Navigating AI in Health Care Policy: How Are Standards Evolving?

Wednesday, October 2, 2024

ALLIANCE FOR HEALTH POLICY

2024 Signature Series

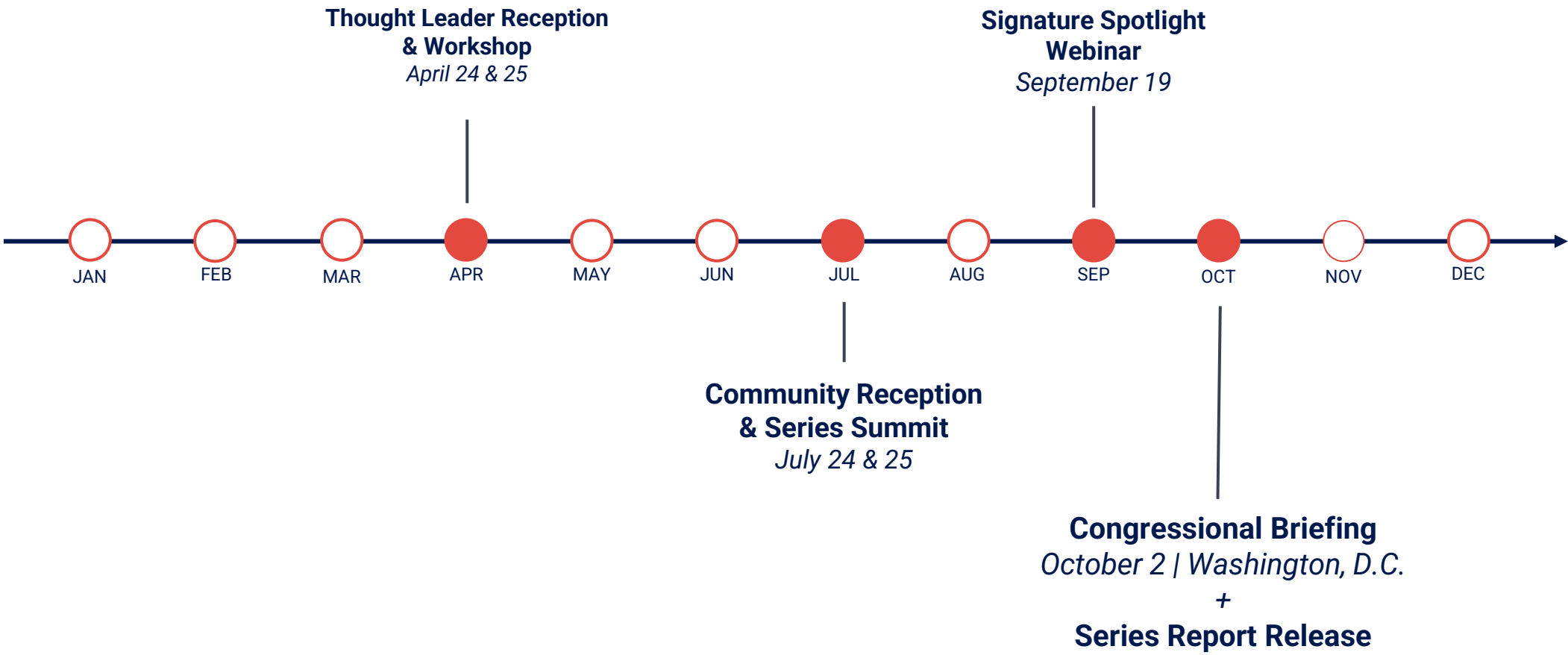
Welcome Remarks

Claire Sheahan, M.Sc.
President & CEO
Alliance for Health Policy

2024 Signature Series

2024 SERIES TIMELINE

AI IN HEALTH – NAVIGATING NEW FRONTIERS



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THOUGHT LEADER WORKSHOP MEMBERS

THOUGHT LEADER GROUP

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David Bennett, Kaiser Permanente

Cynthia Bigley, Otsuka Pharmaceuticals

Tanisha Carino, Ph.D., Brunswick Group

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Rebecca Flournoy, MPH, Kaiser Permanente

Shaheen Gauher, Ph.D.

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Lisa Goldstein, J.D., U.S. Department of Health and Human Services, Office for Civil Rights

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Brandon G. Wilson, Dr.PH, MHA, Community Catalyst

Aubrey Wilson, POPVOX

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Today's Goals

Goal 1

Highlight key thinkers in the emerging area of Health AI best practices

Goal 2

Introduce different takes on the challenges and opportunities of how to envision AI frameworks, and points of view on evaluation opportunities.

Goal 3

Provide you with resources to learn more.

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Emma Beavins

Staff Writer
Fierce Healthcare

Moderator + Panelists

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National Academy of Medicine (NAM)

René Quashie, J.D.
Vice President of Digital Health
Consumer Technology Association

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Population Health and Data Science Lead, Duke Institute for Health Innovation
Co-Lead, Health AI Partnership

Brian Anderson, M.D.
CEO and Founder
Coalition for Health AI (CHAI)

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Laura Adams, M.S.

Senior Advisor
National Academy of Medicine (NAM)

NAM Leadership Consortium
Collaboration for a Learning Health System

ALLIANCE FOR HEALTH POLICY

The NAM AI Code of Conduct for Health Care and Biomedical Science

Alliance for Health Policy

October 2, 2024

NATIONAL ACADEMY OF MEDICINE

The National Academy of Medicine Mission

To improve health for all by advancing science, accelerating health equity, and providing independent, authoritative, and trusted advice nationally and globally

NAM AI Code of Conduct (AICC) Initiative

Goals:

- **To promote responsible use of AI in healthcare and harmonize, fill in the gaps, and align** existing healthcare AI guidelines, principles, and frameworks
- **Translate the Code of Conduct commitments** into clearly defined and observable behaviors
- **Promote national alignment** – ***not*** wholesale adoption of the Code

AI Code of Conduct (AICC)
Steering Committee Co-Chairs

Gianrico Farrugia, CEO
Mayo Clinic

Bakul Patel, Global Lead Digital Health Strategy
Google

Roy Jakobs, CEO
Royal Phillips

Proposed NAM AI Code of Conduct Commitments: The “Simple Rules” for governing AI in health care

1. Protect and advance human health and connection as the primary aims
2. Ensure equitable distribution of risks and benefits
3. Engage people as partners *with agency* in every stage of the AI lifecycle
4. Renew the moral well-being and sense of shared purpose to the healthcare workforce
5. Monitor and openly share methods and evidence of AI’s performance and impact on health and safety
6. Innovate, adopt, collaboratively learn, and continuously improve

All AI is *not* alike

Pre-generative AI

Generative

Responsible Healthcare AI Governance is Multifaceted

- Federal government
- State government
- National/international collaborations
- Assurance labs/accrediting bodies
- Industry collaboration
- Public/private partnerships
- Local health system

-What do we need that is new vs. what we should simply build upon?

Thank you!

Laura Adams, Senior Advisor
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René Quashie, J.D.

Vice President of Digital Health
Consumer Technology Association

Consumer Technology Association, producer of CES®

2024 Signature Series Congressional Briefing

René Quashie
Vice President, Digital Health
Consumer Technology Association

October 2024

CTA Standards

Develop industry standards that ensure product interoperability

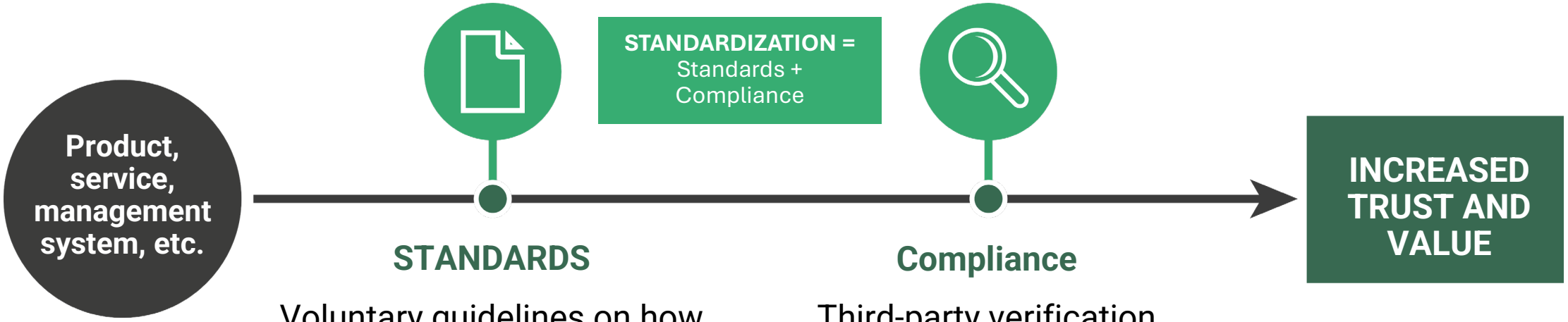
With more than 70 committees, subcommittees and working groups and roughly 1,100 participants, the CTA Technology & Standards program is a flexible standard making body accredited by the American National Standards Institute (ANSI).

CTA has published over 130 standards touching all aspects of the consumer technology industry, including 31 digital health standards, 7 standards related to AI (with 4 AI in healthcare).

Highlights:

- AI
- Airplane Mode
- Closed Captioning
- Radar system development (Ripple)
- Indoor network navigation systems for accessibility
- Physical activity monitoring for heart rate
- HDTV

Standardization Overview



STANDARDS

Voluntary guidelines on how to design, manage, or create materials, products, processes, and services

Created by technical experts from industry, government, consumers, academia, and others—all working together

Compliance

Third-party verification and other methods of compliance demonstrate that the standard was actually met

Instills confidence in the widespread use of products, personnel, services, and systems

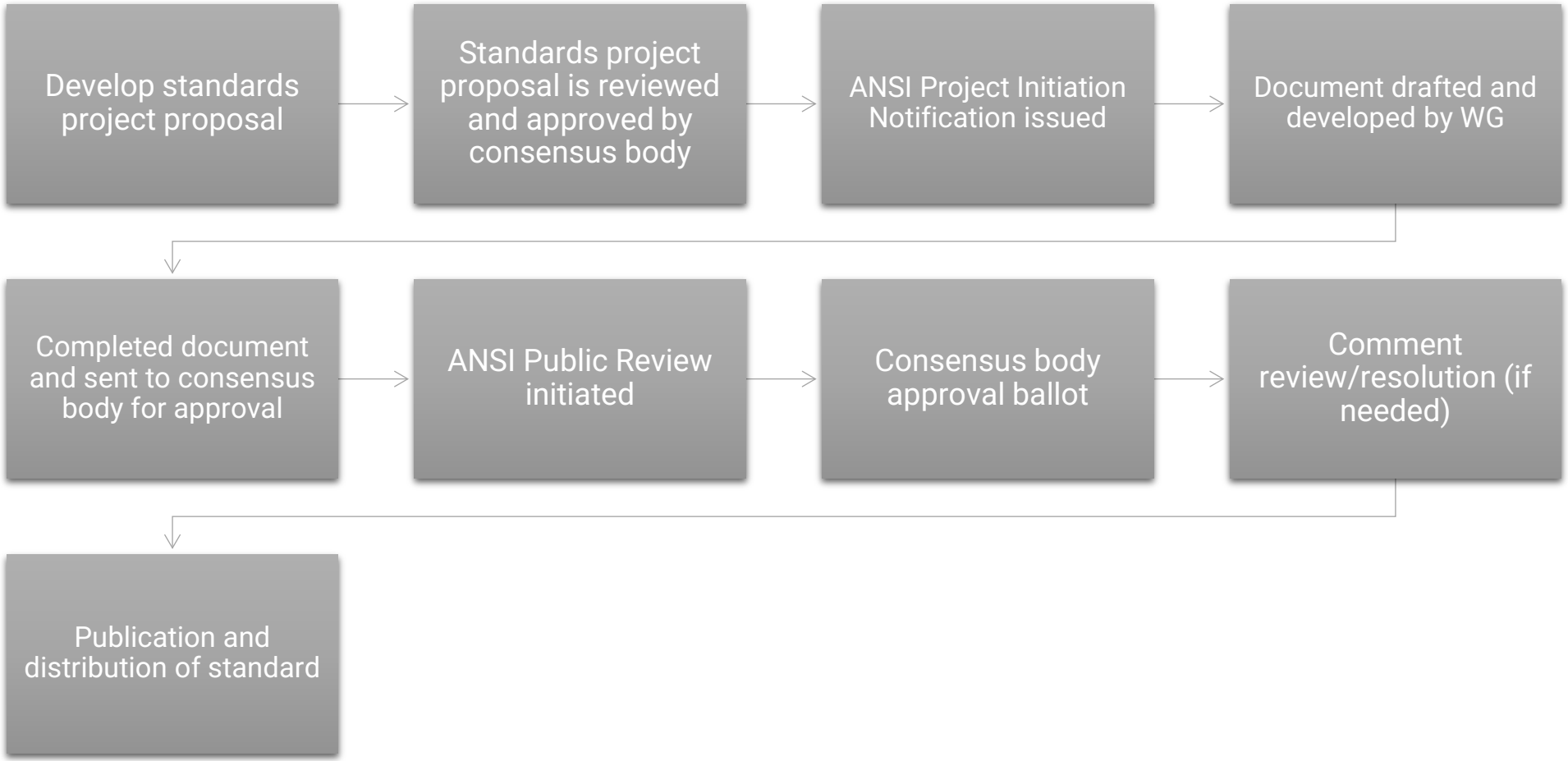
ANSI Accreditation

Designation as an American National Standard (ANS) indicates that ANSI's due process requirements are met – including openness, balance, and consensus

ANS designation is recognized and valued by national and international stakeholders

American National Standards serve as the basis for many ISO, IEC, or other international standards.

Standardization Process



CTA Health AI Project

- Mission: To support the establishment of clear, enforceable standards for development, validation, deployment, and monitoring of AI in healthcare, fostering trust, and innovation
- Key objectives
  - Define a comprehensive healthcare AI lifecycle for predictive AI solutions, encompassing all stages from conception to retirement
  - Map existing standards and tools
  - Identify gaps and needs: Pinpoint areas where standards or tools lacking or insufficient to support the application of health AI.
  - Develop concrete standardization proposals
  - Submit proposals for development of standards

CTA National AI Policy & Regulatory Framework

- New guardrails should be principles-based and focused on outcomes rather than on the technical inputs of AI systems
- Risk-based approach
  - Oversight tailored to the nature and level of potential risk that an AI system may present
  - AI systems making decisions: (1) based solely on automated processing and (2) which have consequential legal or equally significant effect on individuals, or which may impact individuals' health and safety
- Comply with an accepted third-party framework for AI governance, such as the NIST RMF or applicable ISO, IEEE, CTA or related standards

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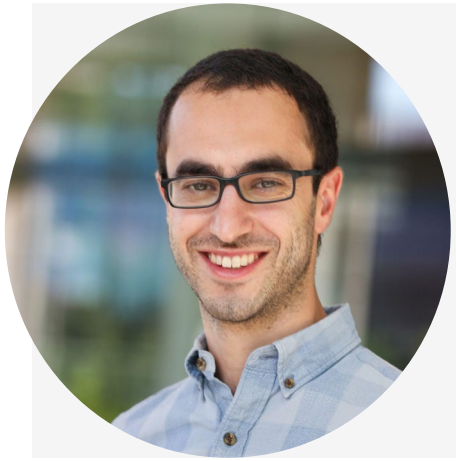


Mark Sendak, M.D., MPP

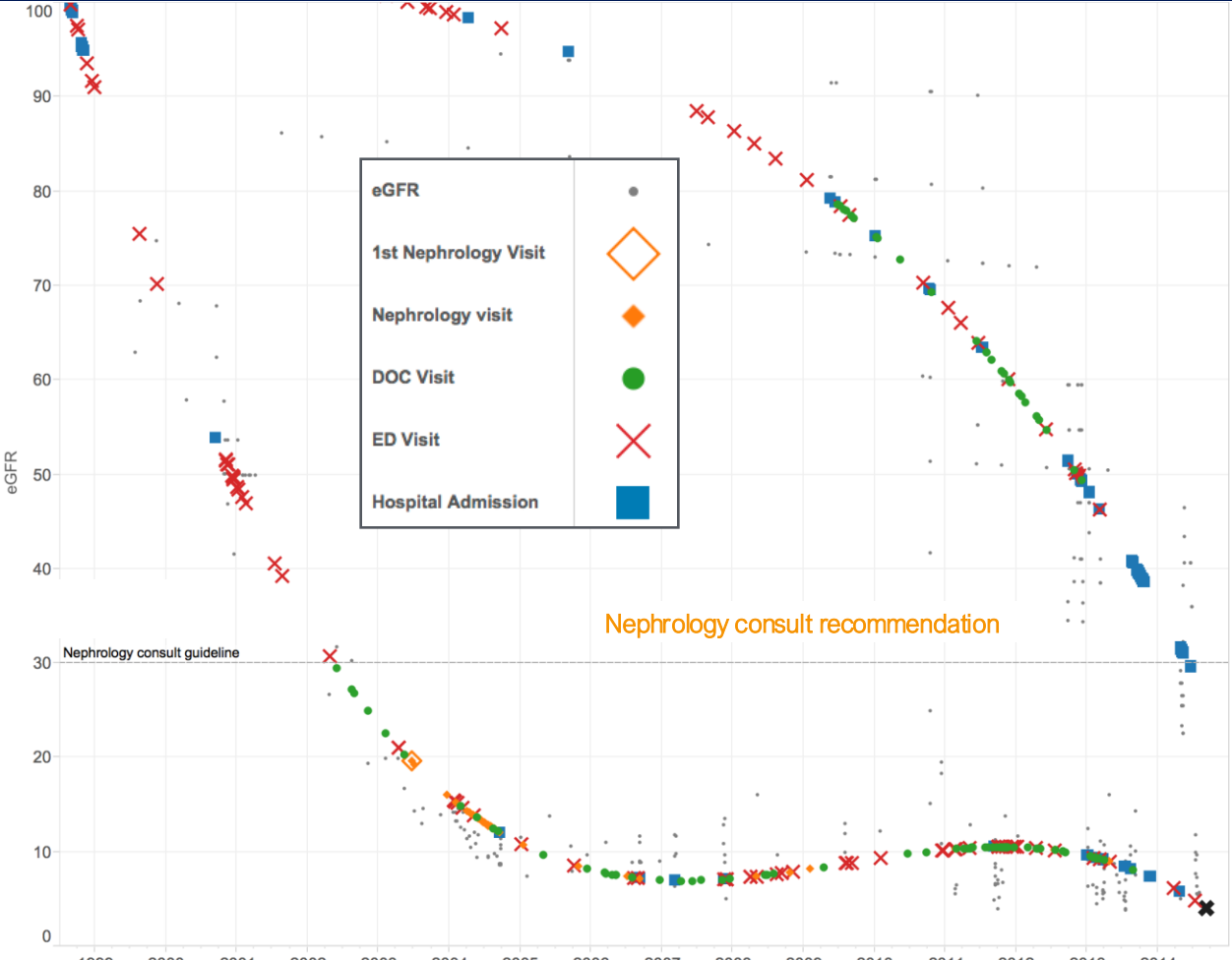
Population Health and Data Science Lead,
Duke Institute for Health Innovation
Co-Lead, Health AI Partnership

DUKE University School of Medicine | DUKE Institute for Health Innovation

Scaling the Safe, Effective, and Equitable Use of AI

Mark Sendak, MD, MPP
Population Health & Data Science Lead, Duke Institute for Health Innovation
Co-Lead, Health AI Partnership

October 2024


eGFR
1st Nephrology Visit
Nephrology visit
DOC Visit
ED Visit
Hospital Admission
Nephrology consult recommendation
Nephrology consult guideline
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Adapt Workflows, Roles, and Organizations

1. Patient arrives with **history of treatment from a variety of settings** (at and outside of Duke).

2. 

All relevant **patient data is aggregated and analyzed** using algorithms and models that incorporate the best statistics theory and medical expertise.

3. 

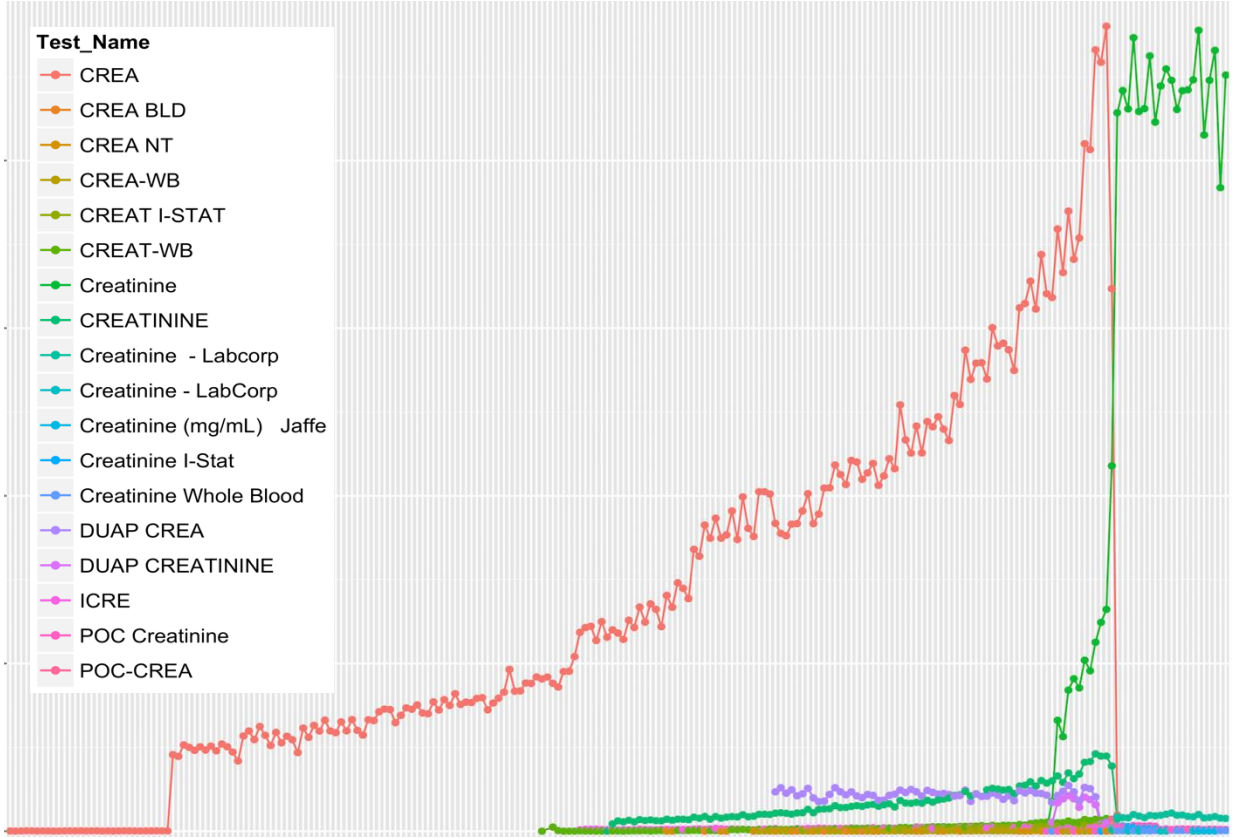
An interdisciplinary team discusses the best plan. Team typically includes a specialists, PCP, data analyst, pharmacist, social worker, and care manager.

4. Next, an **action plan is implemented**. As new data becomes available, the evaluation and action plan **process restarts**.

- ☐ **Specialty visit**
- ☐ **Procedure**
- ☑ **PCP care**
- ☑ **Social worker care**

Result: a better-coordinated, data-supported patient care

Which Creatinine?



DIHI Spectrum of AI Value Creation

Inpatient Innovations		Transition Setting	Outpatient/ Gaps in Care		Patient & Community
LLMs for Cardiothoracic ICU Shift Handoff	Early Detection of Pediatric Deterioration				
Behavioral Emergency Prediction	CTICU bounce back prediction		LLMs for organ transplant matching support		
Reducing Post-Operative Opioid Use After Gynecologic Surgery	RFID Surgical Instrument Tracking to Optimize OR	Machine Learning to Triage Patients with Low Back Pain	LLMs for screening oncology referrals	NAFLD population health rounding	
Immune-Related Adverse Events Following ICIs	Prediction of Steroid-Induced Hyperglycemia	Assistive Triage of Traumatic Brain Injury	LLMs for social service identification and referral	Dermatology clinical decision support for PCPs	
Pediatric Sepsis	Early Detection of Cardiogenic Shock	Patient Identification for Hospital at Home	LLMs for surgery prior authorization	AI to Identify Normal Transthoracic Echocardiograms	
Predicting Bacteremia and Improving Blood Culture Result Interpretation	CTICU Triage Algorithm for Stable NSTEMIs in ED	Immune-Related Adverse Events from ICIs	LLMs for chemotherapy prior authorization	Community-Based Palliative Care	
Early Identification and Management of PE	Improving Goals of Care Conversations	Hospital at Home	Machine Learning to Interpret PFTs	Surgery Risk Prediction for Older Adults	COVID-19 Symptom Monitoring
Maternal Early Warning System	Post-Operative Risk Prediction	Index Admissions with MSSP	Peripheral Artery Disease Population Health Rounding	Implementation of Novel PSA Screening Algorithm	Patient-Directed LVAD Acoustic Surveillance
Early Detection of Adult Deterioration	Mortality Models (inpatient / 30-day)	Readmissions (Social Drivers for HF)	Predicting Post Operative Complications Following Lung Transplant	Surgery Risk Prediction from NSQIP Data	Outpatient Procedure Concierge Program
ED Triaging to Inpatient and ICU Beds	Sepsis Watch	SNF transition	HIV Pre-Exposure Prophylaxis Identification	CKD population health rounding	Autism and Beyond

Network of 22+ Healthcare Organizations and Ecosystem Partners

Health AI Partnership

Mission

Empowering healthcare professionals to use AI effectively, safely, and equitably through community-informed up-to-date standards

Vision

Be the trusted partner and up-to-date source of actionable guidance for healthcare professionals using AI

Values

- Advance health equity
- Improve patient care
- Improve the workplace
- Build community

Multitude of Programs Supporting Responsible AI

Organization	Description
Health AI Partnership (HAIP)	A multi-stakeholder collaborative who seeks to empower healthcare organizations to use AI safely, effectively, and equitably. Vision is to be the trust partner and up-to-date source of actionable guidance for healthcare professionals using AI.
Coalition for Health AI	A community of academic health systems, organizations, and expert practitioners of artificial intelligence (AI) and data science.
Valid AI	A collaborative community to advance generative AI in a responsible manner to improve health care and research
HIMSS (Healthcare Information and Management Systems Society)	A member-based society that covers a large part of health technology ecosystem. This society offers educational resources such as course materials, guides, webinars, and certifications on a range of health information and technology subjects.
HLTH	Community for innovators in the healthcare ecosystem. Has a heavy industry focus. Hosts conferences and creates digital content like webinars, podcasts, and blogs.
Alliance for AI in Healthcare	An international multi-stakeholder membership-based advocacy group organized to influence regulatory principles for development and implementation of AI in healthcare.
AI Healthcare Coalition	An industry advocacy group to influence on health care AI policy and law.
Healthcare Products Collaborative	Promotes discussion and innovation in the healthcare products community, bringing together regulators, professionals, academics, and thought leaders to tackle industry challenges.
Connected Health Initiative	A multi stakeholder coalition that advocates for policies and laws related to AI in healthcare. They educate regulators and lawmakers and publish white papers that define industry best practices.
The AI Collaborative (Nuance + The Academy)	A peer learning and consulting services to clinical and operational executives who oversee their organization's investment in AI tools for healthcare.
KLAS Research	A consulting services that evaluates digital products by aggregating and synthesizing feedback about vendor products.
Machine Learning for Healthcare	Academic publishing and dissemination of scientific work
Association for Health Learning and Inference	Academic publishing and dissemination of scientific work
The Light Collective	A non-profit whose vision is a world in which patients and patient communities participating in health technologies are safe from exploitation and harm and have the right to decide how our collective health information is used and shared.

Organization	Description
American Medical Informatics Association (AMIA)	A society for health informatics professionals that offers education, training, accreditation, and certifications.
Society for Imaging Informatics in Medicine (SIIM)	Healthcare professional organization for those interested in use of informatics in medical imaging.
National Academies of Medicine AI Code of Conduct	Aimed at providing a guiding framework to ensure that AI algorithms and their application in health, health care, and biomedical science perform accurately, safely, reliably, and ethically in the service of better health for all.
Digital Health Collaborative	The Digital Health Collaborative is a group of leading healthcare and consumer organizations that share a commitment to “raising the bar” for evidence and value in digital health technology.
The AI Alliance	A community of technology creators, developers and adopters collaborating to advance safe, responsible AI rooted in open innovation.
Trustworthy & Responsible AI Network (TRAIN)	Through collaboration, TRAIN members will help improve the quality and trustworthiness of AI by: - Sharing best practices related to the use of AI in healthcare settings - Enabling registration of AI used for clinical care or clinical operations - Providing tools to enable measurement of outcomes associated with the implementation of AI - Facilitating the development of a federated national AI outcomes registry for organizations to share among themselves.
Collaborative Community on Ophthalmologic Imaging	A collaborative of academic institutions, government agencies, private businesses, and professional organizations dedicated to establishing standards of practice for innovative ophthalmic imaging.
Center for AI Policy (CAIP)	The Center for AI Policy (CAIP) is a nonpartisan research organization dedicated to mitigating the catastrophic risks of AI through policy development and advocacy.
Center for Public Sector A.I.	The Center' firmly believes that, if managed carefully and prudently by the right leaders, technology like generative AI can significantly improve government agencies' ability to serve the public.
Consumer Technology Association (CTA)	CTA convenes companies of every size and specialty in the technology industry to move us all forward. CTA is the trade association representing the $505 billion U.S. consumer technology industry, which supports more than 18 million U.S. jobs.

Multitude of Programs Supporting Responsible AI

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AI Healthcare Coalition	
Healthcare Products Collaborative	
Connected Health Initiative	
The AI Collaborative (Nuan The Academy)	
KLAS Research	
Machine Learning for Healt	
Association for Health Learning and Inference	Academic publishing and dissemination of scientific work
The Light Collective	A non-profit whose vision is a world in which patients and patient communities participating in health technologies are safe from exploitation and harm and have the right to decide how our collective health information is used and shared.

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	at AI algorithms and their ence perform accurately, ealth for all.
	healthcare and consumer e bar" for evidence and
	adopters collaborating to on.
	rove the quality and
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	AI outcomes registry for
	agencies, private d to establishing ng.
	earch organization rough policy development
Center for Public Sector A.I.	The Center firmly believes that, if managed carefully and prudently by the right leaders, technology like generative AI can significantly improve government agencies' ability to serve the public.
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Organizations vary significantly across:

- Types of content produced (e.g., academic manuscripts, actionable guidance, technical standards)
- Frequency of content updates
- Types of convenings (e.g., public conferences, closed-door workshops)
- Primary target audience (e.g., academic, practitioner, government)
- Business model (e.g., pay for content, pay for events, pay for certification)
- Organization structure (e.g., housed within AMCs, 501(c)3, 501(c)6, for-profit companies)
- Level of industry participation
- Focus on government advocacy

Health AI Partnership

Technical assistance for AI implementation

Voice of healthcare delivery organizations

Support high- and low-resource environments

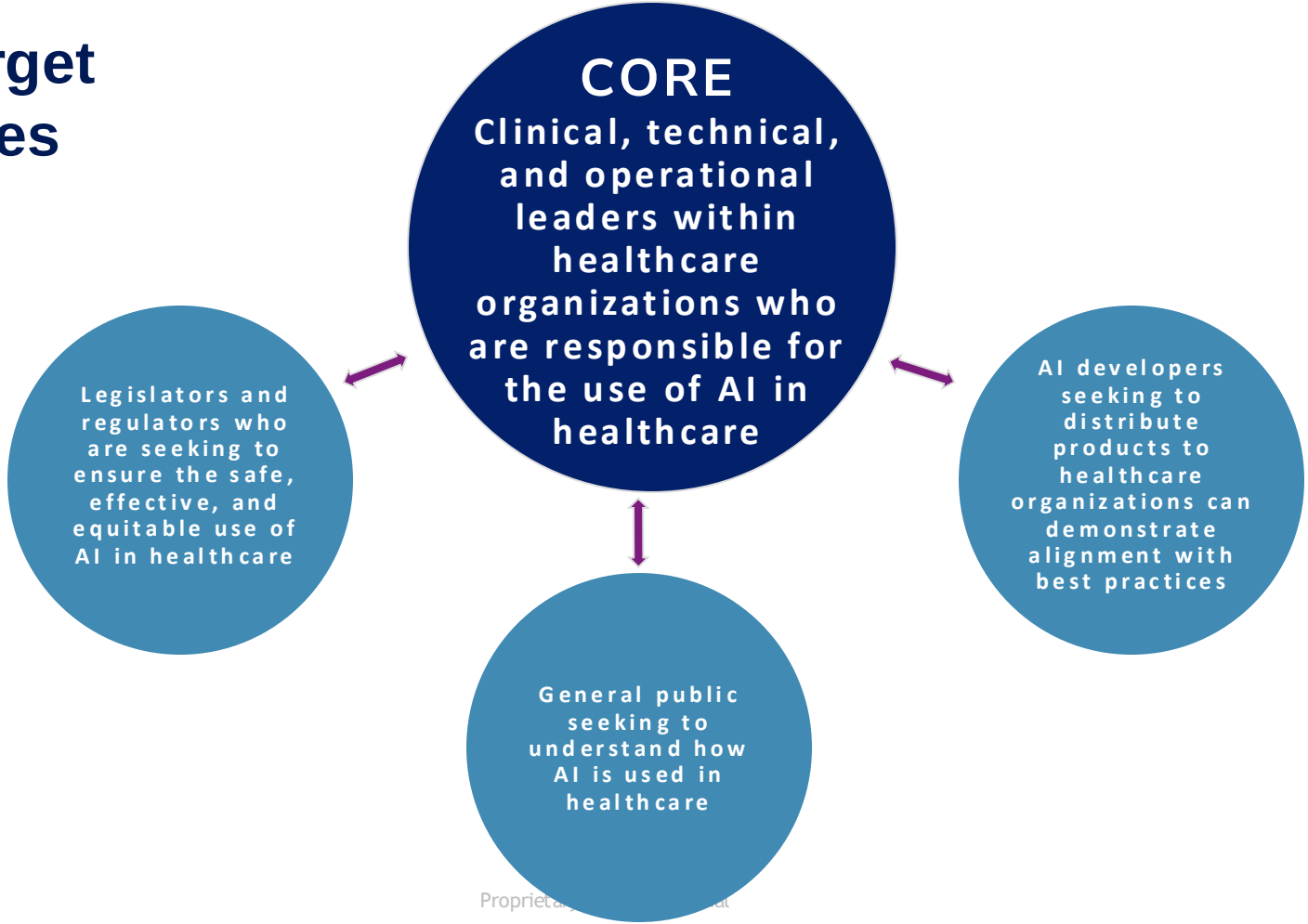
Access clinical, technical, operational, strategic, and regulatory experts

Health AI Partnership Strategic Priorities

Foster AI product and care delivery innovation:

- Focus on post-market integration of AI
  - Pre-market controls alone cannot ensure safe, effective, and equitable integration across settings
- Build and scale local capabilities for AI product lifecycle management
  - Centralized promotion of AI products stifles innovation
- Prioritize the needs of patients and healthcare delivery organizations
  - Incentives between patients, payers, providers, and vendors are misaligned and extract value from society
- Celebrate variability in best practice implementation across settings
  - Enforcing a ‘one size fits all’ approach stifles care delivery innovation and exacerbates the AI digital divide
- Resourcing and partnerships prioritize societal impact vs commercial interests
  - Funding from big tech and elite health systems creates conflict of interest and move towards monopolistic practices

HAIP Target Audiences



8 Key Decision Points in AI Adoption Process

1. Identify and prioritize a problem
2. Evaluate AI as a viable component of the solution
3. Develop measures of outcomes and success of the AI product
4. Design a new optimal workflow to facilitate integration
5. Evaluate pre-integration safety and effectiveness of the AI product
6. Execute change management, workflow integration, and scaling strategy
7. Monitor and maintain the AI product
8. Update or decommission the AI product

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Health AI Partnership – Corps Site Network

Healthcare Delivery Organizations

DukeHealth
VA
MAYO CLINIC
PCCI
KAISER PERMANENTE
NewYork-Presbyterian
Jefferson Thomas Jefferson University
UC San Diego Health
Franciscan Missionaries of Our Lady HEALTH SYSTEM
MOREHOUSE SCHOOL OF MEDICINE
NCPC
Geisinger
UCSF University of California San Francisco
BJC HealthCare
MICHIGAN MEDICINE UNIVERSITY OF MICHIGAN
OCHIN
MetroHealth
Washington University School of Medicine in St. Louis

Ecosystem Partners

NATIONAL ASSOCIATION OF Community Health Centers
AMA
Berkeley UNIVERSITY OF CALIFORNIA
DLA PIPER
CENTER FOR DEMOCRACY & TECHNOLOGY
HL7 International
scan HEALTH PLAN

Federal Agencies

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
*Participating as a federal observer
ASTP Assistant Secretary for Technology Policy

Health AI Partnership – Practice Network

Healthcare Delivery Organizations

COMMUNITY-UNIVERSITY HEALTH CARE CENTER
UNIVERSITY OF MINNESOTA
Driven to Discover®

HEALTH CENTER OF SOUTHEAST TEXAS
YOUR CARE IN OUR HANDS

SAN YSIDRO HEALTH

NORTH COUNTRY HEALTHCARE

WakeMed

Research Partners

UWHealth

Epic

HEALTH TECH

STAT+

AI is becoming the exclusive province of academic medicine. A new initiative aims to change that

By Casey Ross April 29, 2024

Reprints

HAIP Objectives for Long-term Impact

- Level playing field whereby all healthcare delivery organizations benefit from AI innovations
- Nimble learning collaborative that can quickly respond to emerging challenges and opportunities that result from AI innovation
- Efficient market whereby best-in-class AI innovations rapidly emerge and diffuse across healthcare delivery organizations
- Transparency and shared accountability whereby patients and clinicians know and trust how AI innovations are being used in healthcare
- Eliminate inequities, reduce costs, improve provider experience, and improve patient outcomes

Thank you

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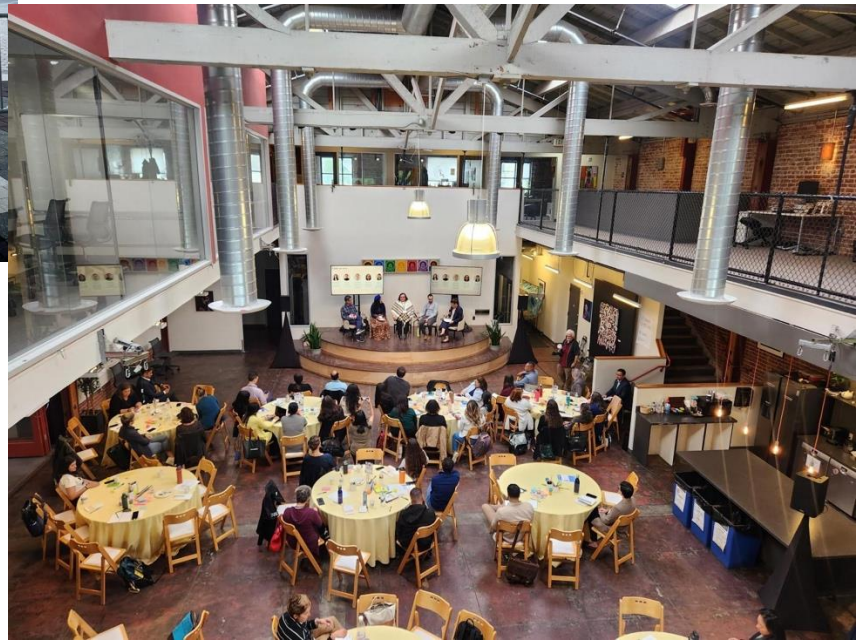

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Brian Anderson, M.D.

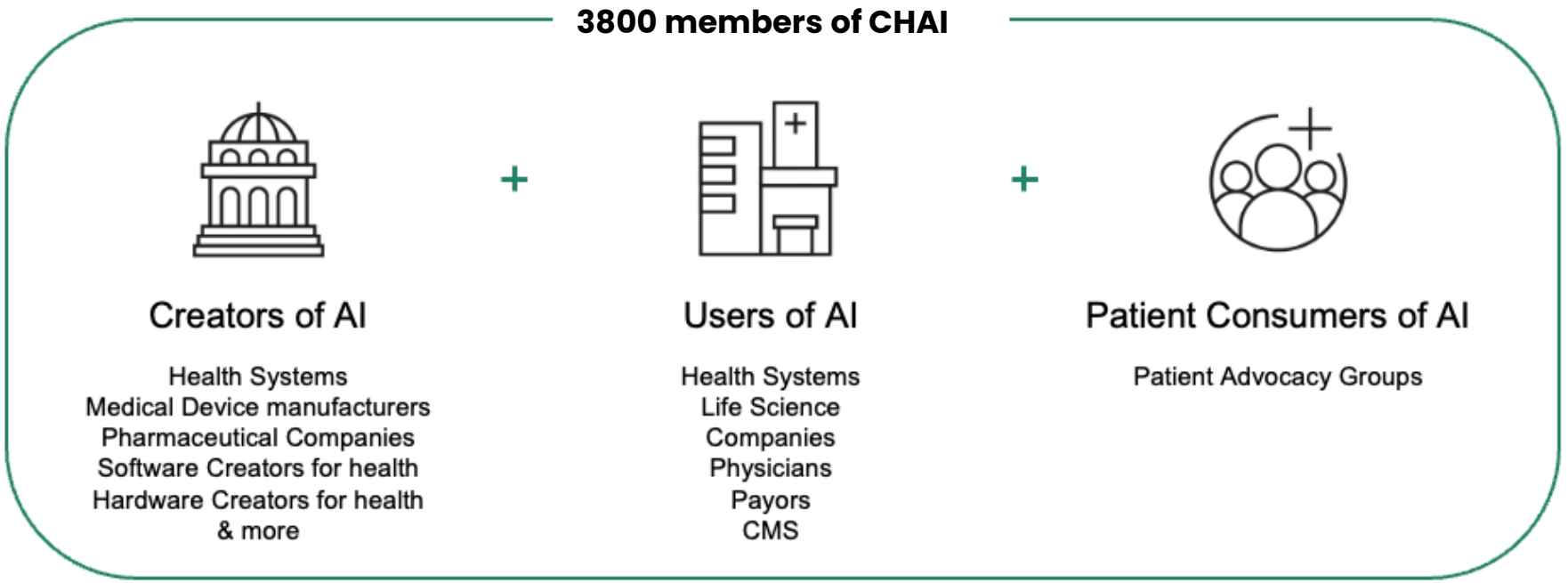
CEO and Founder
Coalition for Health AI

Coalition for Health AI

Alliance for Health Policy Briefing

October 2, 2024

CHAI is bringing together a diverse community of creators, users and beneficiaries to develop consensus-driven products



CHAI is supporting the development of a nationwide network of Assurance Labs with its certification framework

A Federated Network of Labs - All models are local

Assurance Labs will issue model report cards that elucidate model performance and workflow integration

CHAI Model Card (DRAFT) **Model Name:** **Developer:**

Release Stage: **Release Date:** **Version:** Model / Software

Overview:

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Intended Use and Directions:

- **Benefits:**
- **Primary intended users:**
- **Use Cases and how to use:**
- **How frequently it is used**
- **Cautioned out-of-scope settings and use cases:**

How it works:

- **Outcome:**
- **Output:**
- **Target population:**
- **Model type:**
- **Input data source:**
- **Input data type:**
- **Development data source(s) with inclusion criteria:**
- **Bias mitigation approaches:**
- **Assessment and monitoring including fairness:**
- **Maintenance, if available:**

Warnings:

- **Known risks:**
- **Known limitations:**
- **Known biases or ethical considerations:**
- **Population Impact Risk (see checklist):**
- **Clinical Risk (see checklist):**

Testing Data, Factors & Metrics:

	Metric (Usefulness)	Metric (Equity)	Metric (Safety)	Data Description	Validation Process
Internal				*Links to a Dataset Card*	*Links to a method description*
External				*Links to a Dataset Card*	*Links to a method description*
Local				*Links to a Dataset Card*	*Links to a method description*
Prospective	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**

Other information:

- **Funding Source:**
- **3rd Party Information, if Applicable:**
- **Evaluation References, if Available:**
- **Clinical Trial, if Available:**
- **Peer Reviewed Publication(s):**
- **Inquires or to report an issue:** abc@abc.com or +1 (999) 999- 9999

Model cards: Understanding the ingredients of an AI model

Model Card - Title

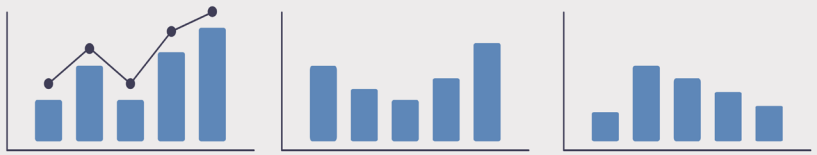
Model Details
- Developers
- Model Date, Version & Type
- Training algorithms
- Resources, Citation, License

Evaluation Data
- Details on data used for quantitative analysis
- Datasets, Motivation, Preprocessing

Training Data
- Same detail as evaluation data if possible (privacy constraints)
- Details of distribution over factors

Intended Use
- Primary intended uses & users
- Out of scope use cases

Quantitative Analysis
Unitary & intersectional results

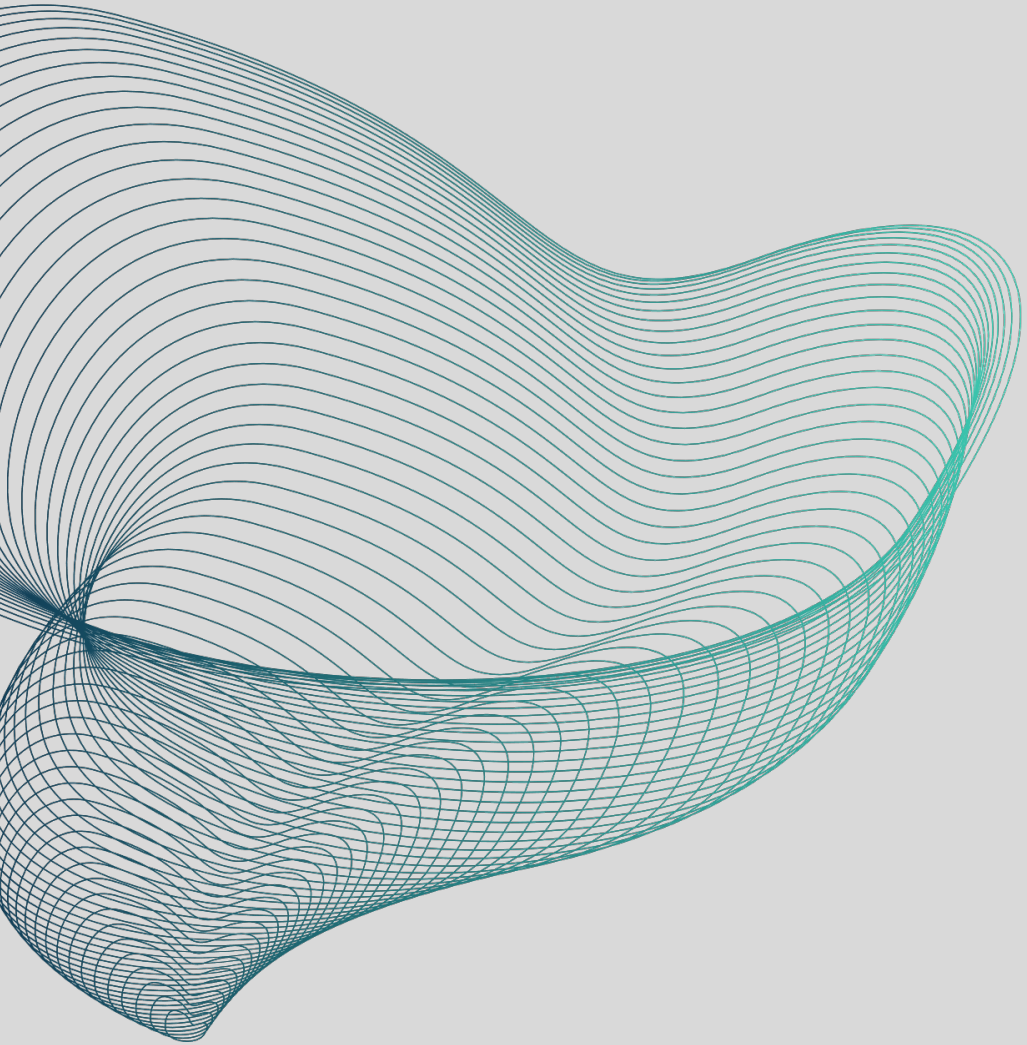


Factors
- Groups, Environments, Instrumentation
- Relevant factors & evaluation factors

Metrics
- Model performance measures
- Decision thresholds
- Variation approaches

Ethical Considerations
- Bias, fairness, ethical considerations
- Mitigation efforts

Caveats, Recommendations
- Concerns not already covered
- Usage information
- Limitations, risks, trade-offs



Thank you

CHAI

Moderated Discussion

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Moderated Q & A

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THANK YOU!!!

Please fill out the evaluation survey by using the QR code or via email this afternoon!

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