The Age of AI in Healthcare: Navigating Regulation, Liability, and Data Privacy

AIM2

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Outline

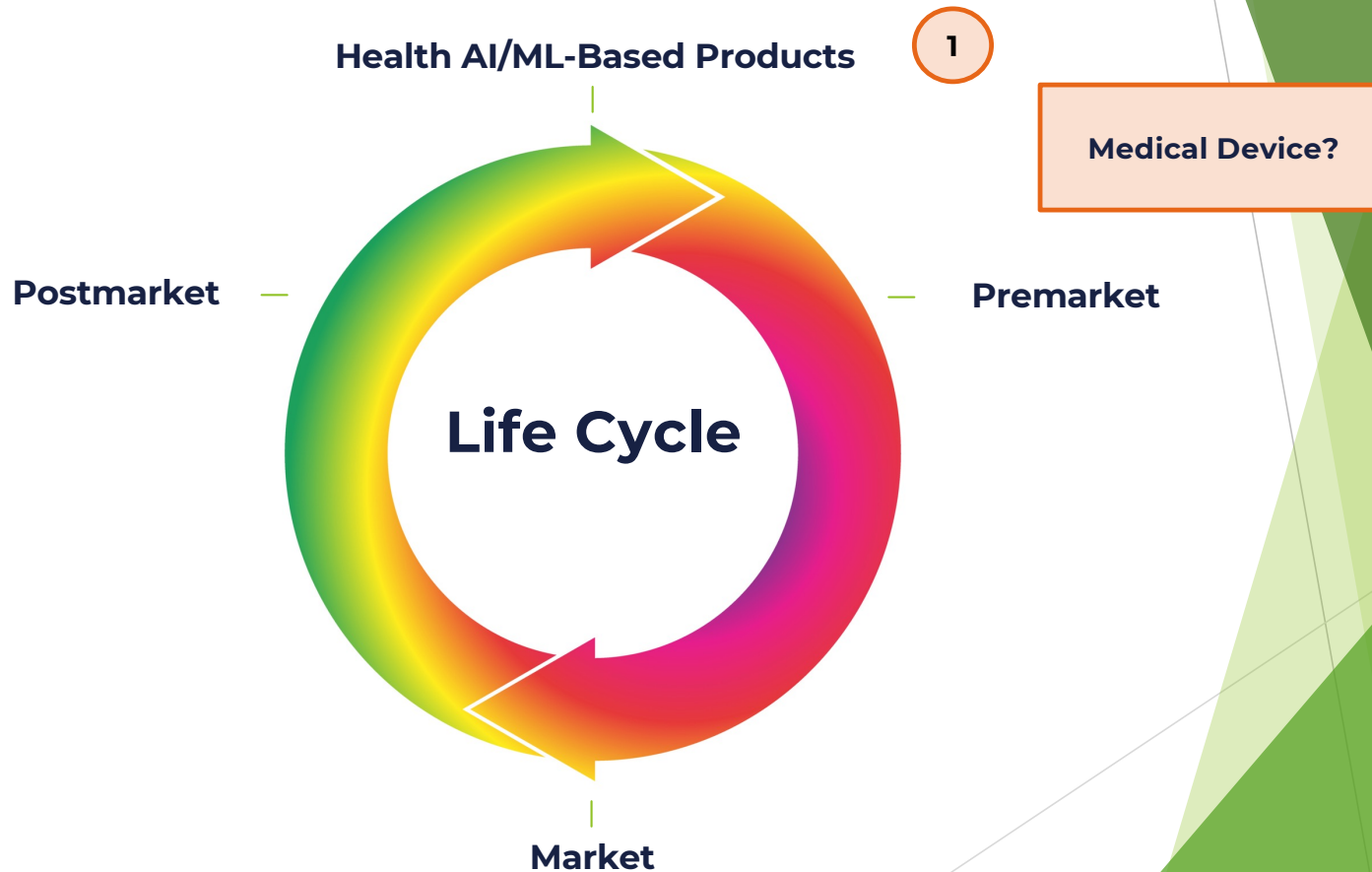**Regulation: Life Cycle of Health AI/ML-Based Products**

Liability

Data Privacy

Regulation: Life Cycle of Health AI/ML-Based Products

The Life Cycle of Health AI/ML-Based Products

Health AI/ML-Based Products

1

Medical Device?

Postmarket

Premarket

Life Cycle

Market

Adapted from: Sara Gerke, *Health AI For Good Rather Than Evil? The Need For a New Regulatory Framework For AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 433 (2021).

Medical Device Definition, FDCA Section 201(h)(1)

The term "device" (…) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

> *(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,*
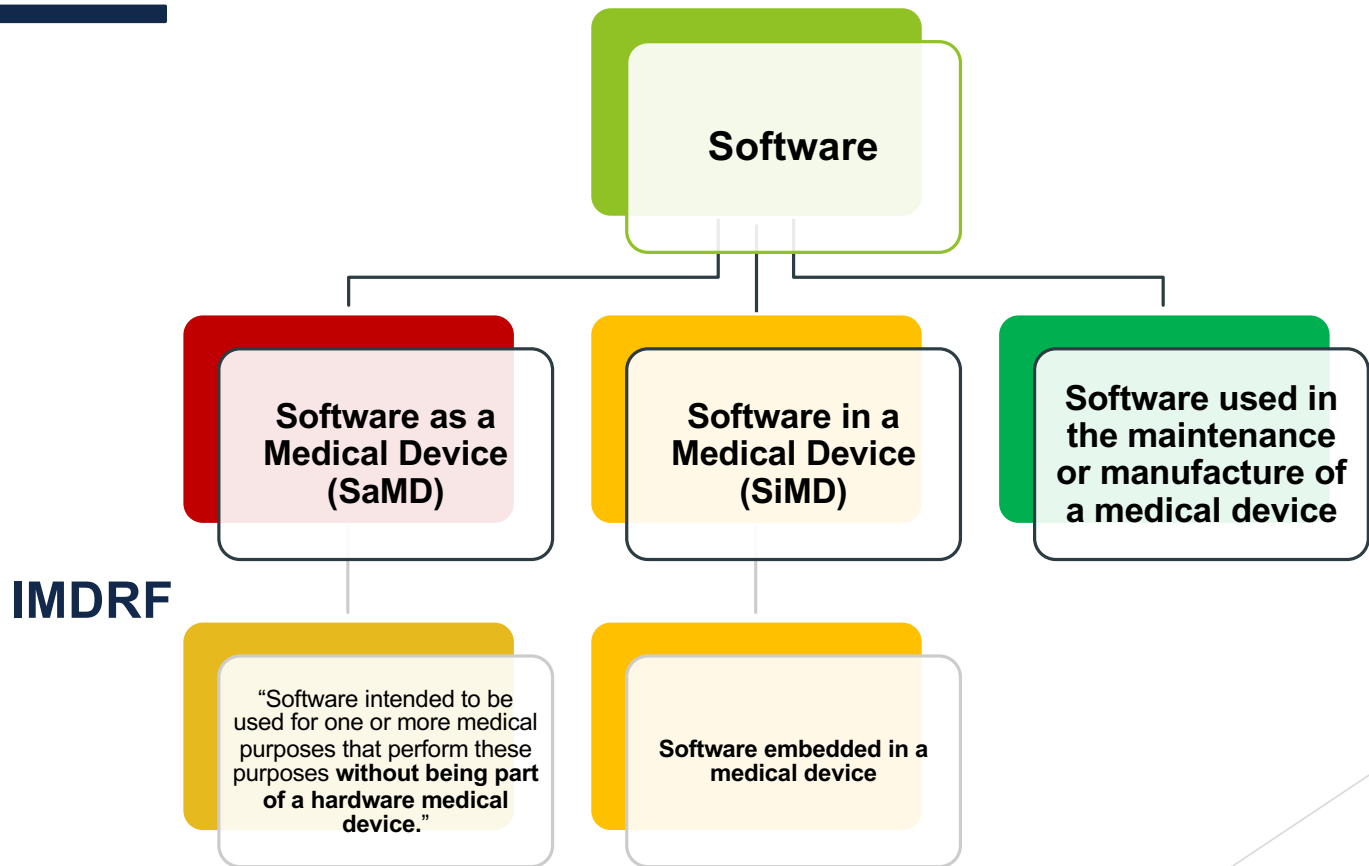>
> *(B) **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man** or other animals, or*
>
> *(C) intended to affect the structure or any function of the body of man or other animals, **and***

*__which does not achieve its primary intended purposes through chemical action within or on the body of man__ or other animals **and which is not dependent upon being metabolized for the achievement of its primary intended purposes**. The term "device" **does not include software functions excluded pursuant to section 520(o).***

Software Types

```
                    ┌─────────────────┐
                    │    Software     │
                    └────────┬────────┘
          ┌──────────────────┼──────────────────┐
┌─────────────────┐ ┌─────────────────┐ ┌─────────────────┐
│ Software as a   │ │ Software in a   │ │ Software used in│
│ Medical Device  │ │ Medical Device  │ │ the maintenance │
│ (SaMD)          │ │ (SiMD)          │ │ or manufacture of│
│                 │ │                 │ │ a medical device│
└────────┬────────┘ └────────┬────────┘ └─────────────────┘
         │                   │
┌─────────────────┐ ┌─────────────────┐
│ "Software       │ │ Software        │
│ intended to be  │ │ embedded in a   │
│ used for one or │ │ medical device  │
│ more medical    │ │                 │
│ purposes that   │ │                 │
│ perform these   │ │                 │
│ purposes without│ │                 │
│ being part of a │ │                 │
│ hardware medical│ │                 │
│ device."        │ │                 │
└─────────────────┘ └─────────────────┘
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IMDRF

Adapted from Sara Gerke, "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, 91 The George Washington Law Review 79 (2023).

Categories of Non-Device Software Functions, FDCA Section 520(o)

(1) Administrative Support of Health Care Facilities,
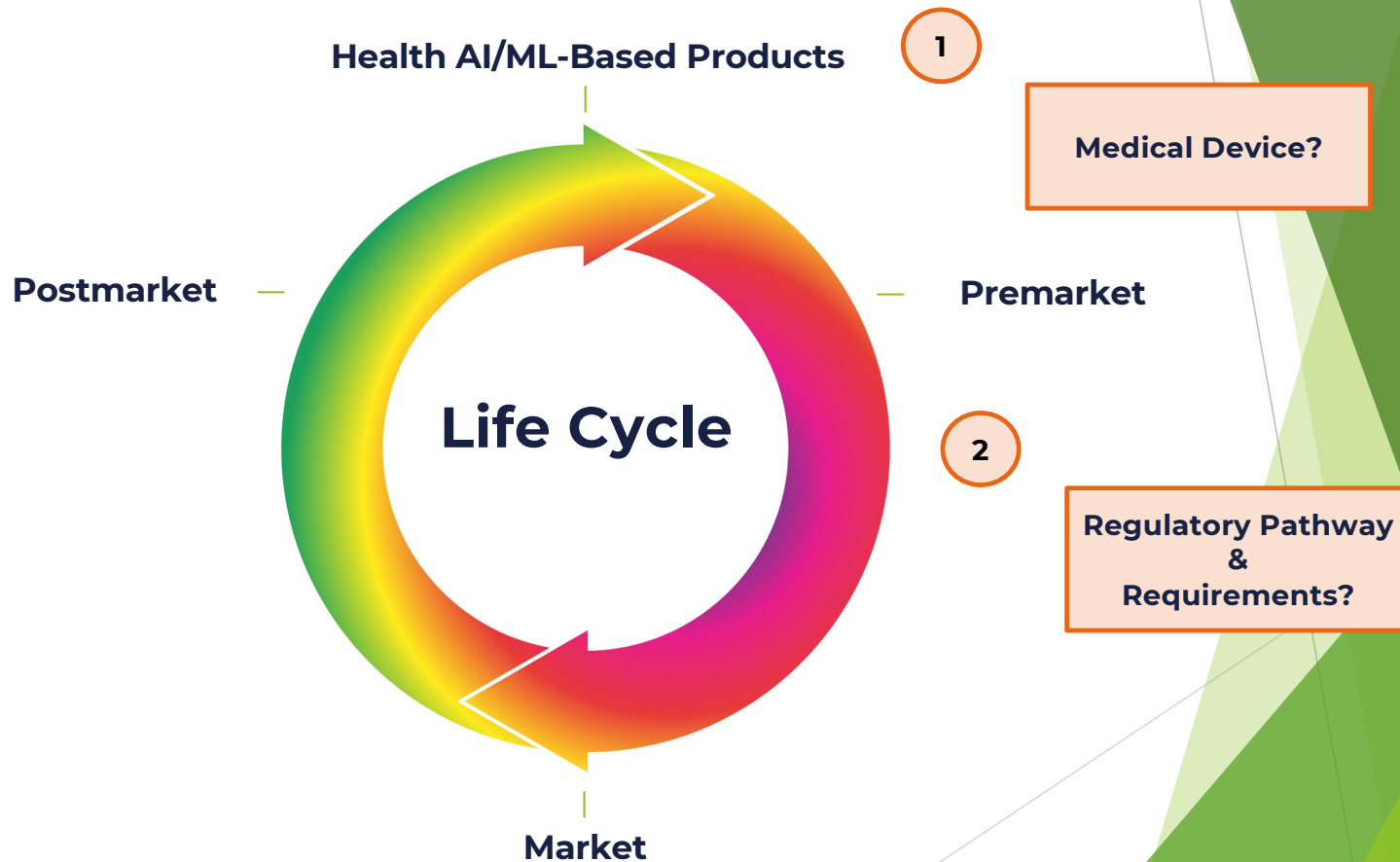FDCA Section 520(o)(1)(A);

(2) Maintenance or Encouragement of Healthy Lifestyles,
FDCA Section 520(o)(1)(B);

(3) Serve as Electronic Patient Records,
FDCA Section 520(o)(1)(C);

(4) Transfer, Store, Convert Formats, or Display Data and Results,
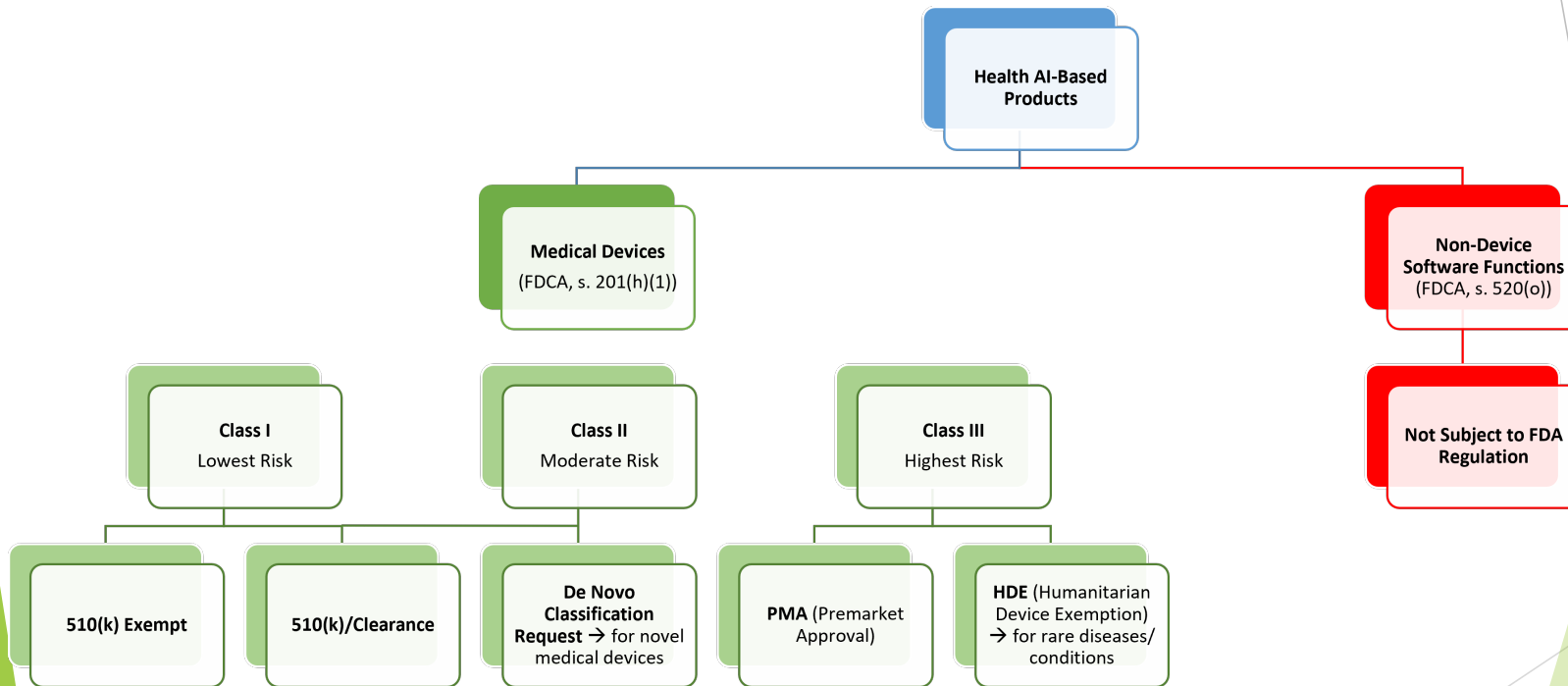FDCA Section 520(o)(1)(D); and

(5) Clinical Decision Support Software,
FDCA Section 520(o)(1)(E).

The Life Cycle of Health AI/ML-Based Products

Health AI/ML-Based Products

①

Medical Device?

Postmarket — **Life Cycle** — **Premarket**

②

Regulatory Pathway & Requirements?

Market

Regulatory Pathways

Adapted from Sara Gerke et al., Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19, 26 Nature Med. 1176 (2020).

Regulatory Pathways

| Criteria	510(k) Clearance	De Novo Classification Request	Premarket Approval (PMA)
Purpose	Clearance for some low- and most moderate-risk devices **substantially equivalent to legally marketed devices** (so-called "predicates").	Classification for **low- to moderate-risk** devices with no predicate.	Approval pathway **for high-risk devices**.
Risk Level	Low to moderate (Class I and II)	Low to moderate (Class I or II, novel devices)	High (Class III)
Data Requirements	**Limited, rarely requires clinical data**	**May require clinical testing, depending on device novelty and risk level**	**Extensive, typically includes clinical trials**
Marketing Authorization Standard	Substantial equivalence to a predicate device	Reasonable assurance of safety and effectiveness (Class II)	Reasonable assurance of safety and effectiveness
Regulatory Burden	Lower	Moderate	High
Regulatory Controls	General controls; special controls if necessary	General controls and often special controls	General controls and premarket approval
Average Cost for Applicant	Lower compared to PMA	Moderate	High (including clinical trials and extensive data)

Black-Box AI
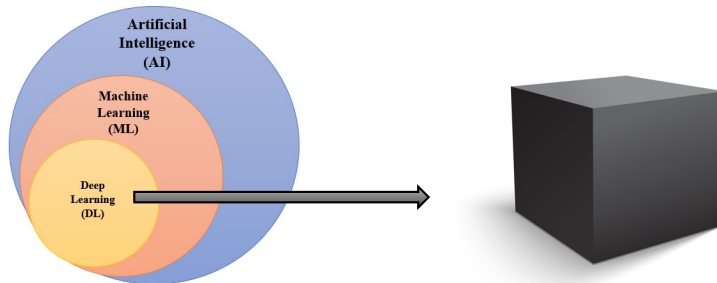
Figure (AI and Relevant Subsets) adapted from Sara Gerke, "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, 91 GEO. WASH. L. REV. 79, 88 (2023); Photo credit (black box): © olga_milagros - stock.adobe.com
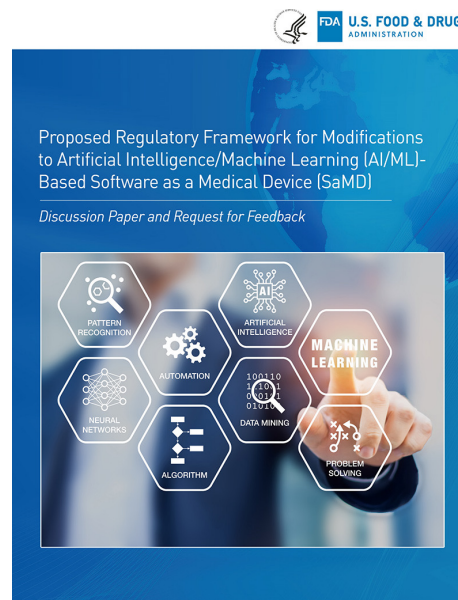
Adaptive Algorithms

"Adaptive" Algorithm

FDA

An algorithm that **may change** as it is **applied to new data.**

FDA **U.S. FOOD & DRUG** ADMINISTRATION

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback

Total Product Lifecycle (TPLC) Regulatory Approach

Predetermined Change Control Plan

U.S. Food & Drug Admin., Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD): Discussion Paper and Request for Feedback 3 (2019), https://www.fda.gov/media/122535/download.

U.S. Food & Drug Admin., Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions Guidance for Industry and Food and Drug Administration Staff (2024), https://www.fda.gov/media/166704/download.
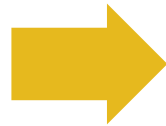
Labeling

	A	B	C	D	E	F	G	H	I	J
1	Product	Company	Description	Code	Approval Type	Validation data	Gender breakdo	Race/ethnicity b	Geographic brea	Clearance date
2	PhysIQ Heart Rhy	Phys IQ	detection of afib	DPS	510k	None reported	None reported	None reported	None reported	7/10/2019
3	Loop System	Spry Health	monitoring vital sig	DQA	510k	24	None reported	None reported	None reported	3/29/2019
4	eMurmur ID	CSD Labs GmbH	heart murmur dete	DQD	510k	120	None reported	None reported	None reported	4/17/2019
5	Steth IO	Stratoscientific Inc	collect heart and l	DQD	510k	None reported	None reported	None reported	None reported	7/15/2016
6	Stethee Pro	M3dicine Pty.	electronic stethec	DQD	510k	None reported	None reported	None reported	None reported	10/30/2017
7	AI ECG Platform	Shenzhen Carewe	ECG analysis	DQK	510k	None reported	None reported	None reported	None reported	11/19/2018
8	KardiaAI	AliveCor heart mo	6-lead ECG	DQK	510k	None reported	None reported	None reported	None reported	3/11/2019
9	Rhythm Analytics	Biofourmis Singap	monitoring cardiac	DQK	510k	None reported	None reported	None reported	None reported	3/7/2019
10	IntraOperative Po	Centerline Biomec	evaluation of vasc	DQK	510k	None reported	None reported	None reported	None reported	6/24/2019
11	Rooti RX System	Rooti Labs	continuous ECG n	DRG	510k	None reported	None reported	None reported	None reported	11/7/2017
12	Peerbridge Cor	Peerbridge Health	ECG analysis	DSH	510k	None reported	None reported	None reported	None reported	9/27/2017
13	Body Guardian R	Preventice	cardiac arrythmia	DSI	510k	None reported	None reported	None reported	None reported	9/17/2015
14	AliveCor	AliveCor heart mo	detection of afib	DXH	510k	None reported	None reported	None reported	None reported	8/15/2014
15	Bioflux	Biotricity Inc.	detecting arryythn	DXH	510k	None reported	None reported	None reported	None reported	10/13/2016
16	Fibri Check	Qompium NV	cardiac monitor	DXH	510k	223	None reported	None reported	None reported	9/28/2018
17	Study Watch	Verily Life Science	ECG features	DXH	510k	None reported	None reported	None reported	None reported	1/17/2019
18	Rhythm Express F	VivaQuant	coninuous monitor	DXH	510k	None reported	None reported	None reported	None reported	2/16/2019
19	RightEye Vision S	RightEye LLC	identify visual trac	GWN	510k	None reported	None reported	None reported	None reported	9/28/2018
20	NeuroEEG	Memory MD Inc.	transmission and	GWQ	510k	None reported	None reported	None reported	None reported	2/16/2018

Casey Ross, *Explore STAT's Database of FDA-Cleared AI Tools*, STAT (Feb. 3, 2021), https://www.statnews.com/2021/02/03/fda-artificial-intelligence-clearance-products.

Food Labeling Is Promising For AI/ML-Based Medical Devices

Key Components of Modern Food Labeling

- Nutrition facts labels
- Front-of-package (FOP) nutrition labeling system
- Use of modern technology like apps
- Additional labeling (e.g., designation of ingredients)

Key Components of AI/ML-Based Medical Device Labeling

- AI Facts labels
- FOP AI labeling system
- Use of modern technology like apps
- Additional labeling (e.g., instructions for use)

Sara Gerke, *A Comprehensive Labeling Framework for Artificial Intelligence (AI)/Machine Learning (ML)-Based Medical Devices: From AI Facts Labels to a Front-Of-Package AI Labeling System—Lessons Learned From Food Labeling*, 74 Emory Law Journal (2025; forthcoming); https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5113487.

AI Facts Labels ("Nutrition Facts Labels")

Food Labeling → **AI/ML-Based Medical Device Labeling**

- Nutrition Facts labels

- AI Facts labels

Nutrition Facts

8 servings per container
Serving size   2/3 cup (55g)

Amount per serving
Calories   **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(1) Primary Addressee of the AI Facts Label

(2) Content of the AI Facts Label

(3) Uniform Design

(4) Location

(5) Mandatory Label

(6) Dynamic Label

(7) Collaborative Stakeholder Approach and Conduct of Empirical Studies

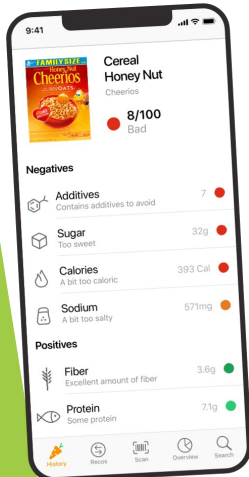**(8) Widespread Education and Communication Campaigns**

Sara Gerke, *A Comprehensive Labeling Framework for Artificial Intelligence (AI)/Machine Learning (ML)-Based Medical Devices: From AI Facts Labels to a Front-Of-Package AI Labeling System—Lessons Learned From Food Labeling*, 74 Emory Law Journal (2025; forthcoming); https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5113487.

11 Key Types of Information

Key Types of Information That Should Be Included on the Label of AI/ML-Based Medical Devices
(1) MODEL IDENTIFIERS
(2) MODEL TYPE
(3) MODEL CHARACTERISTICS
(4) INDICATIONS FOR USE
(5) VALIDATION & MODEL PERFORMANCE
(6) DETAILS ON THE DATA SETS
(7) PREPARATION BEFORE USE & APPLICATION
(8) MODEL LIMITATIONS, WARNINGS & PRECAUTIONS
(9) ALTERNATIVE CHOICES
(10) PRIVACY & SECURITY
(11) ADDITIONAL INFORMATION

Sara Gerke, "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, 91 The George Washington Law Review 79 (2023).

FOP AI Labeling System
("FOP Nutrition Labeling System")

Food Labeling

AI/ML-Based Medical Device Labeling

- FOP Nutrition Labeling Systems

- FOP AI Labeling System

Summary Indicator

Nutrient-Specific

Each grilled burger (94g) contains

Energy 924kJ 220kcal	Fat 13g	Saturates 5.9g	Sugars 0.8g	Salt 0.7g
11%	19%	30%	<1%	12%

of an adult's reference intake
Typical values (as sold) per 100g: Energy 966kJ /230kcal

NUTRI-SCORE
A B C D E

ALTO EN CALORÍAS — Ministerio de Salud
ALTO EN AZÚCARES — Ministerio de Salud
ALTO EN SODIO — Ministerio de Salud
ALTO EN GRASAS SATURADAS — Ministerio de Salud

3.5 HEALTH STAR RATING

ENERGY 1020kJ	SAT FAT 1.0g LOW	SUGARS 2.1g LOW	SODIUM 645mg LOW

FDA Healthy

Nutrition Info

Per serving 1 container	%Daily Value
Saturated Fat	18% Med
Sodium	37% High
Added Sugars	5% Low

FDA.gov

(1) One Standardized FOP AI Labeling System

(2) Primary Purpose

(3) "Nutrient-Specific" ("AI Facts Label-Specific Information") or "Summary Indicator" System?

(4) "Trustworthy AI" Symbol

(5) Criteria

(6) One Location

(7) Voluntary Versus Mandatory

(8) Dynamic Program

(9) Collaborative Efforts with All Stakeholders and Empirical Studies

(10) Widespread Marketing Campaigns

Trustworthy AI ✓

Sara Gerke, *A Comprehensive Labeling Framework for Artificial Intelligence (AI)/Machine Learning (ML)-Based Medical Devices: From AI Facts Labels to a Front-Of-Package AI Labeling System—Lessons Learned From Food Labeling*, 74 Emory Law Journal (2025; forthcoming); https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5113487.
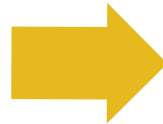
The Use of New Technology to Enhance User Literacy

Food Labeling

- Use of modern technology like apps

AI/ML-Based Medical Device Labeling

- Use of modern technology like apps

Technology, such as apps or online tools, can additionally be utilized to enhance user literacy

➢ **User-friendly**

➢ **Transparent about the methods used**

➢ **Made available by a federal agency like the FDA or independent third party**

Thin Crust Mushroom & Truffle Oil Frozen Pizza - 14.9oz - Good & Gather™
Pizza | Target

DiGiorno Pepperoni Frozen Pizza with Hand Tossed Style Crust - 18.7oz
Pizza | Target

Sara Gerke, *A Comprehensive Labeling Framework for Artificial Intelligence (AI)/Machine Learning (ML)-Based Medical Devices: From AI Facts Labels to a Front-Of-Package AI Labeling System—Lessons Learned From Food Labeling*, 74 Emory Law Journal (2025; forthcoming); https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5113487.

Additional Labeling

Food Labeling

→ **AI/ML-Based Medical Device Labeling**

- Additional Labeling

- Additional Labeling

Examples:

- **Name of the product, its ingredients, manufacturer/distributor/packer information, and the net quantity of contents**
- **Specific health or nutrient content claims**
- **Leaflets and manuals, website links, or QR codes on the food package**

(1) Instructions for Use

(2) Fact Sheet for Patients

(3) Labeling for AI/ML-Generated Content

Sara Gerke, *A Comprehensive Labeling Framework for Artificial Intelligence (AI)/Machine Learning (ML)-Based Medical Devices: From AI Facts Labels to a Front-Of-Package AI Labeling System—Lessons Learned From Food Labeling*, 74 Emory Law Journal (2025; forthcoming); https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5113487.

The Life Cycle of Health AI/ML-Based Products

Health AI/ML-Based Products

Postmarket

Premarket

Life Cycle

1. **Medical Device?**

2. **Regulatory Pathway & Requirements?**

3. **Marketing Authorization**

Adapted from: Sara Gerke, *Health AI For Good Rather Than Evil? The Need For a New Regulatory Framework For AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 433 (2021).
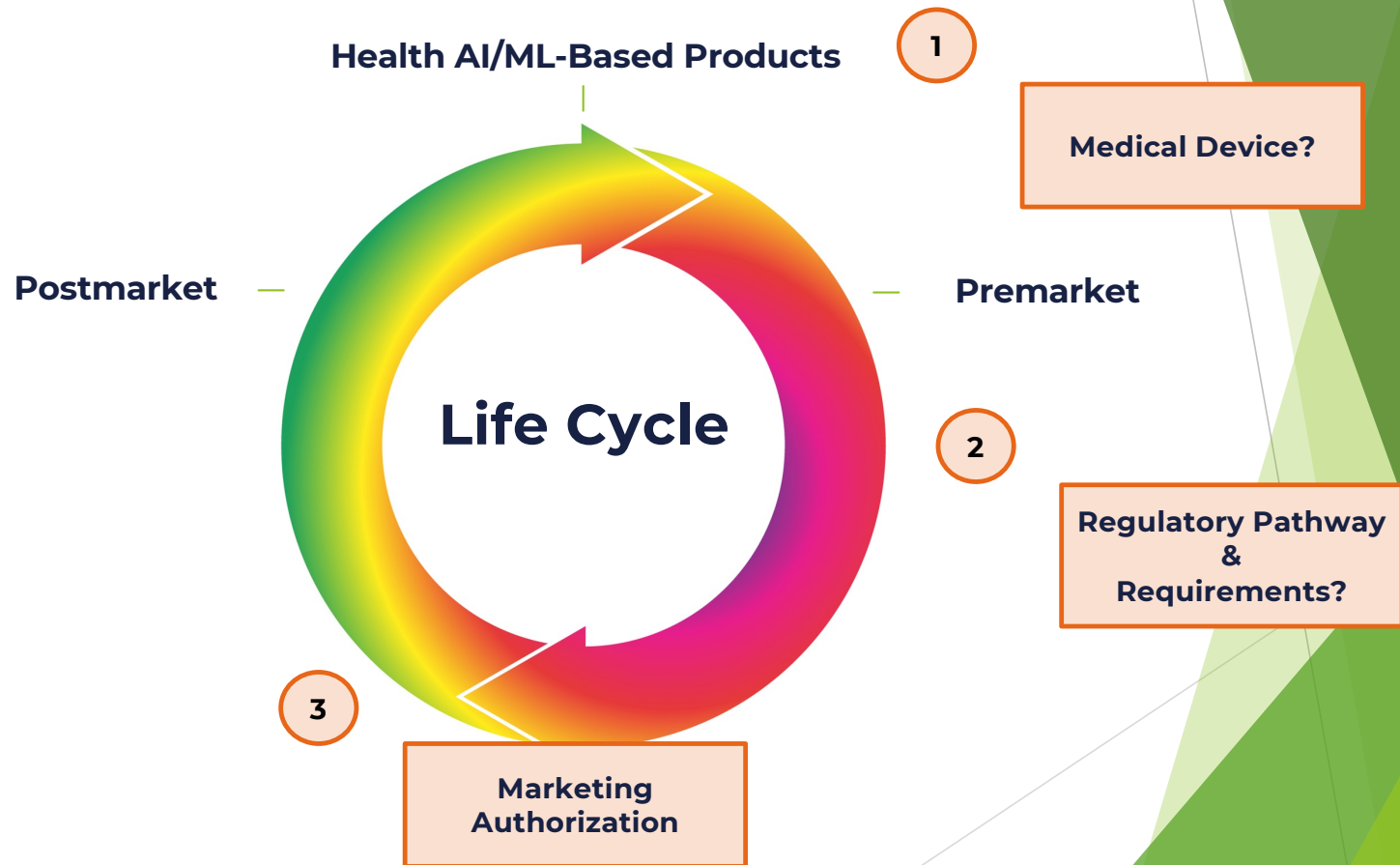
FDA Marketing Authorization

Date of Final Decision	Submission Number	Device	Company	Panel (lead)	Primary Product Code
08/21/2013	DEN130013	VITEK MS	BIOMERIEUX, INC.	Microbiology	PEX
11/17/2014	DEN140025	BrainScope Ahead 100	BRAINSCOPE COMPANY, INC	Neurology	PIW
04/06/2017	DEN160026	23andMe Personal Genome Service (PGS) Genetic Health Risk Test for Hereditary Thrombophilia	23andMe, Inc.	Immunology	PTA
03/16/2018	DEN160044	Acumen Hypotension Prediction Index (HPI) Feature Software	Edwards Lifesciences LLC	Cardiovascular	QAQ
07/19/2017	DEN170022	QuantX	Quantitative Insights, Inc	Radiology	POK
06/12/2018	DEN170043	DreaMed Advisor Pro	DreaMed Diabetes, Ltd.	Clinical Chemistry	QCC
02/13/2018	DEN170073	ContaCT	Viz.AI, Inc.	Radiology	QAS
12/28/2018	DEN170091	EyeBOX	Oculogica, Inc.	Neurology	QEA
04/11/2018	DEN180001	IDx-DR	IDx, LLC	Ophthalmic	PIB
05/24/2018	DEN180005	OsteoDetect	Imagen Technologies, Inc.	Radiology	QBS
02/07/2020	DEN190040	Caption Guidance	Bay Labs, Inc.	Radiology	QJU

FDA, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.

Total: 1,016 AI/ML-Based Medical Devices

510(k): 980
De Novo: 32
PMA: 4

Current Applications

LumineticsCore™

Current Applications

Brainomix
360 Triage ICH

Image Credit: https://www.brainomix.com/stroke/triage-ich/

Current Applications

Apple's ECG App

Image Credit: https://support.apple.com/en-us/HT208955

Key Areas of Applications

Clinical Care

Direct-To-Consumer (DTC) Uses

AI

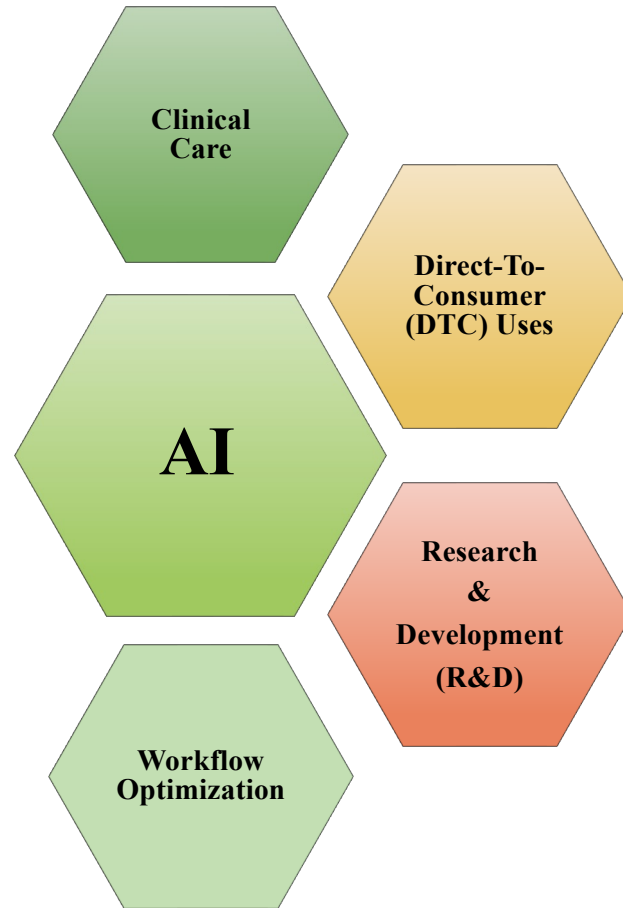**Research & Development (R&D)**
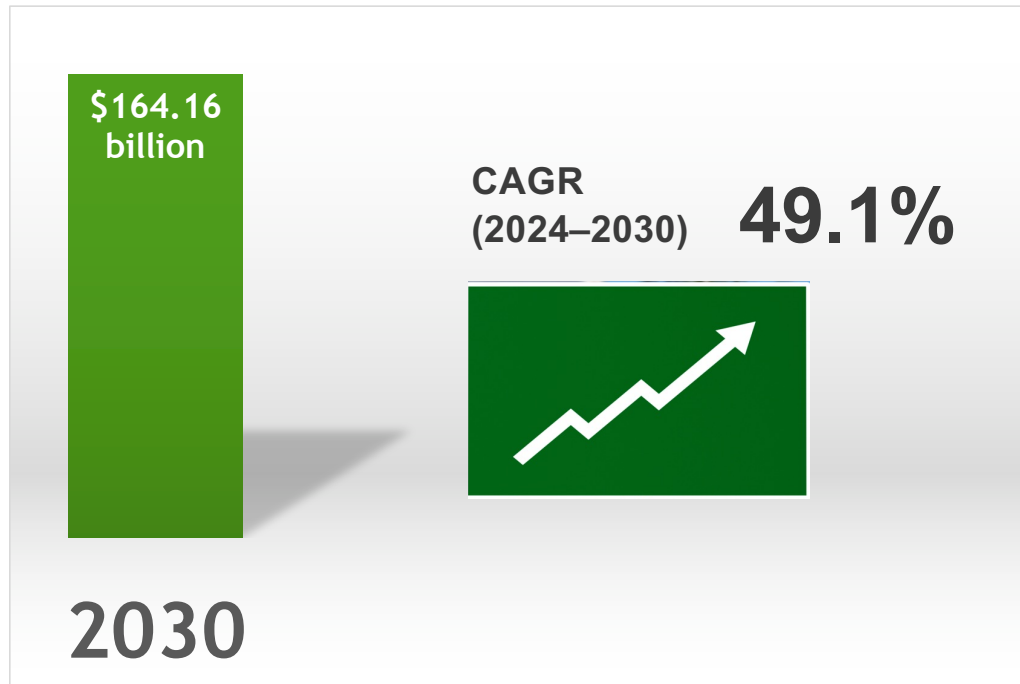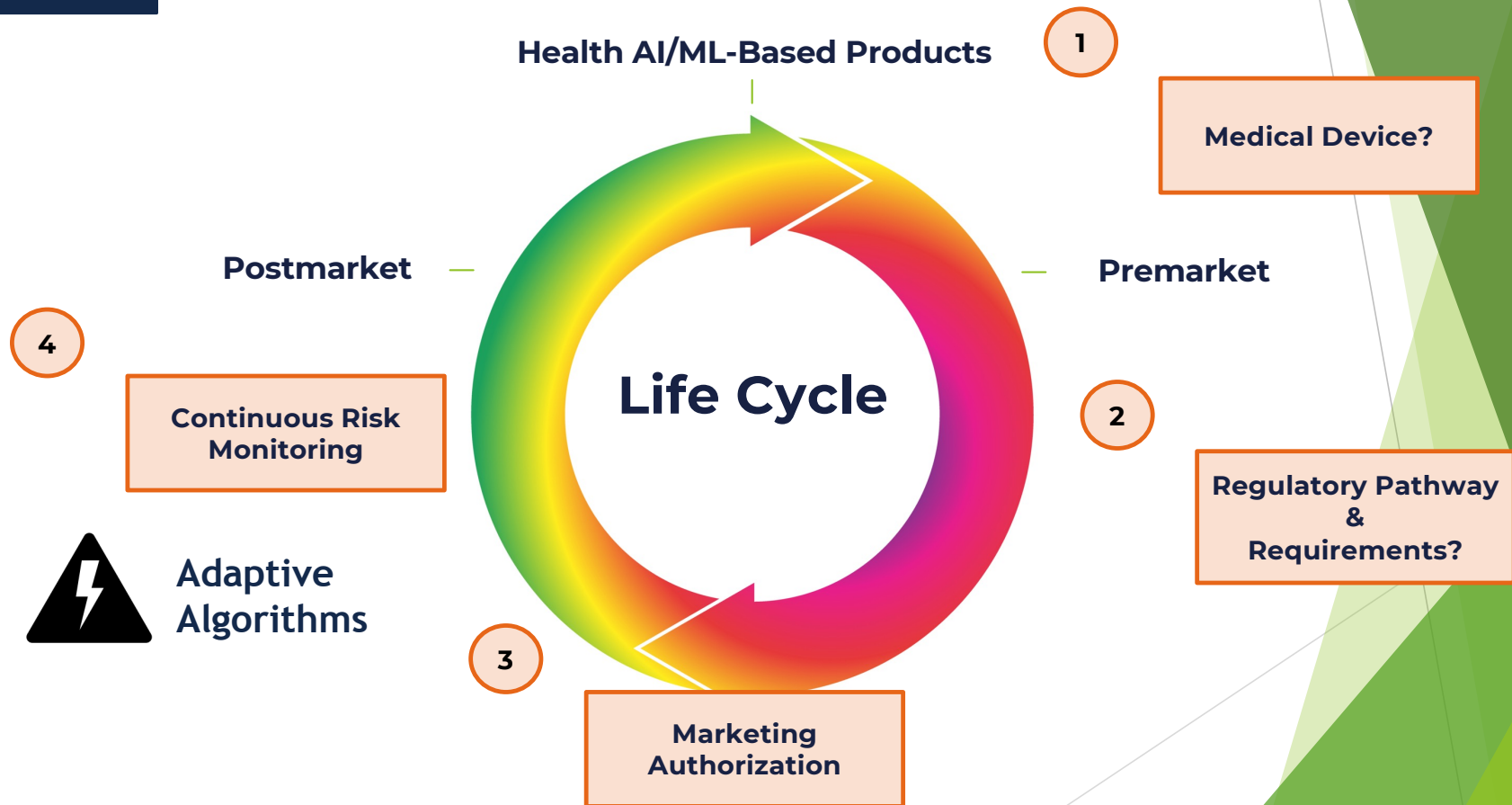
Workflow Optimization

Figure: Sara Gerke, "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices—The Urgent Need for Labeling Standards, 91 The George Washington Law Review 79 (2023).
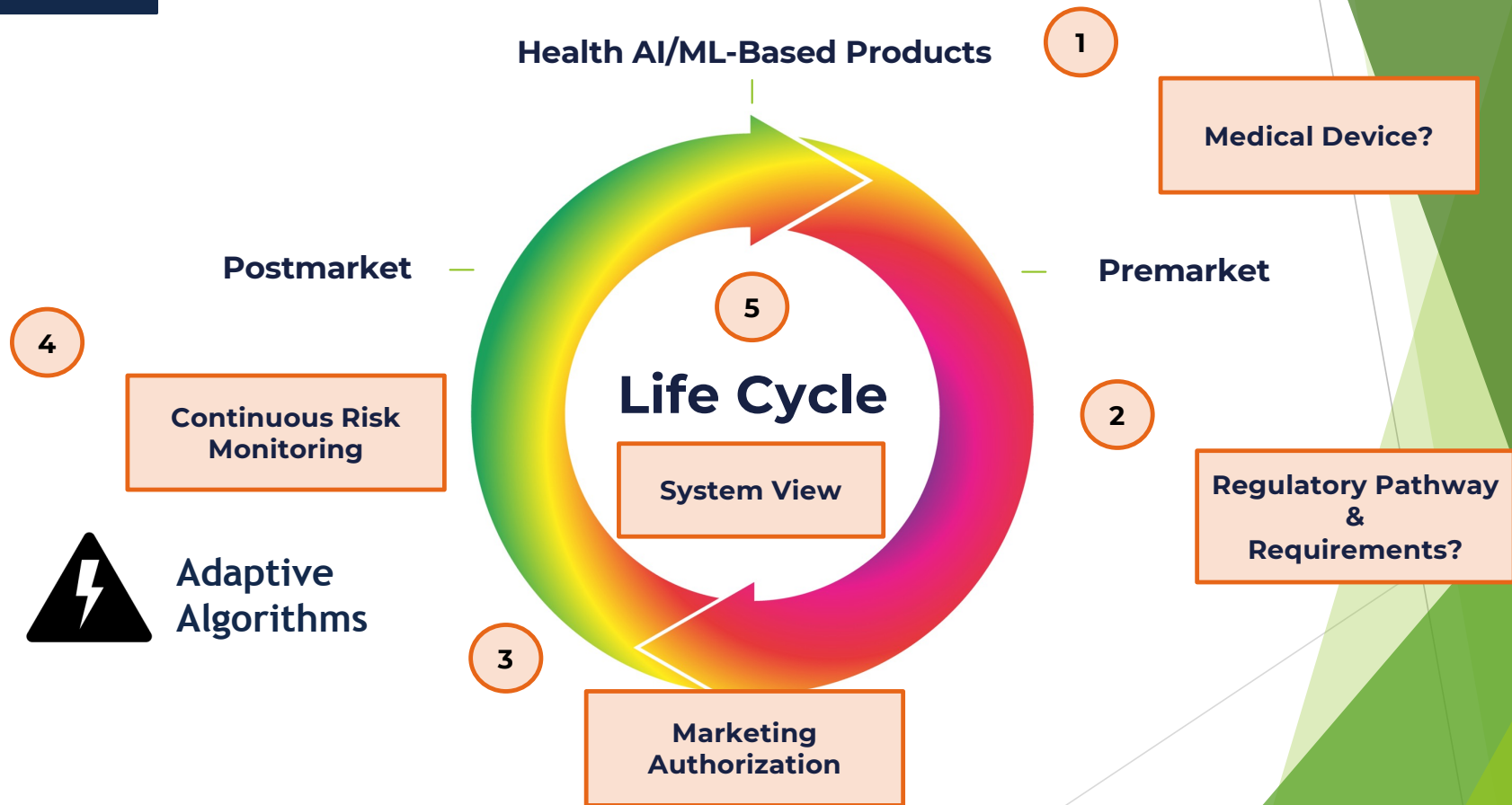
Global Health Care AI Market

$164.16 billion

CAGR (2024–2030) **49.1%**

2030

The Life Cycle of Health AI/ML-Based Products

Health AI/ML-Based Products

Life Cycle

Postmarket — — Premarket

1 — Medical Device?

2 — Regulatory Pathway & Requirements?

3 — Marketing Authorization

4 — Continuous Risk Monitoring

⚠ Adaptive Algorithms

Adapted from: Sara Gerke, *Health AI For Good Rather Than Evil? The Need For a New Regulatory Framework For AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 433 (2021).

The Life Cycle of Health AI/ML-Based Products

Health AI/ML-Based Products

1 Medical Device?

Postmarket — **Life Cycle** — **Premarket**

System View

4 Continuous Risk Monitoring

⚠️ Adaptive Algorithms

5

2 Regulatory Pathway & Requirements?

3 Marketing Authorization

Adapted from: Sara Gerke, *Health AI For Good Rather Than Evil? The Need For a New Regulatory Framework For AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 433 (2021).
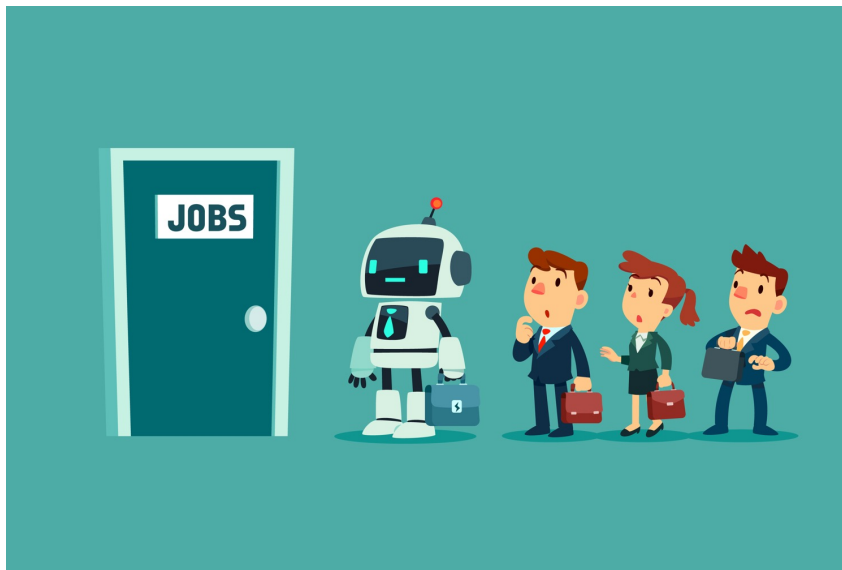
System View

> Regulators like the FDA need to **widen their scope** from evaluating medical AI/ML-based products to **assessing systems.**

Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen, The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device, 3 NPJ DIGIT. MED. Article number: 53 (2020); Photo credit: © blocberry - stock.adobe.com

Case Problem

Regulation of AI/ML-Based Medical Devices

Imagine you are the FDA-equivalent authority in the country Amor. You are considering how best to regulate AI/ML-based medical devices, and you have the statutory authority to fully implement any approach you like.

1. What would you ask AI makers about the data used to train algorithms? How would you check for biases and mitigate them?

2. How would you regulate black-box algorithms? Would you permit the marketing of AI/ML black boxes? If so, under what conditions?

3. How would you regulate adaptive algorithms that can continuously learn and adapt to new conditions? How would you ensure that such AI/ML systems are safe and effective when placed on the market and remain so throughout their lifecycle? How would you monitor such systems?

4. How would you ensure that an AI/ML system is safe and effective when used in different settings (e.g., in a rural hospital and a specialist clinic)?

5. Is there anything else you would like to regulate to ensure that AI/ML-based medical devices are safe and effective throughout their entire lifecycle?
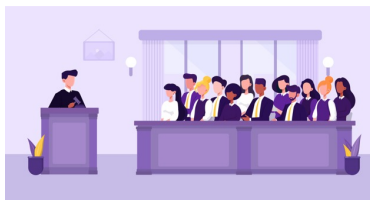
Liability
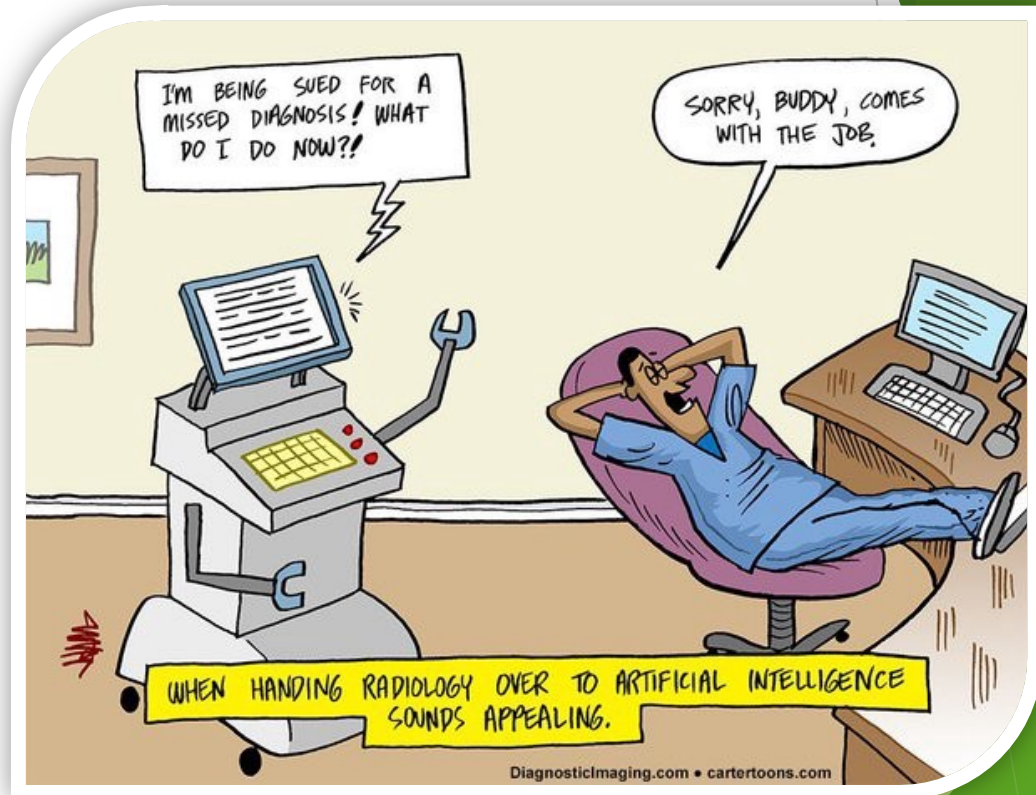
Examples of Potential Legal Outcomes Related to AI Use in Clinical Practice

Scenario	AI recommendation	AI accuracy	Physician action	Patient outcome	Legal outcome (probable)
1	Standard of care	Correct	Follows	Good	No injury and no liability
2			Rejects	Bad	Injury and liability
3		Incorrect (standard of care is incorrect)	Follows	Bad	Injury but no liability
4			Rejects	Good	No injury and no liability
5	Nonstandard care	Correct (standard of care is incorrect)	Follows	Good	No injury and no liability
6			Rejects	Bad	Injury but no liability
7		Incorrect	Follows	Bad	Injury and liability
8			Rejects	Good	No injury and no liability

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *How Much Can Potential Jurors Tell Us about Liability for Medical Artificial Intelligence?*, 62 THE JOURNAL OF NUCLEAR MEDICINE 15 (2021).
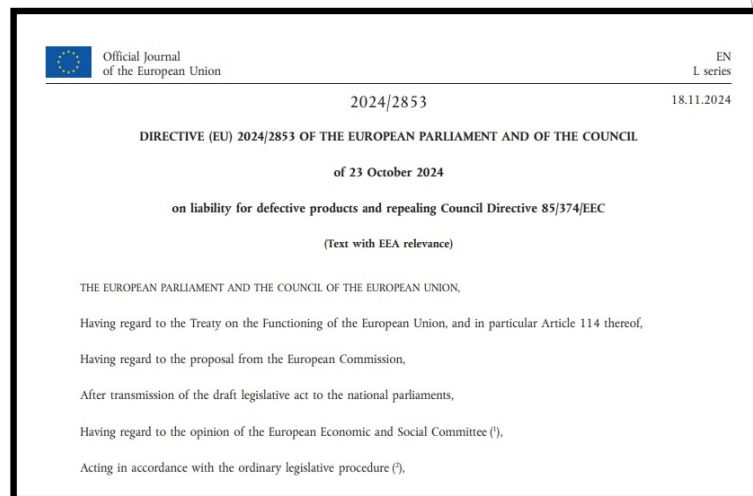
Ecosystem of Liability

Liability

- Physicians
- Hospitals
- AI Developers

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).

Recent Developments in the EU

https://commission.europa.eu/system/files/2022-09/1_1_197605_prop_dir_ai_en.pdf

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202402853

Recent Developments in the EU

PERSPECTIVE   **OPEN**

The proposed EU Directives for AI liability leave worrying gaps likely to impact medical AI

Mindy Nunez Duffourc [1,2] and Sara Gerke [1]✉

Two newly proposed Directives impact liability for artificial intelligence in the EU: a Product Liability Directive (PLD) and an AI Liability Directive (AILD). While these proposed Directives provide some uniform liability rules for AI-caused harm, they fail to fully accomplish the EU's goal of providing clarity and uniformity for liability for injuries caused by AI-driven goods and services. Instead, the Directives leave potential liability gaps for injuries caused by some black-box medical AI systems, which use opaque and complex reasoning to provide medical decisions and/or recommendations. Patients may not be able to successfully sue manufacturers or healthcare providers for some injuries caused by these black-box medical AI systems under either EU Member States' strict or fault-based liability laws. Since the proposed Directives fail to address these potential liability gaps, manufacturers and healthcare providers may have difficulty predicting liability risks associated with creating and/or using some potentially beneficial black-box medical AI systems.

https://www.nature.com/articles/s41746-023-00823-w

Decoding U.S. Tort Liability in Healthcare's Black-Box AI Era: Lessons from the European Union

Mindy Duffourc[*] & Sara Gerke[**]

ABSTRACT

The rapid development of sophisticated artificial intelligence ("AI") tools in healthcare presents new possibilities for improving medical treatment and general health. Currently, such AI tools can perform a wide range of health-related tasks, from specialized autonomous systems that diagnose diabetic retinopathy to general-use generative models like ChatGPT that answer users' health-related questions. On the other hand, significant liability concerns arise
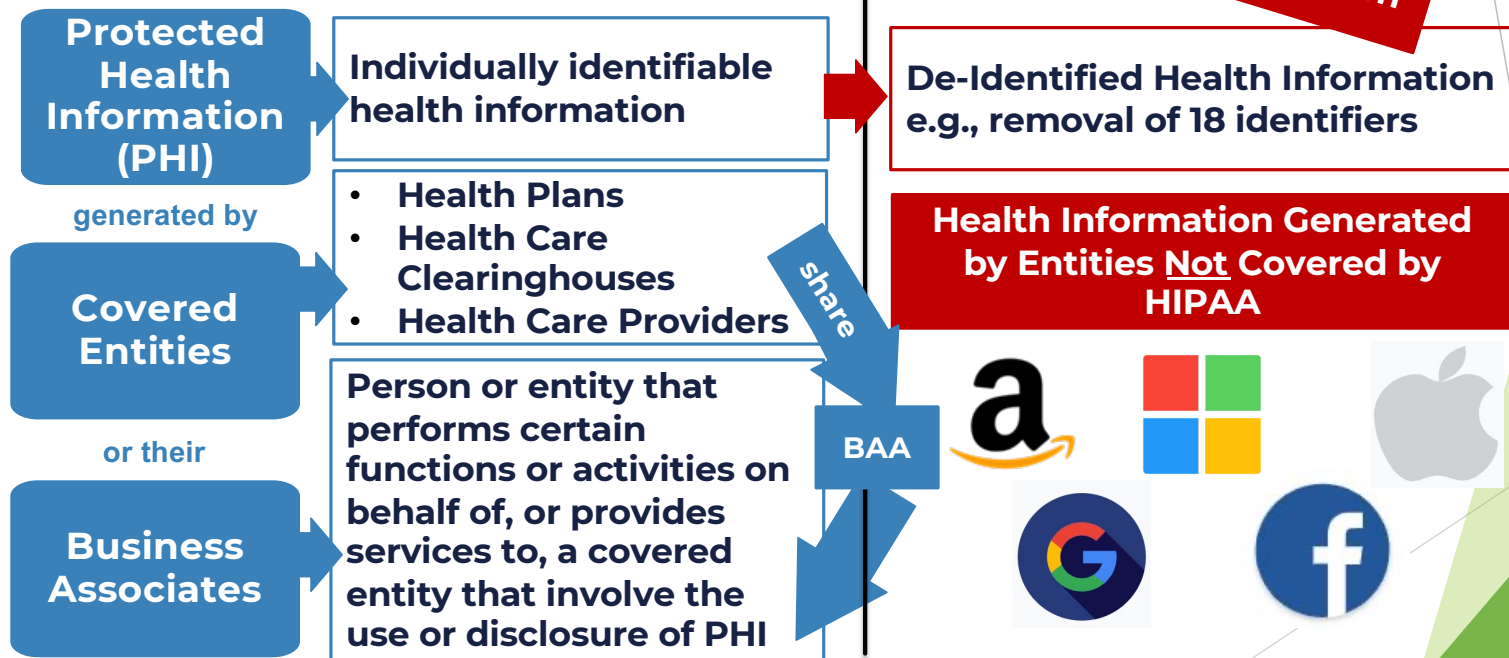
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4569698

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Data Privacy

HIPAA

Health Insurance Portability and Accountability Act

Data Triangulation

Protected Health Information (PHI)

Individually identifiable health information

De-Identified Health Information e.g., removal of 18 identifiers

generated by

- **Health Plans**
- **Health Care Clearinghouses**
- **Health Care Providers**

Covered Entities

Health Information Generated by Entities Not Covered by HIPAA

share

or their

Business Associates

Person or entity that performs certain functions or activities on behalf of, or provides services to, a covered entity that involve the use or disclosure of PHI

BAA

Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare, in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020); Photo credit: ©Tatyana - stock.adobe.com

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Data Privacy

GDPR

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- Has been applied since **25 May 2018 in all EU Member States**

- **Protects fundamental rights and freedoms of natural persons** and in particular their **right to the protection of personal data** (Art. 1(2))

- **Broad material & territorial scope** (Arts. 2, 3)
  - ➢ **Impact on U.S. entities** (e.g., processing activities are related to the offering of goods or services to data subjects in the EU)

Data Privacy → **Legal Developments to Protect Privacy in the U.S.**

California CCPA

Photo Credit: https://redcloveradvisors.com

Became effective on **January 1, 2020**

⬇

Grants various rights to California residents with regard to **personal information that is held by businesses**

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This image was created with the assistance of DALL E.