quest to broadly implement digital pathology and AI/machine learning. The impact of recent regulatory and legislative developments in digital pathology and AI tools in diagnostics will be highlighted as well as the work of the Pathology Innovation Collaborative Community, a regulatory science initiative that aims to facilitate innovations in pathology.

Panelists:

Maryellen de Mars, PhD, Program Director, Clinical Diagnostics, Medical Device Innovation Consortium

Jochen Lennerz, MD, PhD, Director, Center for Integrated Diagnostics, Massachusetts General Hospital; Associate Professor, Pathology, Harvard Medical School

Keith Wharton, Jr, MD, PhD, Global Medical Affairs Leader - Pathology, Roche Diagnostics Solutions

3:15 Close of Conference


Europe

Germany: Data Utilization Law

"Law on the Use of Health Data for Public-Interest Research Purposes and for Data-Driven Advancement of the Healthcare System **Health Data Utilization Act**"

Bundesministerium der Justiz Bundesamt für Justiz

Gesetz zur Nutzung von Gesundheitsdaten zu gemeinwohlorientierten Forschungszwecken und zur datenbasierten Weiterentwicklung des Gesundheitswesens (Gesundheitsdatennutzungsgesetz - GDNG)

Nichtamtliches Inhaltsverzeichnis

GDNG

Ausfertigungsdatum: 22.03.2024

Vollzitat:

"Gesundheitsdatennutzungsgesetz vom 22. März 2024 (BGBl. 2024 I Nr. 102)"

Fußnote

(+++ Nachgewiesener Text noch nicht dokumentarisch bearbeitet +++)

Das G wurde als Artikel 1 des G v. 22.3.2024 I Nr. 102 vom Bundestag beschlossen. Es tritt gem. Art. 6 dieses G am 26.3.2024 in Kraft.
Nichtamtliches Inhaltsverzeichnis

§ 1 Zweck des Gesetzes; Anwendungsbereich

(1) Dieses Gesetz dient der Regelung der Nutzung von Gesundheitsdaten zu gemeinwohlorientierten Forschungszwecken und zur datenbasierten Weiterentwicklung des Gesundheitswesens als lernendes System. Das Ziel der Nutzung von Gesundheitsdaten ist, eine sichere, bessere und qualitätsgesicherte Gesundheitsversorgung und Pflege zu gewährleisten, Forschung und Innovation zu fördern und das digitalisierte Gesundheitssystem auf Grundlage einer soliden Datenbasis weiterzuentwickeln.

(2) Dieses Gesetz gilt für die Verarbeitung von Gesundheitsdaten zu Forschungszwecken, zur Verbesserung der Gesundheitsversorgung und Pflege sowie zu weiteren im Gemeinwohl liegenden Zwecken.

Council of the
European Union

Brussels, 18 March 2024
(OR. en)

7553/24

Interinstitutional File:
2022/0140(COD)

LIMITE

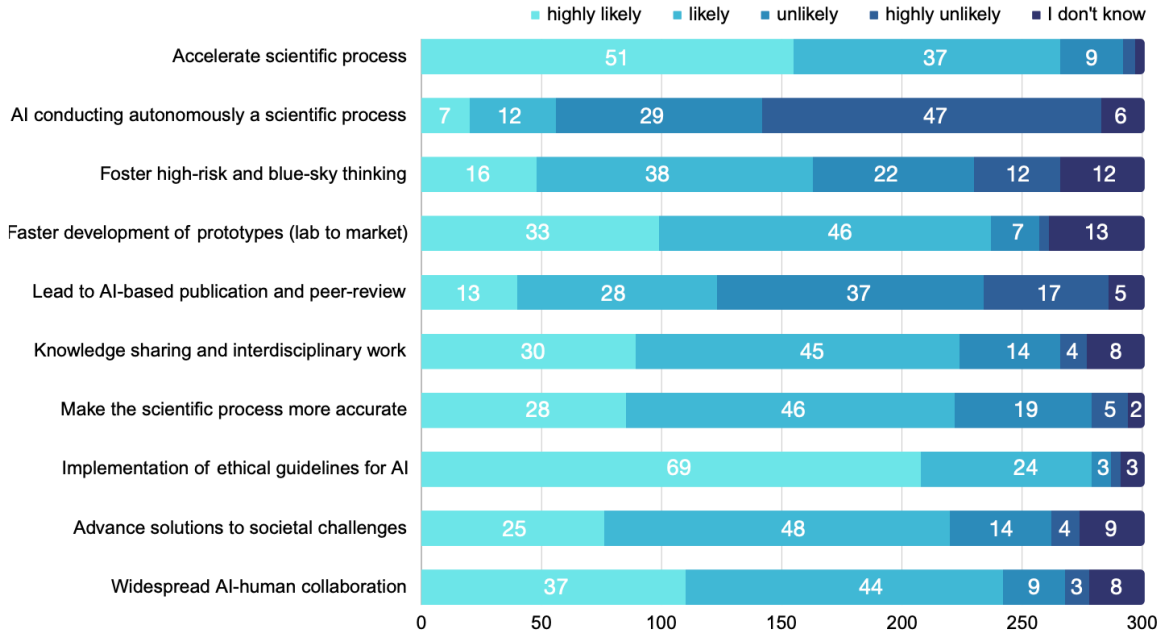
SAN 139
PHARM 41
COMPET 293
MI 279
DATAPROTECT 134
CODEC 741
IA 81

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	8571/22 ADD1-8
Subject:	Proposal for a Regulation on the European Health Data Space - Analysis of the final compromise text with a view to agreement

EUROPEAN RESEARCH COUNCIL

Figure 4: Opportunities and benefits for the use of AI in science by 2030



Professional Societies


APRIL 5, 2024 • NEW YORK, NY
Digital Pathology Course
Includes an optional guided tour of Memorial Sloan Kettering's pathology laboratory areas (space limited).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20th EUROPEAN CONGRESS ON DIGITAL PATHOLOGY
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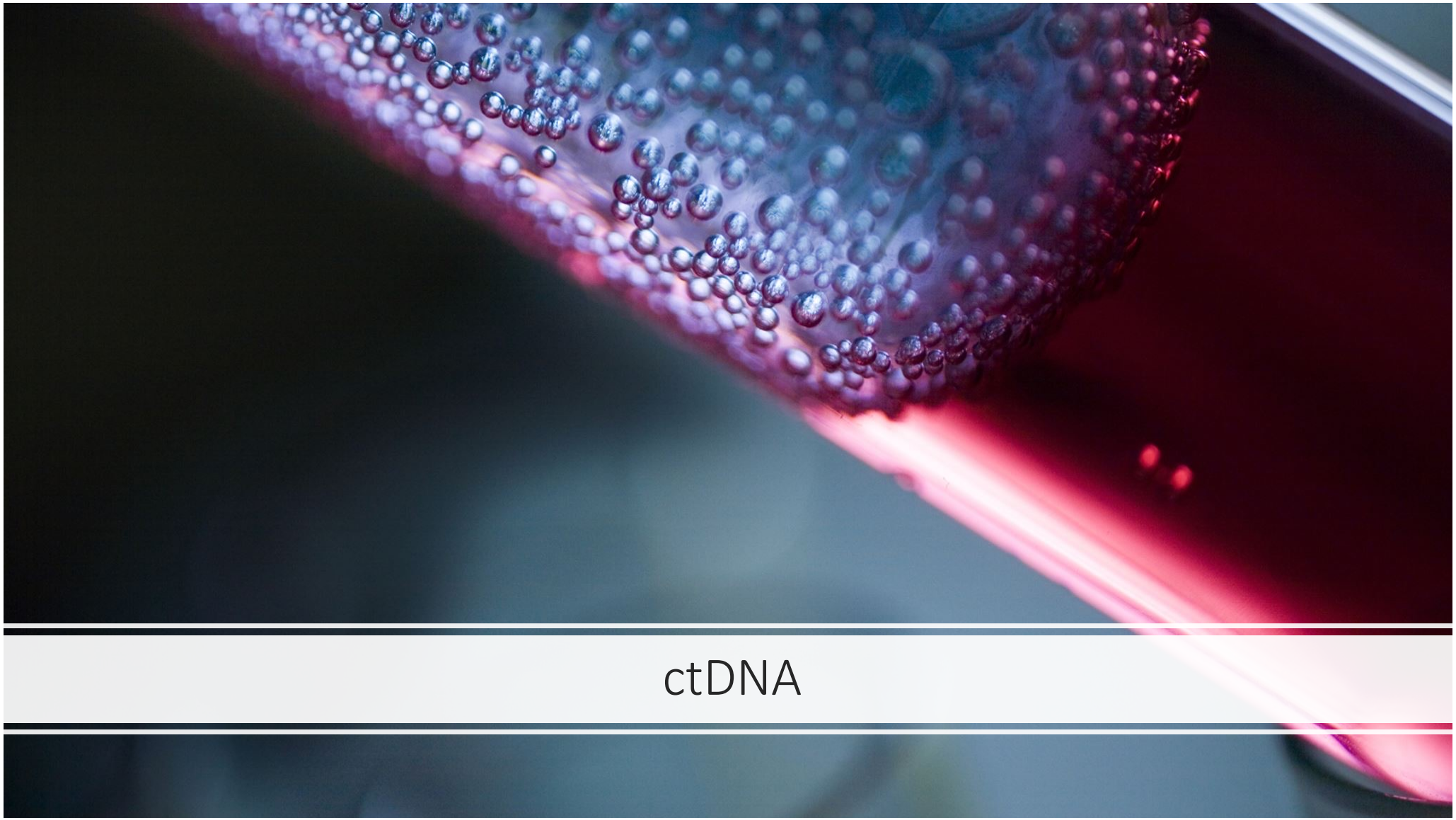
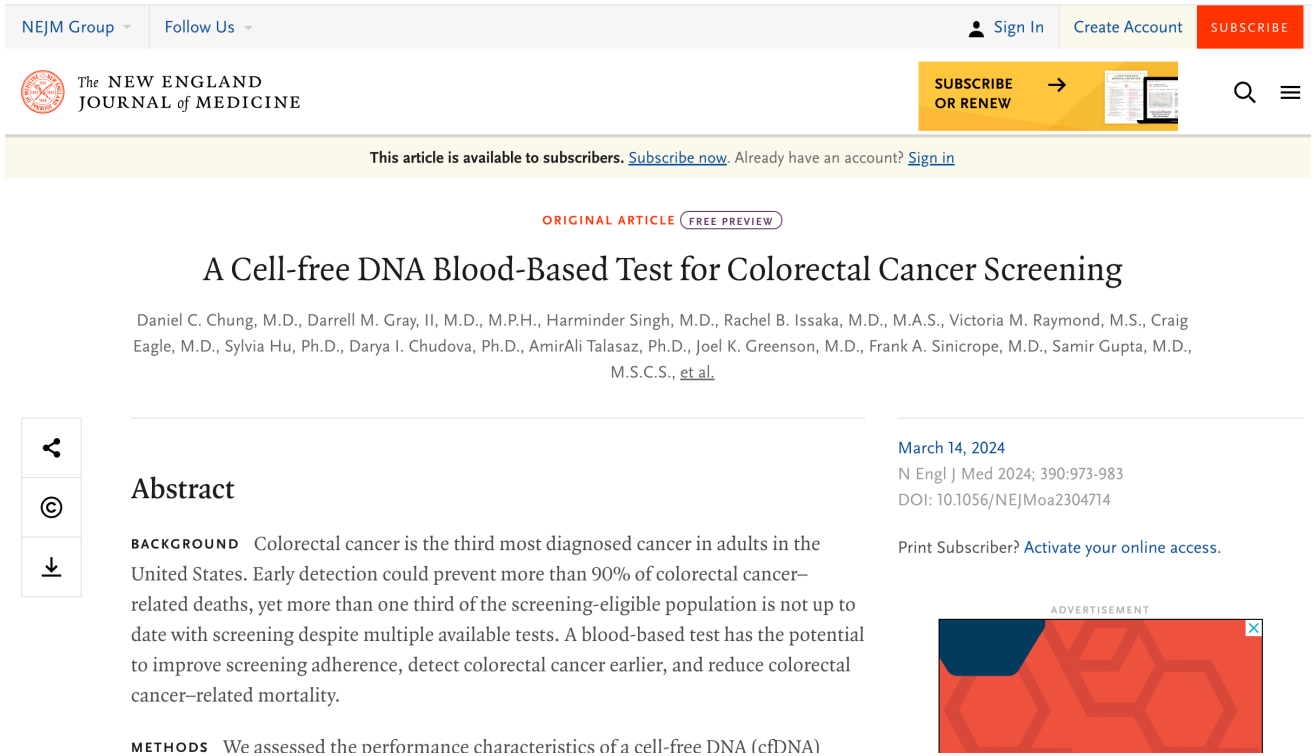


ctDNA



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ORIGINAL ARTICLE FREE PREVIEW

A Cell-free DNA Blood-Based Test for Colorectal Cancer Screening

Daniel C. Chung, M.D., Darrell M. Gray, II, M.D., M.P.H., Harminder Singh, M.D., Rachel B. Issaka, M.D., M.A.S., Victoria M. Raymond, M.S., Craig Eagle, M.D., Sylvia Hu, Ph.D., Darya I. Chudova, Ph.D., AmirAli Talasaz, Ph.D., Joel K. Greenson, M.D., Frank A. Sinicrope, M.D., Samir Gupta, M.D., M.S.C.S., et al.

March 14, 2024
N Engl J Med 2024; 390:973-983
DOI: 10.1056/NEJMoa2304714

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Abstract

BACKGROUND Colorectal cancer is the third most diagnosed cancer in adults in the United States. Early detection could prevent more than 90% of colorectal cancer–related deaths, yet more than one third of the screening-eligible population is not up to date with screening despite multiple available tests. A blood-based test has the potential to improve screening adherence, detect colorectal cancer earlier, and reduce colorectal cancer–related mortality.

METHODS We assessed the performance characteristics of a cell-free DNA (cfDNA)

- In an average-risk screening population, this cfDNA blood-based test had 83% sensitivity for colorectal cancer, 90% specificity for advanced neoplasia, and 13% sensitivity for advanced precancerous lesions.

Diversity Equity & Inclusion

nature medicine

Perspective

https://doi.org/10.1038/s41591-024-02844-8

Self-care interventions for women's health and well-being

Received: 17 November 2023

Accepted: 31 January 2024

Published online: 07 March 2024

Manjulaa Narasimhan[1], Jame
Quarraisha Abdool-Karim[4], Ma
Olive Sentumbwe-Mugisa[8], Allan

Perspective

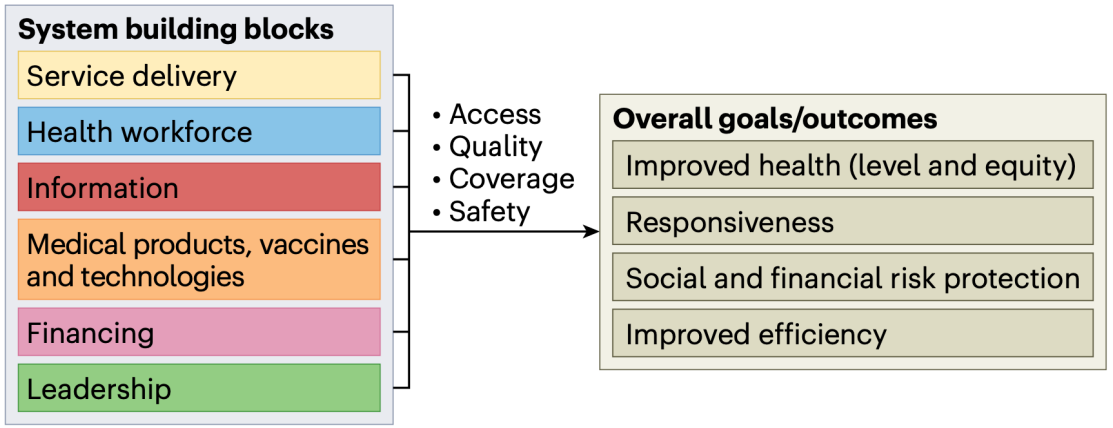


Fig. 2 | WHO health system building blocks to support self-care interventions. These building blocks are interdependent and overlapping, coming together to produce four key health system outcomes. Indicators for each of the blocks are used by countries to assess their health systems' performance.

The Lancet Commissions

Women, power, and cancer: a *Lancet* Commission

Ophira Ginsburg, Verna Vanderpuye*, Ann Marie Beddoe†, Nirmala Bhoo-Pathy†, Freddie Bray†, Carlo Cadufft, Narjust Florez†, Ibtihal Fadhil†, Nazik Hammad†, Shirin Heidari†, Ishu Kataria†, Somesh Kumar†, Erica Liebermann†, Jennifer Moodley†, Miriam Mutebi†, Deborah Mukherji†, Rachel Nugent†, Winnie K W So†, Enrique Soto-Perez-de-Celis†, Karla Unger-Saldaña†, Gavin Allman‡, Jenna Bhimani‡, María T Bourlon‡, Michelle A B Eala‡, Peter S Hovmand‡, Yek-Ching Kong‡, Sonia Menon‡, Carolyn D Taylor‡, Isabelle Soerjomataram**

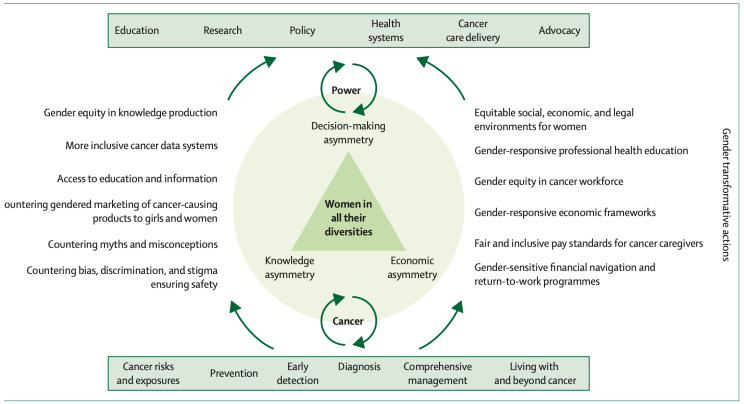
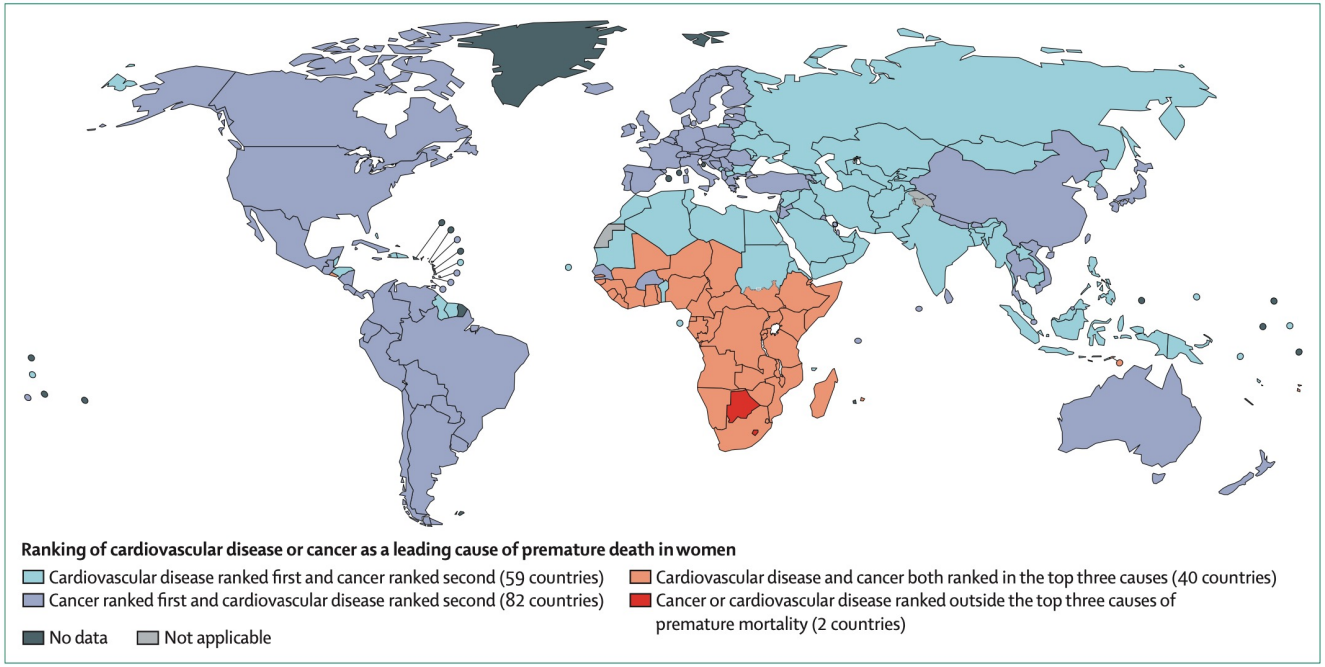


Figure 1: **An intersectional feminist framework for cancer**



Demographic Bias of Expert-Level Vision-Language Foundation Models in Medical Imaging

Yuzhe Yang[1], Yujia Liu[2], Xin Liu[3], Avanti Gulhane[4], Domenico Mastrodicasa[4,5], Wei Wu[4], Edward J. Wang[2], Dushyant W. Sahani[4], Shwetak N. Patel[3,6]

underdiagnose marginalized groups, with even higher rates seen in intersectional subgroups, such as Black female patients. Such demographic biases present over a wide range of pathologies and demographic attributes. Further analysis of the model embedding uncovers its significant encoding of demographic information. Deploying AI systems with these biases in medical imaging can intensify pre-existing care disparities, posing potential challenges to equitable healthcare access and raising ethical questions about their clinical application.

PNAS RESEARCH ARTICLE | SOCIAL SCIENCES OPEN ACCESS

Non-White scientists appear on fewer editorial boards, spend more time under review, and receive fewer citations

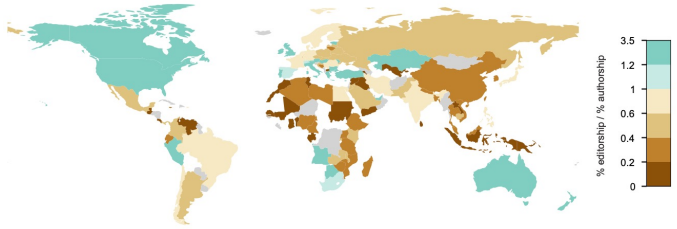
Fengyuan Liu[a,b], Talal Rahwan[a,1], and Bedoor AlShebli[c,1]

Edited by Susan Fiske, Princeton University, Princeton, NJ; received September 7, 2022; accepted January 28, 2023

Disparities continue to pose major challenges in various aspects of science. One such aspect is editorial board composition, which has been shown to exhibit racial and geographical disparities. However, the literature on this subject lacks longitudinal

Significance

be expected based on their share of authorship. Focusing on US-based scientists reveals Black as the most underrepresented race. In terms of acceptance delay, we find, again, that papers from Asia, Africa, and South America spend more time compared to other papers published in the same journal and the same year. Regression analysis of US-based papers reveals that Black authors suffer from the greatest delay. Finally, by analyzing citation rates of US-based papers, we find that Black and Hispanic scientists receive significantly fewer citations compared to White ones doing similar research. Taken together, these findings highlight significant challenges facing non-White scientists.



Editor to authorship querry

Manifesto to address inequalities across Europe in access to innovation for patients with metastatic breast cancer

21 MARCH 2024

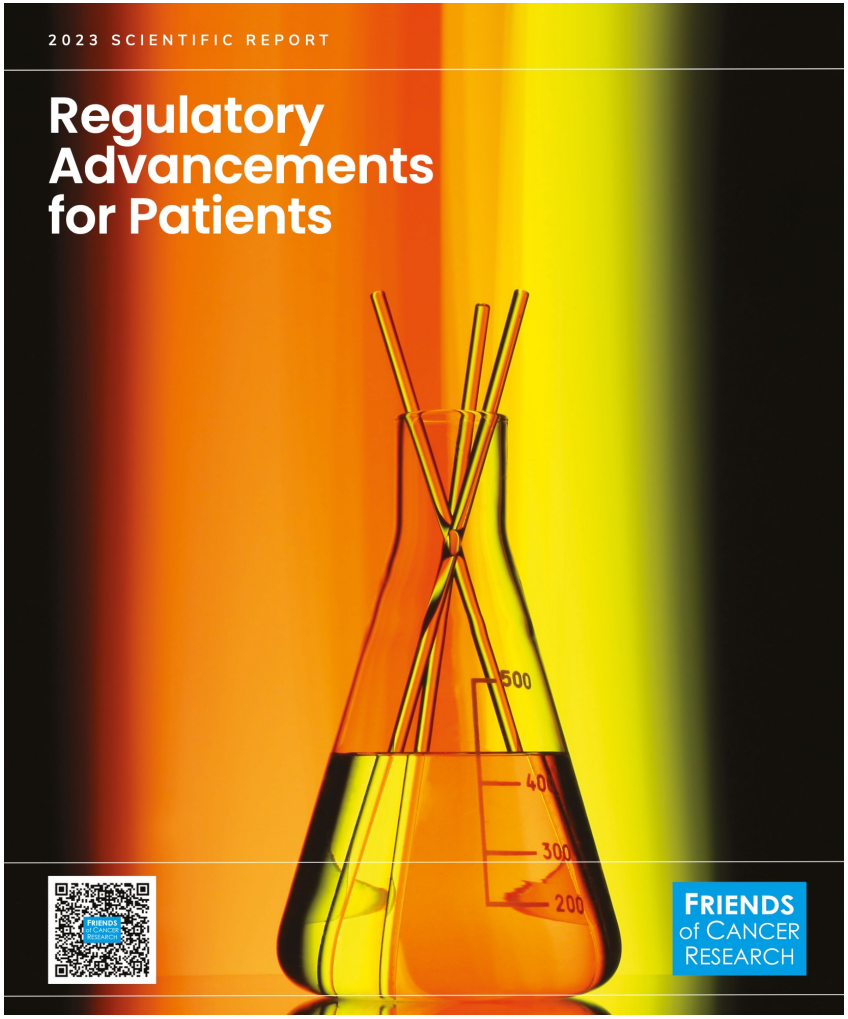
All patients with metastatic breast cancer (mBC) should have equal access to the best treatments and outcomes wherever they live in Europe and regardless of prognosis, according to a manifesto to be agreed on the last day of EBCC14.

The manifesto identifies innovations in breast cancer treatment that bring the greatest benefit to patients but are not equally accessible, highlights barriers to accessing these advances, and proposes steps towards improving access.

of the disease to society, and facilitating patients' involvement in trials, the workplace and everyday life.

- **Implement a national cancer registry** recording stage at diagnosis and relapses in every European country in order to understand how many people are living with mBC. Currently, prevalence is unknown.
- **Real-world and registry data** should be used to improve access to treatment, trials and services, and to evaluate outcomes.
- **Ensure all European patients with mBC have equal access** to high-quality, multidisciplinary information and care.
- **Ensure implementation of newly-established quality indicators across Europe** to help monitor, implement or adapt policies to ensure equitable access.
- **Rate the importance of interventions** beyond anti-cancer drugs by developing and introducing a tool similar to the ESMO Magnitude of Clinical Benefit Scale (MCBS).
- **Re-allocate European funding to level up care**. This will help to improve access to care for the elderly, those living in rural areas, those with lower educational or socioeconomic status, and those with reduced financial means.

Patient advocacy



2023 By the Numbers

5,500+ meeting attendees

16 working groups

8 roundtables & public meetings

9,000+ publication downloads

500+ working group participants

15 white papers, abstracts, posters, & publications

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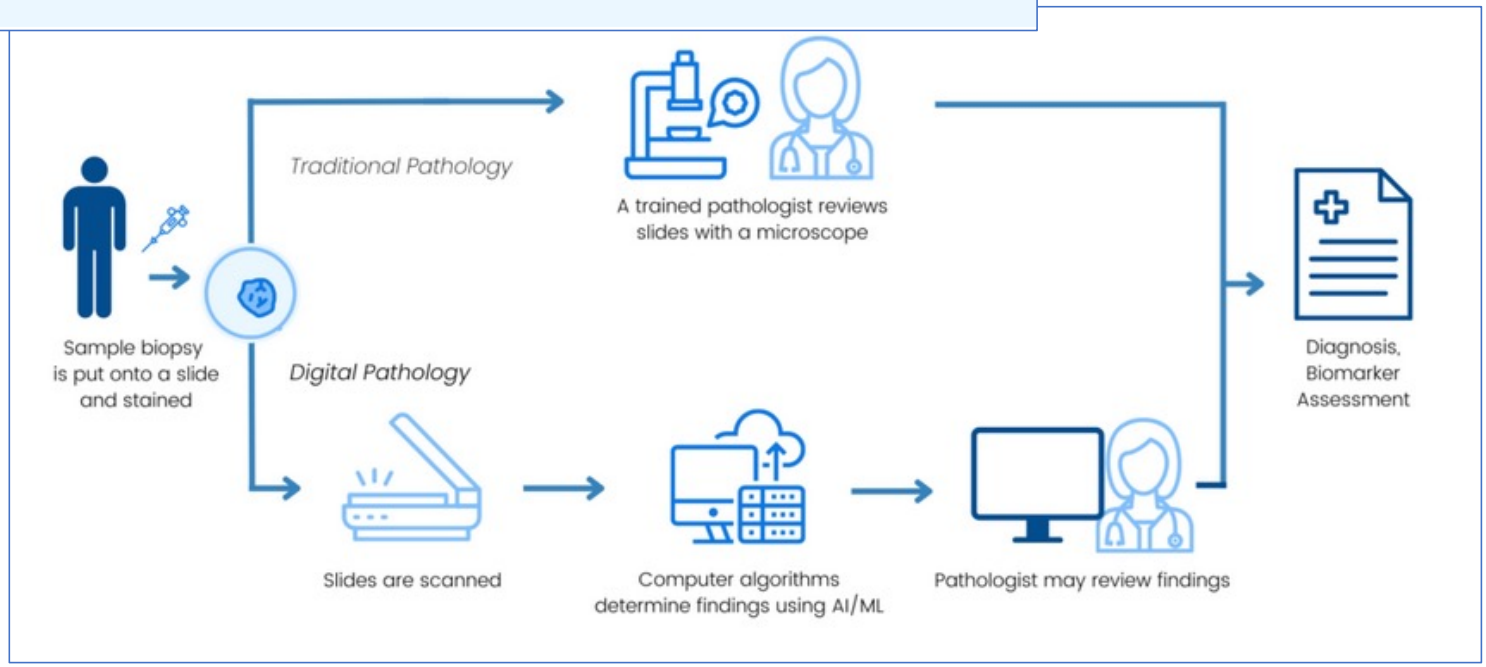
Digital PATH Project

Digital and Computational Pathology Tool Harmonization Project

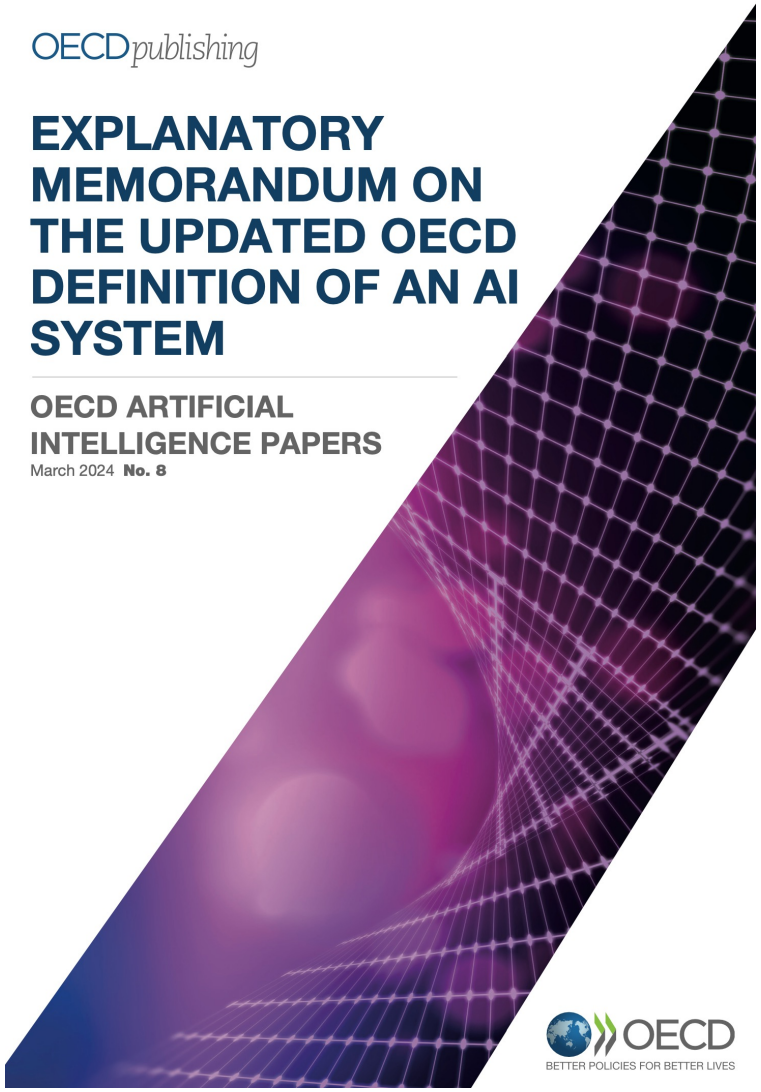


Resources

OECD publishing

EXPLANATORY MEMORANDUM ON THE UPDATED OECD DEFINITION OF AN AI SYSTEM

OECD ARTIFICIAL INTELLIGENCE PAPERS
March 2024 **No. 8**

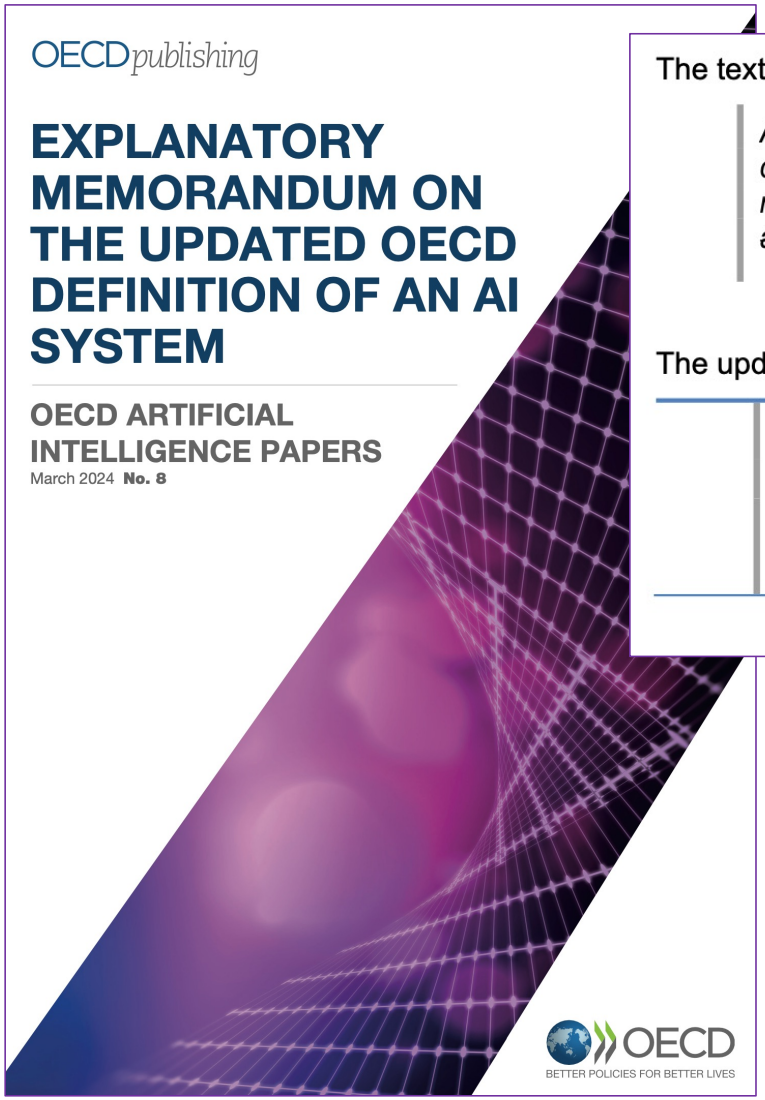


OECD
BETTER POLICIES FOR BETTER LIVES

The report was prepared by Karine Perset, Head of the Artificial Intelligence Unit in the OECD Digital Economy Policy Division, with support from Lucia Russo, Luis Aranda, Yuki Yokomori and Gallia Daor, and under the guidance of Audrey Plonk, Deputy Director of the OECD Science, Technology and Innovation Directorate.

The AIGO meetings leading up to the agreement on the updated definition of an AI system and on the explanatory memorandum were chaired by Marco-Alexander Breit from Germany and Juraj Čorba from Slovakia. The report benefitted greatly from the inputs of Marko Grobelnik, expert researcher at the AI Lab of Slovenia's Jožef Stefan Institute (JSI) and from Stuart Russel, Professor of Computer Science, University of California, Berkeley. The report also benefitted greatly from the inputs of the delegations participating in the Working Party on AI Governance. Among many, the drafting team wishes to thank Jesse Dunietz, Tatjana Evans, Emilia Gomez, Samo Zork, Elham Tabassi, Mark Latonero, David Turnbull, Nobuhisa Nishigata, Robert Kroplewski, Katinka Clausdatter Worsøe, Zumrut Muftuoglu, Arturo Robles Rovalo, Amit Thapar, Sebastian Hallensleben, Pam Dixon, and Barry O'Brien.

The OECD is grateful to John Tarver (consultant to the OECD) for editing this report, and to Andreia Furtado for editorial and publishing support. The report benefited significantly from their engagement.



The text above is replaced with the following updated definition:

> *An AI system is a machine-based system that ~~can~~, for ~~a given set of human-defined~~ explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as ~~makes~~ predictions, content, recommendations, or decisions that can influenc~~ing~~e physical ~~real~~ or virtual environments. Different AI systems ~~are designed to operate with~~ varying in their levels of autonomy and adaptiveness after deployment.*

The updated definition reads as follows:

> ***An AI system is a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.***

Here FOR COMPARISON the official FDA definitions for AI and ML

Artificial Intelligence is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action.

Machine Learning is a set of techniques that can be used to train AI algorithms to improve performance at a task based on data.

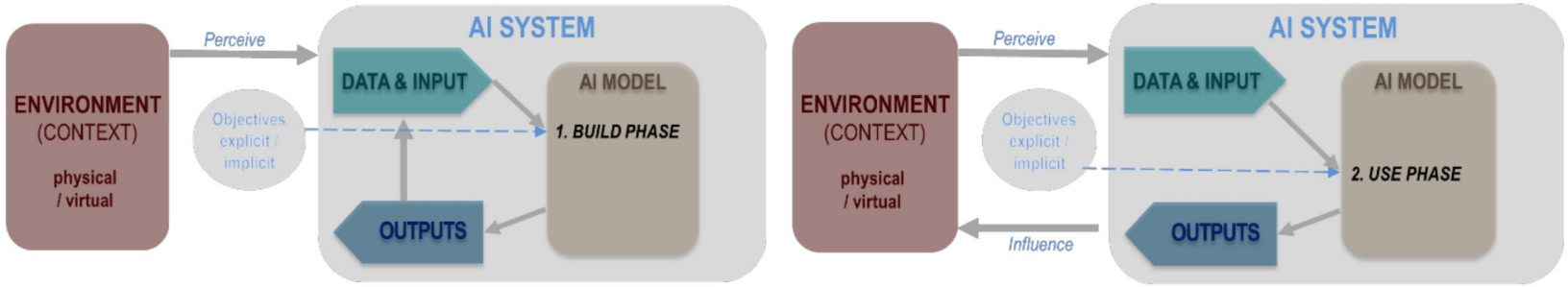
OECD publishing

EXPLANATORY MEMORANDUM ON THE UPDATED OECD DEFINITIO SYSTEM

OECD ARTIFIC INTELLIGENCE

March 2024 **No. 8**

Figure 1. Illustrative, simplified overview of an AI system



Source: (OECD, 2022[6])

Note: this figure presents only one possible relationship between the development and deployment phases. In many cases, the design and training of the system may continue in downstream uses. For example, deployers of AI systems may fine-tune or continuously train models during operation, which can significantly impact the system's performance and behaviour.

BETTER POLICIES FOR BETTER LIVES

Rethinking Health System Performance Assessment

A Renewed Framework

Health systems are under intense pressure to adapt to evolving needs and megatrends driven by population ageing, digitalisation, and climate change. They also need to be better prepared to withstand sudden, large-scale shocks such as pandemics, financial crises, natural disasters, or cyberattacks. This shifting policy context and emerging challenges called for a revision in how OECD countries assess health system performance, to help ensure that health systems meet people's health needs and preferences while providing quality healthcare for all. This document presents the OECD's renewed health More

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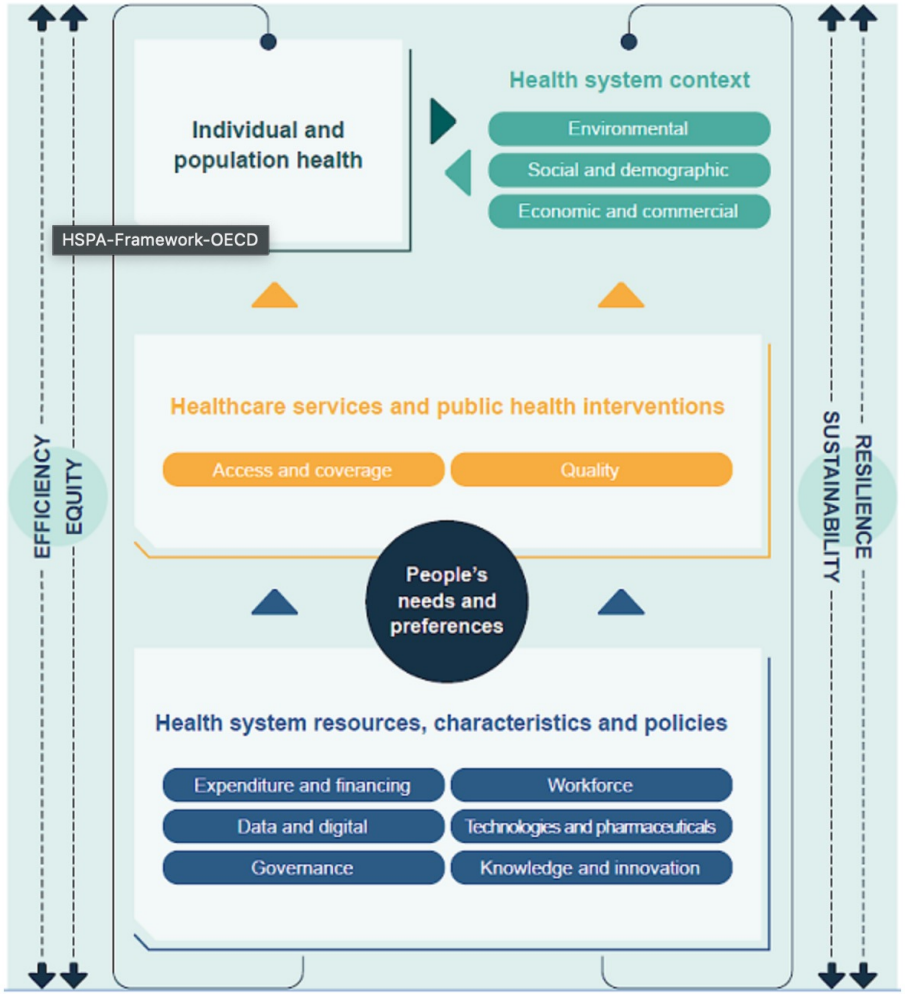
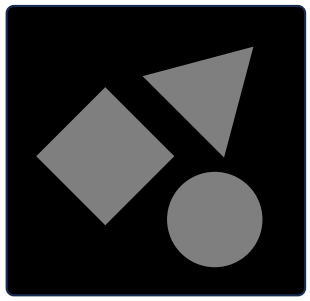
RENEWED OECD HEALTH SYSTEM PERFORMANCE ASSESSMENT FRAMEWORK

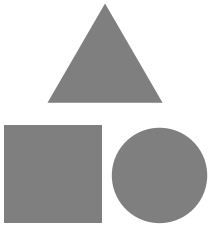


Source: OECD (2024), *Rethinking Health System Performance Assessment: A Renewed Framework*, OECD Health Policy Studies, OECD Publishing, Paris.



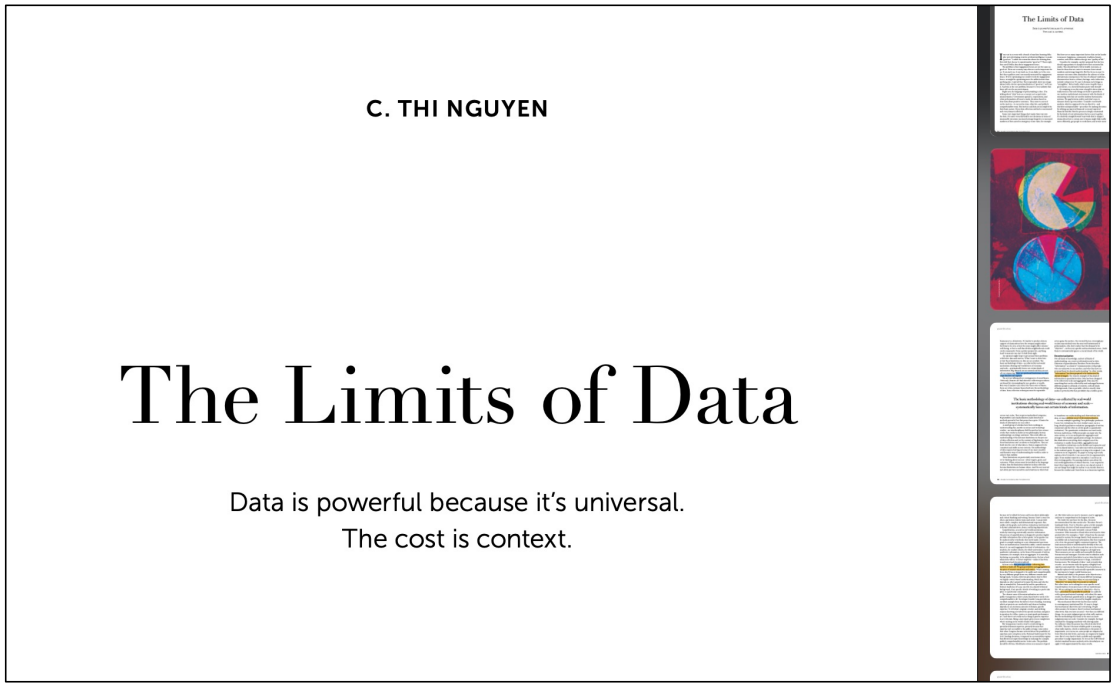
Ground truth

Data Collection



Collected: data

Lost: context



C. Thi Nguyen *is an associate professor of philosophy at the University of Utah.*

1st Principle of data
collecting data involves a trade-off.
We gain portability and aggregability at the price of context-sensitivity and nuance.

2nd Principle of data
Every classification system represents some group's interest

Prepared by the Association for Molecular Pathology Training and Education Committee
For More Educational Resources: *www.amp.org/AMPEducation*

Molecular In My Pocket™…

Bioinformatics: Interpretation Databases

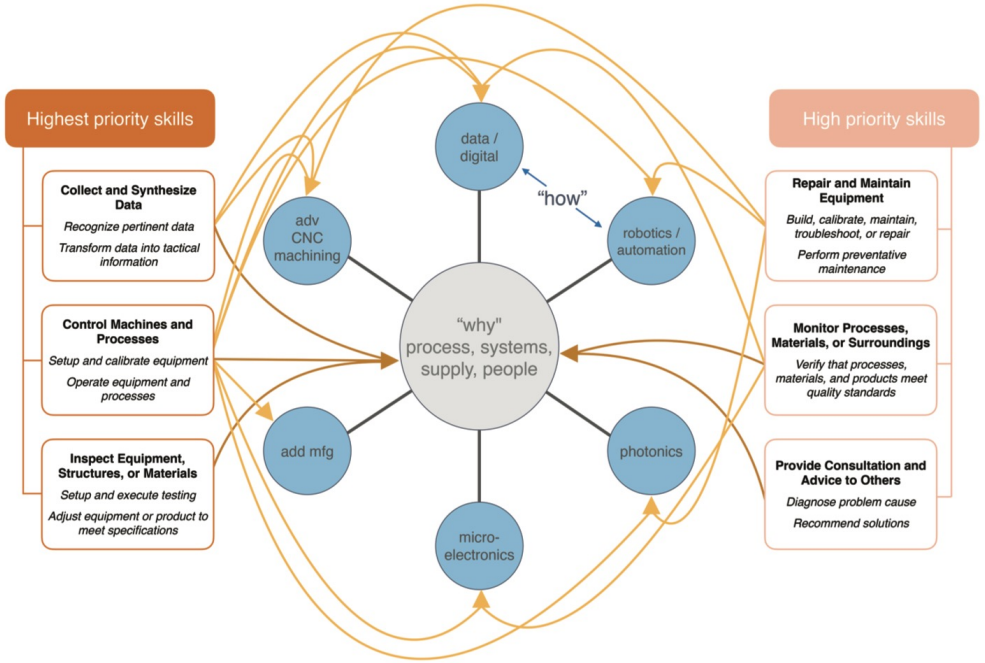
Database	Description	Website
Population Databases Exclude Polymorphisms		
Genome Aggregation Database (gnomAD)	A database that aggregates and harmonizes exome and genome sequencing data from a variety of large-scale sequencing projects and makes summary data available for the wider scientific community. The database includes Exome Aggregation Consortium (ExAC) database.	https://gnomad.broadinstitute.org/
Single Nucleotide Polymorphism Database (dbSNP)	A public archive for genetic variation including SNPs and short indels from 1000 Genomes (1000g) Project and Exome Variant Server (EVS).	https://www.ncbi.nlm.nih.gov/snp/
Interpretation Databases Determine the Importance of Variants. Somatic Interpretation 🟡; Germline Interpretation 🔵.		
Catalog of Somatic Mutations in Cancer (COSMIC) 🟡	A database of somatically acquired mutations found in human cancer.	https://cancer.sanger.ac.uk/cosmic
cBioPortal for Cancer Genomics 🟡	A resource for interactive exploration of multidimensional cancer genomics data sets. The database includes Cancer Hotspots and GENIE (requires registration).	http://www.cbioportal.org/
ClinVar 🟡 🔵	A public archive that aggregates information about genomic variation and its relationship to human health.	https://www.ncbi.nlm.nih.gov/clinvar/
Human Gene Mutation Database (HGMD) 🔵	A comprehensive collection of published germline mutations in nuclear genes that underlie, or are closely associated with, human inherited disease.	http://www.hgmd.cf.ac.uk/ac/index.php
My Cancer Genome 🟡	A precision cancer medicine knowledge resource that contains information on the clinical impact of molecular biomarkers in cancer-related genes, proteins, and other biomarker types on the use of anticancer therapies in cancer.	https://www.mycancergenome.org/
OncoKB 🟡	A precision cancer database with diagnostic, prognostic and therapeutic levels of evidence for genomic alterations in cancer.	https://www.oncokb.org/
PeCan 🟡 🔵	A resource that provides pediatric cancer mutations.	https://pecan.stjude.cloud/home
Prediction Databases Predict Impact of Variants on Proteins		
Polymorphism Phenotyping v2 (PolyPhen2)	Categorical prediction: D: probably damaging; P: possibly damaging; B: benign	http://genetics.bwh.harvard.edu/pph2/
Sorting Intolerant From Tolerant (SIFT)	Categorical prediction: D: deleterious; T: tolerated	https://sift.bii.a-star.edu.sg/
SpliceAI	Delta score ranges from 0 to 1 indicating probability of variant affecting splicing. Cutoffs: 0.2 (high recall), 0.5 (recommended), and 0.8 (high precision).	https://spliceailookup.broadinstitute.org/
Notes: This is not an inclusive list, only the most common databases.		

JOHN LIU AND WILLIAM B. BONVILLIAN

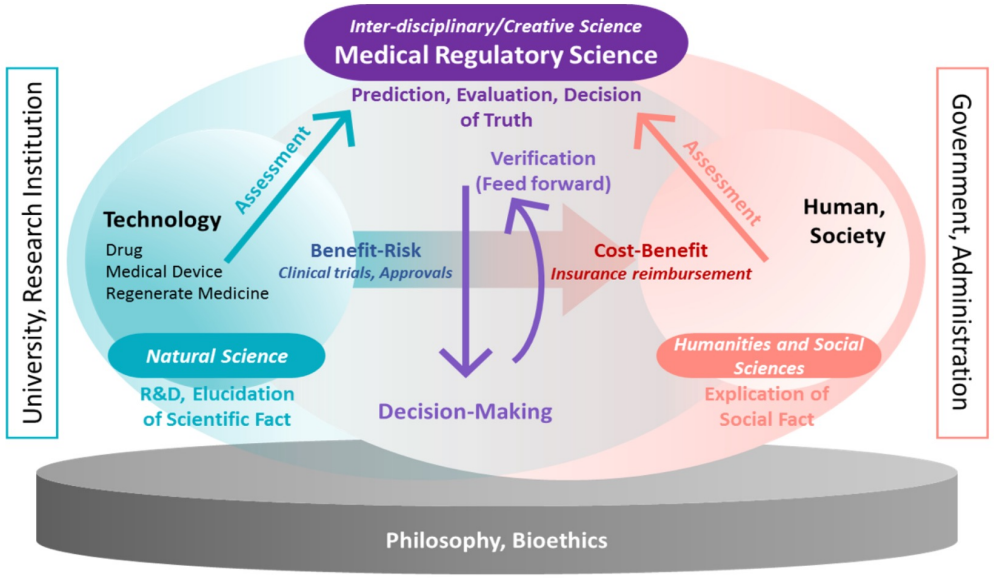
The Technologist

A new occupational category can both create opportunities for workers and position the United States to lead in advanced manufacturing.

Figure 1: **THE HUB-AND-SPOKE MODEL FOR TRAINING TECHNOLOGISTS**



Interdisciplinary Academic Framework for Medical Regulatory Science



Medical Regulatory Science as a Form of Evaluation Science

Medical technologies are approved for public use with human subjects after the completion of a process involving pre-clinical testing; subsequent translational research, clinical trials, and testing; risk-benefit analysis to assess scientific and social feasibility; optimization-planning; and decision-making. Further, a cost-benefit assessment is conducted, and insurance reimbursements are set. The foundation of all such processes is the philosophy and bioethics of “human dignity.”

The results of making decisions based on comprehensive evaluations that incorporate value judgments into the scientific evaluation of benefit/risk information must always be verified, and they can then be used in future evaluations and decision-making (a process called “feedforward”), creating a dynamic integrated system through a chain of evaluations and decision-making.

We believe that evaluation and decision-making through the fusion of the natural sciences with the human and social sciences (humanities-science fusion) across the full lifecycle of a medical technology constitutes medical regulatory science as a form of regulatory science.