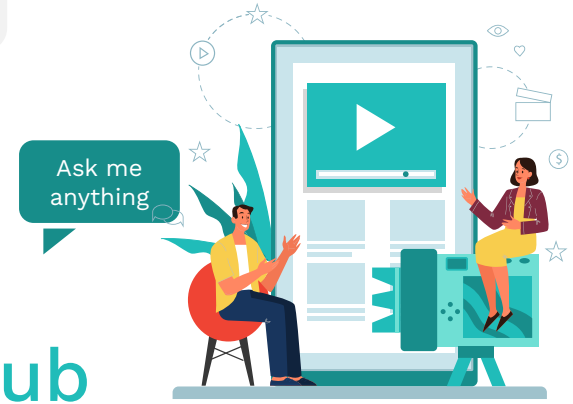
Virtual Journal club



The promise of artificial intelligence (AI) and machine learning (ML) for improving clinical outcomes

Thursday, February 15, 2024 11:00am ET

Stephen Ruberg
President
Analytix Thinking
Adjunct Professor, Department of Statistics,
Purdue University

Charmaine Demanuele
Executive Director, AI/ML Digital and Quantitative Sciences
Pfizer

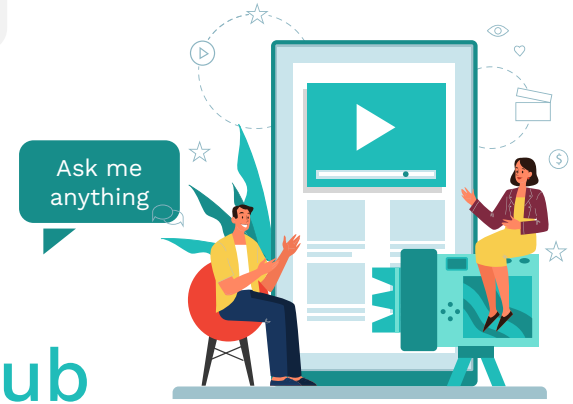
Gregg Gascon
Analytics Advisor
OhioHealth
Assistant Adjunct Professor
Biomedical Informatics, College of Medicine
The Ohio State University
Moderator

Simon Turner
Program Lead
DiMe
Co-moderator

But first, housekeeping

- Please note today's session is being recorded
- To ask a question for discussion during Q&A, please:
    - Either 'raise your hand' in the participant window and moderator will unmute you to ask your question live, or
    - Type your question into the chat box
- Slides and recording will be available after today's session

Virtual Journal club



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Resolving the Credibility Crisis: Recommendations for Improving Predictive Algorithms for Clinical Utility

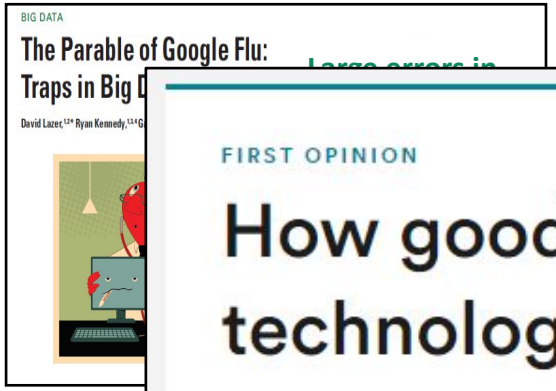
Stephen Ruberg, Sandeep Menon, Charmaine Demanuele

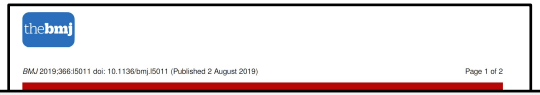
Harvard Data Science Review

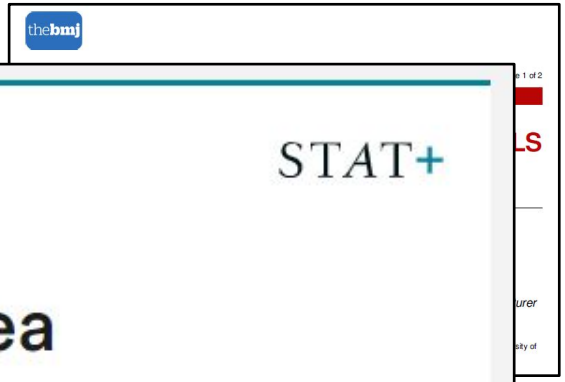
Fall 2023

https://doi.org/10.1162/99608f92.c1292c54

What's the Problem?







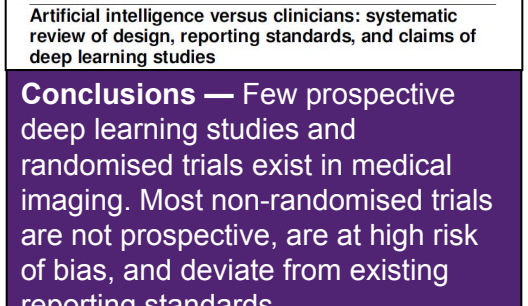
FIRST OPINION

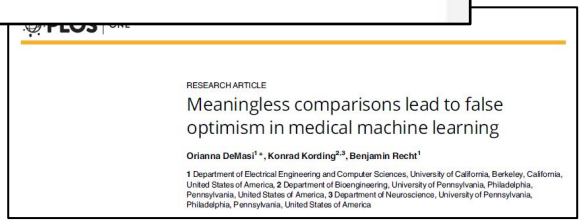
STAT+

How good are AI health technologies? We have no idea

By Cynthia Rudin, Zhicheng Guo, Cheng Ding, and Xiao Hu Oct. 11, 2023

Reprints





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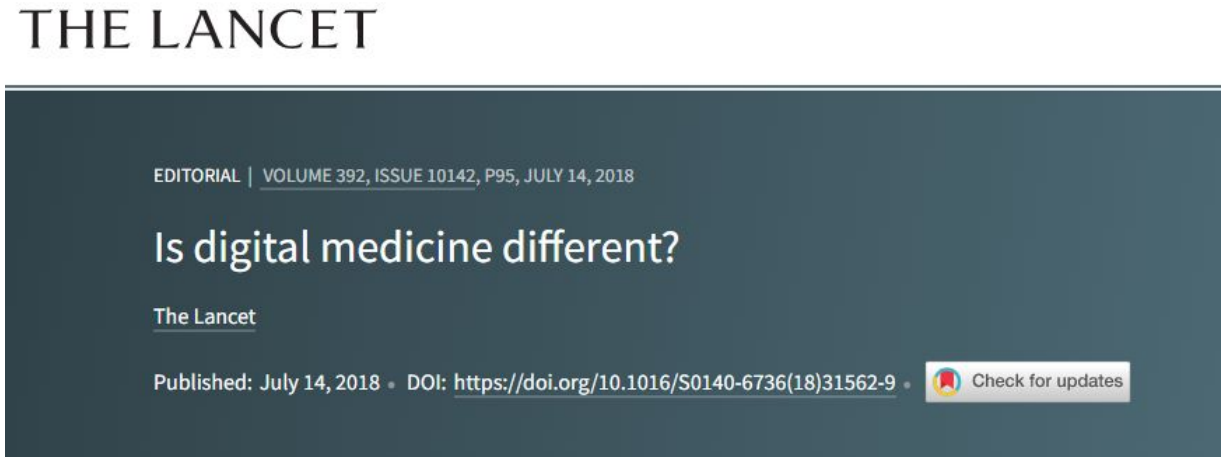


THE LANCET

EDITORIAL | VOLUME 392, ISSUE 10142, P95, JULY 14, 2018

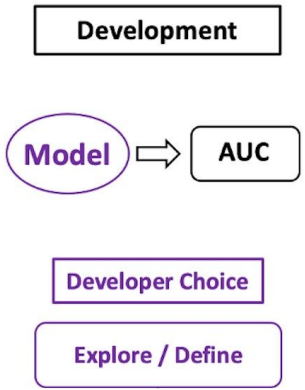
Is digital medicine different?

The Lancet

Published: July 14, 2018 • DOI: https://doi.org/10.1016/S0140-6736(18)31562-9 • Check for updates

the greatest risk for patients and health systems."

What's the Solution? A Framework



Maximize Total Value = $PPV*V_{TP} + (1-PPV)*V_{FP} + NPV*V_{TN} + (1-NPV)*V_{FN}$

What's the Solution? A Framework

Regulatory Approval

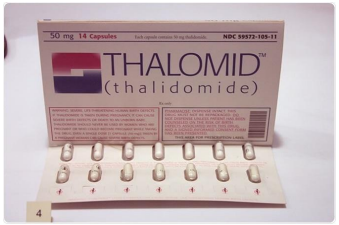
Identification Phase 0	Development Phase 1	Feasibility Phase 2	Evaluation Phase 3	Implementation Phase 4
•Identify diagnostic/ prognostic need •Identify appropriate data sources •Identify modeling approaches •Identify clinical workflows	•Select databases and modeling approaches •Develop model on retrospective database •Test algorithm in healthcare setting outside patient care •Explore cut-off (C); estimate AUC; identify safety concerns	•Conduct multicenter CRTs* in patient care, including clinical workflow •Define protocol & SAP** with surrogate or clinical outcomes •Estimate TV given prevalence by varying cut-off C •Fine-tune algorithm for	•Conduct prospective, broad CRTs with clear protocol (workflow) & SAP •Account for local prevalence •Pre-specify appropriate clinical outcomes (e.g., survival, AEs), benefit-risk and TV •Finalize Model	•Embed CPA in EHS for appropriate setting(s) •Monitor clinical outcomes from implementation of CPA •Conduct studies for utility/TV in other populations or settings •Perform comparative algorithm research using the TV metric

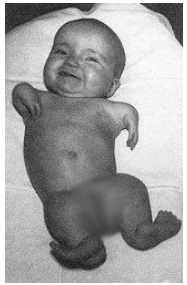
*CRT = Cluster Randomized Trials
**SAP = Statistical Analysis Plan

Historical Context (1)

Pre-1962

No statutory requirements for proving safe and effective treatments





1962 - …

"… substantial evidence from adequate and well-controlled investigations …"

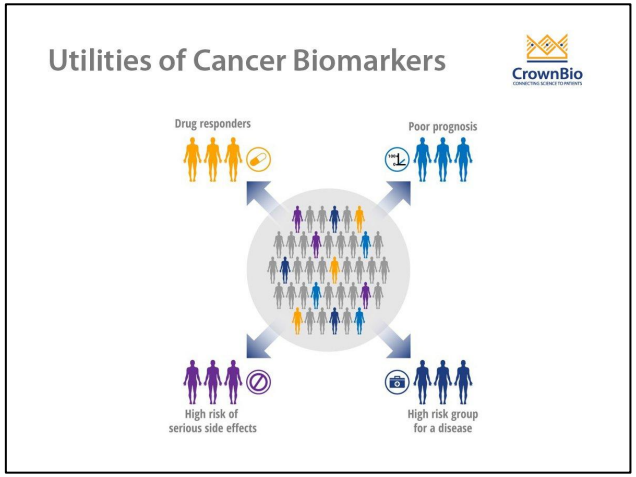
Kefauver-Harris Amendment

"The anarchy of guess and intuition [in the design and analysis of clinical trials] has given way to a benevolent tyranny of statisticians."

Donald S. Frederickson
Director of the National Heart Institute
1968

Frederickson DS, "The field trial: some thoughts on the indispensable ordeal." *Bulletin of the New York Academy of Medicine*, Vol. 44, No. 8, August 1968.

Historical Context (2)



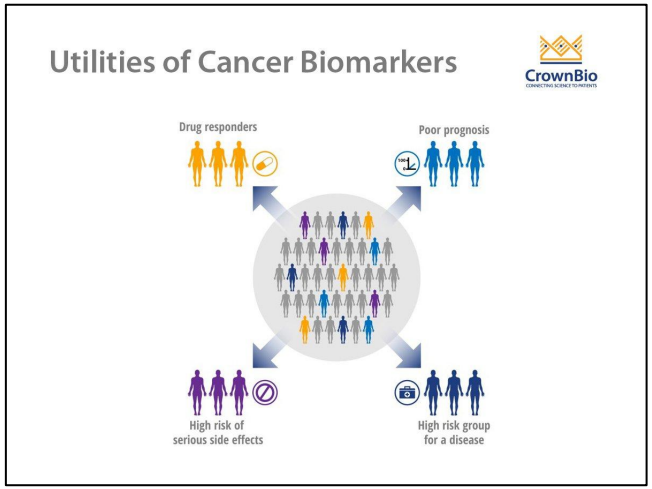
1980-2000

"Isolated laboratory investigators received convenient specimens from their clinical collaborators and applied their favorite technology to search for biomarkers. **Non-reproducible but highly acclaimed findings were rampant**, but few successful translational products made it to clinical use."

Feng, Z., & Pepe, M. S. (2020). Adding rigor to biomarker evaluations—EDRN experience. *Cancer Epidemiology and Prevention Biomarkers*, *29*(12), 2575–2582.

Historical Context (2)

2000 - …



Preclinical Exploratory	***PHASE 1***	*Promising directions identified*
Clinical Assay and Validation	***PHASE 2***	*Clinical assay detects established disease*
Retrospective Longitudinal	***PHASE 3***	*Biomarker detects preclinical disease and a "screen positive" rule is defined*
Prospective Screening	***PHASE 4***	*Extent and characteristics of disease detected by the test and false referral rate are identified*
Cancer Control	***PHASE 5***	*Impact of screening on reducing the burden of disease on the population is quantified*

11

Feng, Z., & Pepe, M. S. (2020). Adding rigor to biomarker evaluations—EDRN experience. *Cancer Epidemiology and Prevention Biomarkers*, *29*(12), 2575–2582.

Learn from History

Pre-2024

Clinical Predictive Algorithms

2024 - …?

Statistical Principles?
Systematic Development?

Learn from History

“We shall not cease from exploration, and the end of all our exploring will be to arrive where we started and know the place for the first time.”

T.S. Eliot

V3+: An extension to the V3 framework to ensure user-centricity and scalability of sensor-based digital health technologies

DATAcc
Digital Health Measurement Collaborative Community
by DiMe

Tuesday, February 27

11 am - 12 pm ET

Bryan Cobb
Pr. Medical Science Director
Genentech

Kim Kontson
Biomedical Engineer
Center for Devices and Radiological Health, U.S. FDA

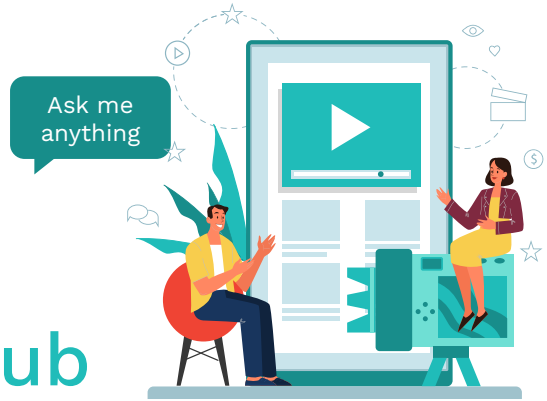
Elizabeth Kunkoski
Health Science Policy Analyst
Center for Drug Evaluation and Research, U.S. FDA

Stéphane Motola
Strategic Partnership Project Manager
SYSNAV

Oana Paun
QA Manager
Aardex Group

Benjamin Vandendriessche
VP, Science
Digital Medicine Society (DiMe)

Virtual Journal Club



Defining the Dimensions of Diversity to Promote Inclusion in the Digital Era of Healthcare

March 27, 2023 | 11 am ET

Anindita (Annie) Saha
Associate Director for Strategic Initiatives
Digital Health Center of Excellence, FDA

Amy Sheon
Digital Health Equity Consultant and President
Public Health Innovators

Michael Crawford
Assistant Vice President for Strategy and Innovation, Office of Health Affairs
Howard University

Yashoda Sharma
Program Director
Digital Medicine Society (DiMe)

Jennifer Goldsack
CEO
Digital Medicine Society (DiMe)

THANK YOU

DIGITAL MEDICINE SOCIETY

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