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[1,2]; Anthony L. Lin, MD[1]; Richard W. Grant, MD, MPH[3,4]

> Author Affiliations

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

🔗 Related Articles

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%).[1] E[...] care teams to promptly implement goal-directed therapy to mitigate clinical dete[...] *Internal Medicine*, Wong et al[2] 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.

Healthcare IT News

TO[...]

Global Edition   Analytics

Research suggests Epic Sepsis Model is lacking in predictive

[...]dy in JAMA Internal Medicine finds that the [...]tify two-thirds of sepsis patients and [...]alse alarms.

[...]2021 | 12:44 PM

Science

RESEARCH

RESEARCH ARTICLE

ECONOMICS

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

Ziad Obermeyer[1,2]*, Brian Powers[3], Christine Vogeli[4], Sendhil Mullainathan[5]*†

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 patients, as evidenced by signs of uncontrolled illnesses. Remedying this disparity would increase the percentage of Black patients receiving additional help from 17.7 to 46.5%. The bias arises because the algorithm predicts health care costs rather than illness, but unequal acce[...] for White patients. Thus, [...] by some measures of pr[...] convenient, seemingly ef[...] bias in many contexts.

There 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*). Facial recognition systems increasingly used [...]

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 year. Large health systems and payers rely on this algorithm to target patients for "high-risk [...]

that rely on past data to build a predictor of future health care needs.

Our dataset describes one such typical algorithm. It contains both the algorithm's predictions as well as the data needed to understand its inner workings: that is, the underlying ingredients 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. Rather it is emblematic of a generalized ap[...] in the health sec[...] range of for- and [...]s and governmental [...]

[...]tions beyond what [...]ar algorithm. First, [...]d by this algorithm [...]r sectors: The predicted risk of some future outcome (in our 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, life-and-death consequences of the decision— health is one of the most important and wide[...]

"At a given risk score, Black patients are considerably sicker than White patients, as evidenced by signs of uncontrolled illnesses. Remedying this disparity would increase the percentage of Black patients receiving additional help from 17.7% to 46.5%. The bias arises because the algorithm predicts health care costs rather than illness…"

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"Wild West" of Algorithms

Regulatory Landscape Changing Rapidly

Local Government Taking Action

State *of* California Department *of* Justice

ROB BONTA
Attorney General

Search

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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 Anna.Rich@doj.ca.gov, or 1515 Clay St., 20th 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
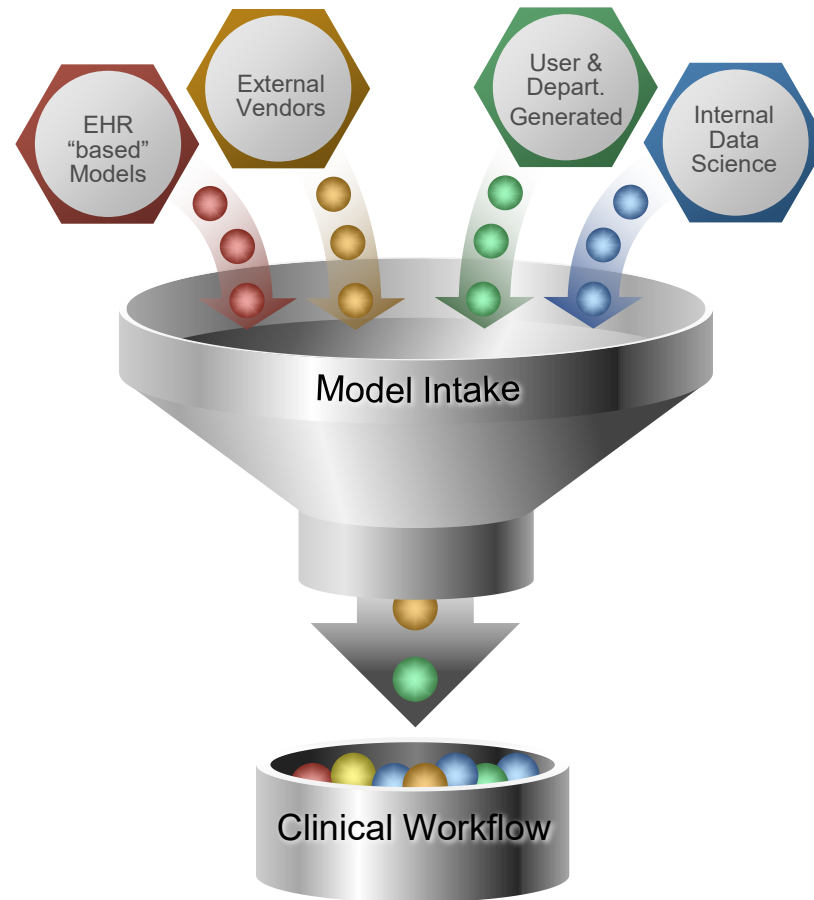 - Pressure Injury

"Our House" Today

- Over 40 registered tools

Duke
AI HEALTH

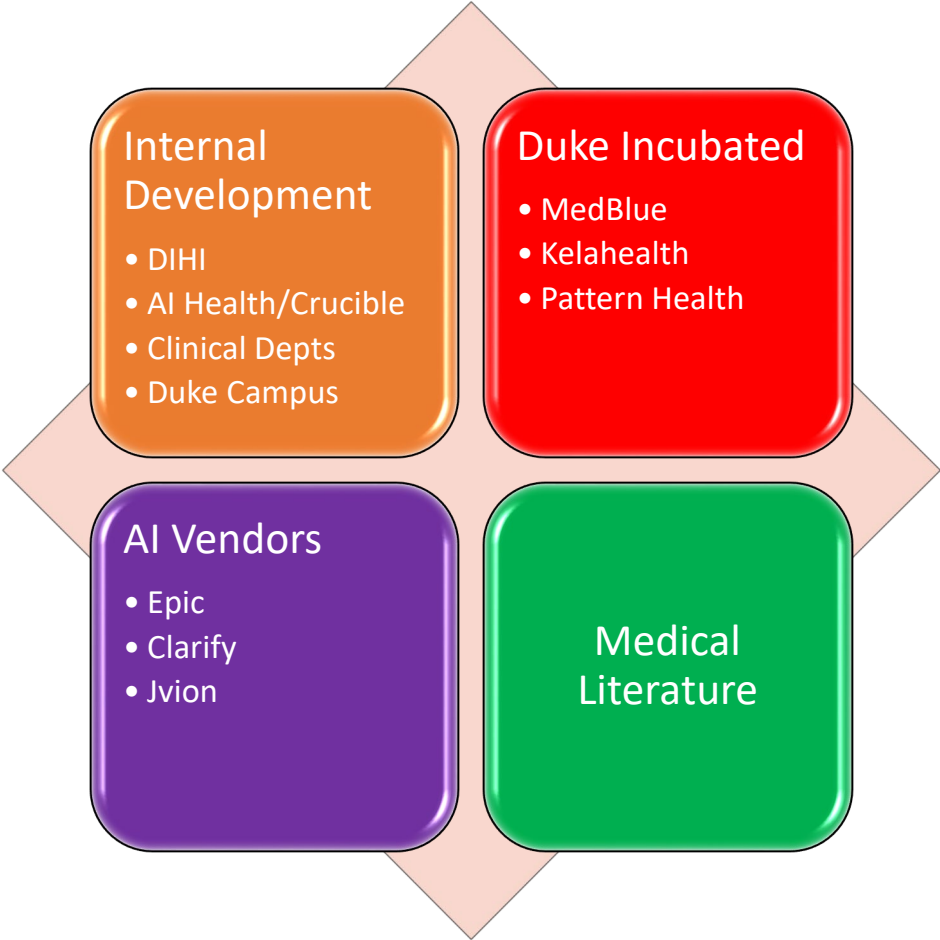# Complex Environment

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

Complex Environment
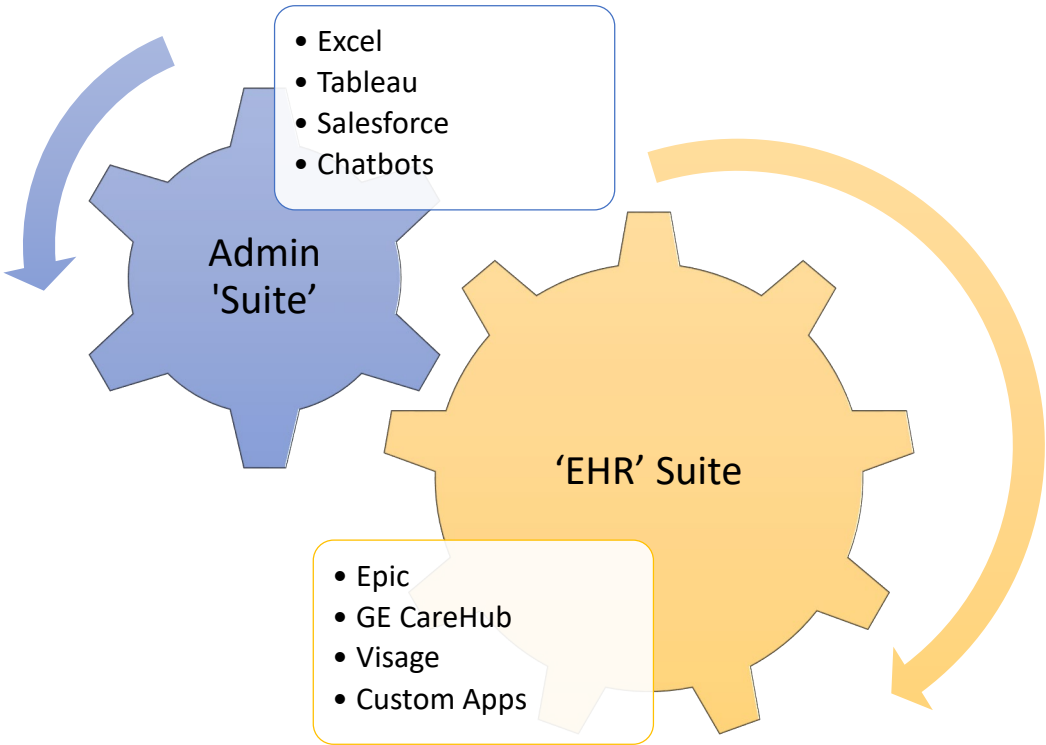
The Formation of the ABCDS Oversight Committee

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.

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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.

Duke AI HEALTH

ABCDS Lifecycle & Our Framework

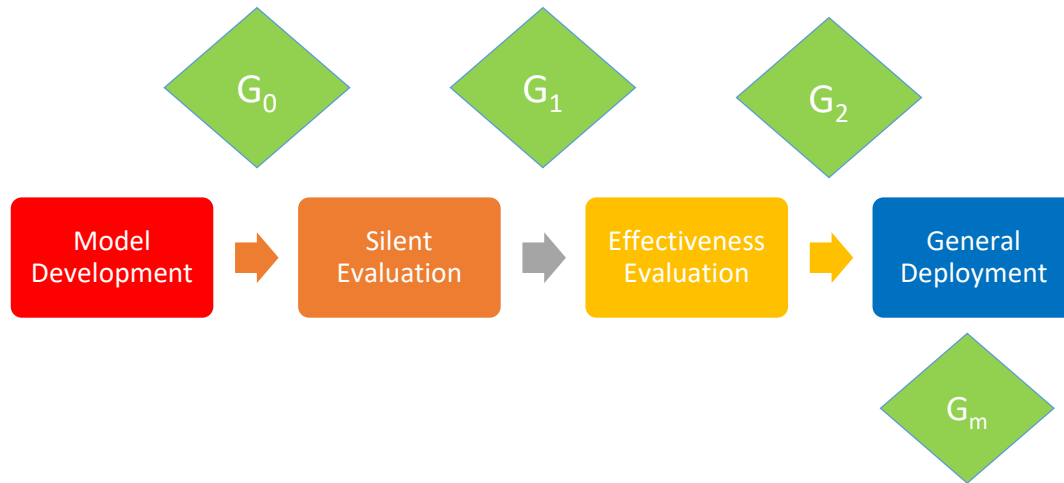‘Just-in-time’ Check-Points (**G**ates) Help Model Owners Get Ready for What's Ahead

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?

...

Implementing Quality & Ethics with Our Framework

Ethical Principles and Requirements

There are six general *ethical principles*[3] 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:

1. **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;
3. **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.
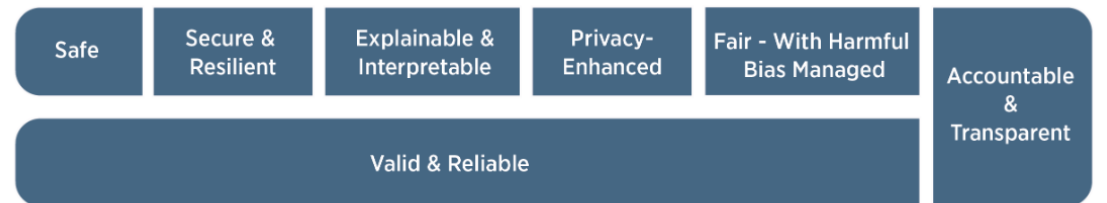
Ethics By Design and Ethics of Use Approaches for Artificial Intelligence, 2021

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.

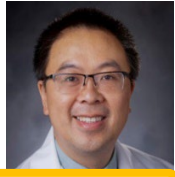NIST AI Risk Management Framework (1.0), 2023

People

People: ABCDS Oversight Committee

Co-Chairs:

M Pencina

E Poon

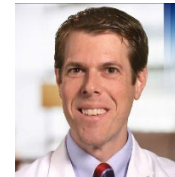Director:

N Economou
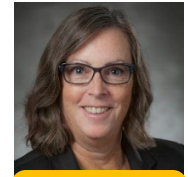
ABCDS Oversight Committee

Additional Committee Members:

S Balu

M Cary

M Lipkin

K Lytle

ABCDS Regulatory Subcommittee

ABCDS Evaluation Subcommittee

ABCDS Implementation and Monitoring Subcommittee

Ops Team:

S Bessias
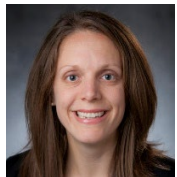
N Walden

Co-Chairs:

A Parrish

S Elengold

S Ellison

Co-Chairs:

B Goldstein
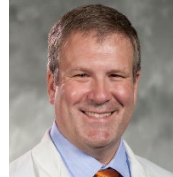
E Jelovsek

Co-Chairs:

A Bedoya

C O'Brien

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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

◉ **High Risk: Data-Derived**

◉ **Medium Risk (e.g. Local Clinical Consensus)**

◉ **Low Risk: Standard of Care**
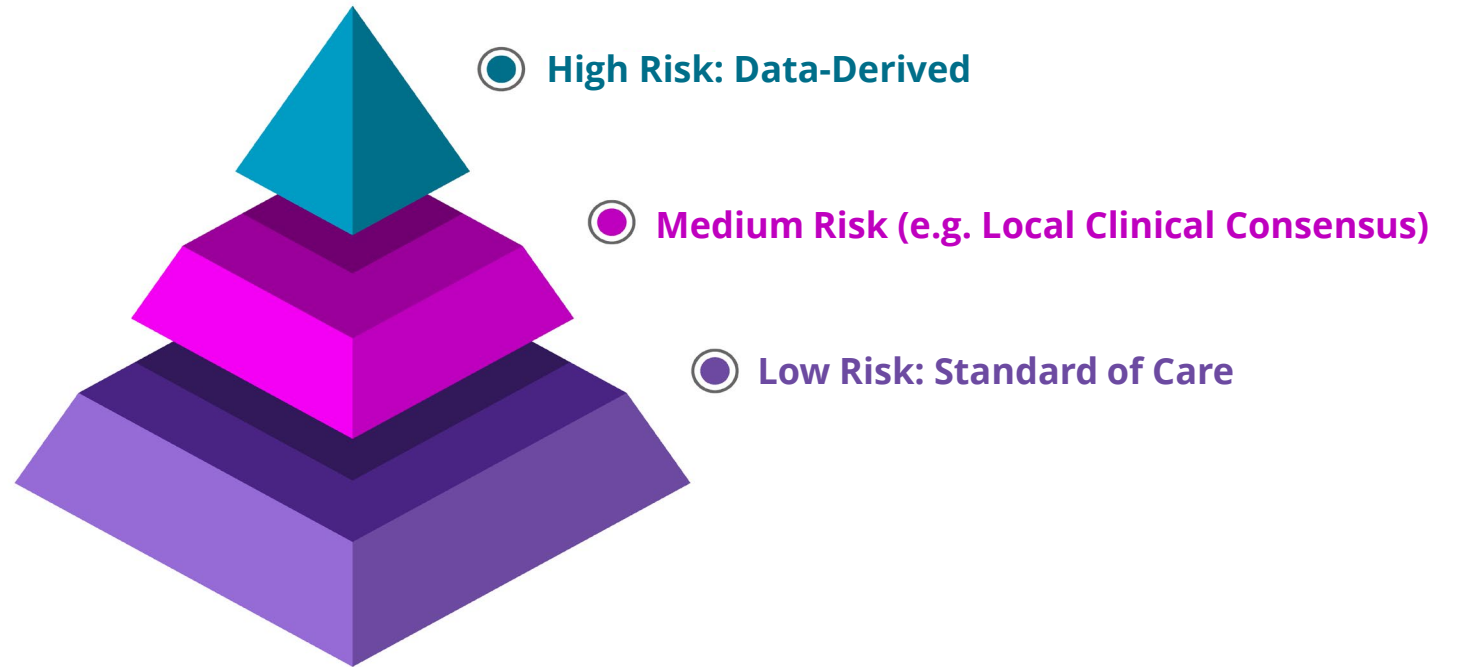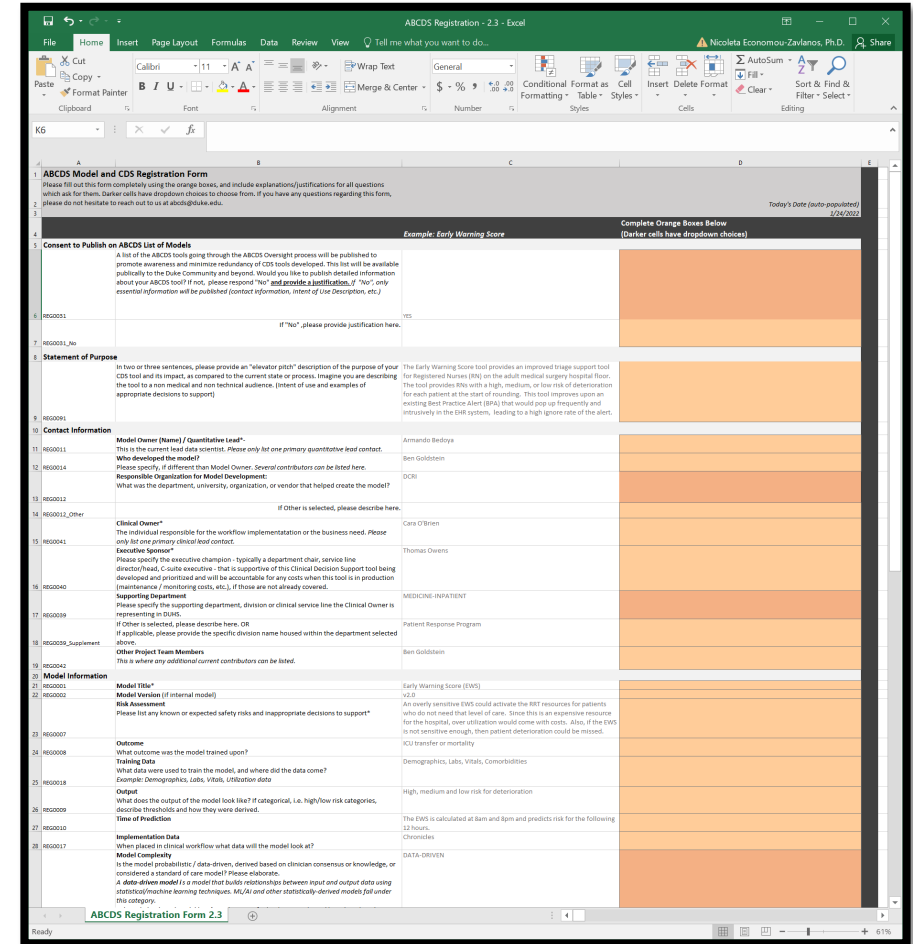
The ABCDS Registration Form

Information Requested

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

What to Expect: ABCDS Checkpoint Review

Registration
Pre-Registration
Triage

Full Review (Asynchronous)
Preview Letter
Review Meeting w/ Committee (Optional)

Outcome
Outcome Letter
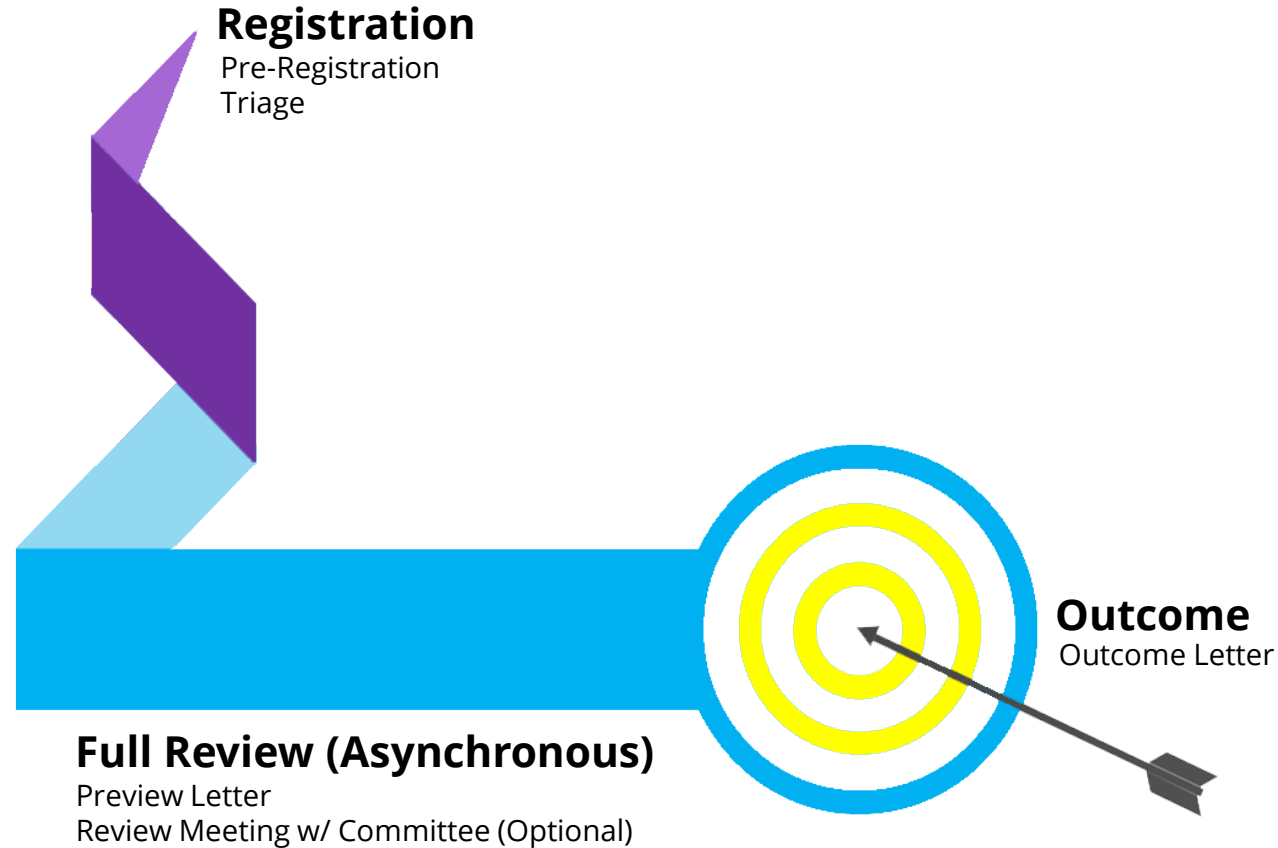
Outcomes
- Approval
- Approval w/ Contingencies
- Re-review
- Denial

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

Full Checkpoint Review
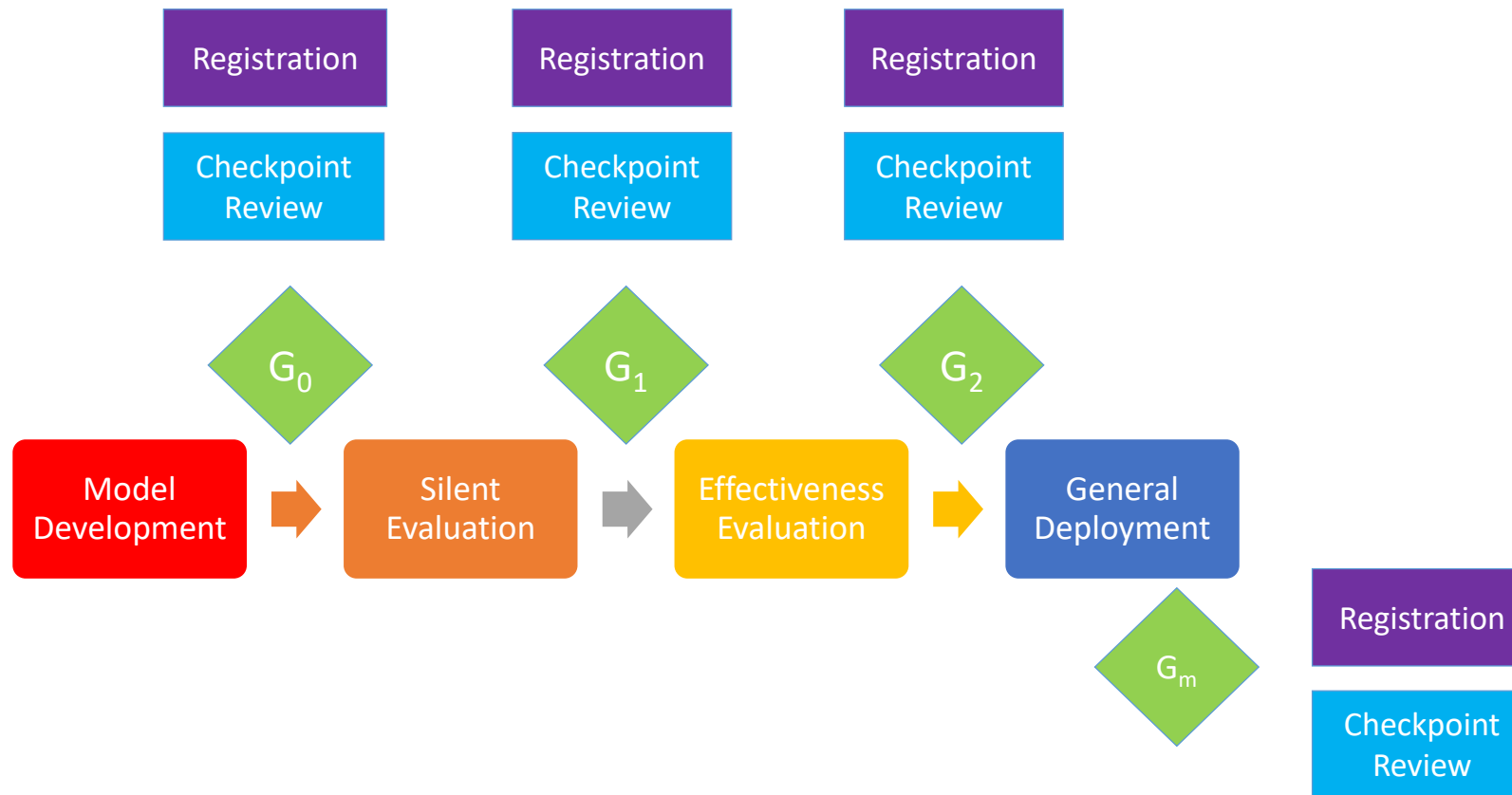
Implementing Quality & Ethics with Our Framework

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.	✓ Evidence that the tool has potential to impact clinical outcomes or processes ✓ List of key impact metrics (clinical outcomes and/or process improvement) with definitions, following TRIPOD guidelines[5] ✓ List of core performance metrics (e.g. sensitivity, PPV, etc.) and results from development ✓ Calibration curves, threshold selections and justification if applicable
	Plans for Silent Evaluation will inform the decision to proceed with pilot implementation in clinic.	Silent Evaluation Plan, including: ✓ Summary of benefits you expect to demonstrate and criteria to proceed into Effectiveness Evaluation ✓ Study design, including in/exclusion criteria, timeframe and sample size considerations ✓ Core performance metrics with shell tables ✓ Data analysis plan ✓ Data quality evaluation plan

Sample evaluation criteria supporting the principle of clinical impact & safety at the G_0 Checkpoint evaluation between pilot implementation and general deployment
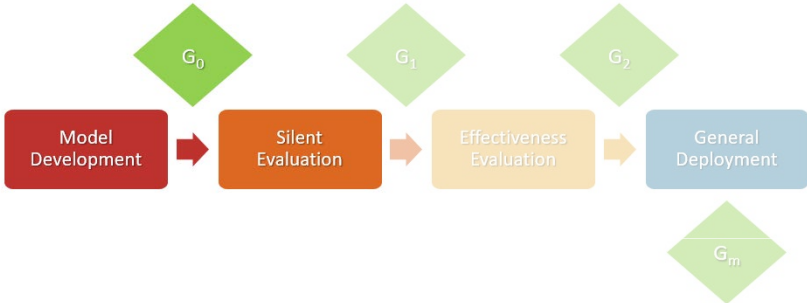
ABCDS Oversight Full Review
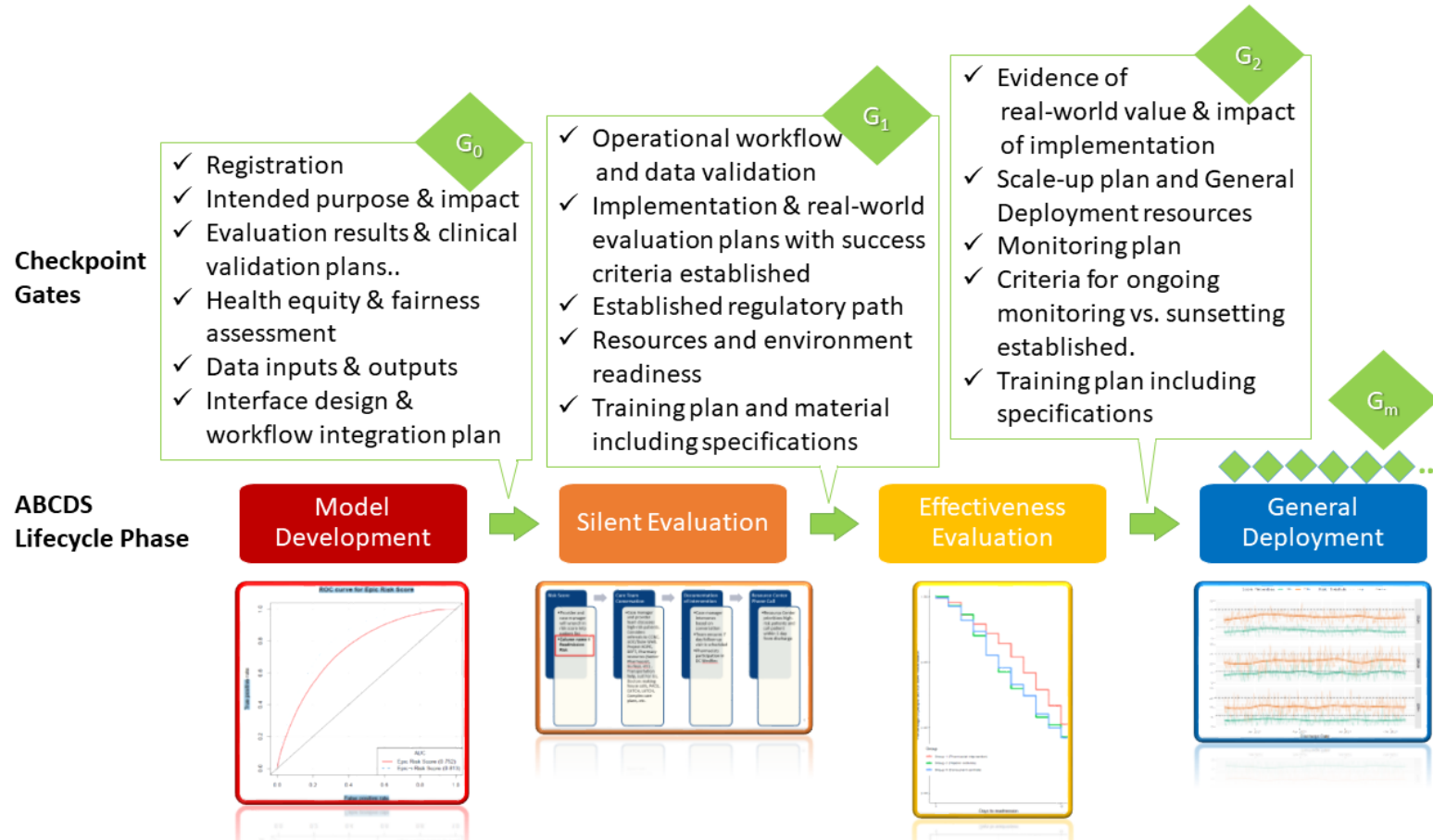
Bedoya, A. D., et al. (2022). "A framework for the oversight and local deployment of safe and high-quality prediction models." Journal of the American Medical Informatics Association.

Scope of ABCDS Oversight Framework

○ High Risk: Data-Derived

○ Medium Risk (e.g. Local Clinical Consensus)

○ Low Risk: Standard of Care
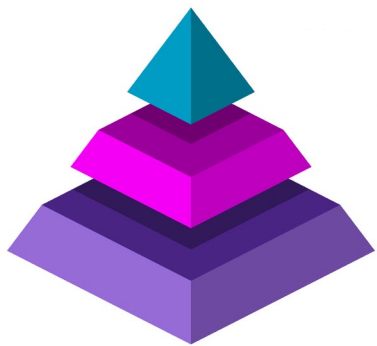
Fast-Track Checkpoint Review

Full Review

G_0 G_1 G_2

Model Development → Silent Evaluation → Effectiveness Evaluation → General Deployment

G_m

Fast-Track Review

Registration & Review

Registration & Review   Registration & Review

FT_0 FT_1

Model Development → Model Build & Qualification → General Deployment

FT_m
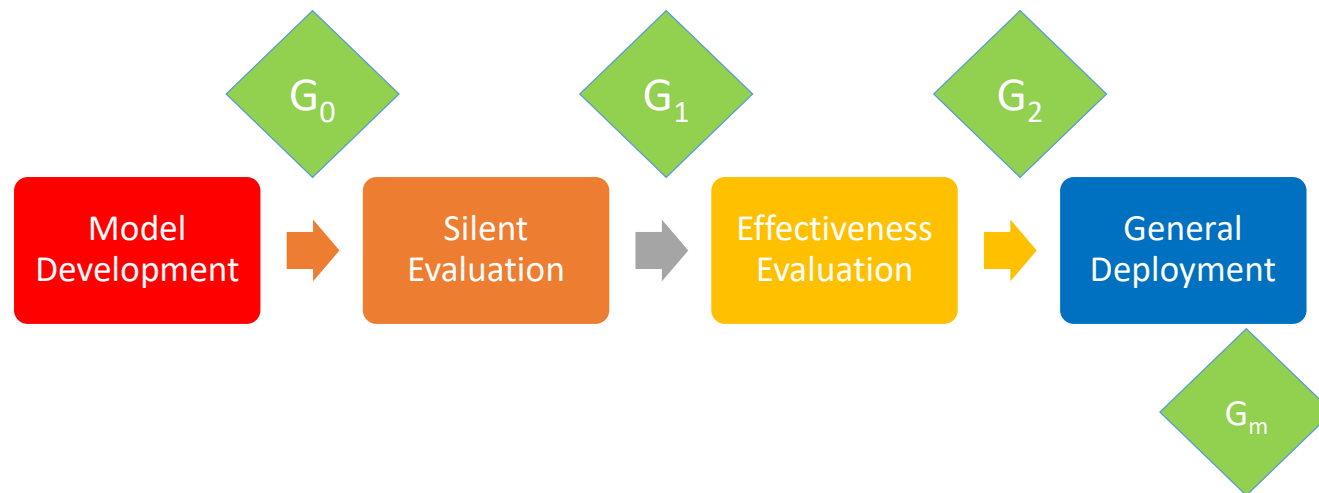
Upon registration:
*Clinical Validation
*Technical Specification Document
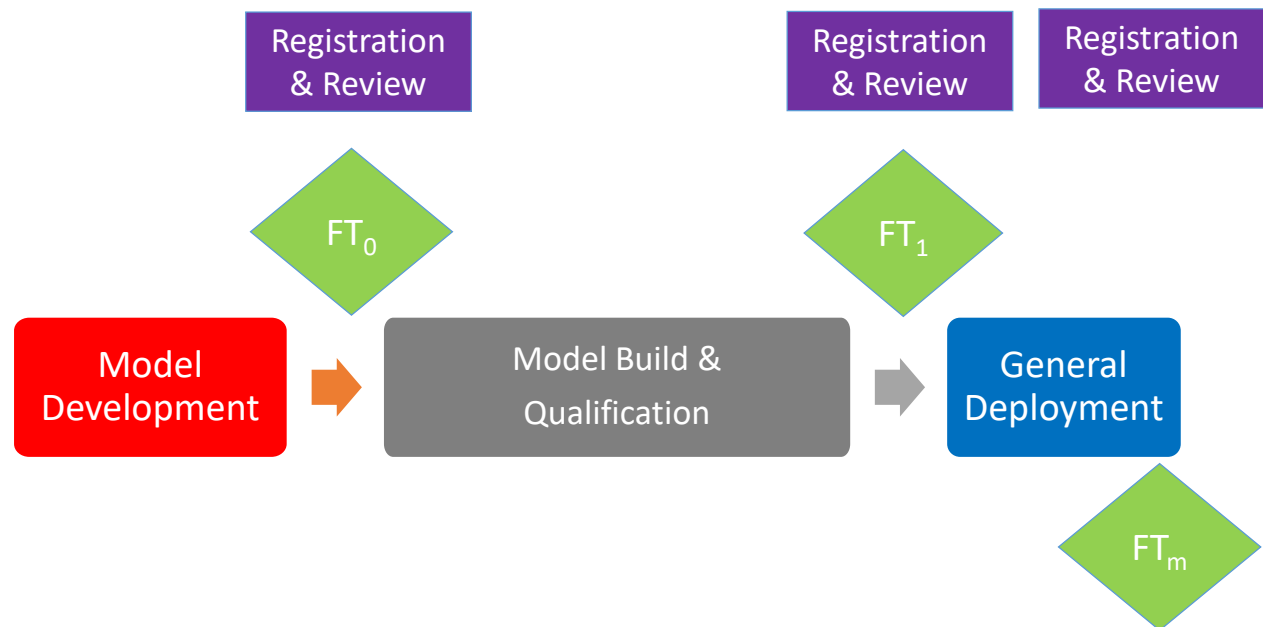
Fast-Track Evaluation – Alignment without Guidelines

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

Meet the definition of a medical device and are <u>higher risk</u>

May meet the definition of a medical device but are <u>lower risk</u>

Do not meet the definition of a medical device

Focus of Regulatory Oversight

Medical Device

"Enforcement Discretion"

Not Medical Devices
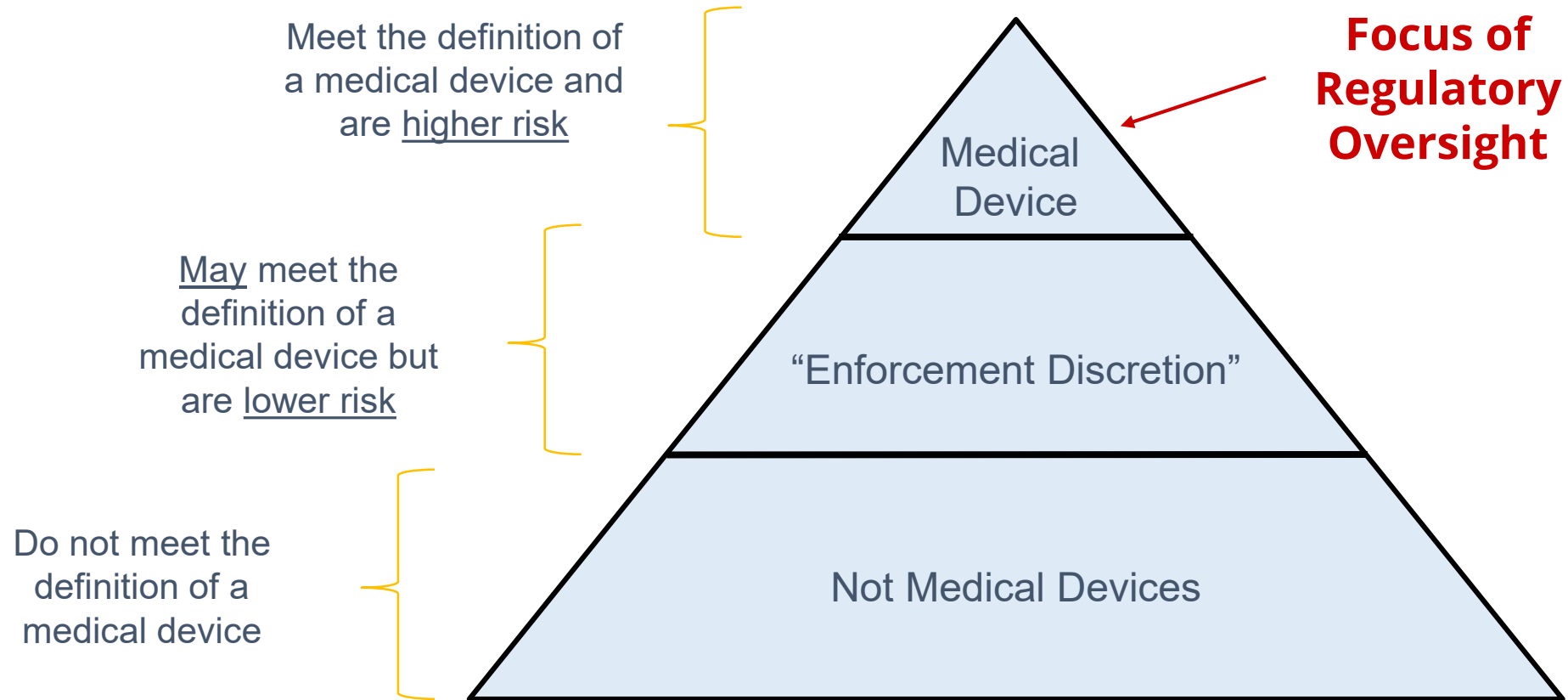
Medical Device

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 in the cure, mitigation, treatment, or prevention of disease</u> 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, **<u>some</u>** clinical decision support, **<u>some</u>** 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
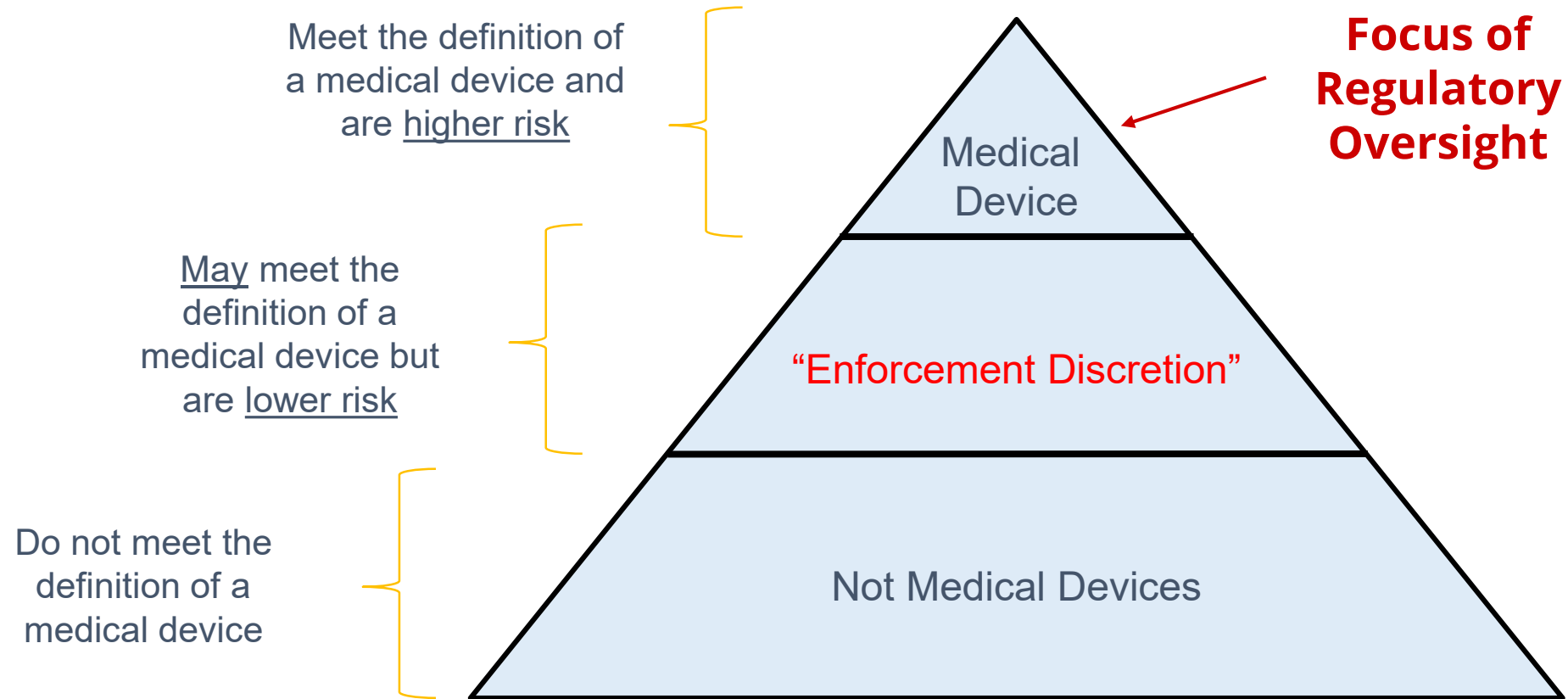
Enforcement Discretion

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

Meet the definition of a medical device and are <u>higher risk</u>

May meet the definition of a medical device but are <u>lower risk</u>

Do not meet the definition of a medical device

Medical Device

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Not Medical Devices

Focus of Regulatory Oversight
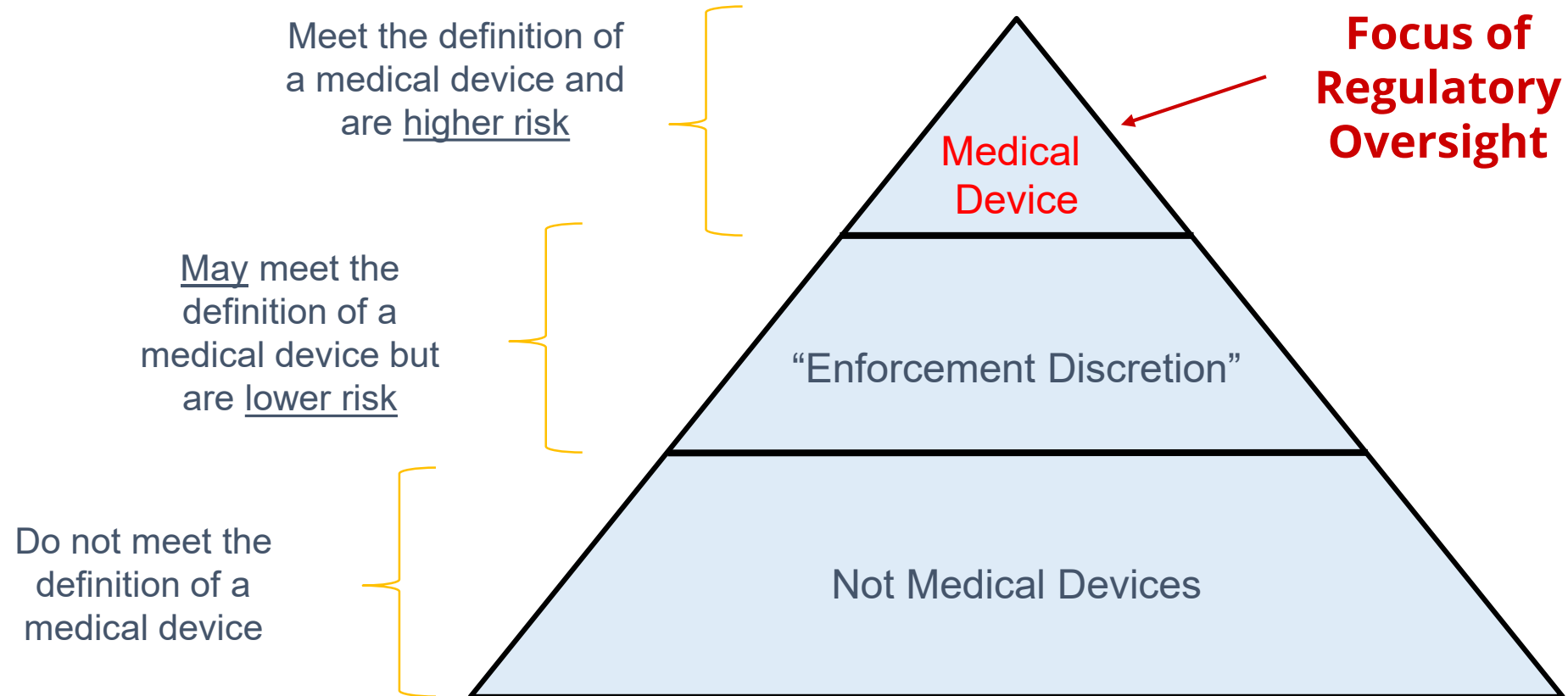
Software Functions that are the Focus of FDA Regulatory Oversight

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

Clinical Decision Support Software

**Guidance for Industry and
Food and Drug Administration Staff**

Document issued on September 28, 2022.

The draft of this document was issued on September 27, 2019.

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 FD&C Act.

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

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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

1. Your software function does **NOT** acquire, process, or analyze medical images, signals, or patterns.

2. Your software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).

3. Your software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.

4. Your software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

→ Your software function may be non-device CDS.

Non-Device Examples

Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

- Information whose relevance to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device examples provide:

- Plain language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other knowns/unknowns for consideration

Device Examples

Device examples acquire, process, or analyze:

- Signal acquisition systems
- In vitro diagnostics
- Magnetic resonance imaging (MRI)
- Next Generation Sequencing (NGS)
- Continuous Glucose Monitoring (CGM)
- Computer aided detection/diagnosis (CADe/CADx)

OR

Device examples display, analyze or print:

- Continuous signals/patterns
- Medical images
- Waveforms (ECG)
- More continuous sampling (aka – a signal or pattern)

OR

Device examples provide:

- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

OR

Device examples:

- Basis of recommendations is not provided

→ Your software function is a device.

*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.

https://www.fda.gov/medical-devices/software-medical-device-samd/your-clinical-decision-support-software-it-medical-device

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

ion Support Software: Is It a Device?

FDA

FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general ...sult 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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Your software function may be non-device CDS.

AND Non-Device examples provide:
- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
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AND Non-Device examples provide:
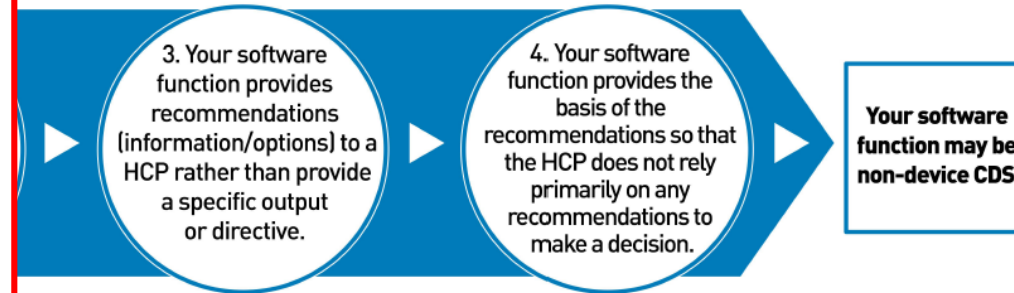- Plain language descriptions of the software purpose, medical input, underlying algorithm
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Non-Device Examples
- A single discrete test result that is clinically meaningful
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Criterion 4: Independent Review
- 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
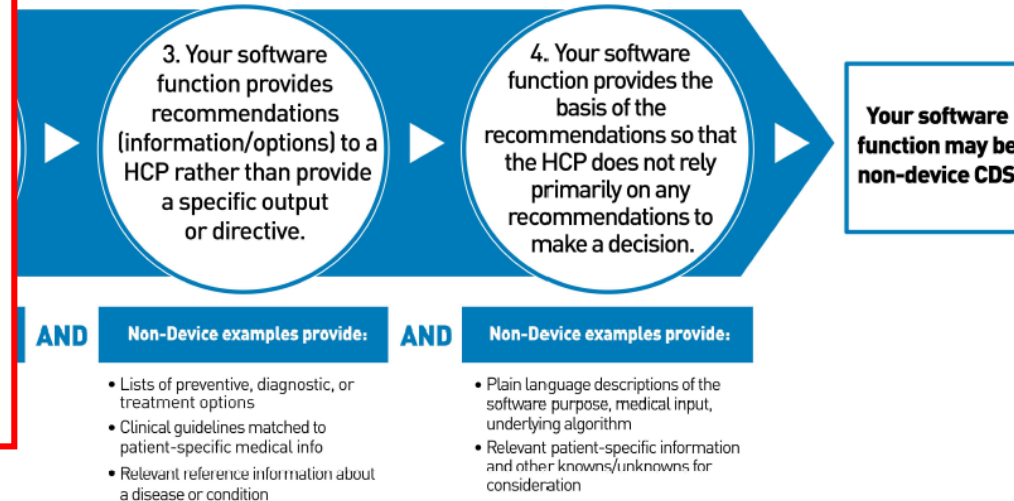- Recommends considering usability testing

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.
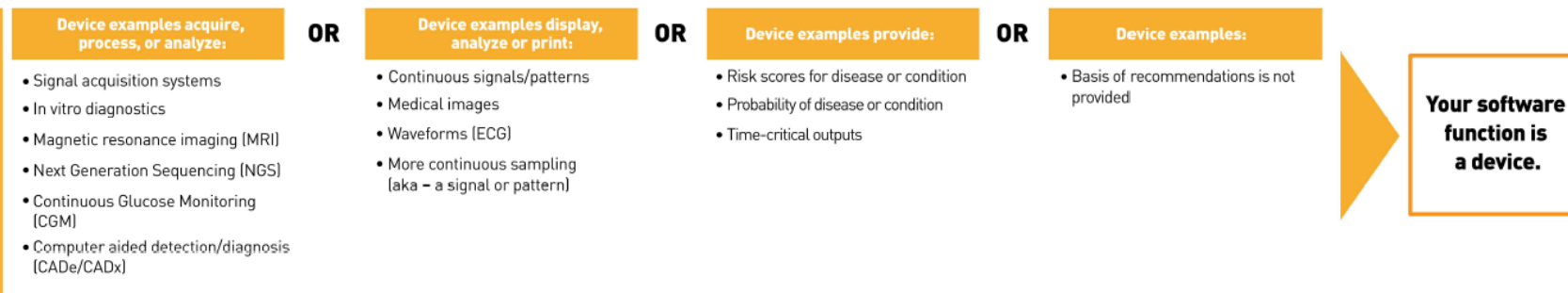

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OR

Device examples provide:
- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

OR

Device examples:
- Basis of recommendations is not provided

Your software function is a device.

*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.

Tools for Engaging FDA

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

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

Impacting How We Deliver Patient Care

Lessons Learned

- Successful AI 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 AI Models

Future Directions

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

Learn More...

What is ABCDS?

Algorithm-Based Clinical Decision Support (ABCDS) Oversight is a "people-process-technology" framework for the governance and evaluation of clinical algorithms created for use at Duke Health. This framework fosters innovative, safe, equitable, and high-quality patient care by introducing checkpoints throughout the development lifecycle as well as after deployment to ensure that transparency, quality, and ownership are maintained for ABCDS algorithms and tools. The ABCDS Oversight is a collaborative effort between the Duke University School of Medicine and the Duke University Health System.

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 abcds@duke.edu

Thank you

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