



The Strategic Landscape for the Evolution of Precision Health: Disruptive Changes in Biomedical Research, Public Health and Care Delivery

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HEALTH CARE LEADERSHIP
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Disclosures



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IMPROVING POPULATION HEALTH

Preventing and managing prevalent, costly, and chronic diseases²,4



REDUCING COST OF CARE

Reducing resource utilization and readmissions while assuming greater risk²





ENHANCING THE PATIENT EXPERIENCE

Motivating and engaging patients to play an active role in their care to improve outcomes and safety⁴



IMPROVING PROVIDER SATISFACTION

Providing access to tools and resources to address provider burden and burnout³

The US Health Ecosystem Fragmentation, Fragilities and Looming Disruptions

- isolated silos of expertise and care services
 - poor continuity in care and myriad embedded inefficiencies
- economically unstainable cost escalation without improved outcomes
- disproportionate investment of \$4.4 trillion annual expenditure on reactive management of active disease (90%) versus proactive focus on health optimization (10%)
 - disease-centric (sick-care) versus health optimization (wellness)
- decoupling of population health initiatives from care delivery to individuals
- myriad fragilities and fault lines revealed and amplified by COVID-19 pandemic
- neglect of social determinants of health and adverse impact on minority/marginalized communities
- systemic vulnerabilities create major opportunities for disruptive innovation

The Health Ecosystem

- facing a confluence of complex events that will radically alter all aspects of biomedical research and health care delivery
 - national and global
- cross-domain technology convergence
 - biomedicine, engineering and computing
- cross-sector industry convergence
 - diagnostics, therapeutics, big data analytics, Al and social media
- economics of scale with drive increased vertical and horizontal consolidation
- public and political expectations
 - access, availability, affordability and outcomes
 - reduce disparities and inequities

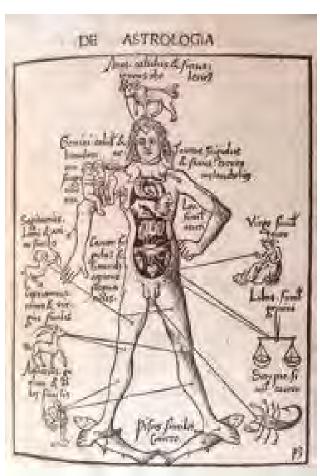
The Evolution of Precision Health: Improved Identification and Mitigation of Health Risks

- increasingly rational public health and clinical interventions to optimized health based on features unique to specific individuals/population cohorts
- improved detection of disease risk predisposition
- earlier detection of overt disease and prognosis/prediction of disease progression patterns
- shift societal disease burden from current predominant focus on treating advanced chronic disease to management of earlier stage disease and disease prevention
- strengthen surveillance and preparedness for rapid, resilient responses to disruptive external biosecurity threats
 - emerging infectious diseases, climate, cyber-risks

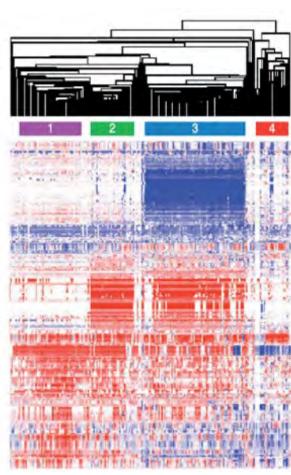
Precision Health

- optimize the health of populations and individuals by improved precision in the identification and mitigation of health risks
- the organization, capabilities, incentives and accountabilities of multiple elements of the current health ecosystem are misaligned with this strategic aspiration

The Path to Precision Health: From Superstitions to Symptoms to (Molecular) Signatures







humors; astrology, shamanism, sin and divine fate

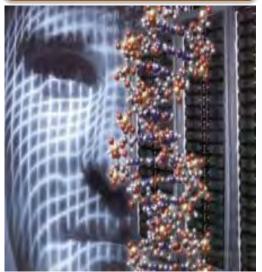
biochemistry and organ-based pathophysiology

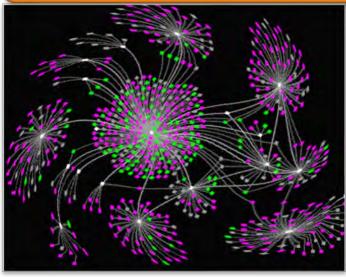
molecular biology and multi-omics profiling

Precision Health

(Epi)Genomics and MultiOmics Profiling

Detection of Altered Molecular Signaling Networks in Disease: A New Taxonomy of Disease and Subtype Classification







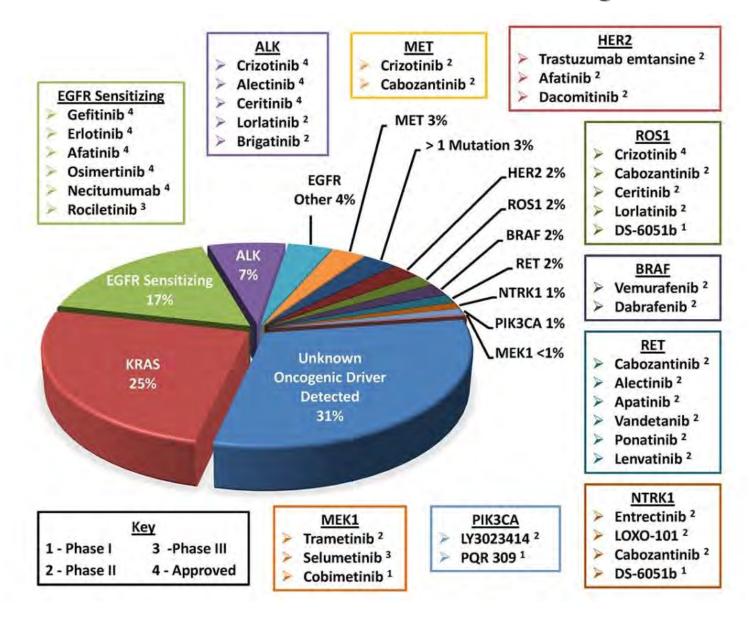


MDx Signatures of Disease Predisposition and Subtyping of Overt Disease for Optimum Rx Selection

- terabytes per limited individual
- zettabyte yottabyte population databases

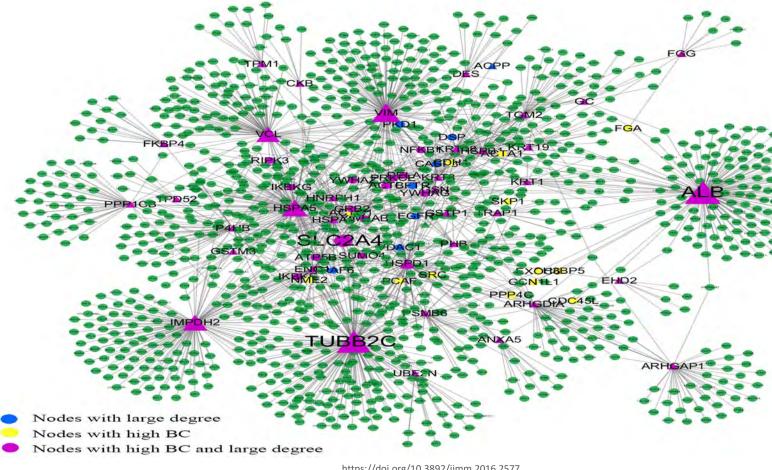
The Challenge of Big (Messy) Data

Molecular Classification of Non-Small Cell Lung Cancer

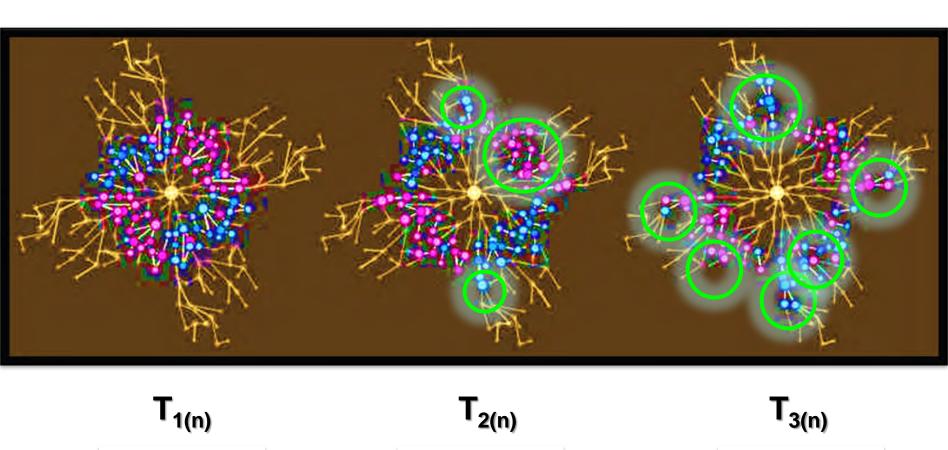


Understanding the Organization and Dynamics of Molecular Information Networks in Health (Physiology) and Disease (Pathology)

- mapping information flow (communication) within and between networks
- the progression from health to disease reflects the graded degradation in the fidelity of signal transmission



Understanding System State Shifts (Phenomes) and Emergent Perturbations in Molecular Signaling Networks in the Health to Disease Continuum



health

subclinical disease overt disease

Precision Health: New Concepts and Methods for More Proficient Identification and Mitigation of Health Risks

- "signatures" of health risk (individuals and populations)
 - disease predisposition, early disease detection
 - disease staging, prognosis and predicted progression
 - optimum treatment selection based on specific disease features in individuals and cohorts with similar phenotypes
 - prediction of Rx response, resistance and adverse events
 - faster alert of clinical deterioration and treatment non-adherence
 - tracking social determinants of health and exposure to environmental hazard exposures
 - proactive monitoring to detect pathogens with epi-/pandemic potential

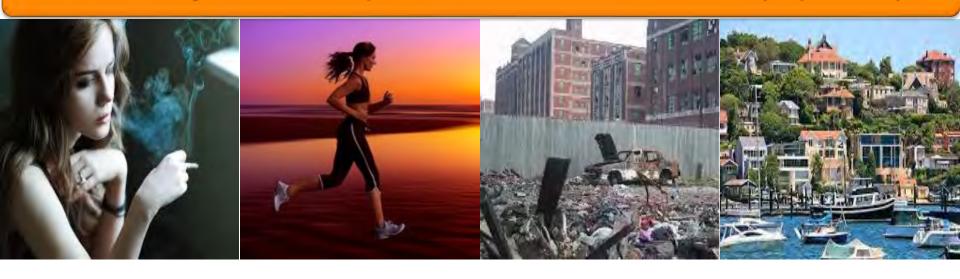
Deep Phenotyping: "Much More Than Omics"

From Womb to Tomb:

Systematic Longitudinal Integration of Multi-modal Health Data



SDoH, Lifestyle, Health Disparities, Environmental Hazards (Exposome)



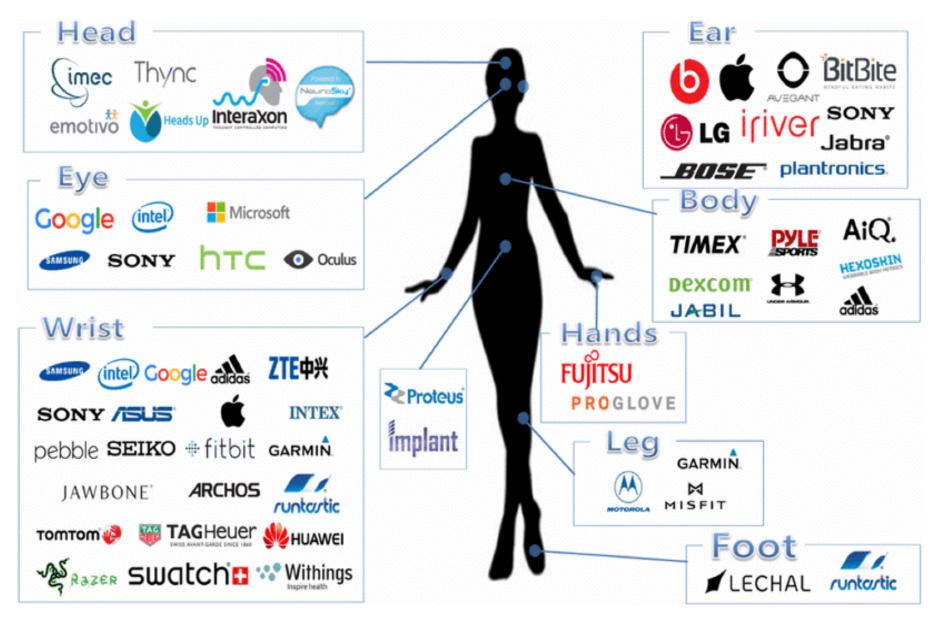
Expanding the 'Care Space' in Healthcare

- the majority of events that influence wellness/disease risk and treatment adherence occur outside of formal interactions with the healthcare system
- daily decisions by individuals have greater effects on their health than decisions controlled by the healthcare system
- rapid evolution of new technologies for real time remote monitoring of health status
 - longitudinal tracking
 - every population cohort/individual becomes their own control (tracking the Delta)
 - Internet-of-Medical Things (IOMT)

Rapid Growth in Wearables, Sensors and Devices for Remote Health Status Monitoring



Wearables and Remote Health Status Monitoring



Smart Devices for Automated Drug Delivery and Improved Therapeutic Adherence







Gecko (now Teva)



CapMedic



Biocorp Inspair







The Eldercare Gap

10,000

boomers turn 65 every day

79%

 increase in boomers age 80 or older from 2010 to 2030

1%

 projected increase in number of caregivers aged 45 to 64 from 2010 to 2030

348,000

 projected number of home health aides needed in next decade Digital Technologies and Aging in Place: Independent But Monitored Living for Aging Populations



Rx adherence



in-home support and reduced readmissions



cognitive stimulation



reduced office visits

Empowered Patients: Social Networking Sites and Their Role in Clinical Care

- logical extension to healthcare of rapid rise of web/apps in mainstream culture
- increasingly proactive and engaged consumers/patients/families
- greater access to information on treatment options, cost and provider performance
- new clinical practice tools to optimize physicianpatient relationships
- Ux and formation of senior executive level Chief Patient Experience Officer posts in large provider organizations

Economies of Scale and Consumer Convenience





Networked Telehealth Between
Provider Organizations:
Centralized 24/7 Monitoring of
Critical Care and Expert
Consultations





Robot-Human Directed Interactions









Cyber-Physical-Biological Systems Immersive Human-Machine Interfaces and Surgery



Cyber-Physical-Biological Systems Immersive Human-Machine Interfaces and Surgery

- robotics, automation and AR/VR/XR
- integration of robot controls with advanced 3D imaging
- multiplex sensor arrays and endoscopes/catheters
- precision actuators, sensing and automated controls
- instant presentation of comparable cases into headdress of surgical team members
- address shortages in surgical specialities
 - 331 million US population
 - 4000 cardiothoracic surgeons
 - 3500 neurosurgeons

AR/VR/XR Neuromodulation in Clinical Care







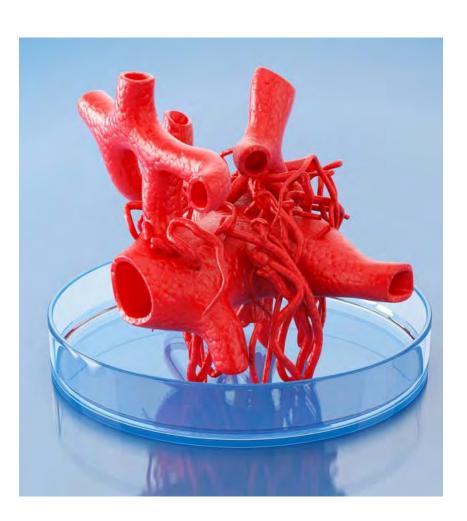






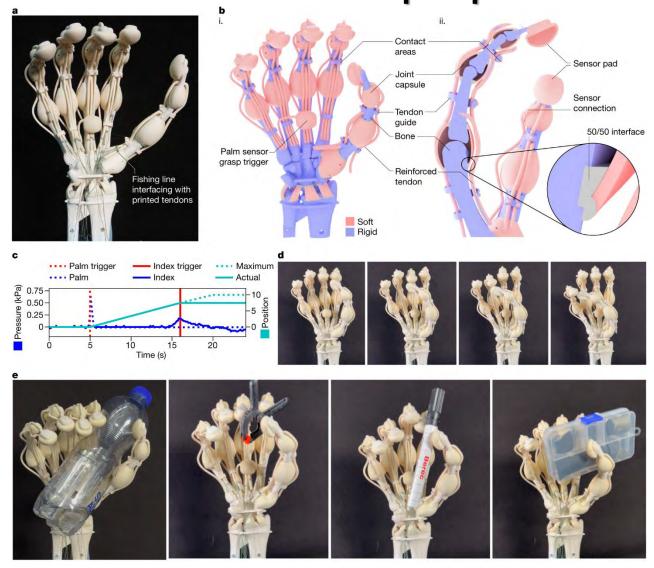
- injury rehabilitation
- reduce apprehension/distraction in painful procedures
- anxiety, depression, PTSD, phobias

The Future of Making: Industry 4.0 Technologies Advances in Materials Science and Bioprinting of New Biological Implants



- automated generative design and assembly
- additive manufacturing
 - multi-materials,
 multi-control elements
 - biotic: abiotic combinations
- real-time remote data transmission on performance
- automated self-repair and agile reconfiguration in response to altered environments

3D One Process Manufacture of Sensorized Robotic Hand with Tendon-Driven Grip Capabilities



T.J.K. Buchner et. al. (2023) Nature 623:522-530; doi.org/10.1038/s41586-023-06684-3

The Convergence of Precision Health and Digital Health: The Expanded Care Space and New Classes of Products and Services

- earlier detection of risk and mitigation
- reduce (re) hospitalization
- improved continuity in care
- telemedicine and remote health monitoring
- independent but monitored living for elderly

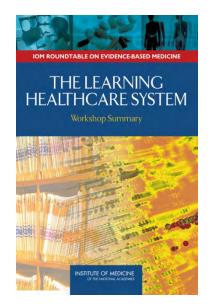
the expanded care space and continuity in care

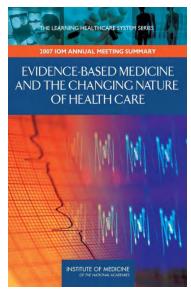
new combination product classes, services and new industry alliances/entrants

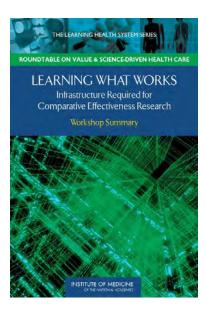
new cross-sector industry alliances and academic engagement

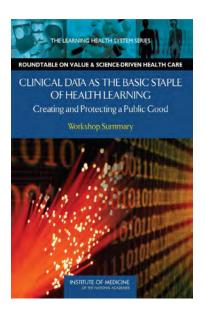
- Dx-Rx
- Dx-Rx-Ix
- Dx-Rx-Device
- DigRx
- materials science/ sensors
- brain-computer interactions
- intelligent agents and robotics
- social data analytics
- big data analytics

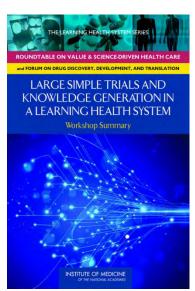
The Learning Healthcare System

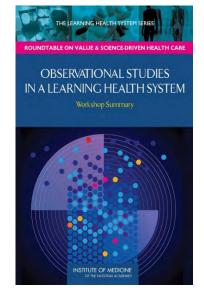


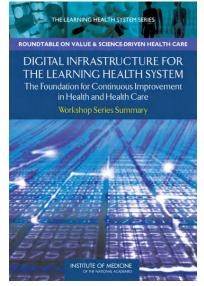


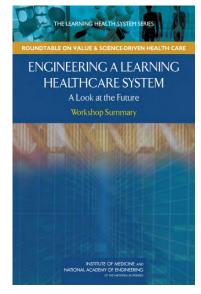


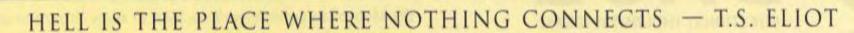












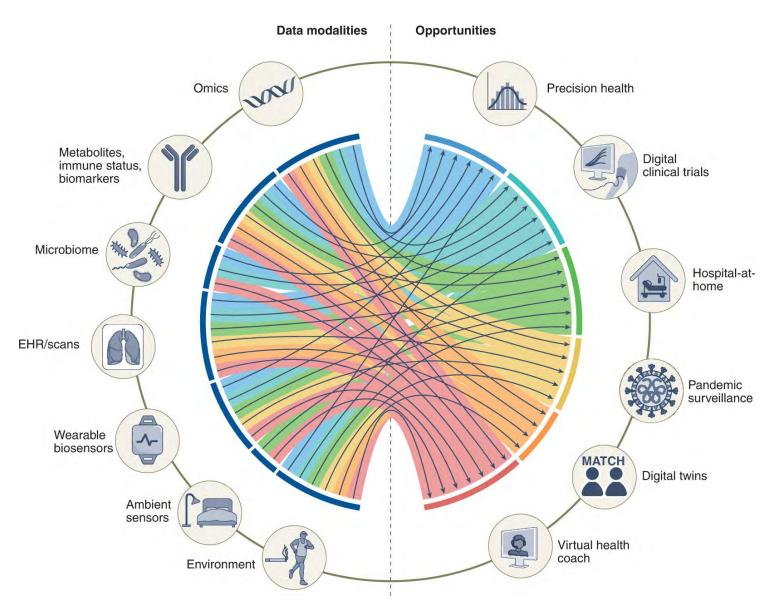


Managing Big Data in Biomedicine Will Not Be a Simple Extrapolation from Current Practices



Evolution of New Professional Competencies for Proficient Use of Advanced Computing, Al and Automated Clinical Decision Systems

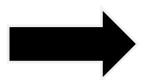
Precision Health and Deep Phenotyping: Multimodal Data Integration for Longitudinal Management of Health Risks



J.N. Acosta (2022) Nat Med 28, 1784

Precision Health and Digital Health: Building a Learning Health System

qualitative, descriptive information of variable quality and provenance



of known provenance and validated quality

of largely
unconnected
data sources



evolving,
inter-connected
networks of data
sources for robust
decisions and
improved care

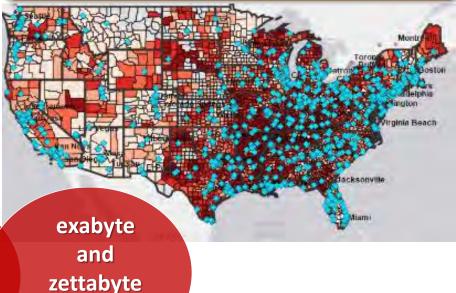
Precision Health and Digital Health: Evolving Inter-Dependencies

Individual Data

Population Data



and analysis of large-scale diverse data



Deep Phenotyping:

- clinical history- EHR/PHR **multiOmics**
- remote health monitoring

- socio-behavioral data environmental exposures

data deluge

Building Personalized 'Digital Twins': Matching Individual Deep Phenotypes to 'Best Fit' Cohorts

Individual Data

Population Databanks

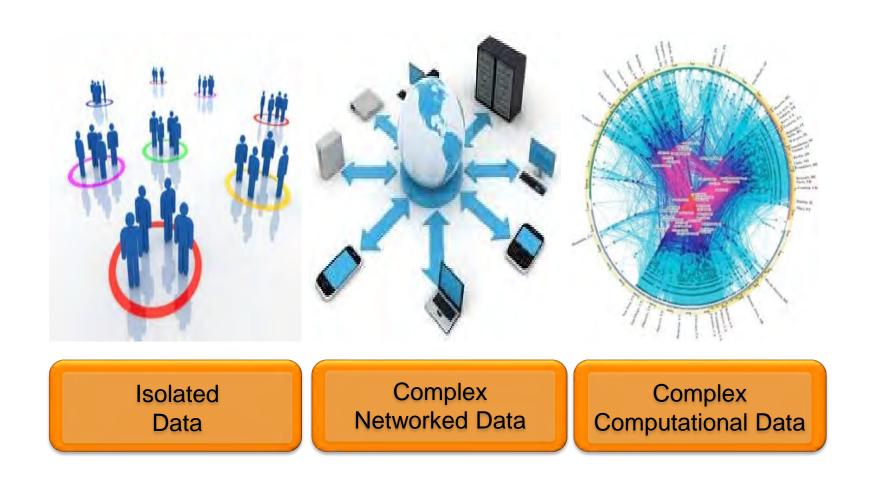




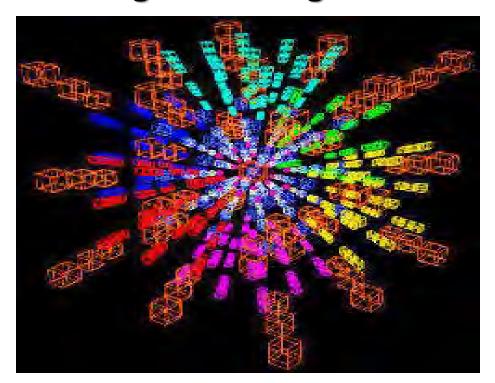


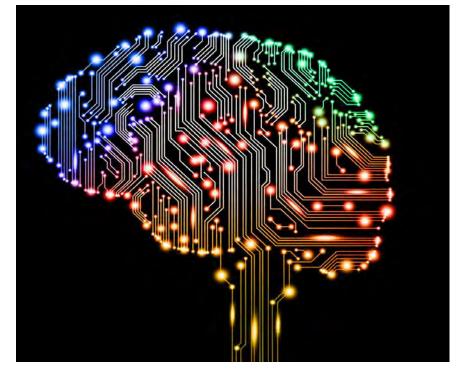
- 'digital twins and siblings' and imputed phenotypes
- risk predisposition and disease prevention
- selection of optimum treatment regimen for overt disease
- improved outcomes and QOL

Big Data Changes the Questions That Can Be Asked



Automated Context: Data Finding Data "Intelligence at Ingestion" and Collapse Time to Decision





Feature
Extraction
and
Classification



Context
Analysis
Persistent
Context



Topologies
Learning
Systems

Knowledge



DataFidelityRapid,

Robust Decisions

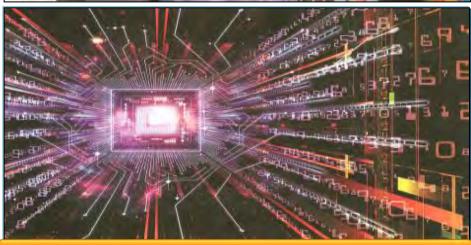
Technology Acceleration and Convergence: The Escalating Challenge for Professional Competency, Decision-Support and Future Medical Education

Data Deluge



Cognitive Bandwidth Limits







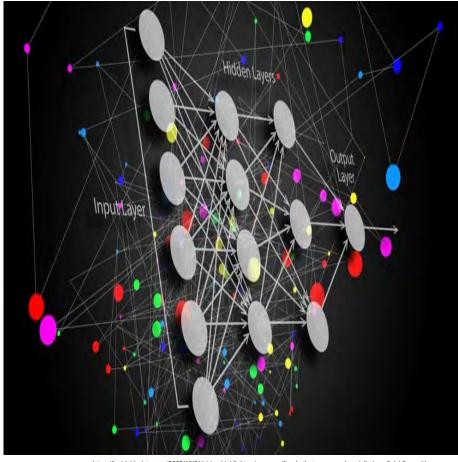
Automated Analytics and Decision Support

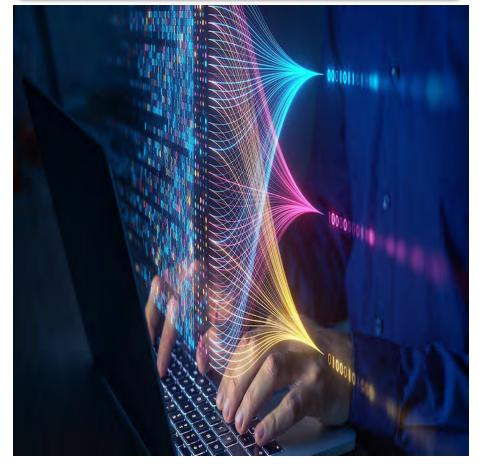
Facile Formats for Actionable Decisions

Al Large Language Models (LLMs): Transformation of the Research Process and Clinical Decision-Making

GAI Platforms

Deep Learning and Pattern Analysis in Multi-model Data Integration





https://insidebigdata.com/2023/10/01/video-highlights-vicuna-gorilla-chatbot-arena-and-socially-beneficial-llms-with-prof-joey-gonzalez/

https://techxplore.com/news/2023-07-chatgpt-people-surprisehere-technologies-difference.html

The GAI Investment Frenzy 2023



PyTorch, LLaMA (24 Feb.)





BARD





GPT4 (14 March) Microsoft







ERNIE (15 March)

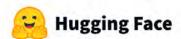




GitHub Copilot X (22 March)



expand partnerships

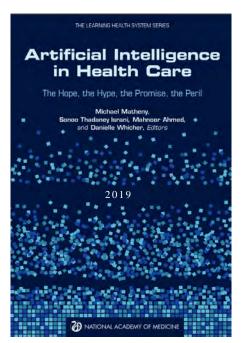


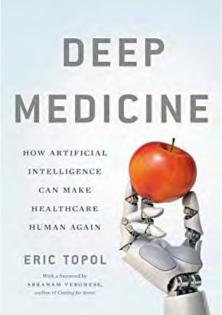


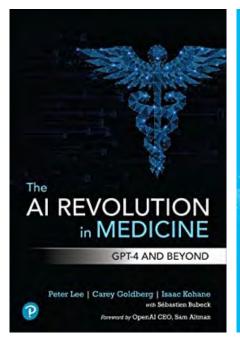


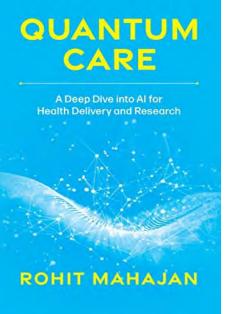
ChatGPT app added its Slack and Einstein platforms

Generalized Artificial Intelligence and Healthcare





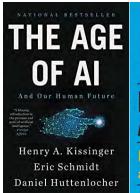


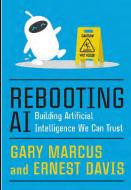


Al and Healthcare

- impressive examples of generation of rapid and accurate responses to questions from HCPs and patients
- but frequency of inaccurate and/or nonsensical responses ("hallucinations") remains problematic
- intrinsic learning property of LLMs with access to more data, new hallucination detection filters and refined 'prompt semantics' is anticipated to rapidly overcome this vulnerability

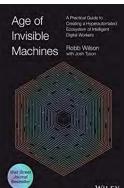
No Shortage of Commentaries on the Potential of Al for Limitless Benefits or the Road to Dystopian Futures and Machine Control





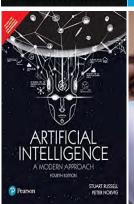






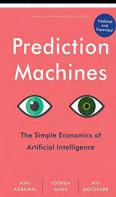


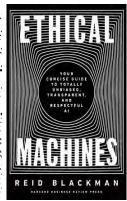




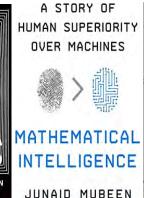


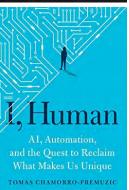




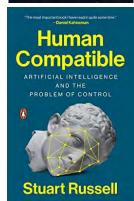


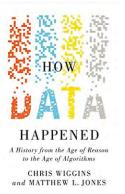


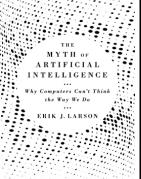


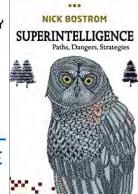


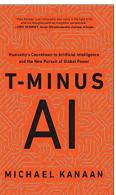














OCTOBER 30, 2023

FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence



9/5/2023

KMB/DA/AS

Committee on the Internal Market and Consumer Protection Committee on Civil Liberties, Justice and Home Affairs

Version: 1.0

DRAFT Compromise Amendments

on the Draft Report

Proposal for a regulation of the European Parliament and of the Council on harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union Legislative Acts

(COM(2021)0206 - C9 0146/2021 - 2021/0106(COD))



December 18, 2023

Preparedness Framework (Beta)

We believe the scientific study of catastrophic risks from Al has fallen far short of where we need to be.

To help address this gap, we are introducing our Preparedness Framework, a living document describing OpenAl's processes to track, evaluate, forecast, and protect against catastrophic risks posed by increasingly powerful models.

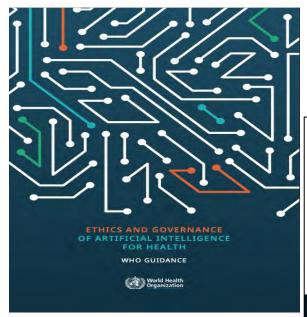


U.S. DEPARTMENT OF DEFENSE RESPONSIBLE ARTIFICIAL INTELLIGENCE STRATEGY AND IMPLEMENTATION PATHWAY

Prepared by the DoD Responsible AI Working Council in accordance with the memorandum issued by Deputy Secretary of Defense Kathleen Hicks on May 26, 2021, Implementing Responsible Artificial Intelligence in the Department of Defense.

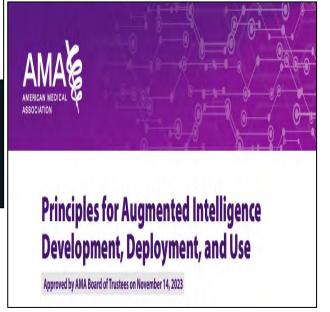
June 2022

Oversight and Regulation of Al in Healthcare





BLUEPRINT FOR TRUSTWORTHY AI IMPLEMENTATION GUIDANCE AND ASSURANCE FOR HEALTHCARE COALITION FOR HEALTH AI VERSION 1.0 _ APRIL 04, 2023



The Rush to Regulate AI: We've Been There Before

Wall Street Journal, 2 January 2024

- each new technology with broad multi-domain applications evokes calls for one-size-fits-all governance policies and regulation
- 1980s: biotechnology
- 1990s: www and internet
- 2023: generative artificial intelligence

Cyberspace and the Law of the Horse: 1996 Opinion by Judge Frank Easterbrook 7th US Grand Court of Appeals

 calls for a single regulator/regulation for governance of the web and the emerging internet would be as futile as an effort to create a single pathway to regulate the multiple uses of horses in the 19th century economy



US Regulation of AI Platforms in Healthcare



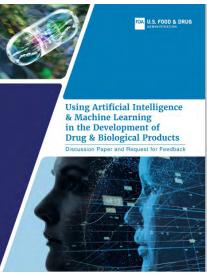
"FDA needs to be nimble in the use and regulation of large language models to avoid being swept up quickly by something we hardly understand."

Dr. R. Califf
FDA Commissioner, 9 May 2023
2023 Science for Patient Engagement Symposium









Regulatory Oversight and Validation of Large Language Model (LLM) Al Platforms in Clinical Decisions

- transparency and patient informed consent when Al tools used in their care
- malpractice liabilities
 - harm from use (platform developers, HCPs, or the health systems which approved adoption)
 - harm from failure to use or ignored recommendations when Al-decision support systems are integrated into SOC, professional guidelines or regulatory labeling

Navigating Disruptive Change



"The greatest danger in times of turbulence, is not the turbulence, it is to act with yesterday's logic."

- Peter Drucker

DNR: Cultural Barriers to Adoption of Innovation



Denial

Negativity

Resistance

New Thinking and New Capabilities











































RAISE-Health Responsible Al for Safe and Equitable Health



Lloyd Minor, MD

Carl and Elizabeth Naumann Dean,
Stanford University School of Medicine



Fei-Fei Li, PhD

Co-Director, Stanford Institute
for Human-Centered Artificial
Intelligence (HAI)

Navigation of Escalating Scientific and Clinical Complexities



Major Transitions in Medical Education and Healthcare

1910 - present

2000 - present

MEDICAL EDUCATION
IN THE

UNITED STATES AND CANADA

A REPORT TO

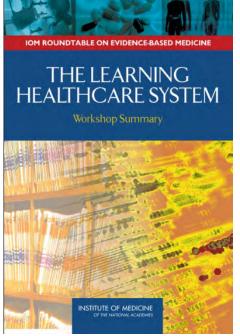
THE CARNEGIE FOUNDATION FOR THE ADVANCEMENT OF TEACHING

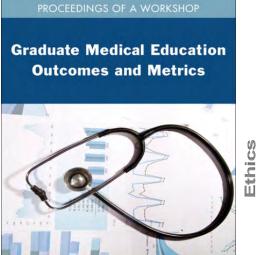
ABRAHAM FLEXNER

WITH AN INTRODUCTION BY HENRY S. PRITCHETT

BULLETIN NUMBER FOUR (1910) (Reproduced in 1960) (Reproduced in 1972)

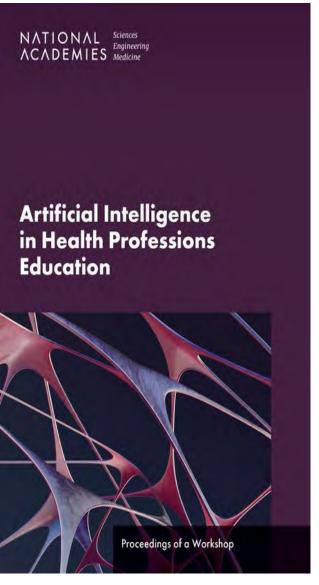
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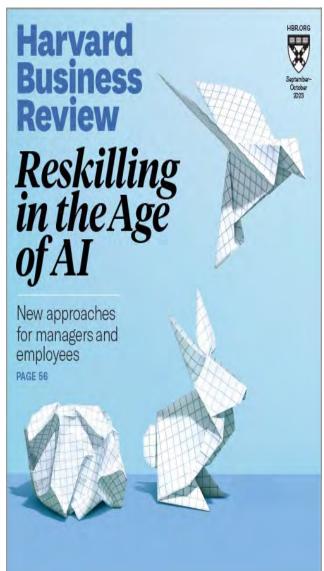




The National Academies of SCIENCES • ENGINEERING • MEDICINE 2015 - ?







Issue Brief

Al Faculty Shortages

Are U.S. Universities Meeting the Growing Demand for AI Skills?

Authors

Remco Zwetsloot Jack Corrigan

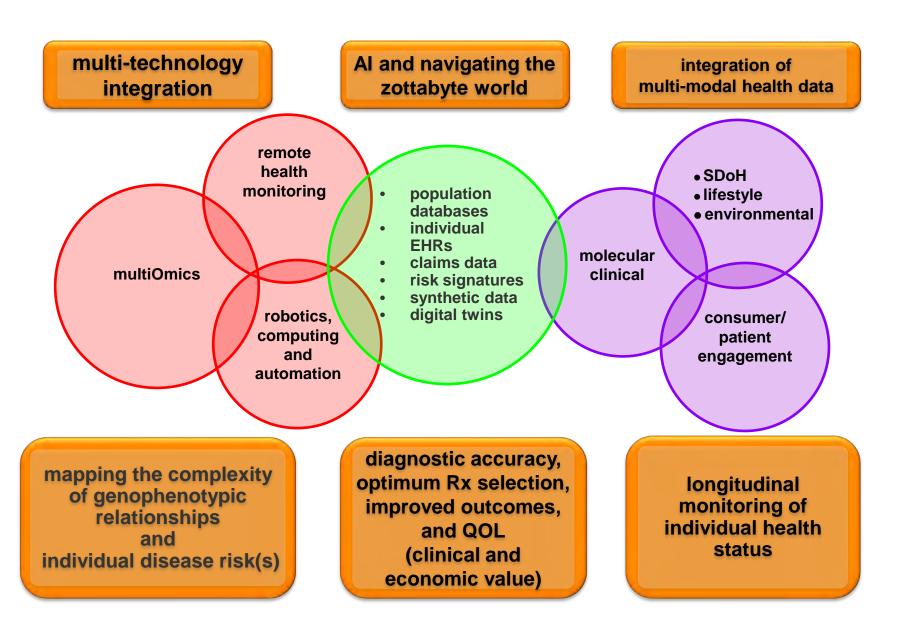


July 2022

"Digital Darwinism": A Looming Digital Divide

- understanding data structure and its productive application/customization for acceleration of research and clinical care will become a critical institutional competency
- major skill gaps and personnel shortages in biomedicine
- training of a new cadre of data scientists (medical and non-medical)
- institutions lacking adequate computational infrastructure and critical mass in data analytics will suffer 'cognitive starvation' and relegation to competitive irrelevance

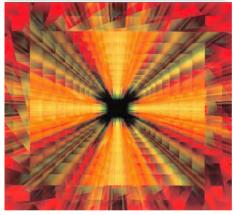
The Co-Evolution of Precision Health, Digital Health and Al



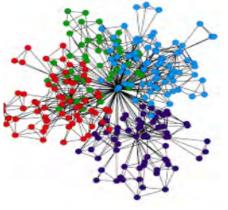
The Evolution of Data-Intensive Precision Health

Technology Convergence and Acceleration Mapping Geno-Phenotype Complexity Topology of Biological Information Networks

Multi-modal Data Integration

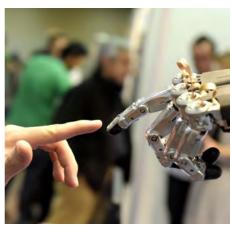


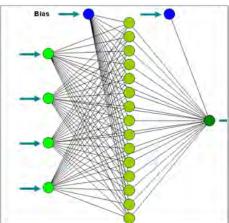














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Robotics and Human Machine Interactions

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Public Policy: Ethics, Risk and Regulation

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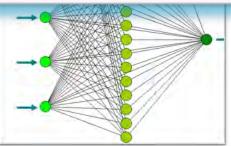




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