



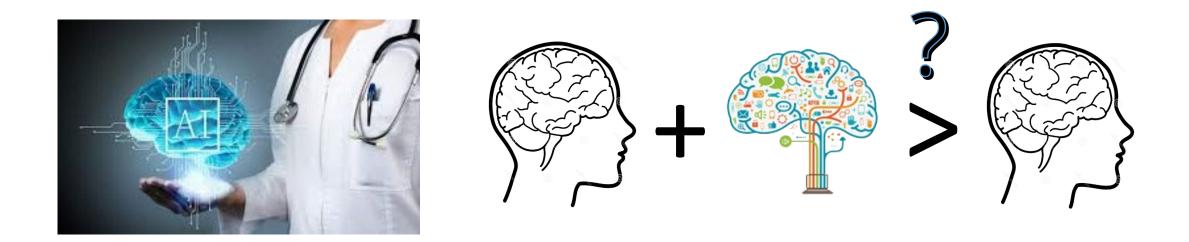
# Algorithm-Based Clinical Decision Support (ABCDS) Oversight

A framework for the governance and evaluation of algorithms to be deployed at Duke Health

NCRAF April 25, 2023

Amanda Parrish, PhD Nicoleta J Economou, PhD

## Promise of Artificial Intelligence/Machine Learning in Health Care





## AI/ML Fails in the Field

#### June 21, 2021

## The Epic Sepsis Model Falls Short—The Importance of External Validation

Anand R. Habib, MD, MPhil<sup>1,2</sup>; Anthony L. Lin, MD<sup>1</sup>; Richard W. Grant, MD, MPH<sup>3,4</sup>

#### » Author Affiliations

JAMA Intern Med. Published online June 21, 2021. doi:10.1001/jamainternmed.2021.3333

Related Articles

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Sepsis accounts for nearly 1 million hospitalizations annually and is a major contri health care expenditures, and in-hospital mortality (ranging from 12.5%-15%).<sup>1</sup> E care teams to promptly implement goal-directed therapy to mitigate clinical dete Internal Medicine, Wong et al<sup>2</sup> report on their external validation of the Epic Seps tool available within the Epic electronic health record that is designed to generat clinicians that patients may be developing sepsis. Based on their examination of 3 University of Michigan (Ann Arbor) between December 2018 and October 2019. had a sensitivity of 33%, specificity of 83%, positive predictive value of 12%, and 95%, with an area under the curve of 0.63 (95% CI, 0.62-0.64). This falls short o 0.76 to 0.83 that was jointly reported by Epic and University of Colorado Health. 18% of all patients, the ESM did not detect sepsis in 67% of patients with sepsis.



## Science

#### **RESEARCH ARTICLE**

#### ECONOMICS

RESEARCH

#### Dissecting racial bias in an algorithm used to manage the health of populations

Ziad Obermeyer<sup>1,2+</sup>, Brian Powers<sup>3</sup>, Christine Vogeli<sup>4</sup>, Sendhil Mullainathan<sup>5+</sup>†

Health systems rely on commercial prediction algorithms to identify and help patients with complex health needs. We show that a widely used algorithm, typical of this industry-wide approach and affecting millions of patients, exhibits significant racial bias: At a given risk score, Black patients are considerably sicker than White nationte as evidenced by size of uncontrolled illnesses

Remedying this disparity "At a given risk score, Black patients are considerably sicker than help from 17.7 to 46.5%. White patients, as evidenced by signs of uncontrolled illnesses. illness, but unequal accer for White patients. Thus, Remedying this disparity would increase the percentage of Black by some measures of pre patients receiving additional help from 17.7% to 46.5%. The bias arises convenient, seemingly ef bias in many contexts. because the algorithm predicts health care costs rather than illness..."

here is growing concern that algorithms may reproduce racial and gender disparities via the people building them or through the data used to train them (1-3). Empirical work is increasingly lending support to these concerns. For example, job search ads for highly paid positions are less likely to be presented to women (4), searches for distinctively Black-sounding names are more likely to trigger ads for arrest records (5), and image searches for professions such as CEO produce fewer images of women (6).

dicted risk of some future outcome (in our researcher-created algorithms (10-13). Without an algorithm's training data, objective function, and prediction methodology, we can only guess as to the actual mechanisms for the important algorithmic disparities that arise. In this study, we exploit a rich dataset that provides insight into a live, scaled algorithm deployed nationwide today. It is one of the largest and most typical examples of a class of commercial risk-prediction tools that, by industry estimates, are applied to roughly 200 million people in the United States each Facial recognition systems increasingly used year. Large health systems and payers rely on life-and-death consequences of the decisionalmorithm to target nationte for "high rick

case, health care needs) is widely used to target policy interventions under the assumption that the treatment effect is monotonic in that risk, and the methods used to build the algorithm are standard. Mechanisms of bias uncovered in this study likely operate elsewhere. Second, even beyond our particular finding, we hope that this exercise illustrates the importance, and the large opportunity, of studying algorithmic bias in health care, not just as a model system but also in its own right. By any standard-e.g., number of lives affected, health is one of the most important and a

that rely on past data to build a predictor of dv in JAMA Internal Medicine finds that the tify two-thirds of sepsis patients and Our dataset describes one such typical algotions as well as the data needed to understand alse alarms. rithm. It contains both the algorithm's predic-

021 | 12:44 PM

**Research suggests Epic Sepsis** 

Model is lacking in predictive

Healthcare **IT** News

**Global Edition Analytics** 

future health care needs.

its inner workings: that is, the underlying in-

gredients used to form the algorithm (data,

objective function, etc.) and links to a rich set of outcome data. Because we have the

inputs, outputs, and eventual outcomes, our data allow us a rare opportunity to quantify

racial disparities in algorithms and isolate the

mechanisms by which they arise. It should be

emphasized that this algorithm is not unique.

Bather it is emblematic of a generalized ap-

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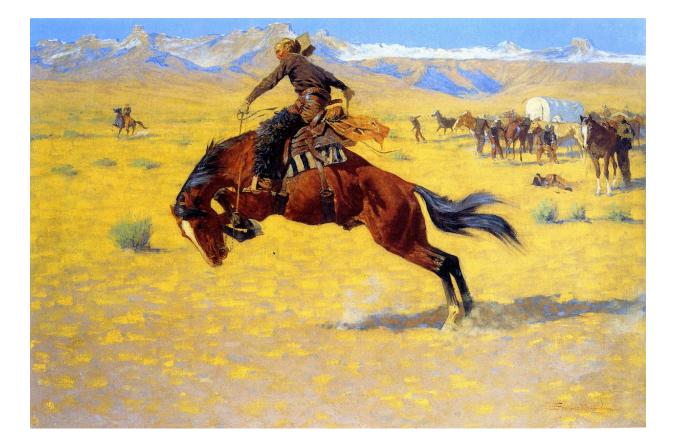




## "Wild West" of Algorithms









## Regulatory Landscape Changing Rapidly

THE WHITE HOUSE



Administration Priorities The Record Briefing Room Español



MAKING AUTOMATED SYSTEMS WORK FOR THE AMERICAN PEOPLE

💼 🕨 OSTP

### HHS.gov < Civil Rights

### Fact Sheet: Nondiscrimination in Health Programs and Activities Proposed Rule Section 1557 of the Affordable Care Act

The Department of Health and Human Services (HHS) has issued a proposed rule to advance health equity and reduce disparities in health care. The proposed rule, *Nondiscrimination in Health Programs and Activities*, revises the implementing regulation for <u>Section 1557 of the Affordable Care Act</u> (ACA), and proposes robust provisions that will be more effective in protecting people from discrimination.

Section 1557 of the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities and is one of the government's most powerful tools to ensure nondiscriminatory access to health care. In addition to proposing revisions to the Section 1557 implementing regulation, this rulemaking also includes proposed revisions to nondiscrimination



Artificial Intelligence Risk Management Framework (AI RMF 1.0)



MENU

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ATIONAL INSTITUTE OF ANDARDS AND TECHNOLOGY DEPARTMENT OF COMMERCE

## Local Government Taking Action

State of California Department of Justice								ه <b>f</b>	y 🗿 🚻	
Received to the second se	<b>ROB BONTA</b> Attorney General					Transla	ate Website   Trad	Search lucir Sitio Web		
HOME	ABOUT	MEDIA	CAREERS	REGULATIONS	RESOURCES	PROGRAMS	APPOINTMENTS	CONTACT		

## Attorney General Bonta Launches Inquiry into Racial and Ethnic Bias in Healthcare Algorithms

Press Release / Attorney General Bonta Launches Inquiry into Racial and Ethn...



Wednesday, August 31, 2022

Contact: (916) 210-6000, agpressoffice@doj.ca.gov

Sends letters to 30 hospital CEOs across the state requesting information regarding the use of commercial healthcare decision-making tools

**OAKLAND** – California Attorney General Rob Bonta today sent letters to hospital CEOs across the state requesting information about how healthcare facilities and other providers are identifying and addressing racial and ethnic disparities in commercial decision-making tools. The request for information is the first step in a DOJ inquiry into whether commercial healthcare algorithms – types of software used by healthcare providers to make decisions that affect access to healthcare for California patients – have discriminatory impacts based on race and ethnicity.

All information provided to our office will be treated as confidential in accordance with California Government Code section 11180 et seq. Please provide the requested information and documents to Deputy Attorney General Anna Rich at <u>Anna.Rich@doj.ca.gov</u>, or 1515 Clay St., 20<sup>th</sup> Floor, Oakland, CA, 94612, by October 15, 2022. We thank you in advance for your cooperation.

Sincerely,

ROB BONTA Attorney General

## "Our House" circa 2018

- Total 6 models
  - Sepsis
  - Early Warning Score
  - First Admission
  - Readmission
  - Falls
  - Pressure Injury





## "Our House" Today

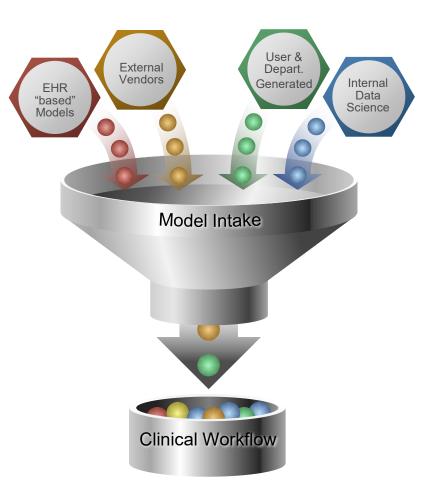
Over 40 registered tools





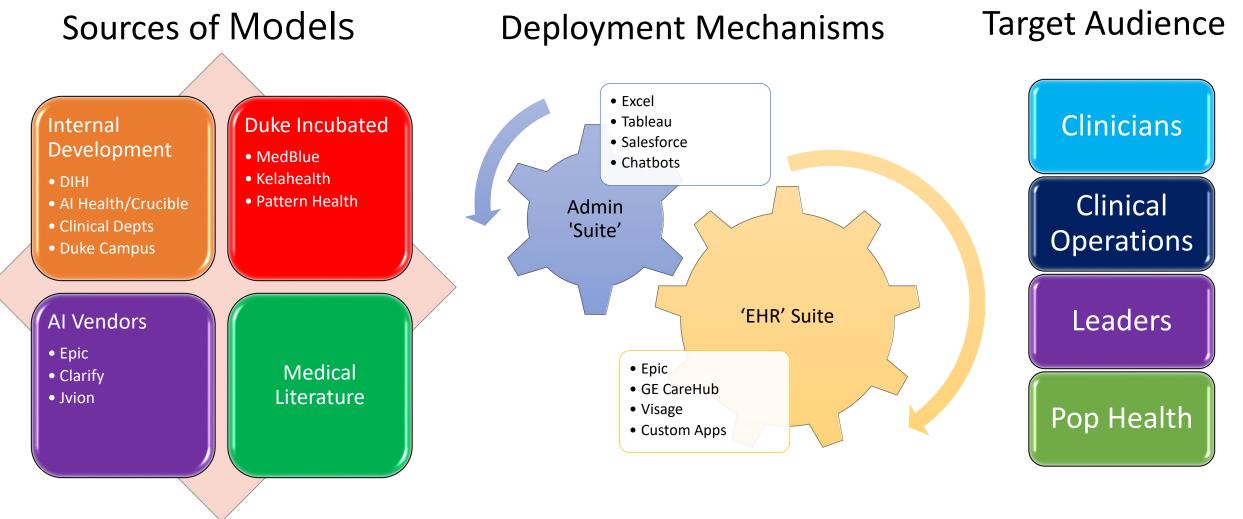
# Complex Environment

- Different skills
- Different knowledge bases
- Different resources available
- Different make up of project teams





## **Complex Environment**



## The Formation of the ABCDS Oversight Committee

In recognition of this changing landscape the Duke Health Chancellor and the Dean of the School of Medicine charged Duke Health leadership to form an oversight framework.



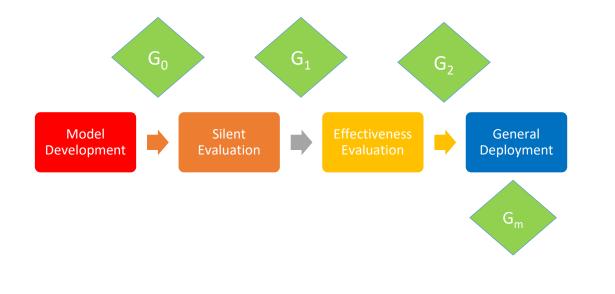
## **Mission Statement**

Out of our primary focus on patient safety and high-quality care, our mission is to guide algorithm-based clinical decision support (ABCDS) tools through their lifecycle by providing governance, evaluation, and monitoring.





## ABCDS Lifecycle & Our Framework



What are the clinical outcome and performance metrics?

How has the model been evaluated?

Who is the Clinical Owner?

Who will cover maintenance costs in production?

Will this ABCDS tool be used outside of Duke Health?

Is this a standard of care model?

...

How will the model be used in the clinic and how is it integrated with the workflow?

'Just-in-time' Check-Points (Gates) Help Model Owners Get Ready for What's Ahead



## Implementing Quality & Ethics with Our Framework

#### **Ethical Principles and Requirements**

There are six general *ethical principles*<sup>3</sup> that any AI system must preserve and protect based on fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union (EU Charter), and in relevant international human rights law:

- Respect for Human Agency: human beings must be respected to make their own decisions and carry out their own actions. Respect for human agency encapsulates three more specific principles, which define fundamental human rights: autonomy, dignity and freedom.
- 2. **Privacy and Data governance:** people have the right to privacy and data protection and these should be respected at all times;
- Fairness: people should be given equal rights and opportunities and should not be advantaged or disadvantaged undeservedly;
- 4. **Individual, Social and Environmental Well-being:** AI systems should contribute to, and not harm, individual, social and environmental wellbeing;
- 5. **Transparency:** the purpose, inputs and operations of AI programs should be knowable and understandable to its stakeholders;
- 6. Accountability and Oversight: humans should be able to understand, supervise and control the design and operation of AI based systems, and the actors involved in their development or operation should take responsibility for the way that these applications function and for the resulting consequences.





## **Transparency & Accountability**

- Impact & Safety
- Fairness & Equity
- **Usability & Adoption**

## **Regulatory Compliance**

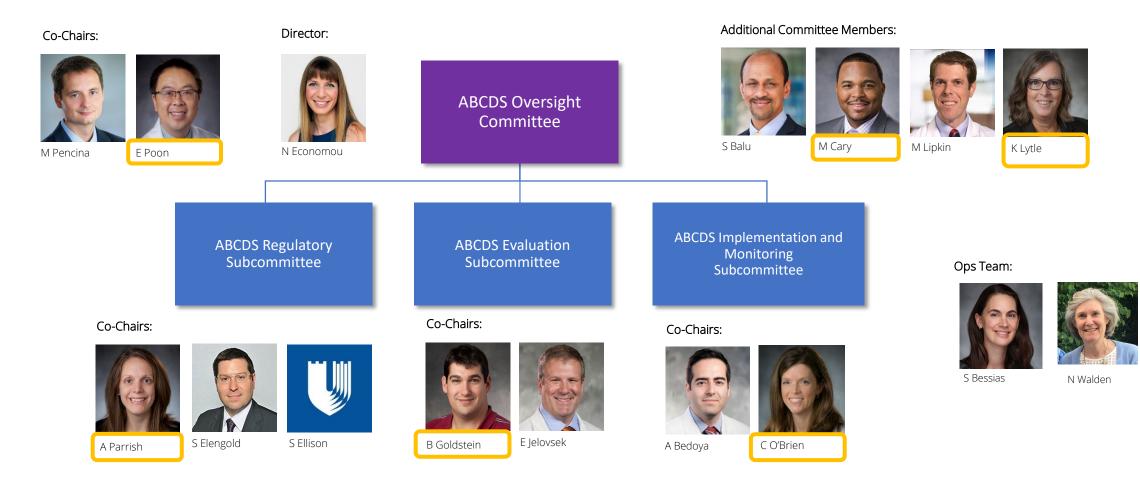


**Fig. 4.** Characteristics of trustworthy AI systems. Valid & Reliable is a necessary condition of trustworthiness and is shown as the base for other trustworthiness characteristics. Accountable & Transparent is shown as a vertical box because it relates to all other characteristics.

# People



## People: ABCDS Oversight Committee



Duke AI HEALTH

# Process



## Scope of ABCDS Oversight Framework

ABCDS Tool = Algorithm(s) + Interface Algorithms Are Presented In

All electronic algorithms that could impact patient care at Duke Health fall within the scope of the ABCDS Oversight Committee and must undergo registration





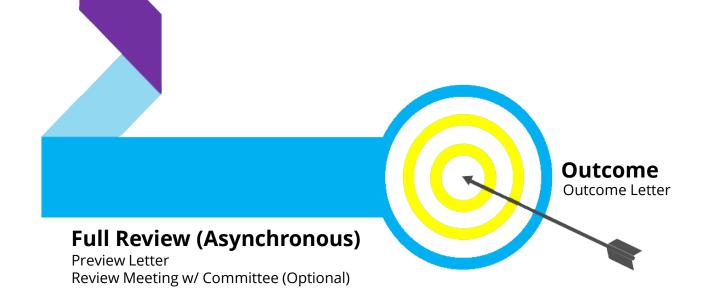
# The ABCDS Registration Form

- Information Requested
- ✓ Consent to publish
- ✓ Purpose
- ✓ Contact Information
- ✓ Model Information
- ✓ Use Case Information
- ✓ Regulatory Information
- (ONLY Standard of Care Literature, society material)

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		ABCDS	Registration Form 2.3		



## What to Expect: ABCDS Checkpoint Review



## Outcomes

- Approval
- Approval w/ Contingencies
- Re-review
- Denial

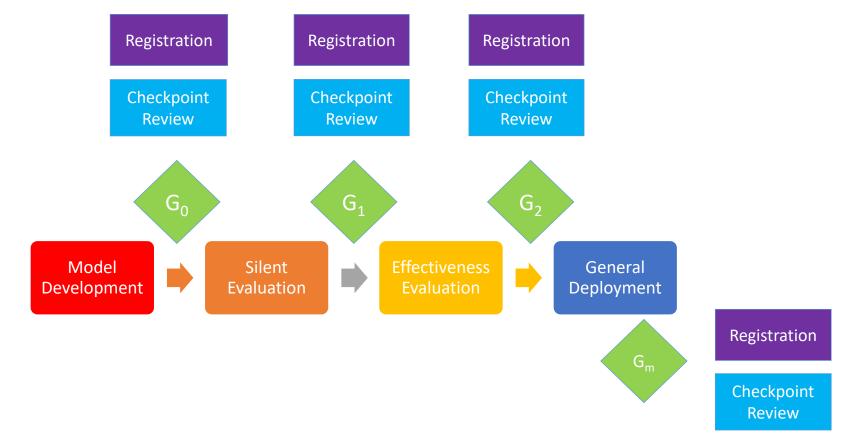
\* Clinical consensus-based models submit their review material during the registration process; these models will typically not require a full checkpoint review.



**Registration** Pre-Registration

Triage

## **Full Checkpoint Review**





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# Implementing Quality & Ethics with Our Framework

Transparency & Accountability Impact & Safety Fairness & Equity Usability & Adoption Regulatory Compliance





# Implementing Quality & Ethics with Our Framework

Transparency & Accountability

Impact & Safety

Fairness & Equity

Usability & Adoption

**Regulatory Compliance** 

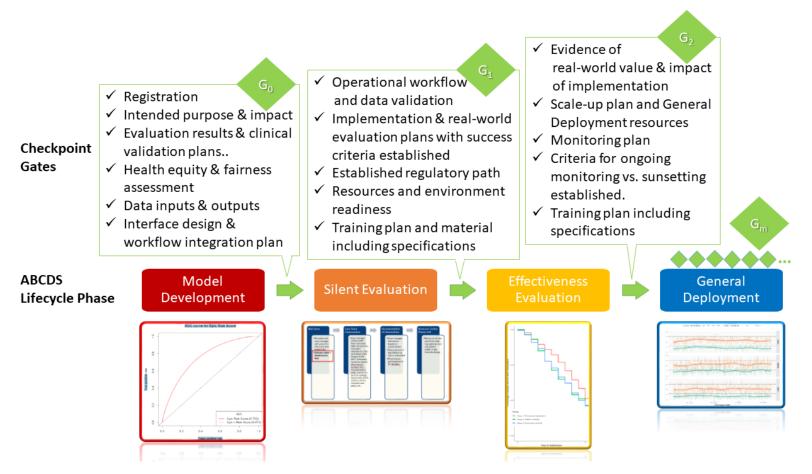
Principle	Criteria	Submission Materials	
Clinical Impact & Safety	The ABCDS software, in comparison to current state, stands to improve clinical care.	<ul> <li>✓ Evidence that the tool has potential to impact clinical outcomes or processes</li> <li>✓ List of key impact metrics (clinical outcomes and/or process improvement) with definitions, following TRIPOD guidelines<sup>5</sup></li> <li>✓ List of core performance metrics (e.g. sensitivity, PPV, etc.) and results from development</li> <li>✓ Calibration curves, threshold selections and justification if applicable</li> </ul>	
	Plans for Silent Evaluation will inform the decision to proceed with pilot implementation in clinic.	<ul> <li>Silent Evaluation Plan, including:</li> <li>✓ Summary of benefits you expect to demonstrate and criteria to proceed into Effectiveness Evaluation</li> <li>✓ Study design, including in/exclusion criteria, timeframe and sample size considerations</li> <li>✓ Core performance metrics with shell tables</li> <li>✓ Data analysis plan</li> <li>✓ Data quality evaluation plan</li> </ul>	

Sample evaluation criteria supporting the principle of clinical impact & safety at the  $G_0$  Checkpoint evaluation between pilot implementation and general deployment





## **ABCDS Oversight Full Review**



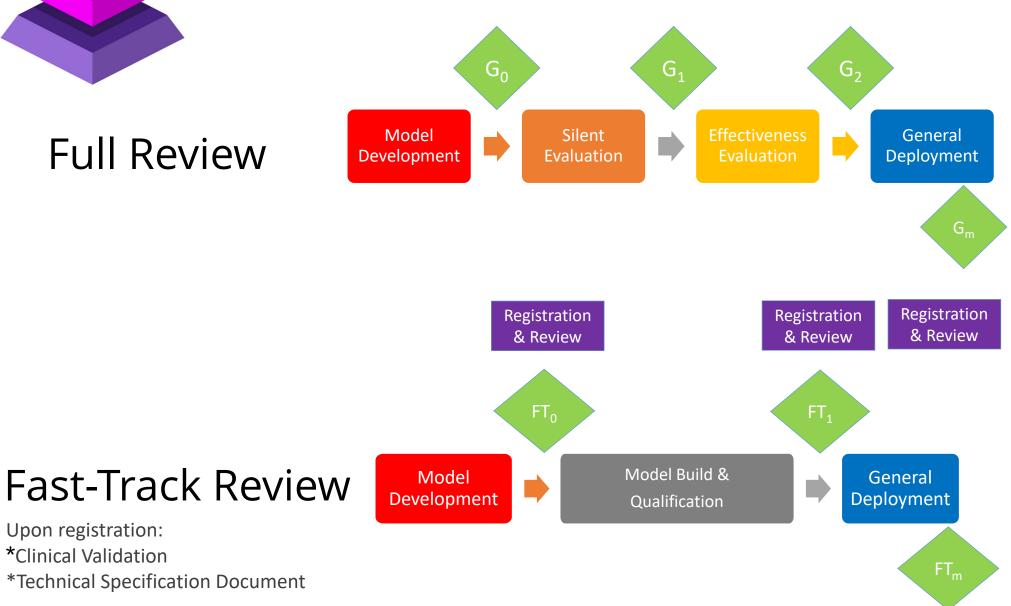
Bedoya, A. D., et al. (2022). "A framework for the oversight and local deployment of safe and high-quality prediction models." Journal of the American Medical Informatics Association.

## Scope of ABCDS Oversight Framework





# Fast-Track Checkpoint Review



# Fast-Track Evaluation – Alignment without Guidelines

Clinical Evaluation				
Valid Clinical Association	Analytical Validation	Clinical Validation		
Is there a valid clinical association between your SaMD output and your SaMD's targeted clinical condition?	Does your SaMD correctly process input data to generate accurate, reliable, and precise output data?	Does use of your SaMD's accurate, reliable, and precise output data achieve your intended purpose in your target population in the context of clinical care?		
Figure 4- Clinical Evaluation Process				

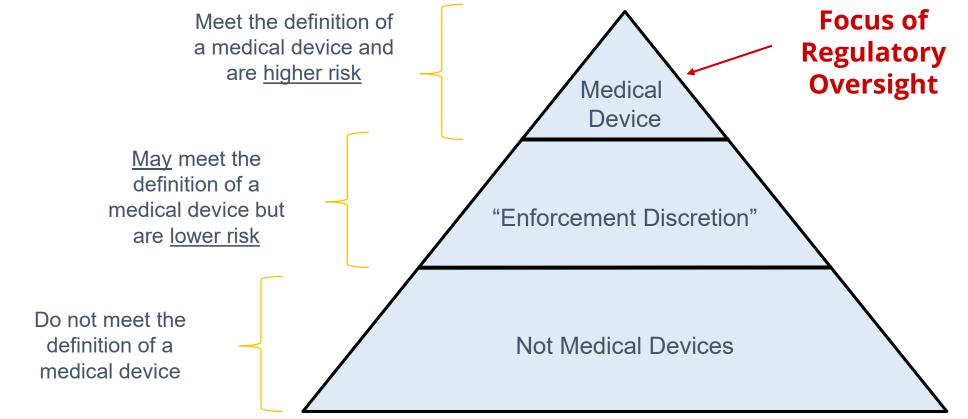
Software as a Medical Device (SAMD): Clinical Evaluation, FDA Guidance, 2017



# **Regulatory Considerations**



# Risk-Based Approach for Regulation of Software Functions





## Medical Device

The Food, Drug, and Cosmetic Act (FD&C) defines a medical device as:

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article or component part or accessory which:
  - Is <u>intended for use in the diagnosis of disease or other conditions, or</u> in the cure, mitigation, treatment, or prevention of disease or
  - Is intended to affect the structure or any function of the body; and
  - Does not achieve any of its primary intended purposes through chemical action within or on the body of man and is not dependent upon being metabolized for the achievement of any of its primary intended purposes



## Software functions that are <u>NOT</u> medical devices

# Software functions that could be used in a healthcare environment, in clinical care or patient management, but do not meet the definition of a medical device.



FD&C Act does not apply;

Not regulated by the FDA!

Examples: general purpose products, data transfer/storage only, **some** clinical decision support, **some** general wellness products

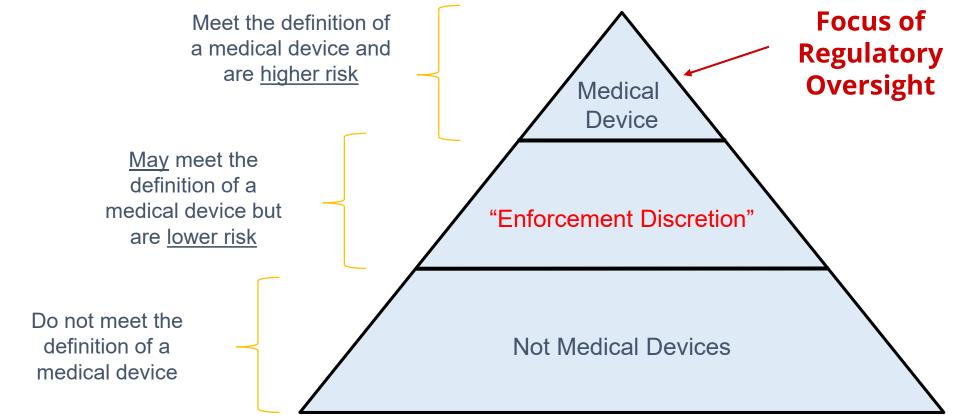


## General Wellness Software

- <u>Not a Medical Device</u>: Software intended to maintain or encourage general state of health
  - Weight management, stress, fitness, mental acuity, sleep, self esteem, etc.
- <u>Enforcement Discretion</u>: Intended use relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions
  - Help living well with or reduce the risk of heart disease, high blood pressure, type 2 diabetes, anxiety, etc.



# Risk-Based Approach for Regulation of Software Functions





## **Enforcement Discretion**

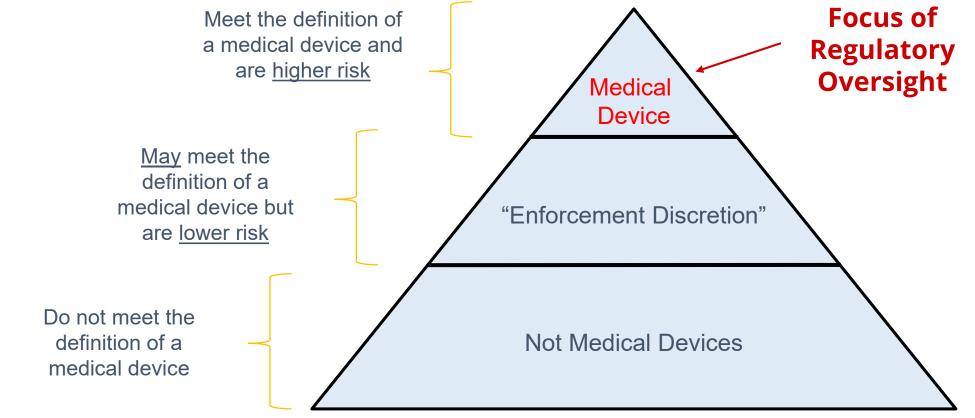
# Software functions that may meet the definition of a medical device for which the FDA intends to exercise 'enforcement discretion'

Under FDA jurisdiction, but "FDA intends not to pursue enforcement action for violations of the FD&C Act".

Examples: **some** general wellness products, apps that coach/prompt, medical calculators



# Risk-Based Approach for Regulation of Software Functions





# Software Functions that are the Focus of FDA Regulatory Oversight

Software that meets the definition of a medical device and either is intended:

- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device.

FD&C Act will be enforced; FDA will regulate this software function.



# FDA Final Guidance 2022

 Contains Nonbinding Recommendations
 1
 Not inter a signal f

 Clinical Decision Support Software
 2
 Intended

 Guidance for Industry and
 2
 Intended

 Food and Drug Administration Staff
 3
 Intended

 Document issued on September 28, 2022.
 3
 Intended

 For a software function to be Non-Device CDS, it must meet all the following four criteria to be excluded from the device definition under section 520(o) of the ED&C Act.
 4
 Intended

1	Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system
2	Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information
3	Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition
4	Intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient



### Your Clinical Decision Support Software: Is It a Device?

FDA

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. \*

#### Your software function must meet all four criteria to be Non-Device CDS. Summary interpretation of CDS criteria 3. Your software 4. Your software 1. Your software 2. Your software function provides the function provides function does NOT function displays, basis of the recommendations Your software analyzes, or prints medical acquire, process, or recommendations so that (information/options) to a function may be information normally analyze medical the HCP does not rely HCP rather than provide non-device CDS. communicated between images, signals, primarily on any a specific output health care professionals or patterns. recommendations to or directive. (HCPs). make a decision. Non-Device examples display, analyze, or print the following examples of Non-Device examples provide: Non-Device examples provide: AND AND medical information, which must also not be images, signals, or patterns: Non-Device Examples · Lists of preventive, diagnostic, or Plain language descriptions of the Information whose relevance to a treatment options software purpose, medical input, clinical decision is well understood underlying algorithm Clinical guidelines matched to · A single discrete test result that patient-specific medical info · Relevant patient-specific information is clinically meaningful and other knowns/unknowns for Relevant reference information about Report from imaging study consideration a disease or condition OR OR OR process, or analyze: Examples Risk scores for disease or condition Basis of recommendations is not Continuous signals/patterns Signal acquisition systems provided Medical images Probability of disease or condition Your software In vitro diagnostics function is Waveforms (ECG) Time-critical outputs Magnetic resonance imaging (MRI) a device. More continuous sampling Next Generation Sequencing (NGS) Device [aka - a signal or pattern] Continuous Glucose Monitoring (CGM) Computer aided detection/diagnosis

\*Disclaimer: This graphic gives a general overview of Section IV of the guidance ("Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act"). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.

[CADe/CADx]

Criterion 3: Automation Bias and Time Criticality

- Propensity of humans to over-rely on a suggestion from an automated system.
- Can result in errors of commission/omission.
- May be more likely to occur if software provides a user with a single, specific output/solution compared to a list of options or complete information to consider.

Signal acquisition systems

Magnetic resonance imaging (MRI)

Next Generation Sequencing (NGS)

Computer aided detection/diagnosis

Continuous Glucose Monitoring

In vitro diagnostics

(CGM)

(CADe/CADx)

OR

 Automation bias increases in time critical situations as the user may not have adequate time to consider other information.

> Non-Exa

> > Examples

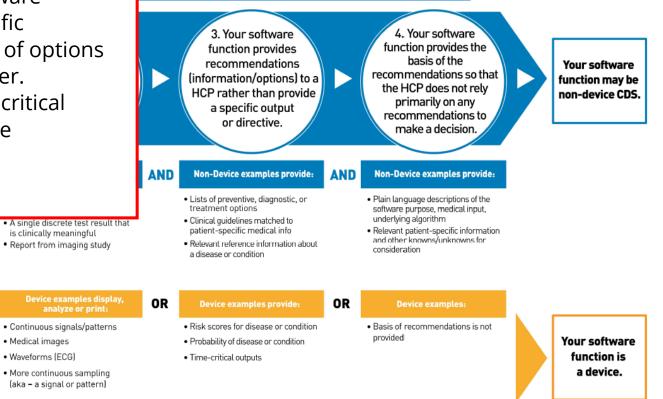
Device

### ion Support Software: Is It a Device?



FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general isult the guidance for the complete discussion and examples. Other software functions that are not listed

### all four criteria to be Non-Device CDS.



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**Criterion 4: Independent Review** 

γü

Examples

Device

- Provides background information in plain language on the inputs, algorithm logic/methods, datasets, validation, and patient information (detailed list in guidance)
- Expected regardless of software complexity and proprietary nature
- Recommends considering usability testing ٠

Note: References time criticality again highlighting that FDA does not consider software functions supporting a critical time sensitive task/decision to meet this criterion as HCP is unlikely to have sufficient time to do independent review.

Signal acquisition systems

Magnetic resonance imaging (MRI)

Next Generation Sequencing (NGS)

Computer aided detection/diagnosis

Continuous Glucose Monitoring

In vitro diagnostics

(CGM)

(CADe/CADx)

is clinically meaning

Medical images

Waveforms (ECG)

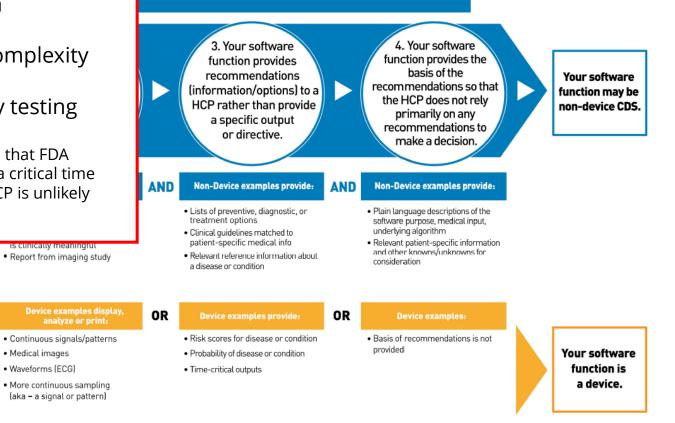
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# Tools for Engaging FDA

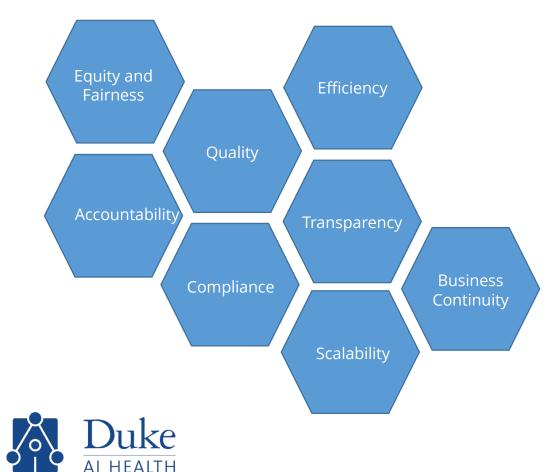
- FDA Digital Health Inbox
- FDA Digital Health Policy Navigator <u>https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator</u>
- Q-Submission



Software functions intended for administrative support of a health care facility are not devices under section 520(0) of the FD&C Act.



## Impacting How We Deliver Patient Care







## Lessons Learned

- Successful Al Governance is a Team Sport
  - Lots of skillsets, perspectives and languages to bring together
- Culture Shift is Hard
  - Governance's role as Coaches and Facilitators (not Punisher)
  - Show Teams how to succeed by addressing gaps in their knowledge, skillsets, and/or bandwidth
  - There is no such thing as over-communication in a complex system
- Benefits of Centralized Governance
  - Transparency of Process & Expectations
  - Institutional Visibility into all the 'skeletons in the closet'
- Conscious Decision (thus far) Not to Regulate Who Gets to Build Al Models





## **Future** Directions

- Translating FDA guidance to practice
- Imaging
- Centralized Model Monitoring

## Learn More...

### https://aihealth.duke.edu/algorithm-based-clinical-decision-support-abcds/



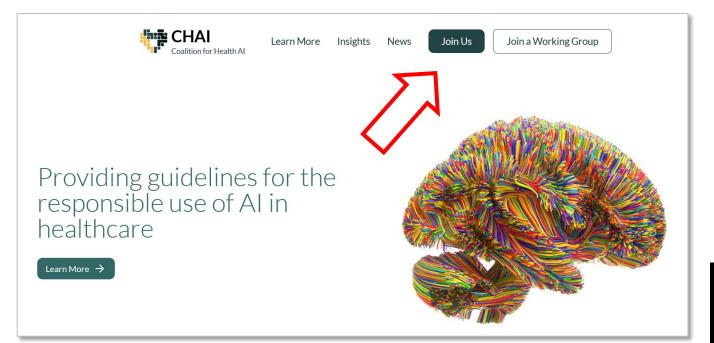
Bedoya, A. D., et al. (2022). "A framework for the oversight and local deployment of safe and high-quality prediction models." Journal of the American Medical Informatics Association.

## **Questions & Feedback**

Contact us at <u>abcds@duke.edu</u>







https://www.coalitionforhealthai.org/

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



# Thank you

