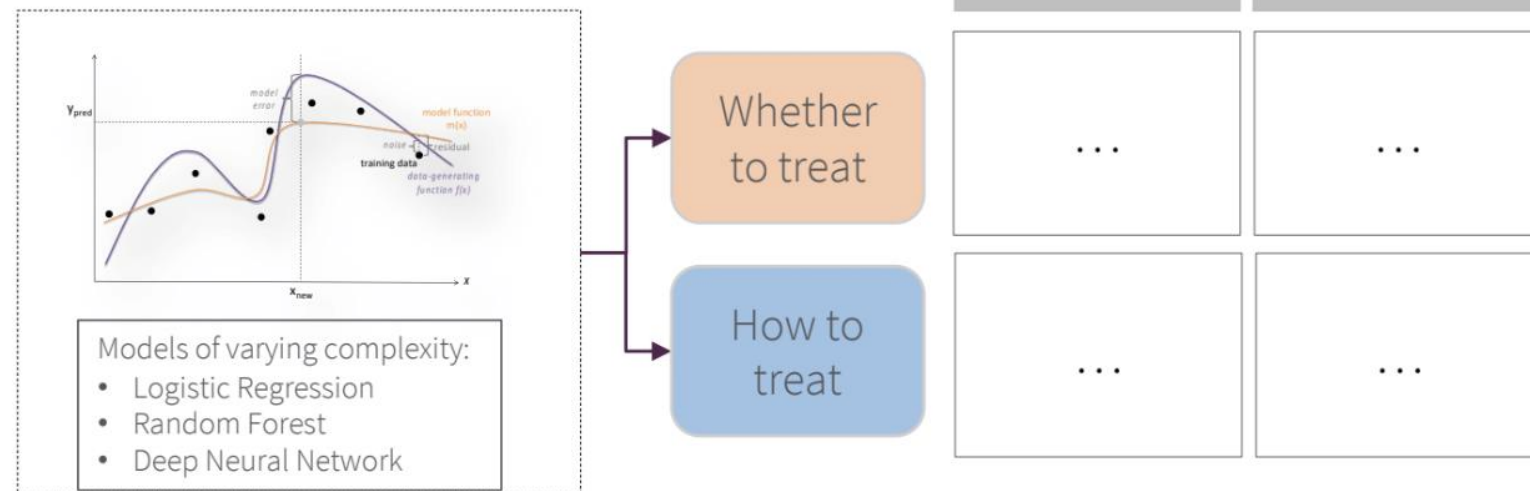




Building Responsible AI that Serves All of Us

Predictive AI helps us risk stratify and make recommendations to improve the delivery of care with responsive action

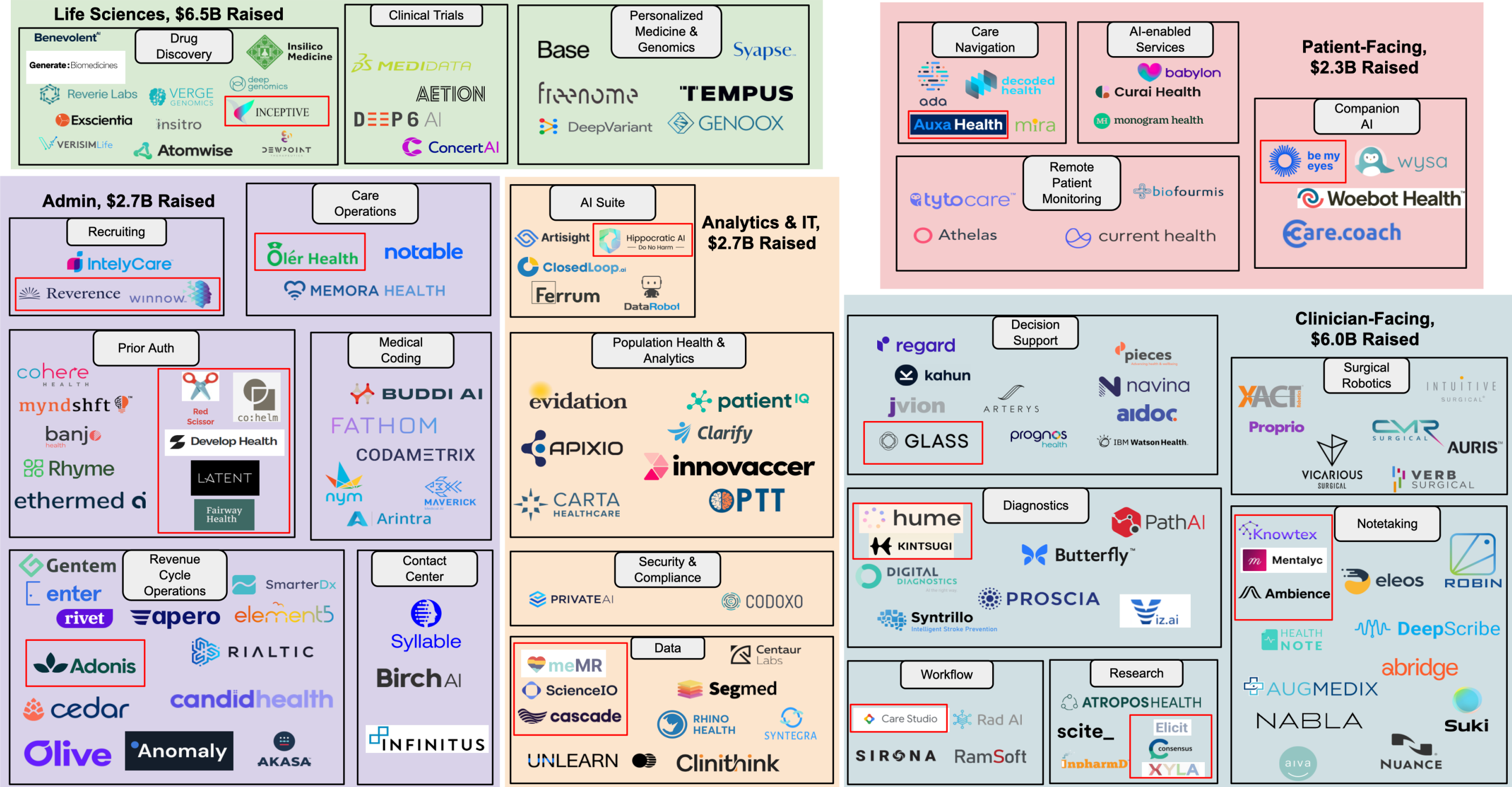


- **Predicting long term outcomes after pulmonary embolism using imaging and EHR data**
 - Multimodal models for predicting recurrence risk in surgically resectable colorectal cancer
 - Opportunistic ASCVD risk estimation, using CT images and EMR data
-
- **Predicting mortality to improve advance care planning**
 - Classifying presence of undiagnosed disease
 - Familial hypercholesterolemia – to order sequencing
 - Peripheral artery disease – to order ABI measurement
- **Classifying ischemic vs. hemorrhagic stroke for prioritizing air ambulance transport**
 - Predicting no-shows for providing transportation support
 - Predicting length of stay, readmissions, bed-demand etc. ...

And we are seeing the Generative AI Landscape evolving rapidly to meet demand from health systems, payors, & life science companies

Where Generative AI Meets Healthcare: Updating The Healthcare AI Landscape

red box = launched product after 2020



The track record of new technologies in healthcare is one marked by a growing digital divide



CHAI is setting the best practice frameworks for AI safety and reliability in Health

CHAI, the Coalition for Health AI, is committed to setting the best practice frameworks for the trustworthy and responsible implementation of AI in health.

By bringing together a coalition of patient-community advocates, technology companies start-ups, public sector organizations, medical device manufacturers, payors and healthcare organizations, we will develop a consensus set of frameworks for Responsible Health AI.



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

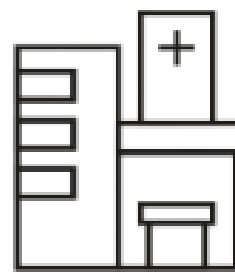
3800 members of CHAI



Creators of AI

Health Systems
Medical Device manufacturers
Pharmaceutical Companies
Software Creators for health
Hardware Creators for health
& more

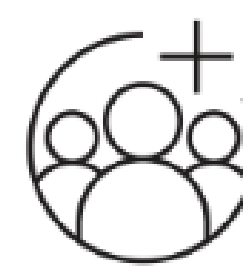
+



Users of AI

Health Systems
Life Science
Companies
Physicians
Payors
CMS

+



Patient Consumers of AI

Patient Advocacy Groups

We are using consensus to develop the gold-standard for trustworthy and Responsible Health AI that Serves All

Need

1

Adherence to **FAVES principles**

2

Current regulation **does not apply** to all Health AI

3

Lack of **transparency**

4

Workforce upskilling and engagement

CHAI's Proposed Solution

1

The development of **Technical Standards**, including Bias, Safety and Surveillance frameworks, and **Implementation Guides**, including Testing and Evaluation and Best Practices frameworks

2

A **nationwide network of CHAI-certified Quality Assurance Labs**, responsible for assuring all AI for use in health, with supportive Assurance Standards

3

A **National Registry Platform**, featuring model report cards, for algorithms that have been through Assurance Labs

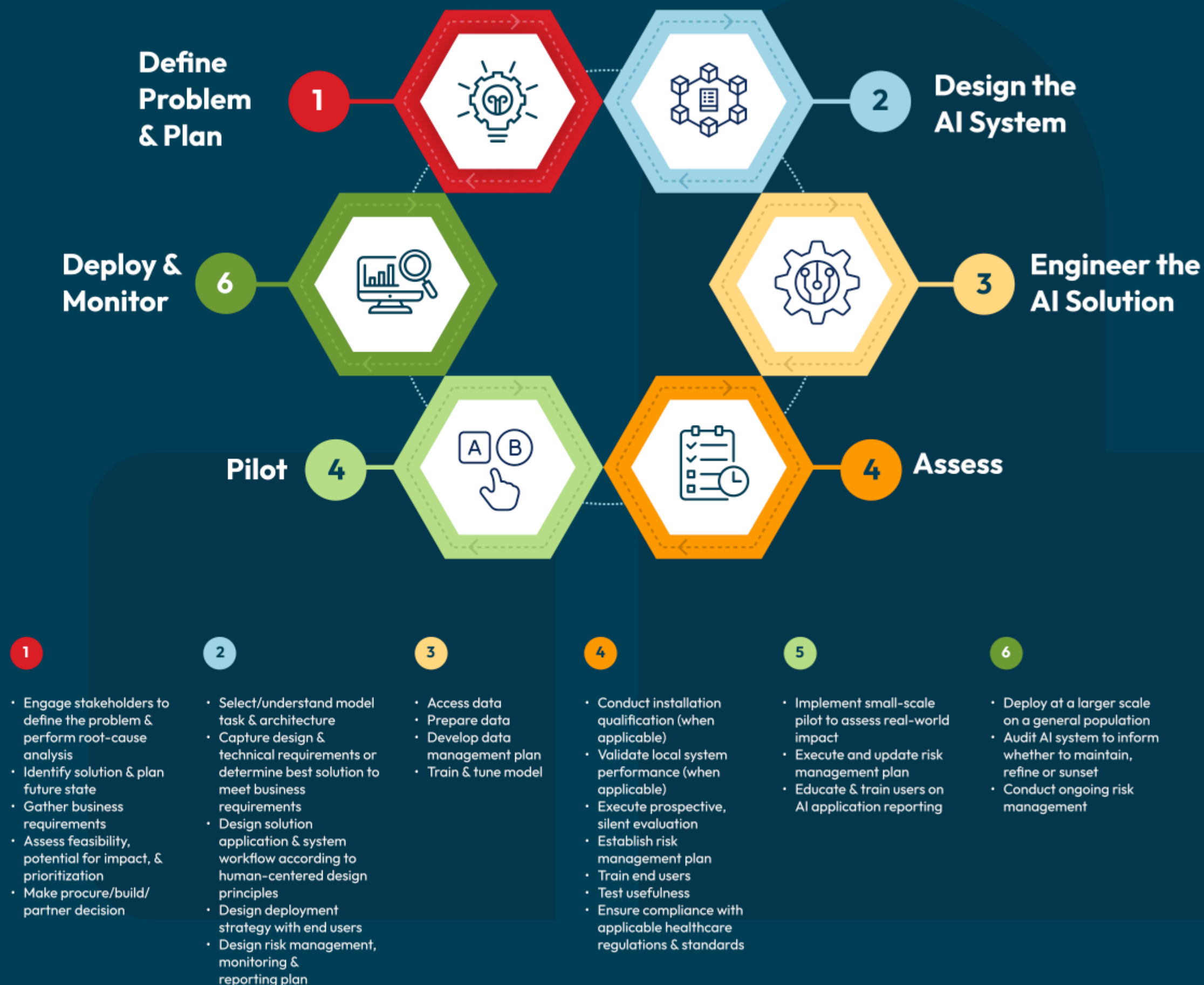
4

Registry publications, **educational materials** and Assurance certification processes

THE AI LIFECYCLE

The AI lifecycle is central to understanding and implementing CHAI's Assurance Standards in healthcare. The six-step lifecycle outlines the essential stages and processes involved in developing, deploying, and maintaining AI systems.

By systematically addressing each phase of the lifecycle the framework ensures that AI systems adhere to the highest standards of safety, efficacy, fairness, transparency, and security. This structured approach supports risk mitigation, managing biases, and promotes accountability and trustworthiness in AI applications.



Generative AI Work Group Goal

Goal: Focusing on a Generative AI Notes Summarization Use Case, we seek to identify a digestible set of criteria and metrics that demonstrate principles of responsible and trustworthy AI, which can be utilized or referenced by an independent AI solution evaluator.



Usefulness



Safety & Reliability



Security & Privacy



**Fairness, Equity &
Bias Management**



Transparency

Meanwhile, the regulatory landscape is similarly changing rapidly

FDA Issues Final Guidance on Clinical Decision Support Software and Software as a Medical Device

NEW PROPOSED RULE

ONC Office of the National Coordinator for Health Information Technology

Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2)

Learn more at HealthIT.gov/ProposedRule

Artificial intelligence assurance labs are coming, HHS chief AI officer says

The private sector will play a role, but Micky Tripathi isn't endorsing any particular plan.

BY: **ERIN SCHUMAKER** | 09/18/2024 11:00 AM EDT | UPDATED 09/18/2024 06:08 PM EDT



ISSUE BRIEF

The Biden Administration's Final Rule on Section 1557 Non-Discrimination Regulations Under the ACA

2023



Greatest Hits

**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 need to be trusted by both model developers, their customers and by patients



Access to data



Required disclosures on impartiality – ISO standards



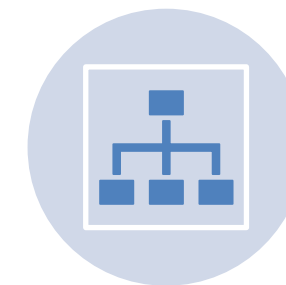
Security Certification
SOC II Certification



Data de-identification
or Privacy Preserving
Approaches



Infrastructure



Established and well-
documented processes



Demonstrated
competence in
validation methods



Use of CHAI Metrics



Post-deployment
Monitoring

An AI “Nutrition Label”: CHAI Consensus Model Cards



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

Factors

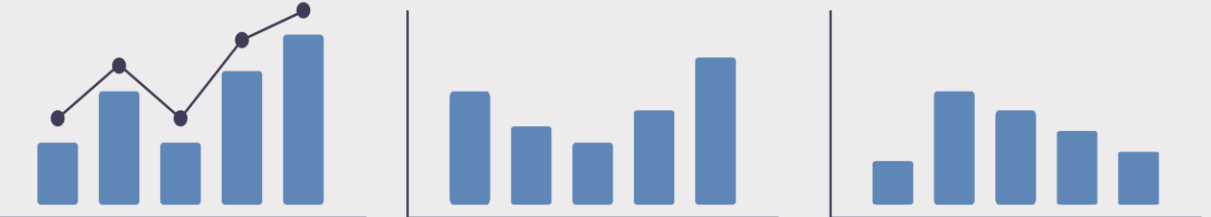
- Groups, Environments, Instrumentation
- Relevant factors & evaluation factors

Metrics

- Model performance measures
- Decision thresholds
- Variation approaches

Quantitative Analysis

Unitary & intersectional results



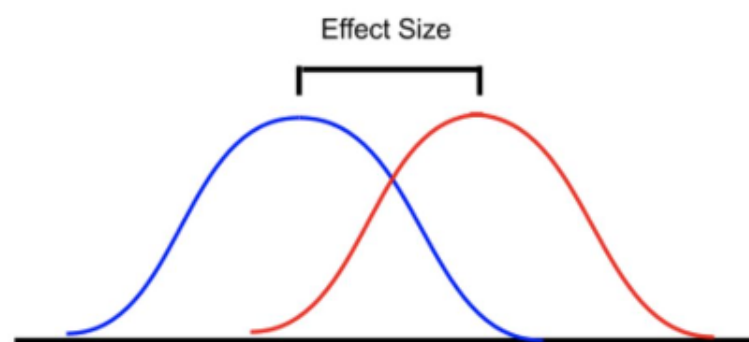
Ethical Considerations

- Bias, fairness, ethical considerations
- Mitigation efforts

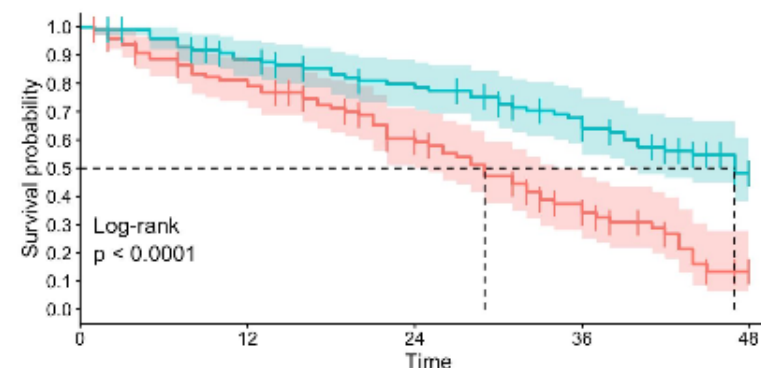
Caveats, Recommendations

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

Need for Advancing Evaluation and Regulatory Science in AI



ANOVA
(1925)



Kaplan-Meier estimator
(1958)

?

Diagnostics for AI tools
(2025)

What will the the next generation of statistical tools applied to medicine look like?



The Road Ahead



Is Human Flourishing Possible?

The story of the humble sewing machine





An Urgent Need to Develop Consensus Guidelines for GenAI