April 7, 2025

The Honorable Marty Makary, M.D.
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

RE: Consideration for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products, Guidance for Industry and Other Interested Parties

Submitted electronically via regulations.gov

Dear Dr. Makary:

The Health Innovation Alliance (HIA) is pleased to submit comments to the draft guidance document, *Consideration for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products*. HIA encourages the Trump administration to accelerate the use of artificial intelligence and similar tools (AI) in health care with federal resources and incentives and to take a commonsense regulatory approach using existing authorities that balance safety and effectiveness while allowing for continued innovation and efficiency. Specifically, we believe the Food and Drug Administration (FDA) should harness the power of AI to improve the regulatory process and efficiency related to drug and biologics policy.

HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers working together to improve health care through the commonsense use of data and technology. Founded in 2007, HIA has been a stalwart supporter of health information technology and interoperability, having worked on key legislation ranging from the HITECH Act to the 21st Century Cures Act.

We are particularly pleased with the FDA's embrace of a risk-based approach to AI that varies according to the context of use. This is exactly the type of approach necessary to consider the vast variation across these tools, their capabilities, their applications, and the specifics of each application. We are attaching our recent report on AI use cases for your reference, which provides more justification and support for this approach to AI regulation, as well as our principles for regulating AI in health care.

HIA is excited about the impact AI is having on the health community and its potential to address many of health care's most challenging problems, particularly for administrative burden, provider burnout, and provider shortages. For too long, the health care industry has faced increasingly complex regulations and compliance burdens due to an expanding and seemingly endless government bureaucracy. The Trump administration is uniquely situated to recast federal health technology policy and reorient to market-driven, practical approaches rather than a top-down, government-led system.

Health care is a hyperregulated industry, and numerous existing authorities are already governing the use of AI in health care. The Biden administration began this expansion by creating the Assistant Secretary for Technology Policy (ASTP), which issued AI policies that conflicted with existing ones at the FDA. In particular, several requirements on AI from ASTP take a "function-based" approach, where any technology that possesses machine learning or AI functionality is subject to increased regulatory requirements. In contrast, the

FDA has taken a risk-based approach to regulating medical products for decades. HIA believes this is the correct approach to AI and urges the Trump administration to use existing authorities at HHS, particularly the FDA, to streamline regulatory processes where possible to encourage the proliferation of AI technology.

The volume of current and potential uses of AI in health care – and the different forms these AI tools take given the dynamic circumstances of each health care encounter or transaction – underscores the need to view health care AI with a risk-based lens and an adaptive regulatory model. There is no way to regulate AI in a one-size-fits-all approach, and we encourage the FDA to be flexible as we learn the true utility and limitations of AI tools. By adhering to our principles, particularly related to transparency, the FDA can be sure to find balance between ensuring the safety and effectiveness of products while protecting IP.

Finally, we encourage the Trump administration to invest in AI across the health care industry. Without support from the government, we run the risk of only the largest or wealthiest health care organizations adopting AI tools. Artificial intelligence should be available throughout, including in less resourced areas like rural and behavioral health care. Since health care currently constitutes one-third of non-defense spending, HIA believes the investment can come from one-third of non-defense AI spending.

We thank FDA for the opportunity to respond to this draft guidance, and we look forward to working with you to achieve American AI dominance and excellence in health care.

Sincerely,

Brett Meeks
Executive Director

HEALTH INNOVATION ALLIANCE

Principles for the Use of Artificial Intelligence in Health Care and Life Sciences

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HEALTH INNOVATION ALLIANCE

About
Health Innovation Alliance

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs.

Formed in 2007, HIA has been on the front lines of federal policy related to healthcare technology and interoperability since our inception. HIA staff and members have helped pass the original Health Information Portability and Accountability Act (HIPAA), helped influence the Health Information Technology for Economic and Clinical Health (HITECH) Act, and helped draft, negotiate, and pass the 21st Century Cures Act.

HEALTH INNOVATION ALLIANCE

Foreword

The Health Innovation Alliance is proposing principles for the regulation of artificial intelligence (AI) in health care and life sciences. We have been advocating for the improvement of health care through the commonsense use of data and technology since 2007.

Our organization represents stakeholders across the industry, from some of the largest names in health tech to small and resource-strapped patient advocates, and we work collaboratively with our members to promote consensus policies for adoption by the government.

At the outset of this project, we recognized that there are many opinions, frameworks, and principles already circulating about AI. However, HIA's principles differ in two ways: they are intended to guide Congress and the administration and are focused exclusively on the use of AI in health care.

AI has tremendous potential to relieve many symptoms afflicting the healthcare industry, such as administrative fatigue and rising compliance costs. Providers report increasing burnout and a need to spend nearly half of their time on paperwork or documentation rather than treating patients. AI tools can automate tasks, freeing up caregivers to spend more time in the exam room. HIA believes that technology and data can and will make health care better, and we are hopeful about the role AI will play in improving the lives of providers and patients alike.

Health care is a hyper-regulated industry, and AI has been present in health settings for at least a decade. Existing regulations are already being used to review AI products for use in health care. The Food and Drug Administration (FDA) has approved nearly 900 medical devices that include AI as of July 2024.[1] Despite this, there have been calls to pass new regulations specific to AI. HIA urges Congress to use existing authorities to continue regulating AI in health care and to learn more about the technology, its potential, and its limitations before passing further regulation of AI products.

HIA believes regulation under a risk-based approach is best for AI. The different solutions using AI need to be reviewed on a case-by-case basis: just because an AI model works in one application and setting does not mean it will work in another. AI is just a tool, and it is being adopted in different places under different circumstances by different people. Review of health AI solutions must take all these variables into account. The FDA is already using this type of analysis, and we look forward to working with the FDA, Congress, and others to ensure the advancement of innovative health AI products that are safe and effective.

Finally, government must support the private sector in developing, adopting, and maintaining AI tools in health care. The bipartisan Senate AI work group roadmap released in May 2024 recommends an annual investment of $32 billion to support non-defense AI innovation, adopting the recommendation of the National Security Council on Artificial Intelligence.[2] Health care takes up about a third of non-defense spending currently, and HIA recommends that at least $10 billion of this funding be reserved for AI in health care.

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[1] See https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

[2] Available at https://www.young.senate.gov/wp-content/uploads/Roadmap_Electronic1.32pm.pdf

This funding will be needed to promote access to technology and help ensure that health AI is available broadly and not just by organizations with more resources. Healthcare organizations across the country will need support not just in acquiring these technologies, but also in supporting them. The government will need to encourage access to supporting technologies like cloud services and graphics processing units and support the ability of organizations to monitor and maintain AI tools.

HIA is excited about the future of health care, and we look forward to working with Congress and the administration to ensure the commonsense regulation and robust use of AI in the health industry.

AI Principles

HEALTH INNOVATION ALLIANCE

Risk-Based

- AI in health care should be regulated according to a context-dependent, risk-based approach.
    - Lower-risk use cases of AI may not require human oversight, particularly when the use case is administrative and has little to no impact on patient outcomes.

    - When used without a human in the loop, the use of AI to diagnose or treat patients is not low risk.

Transparent

- Individuals should have access to information about AI being used in health care, including the AI's intended use and limitations.
    - Patient- or consumer-facing information to improve AI transparency should be accessible to and capable of being easily understood by a reasonably informed individual.

- Transparency requirements in AI should not require the publication of proprietary information or trade secrets.

- Developers of AI should create documentation sufficient to inform users about the tools. This documentation should include information about fairness, bias, privacy, security, intended use constraints, necessary oversight requirements, and functionality limitations.

- Regulators should be able to assess AI models intended for use in health care to determine safety, effectiveness, reliability, and limitations.
    - In the event a regulator believes information is required for an assessment that an AI developer maintains is proprietary, the regulator must provide reasonable safeguards and protections to preserve confidentiality.

    - Information required to assess an AI model deployed or intended for deployment in health care should be reasonably limited to the purpose of that particular assessment.

Private

- AI use of health information should be compliant with all applicable privacy and security laws and regulations, such as the rules promulgated under HIPAA, and should follow patient preference through existing authorization and consent processes.

- Use of identifiable health information to train an AI model should be authorized by the individual through existing consent requirements.

Responsible

- Both developers and deployers should adopt and adhere to responsible and reasonable best practices throughout the development and deployment of AI models in health care.

- Government should work with the AI developers and deployers to encourage the development and adoption of AI best practices and processes.

- Developers of AI models for use in health care should participate in the development and coordination of best practices for the responsible use of AI models.

- Deployers of AI in health care should be responsible for the use of the AI models they deploy.
  - This includes testing of a model within the intended environment, on intended populations, for the intended use case, and;

  - Appropriately monitoring the models in use and implementing any necessary safeguards.

Equitable

- Developers and deployers of AI in health care should take reasonable effort to mitigate bias, and where possible, remove bias.

- AI should be tested in the environment and population intended for its use and monitored for bias and inequity while in use.

- AI should be accessible and usable by the entire health care community – not just those who can afford it.
    - Government should provide resources to encourage the adoption, deployment, and use of AI in health care, including supporting technologies and services, to facilitate equitable adoption.

    - Government should provide resources for both the development of best practices and management protocols as well the adoption, implementation, and management of those best practices and management protocols in health care.

Acknowledgements

These principles were made possible through the substantial contributions and thoughtful discussion of the workgroup members. While participation in the workgroup does not imply affiliation with or endorsement of the recommendations in this report, HIA wishes to thank the following organizations who participated in the AI Workgroup process:

- Association of Behavioral Health and Wellness
- The Association of Clinical Research Organizations
- Altitude Ventures
- Amazon
- AstraZeneca
- athenahealth
- Autoimmune Association
- Avalon Healthcare Solutions
- Cambia Health Solutions
- Cancer Support Community
- CoverMyMeds
- Consumer Technology Association
- Digital Medicine Society
- Duke AI Health
- GO2 For Lung Cancer
- Greystone Group
- Healthcare Information and Management Systems Society
- iRhythm Technologies
- Maven Clinic
- Maverick Health Policy
- McKesson
- National Multiple Sclerosis Society
- National Council for Prescription Drug Programs
- Partnership to Fight Chronic Disease
- RELX
- STChealth
- Teladoc Health
- Tempus
- The Joint Commission
- The National Council for Mental Wellbeing
- United Spinal Association
- US Chamber of Commerce

Appendix

HEALTH INNOVATION ALLIANCE

Methodology

HIA held two workgroup meetings and numerous individual discussions over the first half of 2024, with more than 30 different participating organizations. Participants represented solutions providers, established tech companies, tech startups, patient advocates, pharmaceutical manufacturers, provider organizations, and others.

The purpose of the workgroup was to produce a set of principles for the use of AI in health care and life sciences. HIA staff proposed five subcategories, based on a review of existing AI frameworks, through which principles could be formatted: transparent, risk-based, private, responsible, and equitable.

During the first meeting in February 2024, participants raised several points within each category for consideration. Participants agreed that existing regimes such as HIPAA may be sufficient to adequately regulate AI, though other considerations on informing patients, and ensuring copyright protections and data ownership are necessary. There was also agreement that a risk-based approach would be best to manage and regulate AI, but significant attention would be needed to develop and deploy AI models responsibly and minimize bias.

The second meeting of the workgroup was held on March 21, 2024. HIA staff reviewed existing principles for AI and created a summary document to help inform the workgroup. We reviewed and discussed AI principles from outside organizations during this meeting.

Participants also discussed the types of information needed by patients and regulators to understand and oversee AI tools, respectively, and how risk levels vary with clinical uses of AI. There was again agreement that HIPAA is sufficient to address privacy concerns, though de-identification of data and internal governance are key considerations.

A recurring theme was the need to monitor AI models for drift to avoid bias, and that data selection affects the development and may limit the breadth of final use cases.

On June 4, 2024, HIA staff introduced an initial draft principles document based on the discussion and feedback from participants throughout the workgroup process. After robust feedback and discussion with participants, HIA crafted the principles included here.

Industry Principles Review

The following is a review of AI principles released by various organizations within or relevant to the health care community. The purpose of this document is to catalog publicly available positioning on health care AI to inform the workgroup. This list is not exhaustive, and some information may be outdated. The following is an interpretive summary and is not intended to directly represent the thinking of any organizations listed or to be an endorsement of any specific position by any of the organizations listed.

The chart below reflects which organizations principles or best practices touched on each of the listed topic areas.

Breakdown				
Transparency	**Risk-Based**	**Private**	**Responsible**	**Equitable**
AAFP	AAFP	AAF	AAFP	AAFP
ACRO	ACRO	AdvaMed	ACRO	ACRO
AMA	AMA	ATA	AMA	AdvaMed
ATA	ATA	AWS	ATA	AMA
AWS	AWS	BastionGPT	AWS	ATA
BastionGPT	BastionGPT	Biden EO	BastionGPT	AWS
CHI	CHI	CHI	Biden EO	Biden EO
EU AI Act	EU AI Act	IFPMA	Forbes	CHI
Forbes	Forbes	Merck	IFPMA	Google
IFPMA	IFPMA	Microsoft	Merck	IFPMA
Merck	Merck	Optum	Microsoft	Merck
Microsoft	Microsoft	OSTP	ONC	Microsoft
ONC	ONC	Pfizer	Optum	Optum
Optum	Optum	RELX	Philips	OSTP
OSTP	Philips	Roche	Roche	Pfizer
Pfizer	RELX	WHO	WHO	Philips
Philips	Roche			RELX
RELX	WHO			Roche
Roche				WHO
WHO				

Organizations included:

- American Academy of Family Physicians (AAFP)
- Association of Clinical Research Organizations (ACRO)
- AdvaMed
- American Medical Association (AMA)
- American Telemedicine Association (ATA)
- Amazon Web Services (AWS)
- BastionGPT
- President Biden Executive Order on AI (Biden EO)
- Connected Health Initiative (CHI)
- European Union AI Act (EU AI Act)
- Forbes
- Google
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Merck
- Microsoft
- Office of the National Coordinator for Health Information Technology (ONC)
- Optum
- White House Office of Science and Technology Policy (OSTP)
- Pfizer
- Philips
- RELX
- Roche
- World Health Organization (WHO)

Transparency

Major Themes			
Governance & Best Practice	**Inform that AI is Used**	**Disclose/Publish Inner Workings**	**External Oversight & Review**
AMA, AWS, EU, ONC, RELX — governance policies are necessary, best practices also helpful	*ACRO, AWS, Google, IFPMA, Merck, Microsoft ONC, Philips, RELX, Roche, WHO* — Disclose how AI is used in a process, inform about AI-generated content.	*AAFP, ATA, AWS, Forbes, Microsoft, RELX* — Disclose how data is processed, how algorithms developed, design system to enable that.	*AWS, BastionGPT, CHI, RELX, Roche, WHO* — All think that there should be healthcare/ other experts vigilant/reviewing.
		[similar thought, but all don't say the above] *IFPMA, OSTP, Pfizer,* — End-user must understand how they are impacted, understand limitations.	*OSTP* — Goes further to say independent evaluation is needed.

Risk-Based			
Major Themes			
Risk-based Approach	**Oversight, Testing, Compliance**	**Patient Safety**	**Cybersecurity, Data Security**
AAFP, AMA, CHI, EU, Merck, RELX — Agreement on risk-based approach in some capacity	*ACRO, BastionGPT, Forbes, Merck, Microsoft, Optum, Philips, RELX, Roche, WHO* — Human oversight necessary	*BastionGPT* — No communication with patients unless very strictly controlled.	*WHO* — Cybersecurity and safety of data takes precedence.
AAFP — Companies should take on liability based on the risk, accounting for role of AI/ML in the process	*AMA, AWS, IFPMA* — Level of oversight should be proportionate to risk	*Merck, RELX* — Goal of all systems to benefit people without harm.	*RELX* — We respect privacy champion robust data governance
Microsoft, RELX — Impact assessment on our AI, oversight of significant adverse impacts, data/management practices.	*Microsoft, Optum, OSTP, RELX* — Emphasis on testing before deployment and afterward		
AWS, RELX — Organization's role to define, implement, and enforce responsible AI practices	*ATA* — Clear regulation and uniform compliance		

Private			
Privacy of Patients/Users	**Health System Policies**	**Consent**	**Built-In Privacy Protections**
AAF, AdvaMed, BastionGPT, CHI, IFPMA, Merck, Microsoft, Pfizer, WHO — Agree privacy is needed to protect patients. Never compromised.	*CHI* — Modern privacy framework	*AAFP, CHI, Google, OSTP, WHO* — Consent in use of Data with AI	*AWS, Google, Microsoft, Optum, OSTP, Pfizer, RELX* — Incorporate privacy practices into AI Systems/Policies
Optum, OSTP, Biden EO, Roche — Protect data privacy, but no mention of patients.	*WHO* — Adopt new legal frameworks		
AWS, RELX — Data protected from theft and exposure (all uses)	*ATA, BastionGPT, IFPMA* — Utilize current system policies/regulations.		

Responsible			
Development & Deployment	**Organizational Accountability**	**Responsible Advancement of AI**	**Governance**
AMA, AWS, Biden EO, Google, Merck, Microsoft, WHO, RELX — Agree that responsible development and deployment is necessary to ensure safety	*AAFP, ACRO, ATA, AWS, Google, IFPMA, Merck, Microsoft, Optum, RELX, Roche, WHO* — It is the organization's responsibility to maintain rigorous evaluation of AI/ML safety.	*AWS, Biden EO, Merck, RELX* — Build policies that ensure responsible innovation and use of AI/ML	*AMA, Optum* — Develop a national governance applying to all AI/ML Solutions
ONC — Fair, Appropriate, Valid, Effective, Safe (FAVES) principles in deployment			*AWS, ACRO, Google, Merck, RELX, Roche* — Organizations should develop their own governance teams
ACRO — Orgs develop teams to govern Dev. & Deployment.			

Equitable		
Reduce Bias in Design + Development	**Use AI to Reduce Inequities**	**AI should be Ethical**
ACRO, AAFP, AdvaMed, AMA, ATA, AWS, CHI, Google, IFPMA, Merck, Microsoft, Optum, OSTP, Pfizer, Philips, RELX, Roche, WHO —— Avoid bias in design and development	*Biden EO, Google,* —— Don't exacerbate existing inequities	*General Agreement* —— AI design, deployment, and use should be ethical
AAFP, CHI, IFPMA, Philips, RELX, Roche —— Training data should be diverse and representative.	*AMA, AWS, RELX* —— Avoid bias in deployment and use	
ATA, AWS, RELX —— Make publicly available information to show algorithms and outputs are free from bias. Perhaps necessary for policy for transparent exposure of bias.	*AdvaMed, Optum* —— Reduce health disparities	
Optum —— Designers, developers and deployers must protect from algorithmic discrimination	*Pfizer* —— Actively design and use AI systems to promote equity	

Resources

ACRO: https://www.acrohealth.org/wp-content/uploads/2023/12/ACRO-AI-Principles-Final.pdf

AAFP: https://www.aafp.org/about/policies/all/ethical-ai.html

AMA: AMA Principles for Augmented Intelligence Development, Deployment, and Use (ama-assn.org)

ATA: AMERICAN TELEMEDICINE ASSOCIATION PUBLISHES NEW ARTIFICIAL INTELLIGENCE (AI) PRINCIPLES - ATA

AWS: https://aws.amazon.com/machine-learning/responsible-ai/

BastionGPT: Generative AI Healthcare Principles (bastiongpt.com)

ConnectedHealth Initiative (CHI): Policy-Principles-for-AI.pdf (connectedhi.com)

European Union AI Act: The Act Texts | EU Artificial Intelligence Act

Forbes Walter Kluwer Four Guiding Principles for Generative AI: Do No Harm: Four Principles For Adopting Generative AI In Healthcare (forbes.com)

Google: https://ai.google/responsibility/principles/

IFPMA: IFPMA Artificial Intelligence Principles - IFPMA

Merck: AI_MRK_MAY23docx.pdf (merck.com)

Microsoft: Responsible AI Principles and Approach | Microsoft AI

ONC Health Sector Commitments: https://www.healthit.gov/sites/default/files/2023-12/Health_Sector_AI_Commitments_FINAL_120923.pdf

Optum Responsible Use of AI: Ensuring Responsible Use of AI in Health Care | Optum

OSTP AI Bill of Rights: https://www.whitehouse.gov/ostp/ai-bill-of-rights/

Pfizer Principles: Artificial Intelligence (AI) Responsibility in Healthcare is Critical | Pfizer

Philips 5 Guiding Principles for Responsible Use of Ai in Healthcare and Healthy Living: Five guiding principles for responsible use of AI in healthcare and healthy living - Blog | Philips

RELX: relx-responsible-ai-principles-0622.pdf

Roche: Roche AI Ethics Principles-UX formatted

WHO Ethics and Governance of AI for Health: Ethics and governance of artificial intelligence for health (who.int)

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HEALTH INNOVATION ALLIANCE

Use Cases for AI Tools to Improve Health Care

March 2025

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HEALTH INNOVATION ALLIANCE

About
Health Innovation Alliance

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, health care providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs.

For 18 years, HIA has been a leader on federal policy related to health care technology and interoperability. HIA staff and members successfully ushered through the original Health Information Portability and Accountability Act, influenced the Health Information Technology for Economic and Clinical Health Act, and drafted, negotiated, and passed the 21st Century Cures Act.

HEALTH INNOVATION ALLIANCE

Introduction

Artificial intelligence (AI) models present tremendous opportunities to make the American health care system the best in the world. From increasing novel drug discoveries through AI-created problem solving that has already figured out protein folding – a biological process that has eluded scientists for over 50 years – to cleaning up the processes surrounding care delivery, coverage, and payment, AI can help us break through some of the health care industry's most entrenched problems. Take physician burnout – ninety-three percent of physicians regularly feel burned out, and over half would prefer to quit or at least stop seeing patients.[1] One of the largest contributors to this sentiment is documentation and compliance burden: doctors and their teams spend more time doing paperwork to get paid by insurers or comply with government rules than caring for patients. AI models are helping to address this problem with clinicians reporting a significant reduction in documentation burden after incorporating AI tools.[2]

In 2024, HIA formed a working group of more than 30 different organizations to produce a set of principles for the use of artificial intelligence (AI) in health care and life sciences:

- **Risk-Based Approach**: Regulation of AI in health care should be proportionate to risk
- **Transparency**: Patients, users, and regulators of AI should have access to information about how technology is being used, but not to proprietary information
- **Privacy**: Any use of health information by AI should be compliant with current laws and regulations, including HIPAA
- **Responsibility**: Developers and users of AI programs in health care should adopt and adhere to best practices and processes
- Fairness: AI tools should ·should mitigate bias and be available for all users, not just those who can afford it

[1] https://www.athenahealth.com/resources/blog/ai-help-clinician-burnout
[2] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2830383

Since the release of HIA's principles, there has been increased interest in the safety of using AI in health care. To help guide those discussions and to highlight why AI should be regulated according to a context-dependent, risk-based approach, HIA examined currently available AI health care tools and their uses through the lens of the life cycles patients, drugs, and medical devices undergo in our health care system.

The following report serves as a catalog of AI use cases, exploring the different types of AI tools that are and can be used across the healthcare system. HIA strongly believes these cases highlight the need for AI oversight to follow a risk-based model to ensure product innovation and effectiveness while maintaining patient confidentiality.

Overview of Risk Analysis for Health Care

HEALTH INNOVATION ALLIANCE

Before exploring the considerations for artificial intelligence specifically, it is necessary to review the current state of risk analysis in health care more broadly.

Evaluating risk is necessary to ensure safety in patient care. Each step and process undertaken must be evaluated separately, ranging from diagnostic procedures performed by a clinician to diagnostic lab tests, pharmaceutical treatments, surgeries, imaging procedures, and more. Health information technology (health IT) solutions are present in many, if not all, of these processes to varying degrees – whether recording and transmitting or processing information.

Risk in the context of health IT solutions contemplates 1) the chance that output of a system will be inaccurate; 2) the likelihood or frequency of potential inaccuracy; and 3) the level of severity of the outcome resulting from an inaccurate output.[3] There are underlying assumptions in any quantification of risk, such as whether all available information was used to arrive at the outcome or output, and how information or sources were weighted to generate the output.

The Food and Drug Administration (FDA) currently evaluates risk for medical products as a part of its mission to assure their safety and effectiveness. More than 1,000 medical devices have been approved by the FDA using their risk-based framework that includes the use of AI.[4] The FDA uses a variety of structures to evaluate the level of risk a particular device carries, whether it uses AI or not. Devices fall under Class I (low to moderate risk), II (moderate to high risk), or III (high risk).[5] Class I devices are generally exempt from premarket notification and approval processes from the FDA as are some Class II devices.

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[3] This framework is the result of synthesizing and simplifying existing literature on risk analysis management practices in health IT and health care more broadly. Materials referenced include: Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables, What is Risk Management in Healthcare?, and Risk Management Event Evaluation and Responsibilities.
[4] August 7, 2024 update: The U.S. Food and Drug Administration updated the list of Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. With this update, the FDA has authorized 950 AI/ML-enabled medical devices. Accessed October 23, 2024: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices
[5] https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

If a device is classified as Class III, then it undergoes more rigorous evaluation processes than a Class I or II device, including the full premarket approval process.

Examples of products that fall into the different risk categories are:[6]

- Class I
  - Bandages, manual stethoscopes, oxygen masks, surgical masks, hospital beds
- Class II
  - Syringes, pregnancy tests, transfusion devices, blood pressure readers
- Class III
  - Pacemakers, cardiac stents, ventilators, defibrillators

The FDA currently deals with AI in a few different ways. AI-enabled devices generally fall under Class II or Class III based on the intended use, level of risk, and potential impacts on users. If the device is substantially similar to an existing device, it might undergo a 510(k) clearance (this is common for Class II devices).[7] If the AI-enabled device presents greater risks or provides new functionality, it goes through a pre-market approval process, requiring greater evidence of safety and efficacy.

For modifications to AI-enabled devices that have already been approved for marketing and use, the FDA has established a process called predetermined change control plans (PCCP).[8] [9] A device manufacturer submits a plan regarding how it may change the device over time, rather than submitting a new application every time it is updated. The FDA then reviews and approves the plan before it is carried out. The PCCP must contain an explanation of the proposed modifications and an assessment of how those modifications will impact the use of the device. In general, modifications that introduce some new risk to the use of the device require a separate application, rather than a PCCP. In general, low-risk modifications are acceptable and considered as changes that slightly modify existing risk considerations.

Additionally, some tools fall outside of FDA's purview: electronic health records and certain clinical decision support tools, for example. Electronic health records are regulated by the Assistant Secretary for Technology Policy (ASTP), formerly known as the Office of the National Coordinator for Health Information Technology.

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[6] https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels
[7] https://www.qualio.com/blog/fda-medical-device-classes-differences
[8] https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles
[9] https://www.fda.gov/media/180978/download

ASTP issued several transparency requirements for AI tools embedded in EHRs that mandate the publication of certain information.[10] Unfortunately, ASTP adopted what they call a "function-based approach" for these transparency requirements, meaning that if an algorithm is in use, then it is subject to the requirements. This is the opposite of a risk-based approach, and HIA believes that AI should be regulated consistently by HHS through a risk-based lens.

In the clinical trials space, the FDA recently issued draft guidance on how pharmaceutical manufacturers can submit AI-generated information to assist the regulatory approval process for drugs and biologics.[11] In their Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products, FDA lays out a risk-based framework whereby credibility and trust can be established for an AI model for a particular context of use.

HIA believes that new technologies, like some AI models, should be considered by the government under the existing regulatory structure. A risk-based approach is the most sensible approach to regulating AI in health care, and that is why it is current practice by the FDA.

When AI is used in health care applications, many factors go into an overall determination of risk. These vary not only by how an AI model itself is constructed, but also what the model is being used for (the use case), how and where the model is being implemented, and who is using the model on whom (or what). The following chart breaks down several categories of risk that commonly arise across health care use cases for medical products along with some factors that can impact the degree of risk. It is important to note that these factors impacting risk exist whether or not AI is being used.

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[10] https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and
[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological

Categories of Risk	Factors Influencing Risk
Patient Harm and Safety Risks	Patient acuity Level of reliance on AI output for decision/action Invasiveness to patient Patient medical history Intended user(s) Provider/implementer training Environmental factors/site of service Ongoing monitoring of the AI system
Data Accuracy – Training and Testing Data	Representativeness of data Insufficient data leading to delays or errors Intended use and level of reliance on AI output for decision/action Model trained and/or tested on outdated or historical patterns, resulting in a gap between simulate scenario vs. experimental validation
Bias and Ethical Concerns	Training and testing of model Level of reliance on AI output for decision/action Level of oversight and remedial processes
Misallocation of Resources and Operations Issues	Intended use of model or output Reliance on output for decision/action Level of oversight
Privacy and Security	Intended use Security systems and processes in place Sensitivity of data in question Likelihood of data misuse in case of disclosure and severity of resulting harm
Technical Issues	Processes for system upgrades and corrections System resiliency and redundancy Level of reliance on AI output for decision/action Understandability of assumptions, intended use, etc. User sophistication Reliability of connected systems
Liability and Compliance Issues	Intended use of data or outputs User sophistication Reliance on data or outputs Process or system for oversight and checks

Discussion
on
Identifying Use Cases

HEALTH INNOVATION
ALLIANCE

To map the various use cases in health care where AI can be used, HIA evaluated at the general life cycles of patients and medical products as they move through the health care system.

For example, a patient may use **wearables and remote monitoring tools** that incorporate AI to track aspects of their lifestyle by collecting data in real-time, such as physical activity, sleep, and blood pressure. As patients begin to feel unwell, **virtual health assistants** can provide information on symptoms, mitigation strategies, and even suggest scheduling a visit with a clinician. During the **scheduling** of a doctor's visit, AI tools can book appointments. While at a clinic, **chatbots** can guide patients to their provider, as well as answer queries. To treat patients, providers use **AI-powered medical imaging software**, **EHR systems**, and **ambient speech recognition (ASR) tools** to generate suggested diagnoses. Once diagnosed, **clinical decision support (CDS) tools** provide personalized treatment plans. After treatment, patients may use wearables to track their health and use **EHR systems or portals with automated messaging and reminders** for future checkups and to flag potential complications.

HIA applied the same thought model to examine how AI can be used in the stages of the medical product development process, from discovery to post-market surveillance. At the beginning of **drug discovery**, AI-driven research accelerates the identification of potential drug candidates through screening datasets and simulating chemical processes that predict drug safety and efficacy in **preclinical testing**.[12] During **clinical trials for drugs and medical devices**, AI streamlines patient recruitment, the design of the trial, experimental data, and dosing suggestions, allowing researchers to conduct more accurate **Phase I, II, and III trials**. In Phase I, AI tools assist in recruiting patients to achieve the best possible sample size. In Phases II and III, AI can help assess the drug's efficacy by refining patient profiles within the sample size and increasing the sample size by checking application within a larger population.

[12] https://pubmed.ncbi.nlm.nih.gov/37514102/

Once a drug passes trials, AI can track compliance, helping speed up **regulatory approval processing for drug or device launch, as well as assist with ongoing compliance reporting**. Afterward, AI optimizes production through heightened **quality control measures** and **supply chain management** during the **manufacturing** and **distribution** processes. This includes monitoring and identifying equipment that is operating out of tolerance or at risk of failure, conducting quality control and consistency checks, and ensuring distribution is optimized for a product's shelf life. After the drug is introduced, AI supports **pharmacovigilance** by monitoring patient safety data. AI can then take the results of pharmacovigilance into the **post-market surveillance safety and recall** phase to inform and advertise new iterations of the product and future innovations.

In the provider domain, we applied the life cycle model to identify key AI-driven tools that streamline the operational aspect of health care delivery. Functions like **billing**, **scheduling**, and **error/fraud detection** ensure resource management efficiency, reduce administrative burden, and ease the patient experience, especially during transitions.

AI-powered billing can automate the claims process accurately and quickly. These AI tools can analyze claims data, detect anomalies, and identify coding errors before a patient enters the hospital system. This can reduce the likelihood of claim denials and shorten the reimbursement cycle.

AI-powered scheduling can optimize appointment bookings, manage patient flow, and reduce patient wait times. AI-driven platforms may also help schedule appointments based on patient preferences and clinician availability in a way that reduces bottlenecking.

In addition to billing and scheduling, AI models can transform and improve error and fraud detection by scanning claims and transactional data and using machine learning algorithms to detect anomalies or patterns. This may help hospitals and insurers reduce financial losses and maintain compliance with health care regulations by safeguarding against erroneous or improper billing practices.

The taxonomy lays out various AI use cases in health care. Each use case may carry a different level of risk, and that risk level can vary depending on the specific implementation and other factors within the context of use. In most circumstances, a use case will not always be a single risk level across implementations.

Taxonomy of Use Cases

HEALTH INNOVATION ALLIANCE

The taxonomy below breaks out the potential use cases for AI in health care. This list is not exhaustive, nor would it be feasible to generate one as AI technology is constantly developing and is increasingly capable of more complex tasks.

HIA offers this list for use by policymakers when considering AI's potential applications, implementations, benefits, and associated risks and risk variation specific to health care. It is important to note that for a given use case, risk may vary depending on what the AI model is applied to – for example, the risks associated with scheduling a primary care visit are not the same as the risks associated with scheduling an emergency open-heart surgery.

In addition, these risks apply to a given application regardless of whether or not AI is being used. In some cases, an AI-enabled application would lower the risk in the context of use compared to a non-AI solution, even if the risk still exists.

Examples of commercially available AI solutions for some use cases below may be found in the appendix.

Patient Life Cycle / Journey

Pre-Diagnosis

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Symptom Research	Patient researches condition using AI-powered search engine or symptom search tool	Faster information to patient Increases patient involvement in care Reduces burden on providers	Misinterpretation of symptoms Patient steered in incorrect direction or to harmful action by model Patient accepts erroneous diagnoses Privacy concerns
Appointment Scheduling	AI finds and books an appointment for patient	Faster and easier patient experience Burden reduction on office staff	Delayed care for emergency/ high-priority visits Discrimination risk
Provider Search	AI tools query provider directory and check insurance participation	Lowers barrier to entry to find provider for patients with limited health/digital literacy Faster and more accurate network participation determination	Incorrect provider information Insurance participation errors Potential for delayed care based on patient reliance on incorrect information
Price Estimator Tool	AI tool estimates price of given services/drugs, in coordination with insurance coverage if applicable	Faster, easier, more accurate cost estimation for patients	Inaccurate price estimates Inaccurate coverage representation Potential for delayed care based on patient reliance on incorrect information
Patient Intake	AI collects and summarizes patient clinical and clinically adjacent information	Reduces clinician burden Reduces patient burden on redundant intake forms	AI leaves out important patient information AI inaccurately summarizes patient record Bias concerns – how AI portrays social determinants of health or health-related social needs information

Patient Life Cycle / Journey

Diagnosis

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Clinical Decision Support (CDS) Tools	AI provides clinicians with treatment options or suggestions based on patient data, including genetic testing/mapping; patient summary generation	Faster and potentially more tailored diagnosis and treatment suggestions Provider burden reduction – time, mental load Accounts for latest research and best practices	Inappropriate suggestions based on incomplete or inaccurate patient history Suggestions conflict with best practice guidelines Tool suggests harmful treatment Provider relying too heavily on AI tool
Diagnostics	AI is used for precision lab testing; real-time medical device data collection, recording, analysis, and interpretation	Faster, more integrated data collecting, recording, reporting More accurate testing Faster results and next steps suggestions, faster treatment to patient	Erroneous test results and downstream effects of said results Inappropriate testing or services based on incorrect recommendations
Vitals Collection	AI-powered medical devices collect vital signs data and input to patient record	Provider burden reduction Faster/easier integration with other technologies	Privacy concerns Erroneous readings or miscalculated values
Medical Imaging Analysis (X-rays, MRIs)	AI algorithms detect abnormalities in imaging data to assist clinicians	More accurate, faster diagnosis Provider burden reduction Detect disease further in advance	Misinterpretation of imaging results Algorithmic bias
Ambient Listening Tools	AI-driven ambient speech recognition (ASR) helps clinicians document patient interaction	Provider burden reduction Better documentation and integration with patient record and other technologies	Privacy risk Transcription inaccuracy

Patient Life Cycle / Journey

Treatment

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Personalized Treatment Plan	AI leverages patient data to create tailored treatment plan, drug recommendation (including contraindicated warnings), including patient's genetic information	Relieves provider burden Better error detection and reduction More comprehensive analysis of whole patient record	Errors in data interpretation lead to inappropriate treatments Errors result in no treatment when treatment would have been appropriate Privacy concern
Virtual Health Assistant	AI provides patients with medication reminders, hospital support	More tailored reminders Increases adherence to medication and keeping appointments	Erroneous communication or no communication when action would have been appropriate Security concern Leading patients to incorrect treatment or care choices
Medication/ Equipment Ordering and Delivery	Optimize prescription, device, or equipment delivery method based on patient data	Mitigate out-of-stock situations More patient-centered care	Incorrect item(s) delivered; deliveries missed Drug diversion Privacy
Medical Procedure Assistance	Surgical technology augmented by AI	More precise than human alone Potentially more up-to-date on best practices	Patient harm Potential for physician reliance on tool Potential for deviation from best practices Malpractice liability
Vitals Monitoring	Monitor vital signs, record data, notify providers of important changes	Faster actionable information Better integration with electronic records	Misallocation of staff resources if a false positive Failure to notify provider in dangerous situation

Patient Life Cycle / Journey

Post-Treatment and Follow-Up Phase

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Remote Monitoring with Wearables	AI analyzes data from wearables to track recovery and detect complications	Check incoming data more frequently than patient or provider Faster notice of warning signs of adverse health events	Data breach Privacy concerns Incorrect readings or assumptions
Patient Follow-up Scheduling	AI streamlines scheduling process based on treatment timelines	Administrative staff burden reduction Optimize treatment timelines for individual patients and facility usage	Scheduling errors Delayed treatment
Recurring Orders	Organize recurring deliveries of medical supplies for patient or practice location	Reduce adverse events for patients Increase patient convenience Increase adherence to treatment regimen	Deliveries too often, not often enough, or not at all Issues when the course of care is changed, or product is not available
Monitoring Treatment Guidelines	Monitoring and notifying providers of changes to best practices, treatment guidelines, etc.	Provider burden reduction Lower chances of adverse events due to outdated best practices	Erroneous information Misrepresentation of guidelines

Patient Life Cycle / Journey

Administrative and Logistics Support; Public Health

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Billing, Coding, and Claims	AI automates billing processes and medical coding, claims submission, adjudication, and review	Administrative burden reduction Increase cost efficiency Faster adjudication of claims	Incorrect billing due to flawed algorithm Security concern
Fraud Detection	AI identifies patterns in claims data to detect fraud	Increased accuracy of fraud detection, resulting in more money saved for payers Increased cost efficiency of fraud detection	False positives Privacy concern
Resource Allocation and Optimization	AI suggests allocation or allocates resources based on projections/reports	Administrative burden reduction More efficient allocation of resources Reduce unnecessary surpluses or shortages	Resource misallocation Shortage/surplus of supplies
Insurance Optimization	Real-time checks and coverage efficiency suggestions	Reduce unnecessary expenditures for patients Increase medication pick-up rate	Incorrect information Care avoidance due to inaccurate information or flawed assumptions
Caregiver Staffing	Allocate medical staff	Increase efficiency of staff allocation, reduce costs	Staffing misallocation due to incorrect data or assumptions Patient harm
Site Allocation	Synthesize schedules and room usage to optimize the use of the site	Increase efficiency Advanced warning of capacity issues	Suboptimum allocation of resources Misplaced providers unable to give timely care Patient harm

Patient Life Cycle / Journey

Administrative and Logistics Support; Public Health Cont.

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Care Team Coordination	Notify providers of new medications, treatments, and diagnoses of patients	Provider burden reduction Improve patient experience Increased visibility for contraindicated medication or treatments, reduces adverse events	Incorrect/misrepresented information
Public Health Surveillance and Prediction	AI systems analyze data patterns to identify potential outbreaks and monitor disease spread	More advanced warning for emerging threats	False positives Privacy concern

Patient Life Cycle / Journey

Data-Management and Security

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
EHR System Tools	AI-enabled EHRs integrate patient data for care coordination; summarize patient information; help automate compliance and documentation	Provider burden reduction Improved patient outcomes and experience	Data breach System inoperability Incorrect data or assumptions lead to inappropriate care or patient harm
Drug Discovery and Development	AI analyzes molecular structures and trial data to develop new drugs	Faster and less expensive discovery of new molecules	Algorithmic bias Lack of validation in clinical environments
Clinical Trial Optimization	AI identifies candidates and predicts outcomes for clinical trials	More diverse clinical trial representation Faster, lower cost clinical trials	Outcomes may not be diverse
Compliance	Compliance with government requirements around cybersecurity, value-based payment, etc.	Lower cost compliance	Financial, civil, and criminal liability Breach of contract

Drug Discovery Life Cycle

Pre-Development

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Target ID and Validation	AI identifies biological targets for drug intervention	Faster, more efficient process Enhanced capability for rapid response to emerging pathogens	False positives/ negatives Excluding diverse populations in a dataset
Additional Indication Research	AI identifies additional uses for existing drugs/molecules	More efficient use of resources – more targeted investment in molecules with promise	Inaccurate predictions create resource waste

Drug Discovery Life Cycle

Development & Clinical Trials

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Drug Design and Optimization	AI uses predictive modeling to generate molecular compounds to identify candidates	Faster, less costly drug development Provides another reference point for people making decisions	Relying on simulations vs. experimental validation Potential to miss side effects
Preclinical Testing	AI models predict drug efficacy as a replacement for animal testing	Provides additional reference points, more data supporting decisions Faster, less costly drug development	Inaccurate predictions lead to side effects Ethical concern about relying on incomplete models
Clinical Trial Design and Optimization	AI predicts trial outcomes	Provides additional reference points, more data supporting decisions Can help mitigate shortcomings of clinical trial participation/design	Potential risk of excluding underrepresented groups Bias in predictive models
Clinical Trials Search Tool	Patient or provider uses AI tool to search clinical trials for given condition(s)	Streamlined clinical trial participation pathway Provider burden reduction Increased clinical trial diversity	Patient pursues a trial they are not eligible to participate in Delayed care based on incorrect data or model assumptions
Funding	AI evaluates historical funding data to recommend an investment timeline	Greater financial predictability More efficient investment in clinical trials	Historical patterns might not predict current trends
Trial Participant Recruitment and Communication	AI identifies trial subjects	Increased diversity in clinical trials Patient benefits from access to medicine in trials	Possible narrow inclusion criteria

Drug Discovery Life Cycle

Development & Clinical Trials Cont.

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Data Validation	AI evaluates clinical trial data to determine effectiveness	Faster, more efficient evaluation	Safety concerns Risk of inappropriately weighing results and demographic trends
FDA Approval Preparation	AI is used to compile information for the FDA approval process	Faster, more efficient data compilation	Errors in documentation, delaying the compliance process

Post-Market

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Logistics for Shipping	AI optimizes the supply chain	Faster, more efficient shipping Lower costs for logistics providers and customers	Possible algorithm issues and errors in handling that can cause delays
Post-Approval Safety Monitoring	AI analyzes patient and clinician data to detect adverse events post-market	Faster identification of events Fewer adverse events as trends are detected faster	Missing rare adverse events Underreporting from incomplete data sources
Post-Market Surveillance	AI monitors databases for signals of drug-related safety issues	Faster identification of events Fewer adverse events as trends are detected faster	False positives/ negatives

Medical Device Development Life Cycle

Pre-Development

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Funding	AI identifies investment timeline	Greater financial predictability Greater predictability in timelines	Outdated market trends may not supply a good timeline for the current landscape

Development & Clinical Trials

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Device Design	AI generates prototypes of medical devices	Lower cost prototyping Faster iteration on prototypes	Chance of faulty designs that do not withstand real-world application
Clinical Trial Efficiency	AI predicts patient outcomes, device failure rates	More efficient iteration process for devices Better identification of potential issues	Biased data sets
Trial Participant Communication	AI provides real-time updates to participants to collect feedback	Better communication with patients; patients more engaged Enhanced feedback loop from trial participants	Communication gaps between AI and human participants
Regulatory Submission	AI compiles data and documentation to ensure regulatory compliance for FDA approval	Faster, more efficient data compilation	Errors in documentation, delaying the compliance process
Data Validation	AI evaluates clinical trial data to determine effectiveness	Better detection of underlying trends in data Additional validation of safety and effectiveness	Safety concerns Risk of inappropriately weighing results and demographic trends

Medical Device Development Life Cycle

Post-Market

Use Case	Description	Benefits of Applying AI	Factors Impacting Level of Risk
Logistics for Shipping and Deployment	AI optimizes the supply chain to deliver devices	Faster, more efficient shipping Lower costs for logistics providers and customers	Failure in prediction can lead to delays Improper handling may result in damages
Safety Monitoring	AI tracks device usage data and adverse events	Faster identification of events Fewer adverse events as trends are detected faster	False negatives/ positives
Post-Market Surveillance	AI monitors user feedback and performance logs to identify trends in device malfunctions	Faster identification of events Fewer adverse events as trends are detected faster Better and more information for future device modifications	Algorithmic blind spots

Conclusion

The future of health care includes AI. How it is incorporated and used depends on the constraints placed on it and resources allocated to support it by both Congress and the administration. As regulators continue to evaluate the use of AI in health care, they must consider what the technology is being used for and decide how it is being deployed to appropriately consider the potential risk factors inherent to every individual scenario. The federal government must also consider how best to support the development and deployment of AI broadly and in the health care ecosystem, including how to train the workforce to use these new tools. HIA believes that government should work with the private sector to ensure that these tools are available across the health care industry so that AI can realize its full potential to solve some of the industry's most challenging problems.

HIA encourages policymakers and regulators to be thoughtful and forward-looking, rather than reactionary, in their approach to the rules and regulations around AI in health care. A one-size-fits-all approach is not appropriate and risks mitigating any of the potential benefits of the technology now and in the future.

If you have questions about the findings of HIA's use cases, please contact Brett Meeks at bmeeks@health-innovation.org.

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Appendix

HEALTH INNOVATION ALLIANCE

Resources

AI model in EHRs

- https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2695078
- https://aws.amazon.com/solutions/case-studies/anthem/?did=cr_card&trk=cr_card

Efficacy of AI models

- https://www.thelancet.com/journals/landig/article/PIIS2589-7500(21)00208-9/fulltext

AI transforming lab and clinical trials, drug development

- https://www.tandfonline.com/doi/full/10.2144/btn-2021-0077?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org
- https://pmc.ncbi.nlm.nih.gov/articles/PMC9424628/
- https://aws.amazon.com/solutions/case-studies/AstraZeneca-case-study/?did=cr_card&trk=cr_card

AI detecting diabetic retinopathy

- https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30060-1/fulltext
- https://jamanetwork.com/journals/jama/fullarticle/2588763
- https://www.thelancet.com/journals/landig/article/PIIS2589-7500(20)30250-8/fulltext

AI in decision making process

- https://arxiv.org/abs/1905.02599v2
- https://www.nature.com/articles/s43856-022-00214-4

AI assessment of cardiac function

- https://www.nature.com/articles/s41586-020-2145-8
- https://www.nature.com/articles/s41586-023-05947-3
- https://www.nature.com/articles/s41746-019-0216-8

2023 AI developments

- https://iapp.org/news/a/ai-lang-syne-a-look-back-on-2023-and-considerations-for-2024/

State to state differences in AI regulation

- https://www.csg.org/2023/12/06/artificial-intelligence-in-the-states-emerging-legislation/
- https://www.brennancenter.org/our-work/research-reports/states-take-lead-regulating-artificial-intelligence#:~:text=Though%20most%20states%20have%20yet,government%2Dorganized%20entities%20to%20increase
- https://www.ncsl.org/technology-and-communication/artificial-intelligence-2023-legislation

FDA Approval

- https://medicalfuturist.com/the-current-state-of-fda-approved-ai-based-medical-devices/
- https://encord.com/blog/ai-algorithm-fda-approval/
- https://crsreports.congress.gov/product/pdf/R/R47374
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices?utm_medium=email&utm_source=govdelivery
- https://www.fda.gov/vaccines-blood-biologics/artificial-intelligence-and-machine-learning-aiml-biological-and-other-products-regulated-cber
- https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/artificial-intelligence-drug-development
- https://www.fda.gov/media/167973/download
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de

History of artificial intelligence in medicine

- https://www.giejournal.org/article/S0016-5107(20)34466-7/fulltext
- https://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-023-04698-z

Examples of AI Technologies

Below are examples of real-life products, solutions, and ecosystems that incorporate AI technologies in some capacity, organized by use case. This is by no means an exhaustive list of all products available on the market – rather it is meant to be illustrative of the fact that AI is already being used across the health care system.

- **Treatment Assistance**
  - Surgical Robots
    - Da Vinci Surgical System
    - Mazor X Stealth Edition
    - Monarch platform
  - Medical Imaging Data
    - X-Rays
      - Zebra Medical Vision's Al1
    - MRIs
      - Philips SmartExam AI
      - Siemens AI-Rad Companion Brain MR
    - CT Scans
      - GE HealthCare's Revolution CT with Deep Learning Image Reconstruction
    - Ultrasound
      - Philips EPIQ Elite with AI-assisted quantification
    - Mammography
      - iCAD ProFound AI
      - Kheiron Medical's Mia
    - Retinal Imaging
      - IDx-DR for diabetic retinopathy detection
    - General
      - AWS HealthImaging
  - Diagnosis
    - MYCIN
    - IBM Watson
    - Jvion

- **EHR systems**
  - Athenahealth
  - McKesson
  - Epic
  - Cerner
  - MEDITECH

Examples of AI Technologies Cont.

- **CDS Tools**
  - ClinicalKey
  - UpToDate
  - Epocrates
  - VisualDx
  - DynaMed and Microdex with Watson
  - Medscape
  - MDCalc

- **Transcription and Automatic Speech Recognition (ASR)**
  - Nuance Dragon Medical One
  - M*Modal Fluency Direct
  - DeepScribe
  - AWS Healthscribe

- **Administration**
  - Billing
    - Waystar
    - Change Healthcare
    - Scheduling
    - Qventus
    - Lumeon
    - Zocdoc
  - Fraud Detection
    - LexisNexis Risk Solutions
    - HMS Healthcare / Gainwell Technologies
    - OptumInsight

- **Pharmaceutical Development**
  - Atomwise
  - Excientia
  - BenevolentAI

- **Clinical Trials**
  - AiCure
  - Unlearn.ai
  - Medidata (Acorn AI)

Examples of AI Technologies Cont.

- **Public Health Research**
  - Disease Outbreak and Prediction
    - BlueDot
    - HealthMap
    - Metabiota

- **Patient Experience**
  - Virtual Health Assistants
    - Ada Health
    - Babylon Health
    - Woebot
  - Remote Patient Monitoring
    - Wearables
    - Apple Watch
    - Fitbit
    - Garmin
    - Whoop Coach

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