Artificial Intelligence 2025: Utility, Benefits and Risks

An Innovation, Medicine, MCS and Society Perspective

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ASAIO 2025

Questions Posed:

Is AI/ML ready for primetime in clinical decision making in patients? In those requiring MCS?

Yes and No

It depends

AI – Define, History, The Spectrum

AI – in Medicine – Today

AI – in Medicine – Analytical/Application Framework

AI - Issues and Studies – Slepian/ACABI

AI – Next steps/Future

AI is the Buzz word of 2025

AI is all around us

AI has raised hope

AI has raised (deep) concern (Fear)

AI is transformative

AI is here to stay

November 30, 2022

when ChatGPT was released for public use.

ChatGPT 3.5

In reality AI has had a near 70 year history, if not longer

With the advent of the computer, and the progression of technologic advances including personal computing, the web, the cellphone and the smartphone AI has become deeply embedded in our daily lives

- **The bulk of AI is embedded and “behind the scene"**

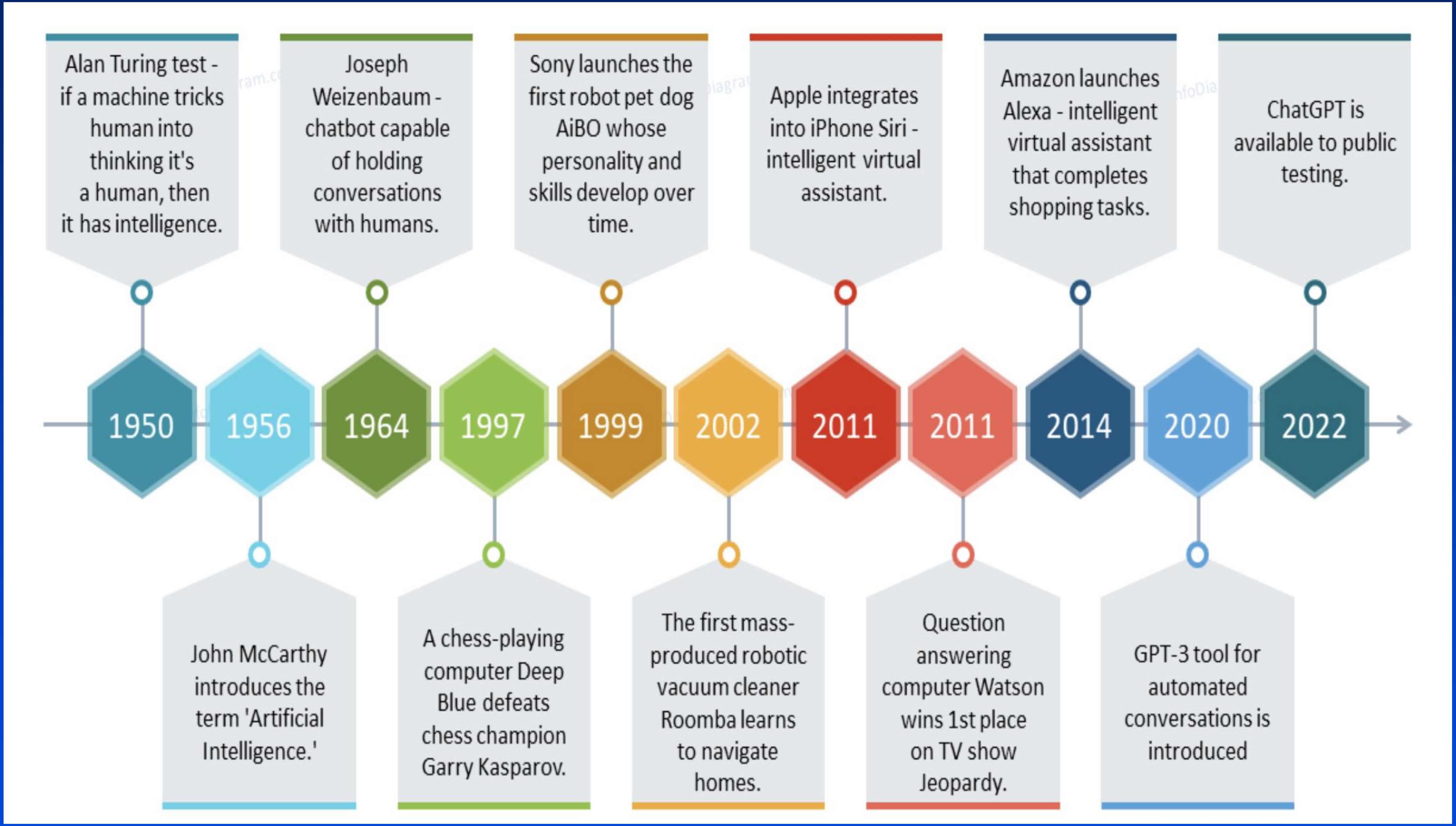
Forbes

The 10 Best Examples Of How AI Is Already Used In Our Everyday Life

1. Open your phone with face ID
2. Social Media – personalization of what you see
3. Send an email or message – spell check
4. Google search
5. Digital Voice Assistants - Siri and Alexa, Cortana
6. Smart Home devices
7. Commuting to work – Google Maps, Waze
8. Banking – transaction monitoring, balance
9. Amazon recommendations
10. Netflix.

December 19, 2019

Artificial Intelligence: History/Timeline



Artificial Intelligence

Big Data

Predictive Analytics

Machine Learning

Neural Networks

Deep Learning

Natural Language Processing

Large Language Models

Generative AI
Associative Generative AI

More Reliable
"Truthful"

Less Reliable
"??Truthful"

Intelligence

The capacity for abstraction, logic, understanding, self-awareness, learning, emotional knowledge, reasoning, planning, creativity, critical thinking, and problem-solving.

Intelligence

Encounter
Event
Fact

Learning

Knowledge

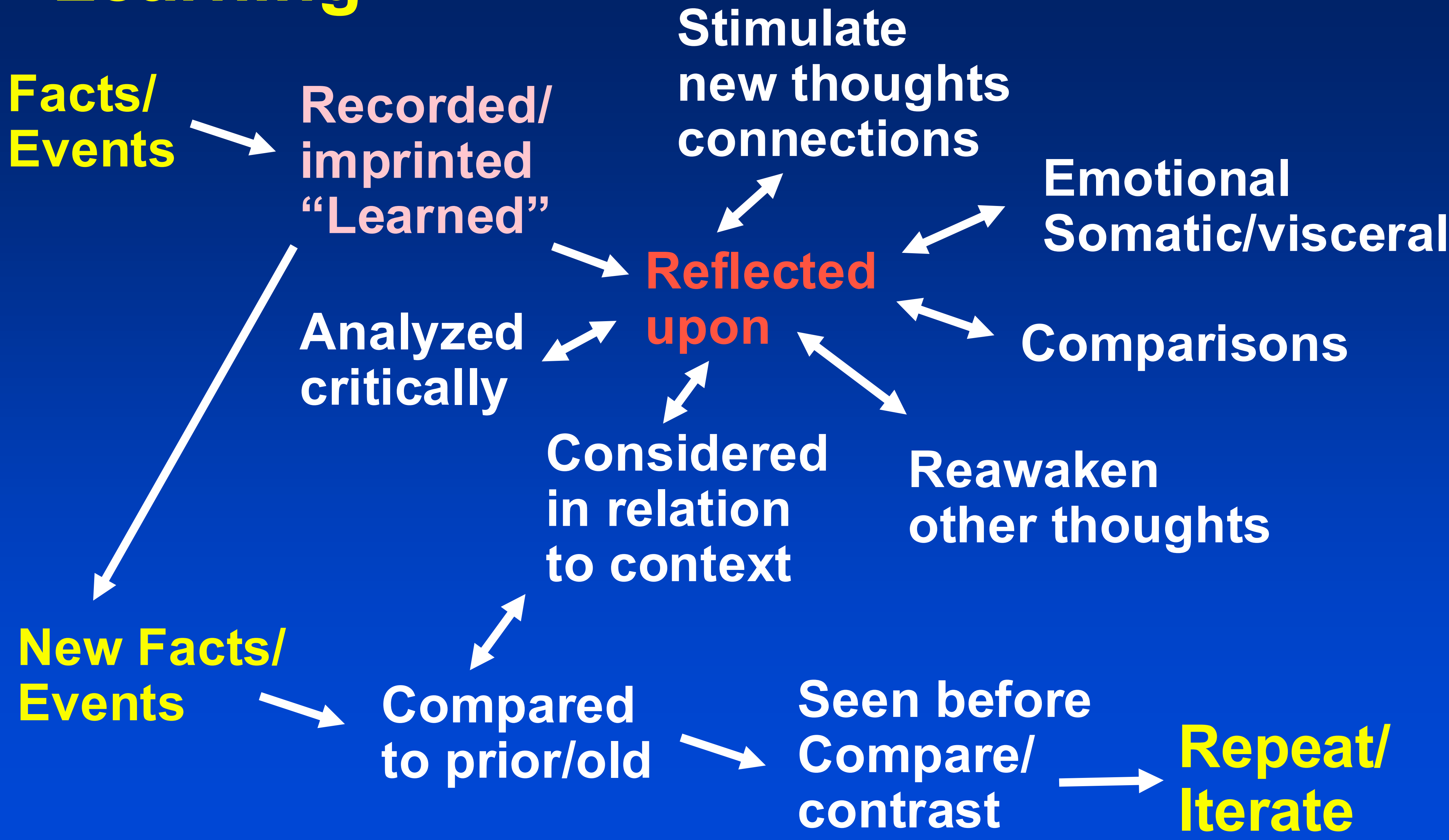
Reasoning
Analysis
Critical Thinking

Experiences
Context/Δs
Repetition
Emotion

Understanding

Wisdom

Learning


Facts/
Events
Recorded/
imprinted
“Learned”
Stimulate
new thoughts
connections
Emotional
Somatic/visceral
Reflected
upon
Analyzed
critically
Comparisons
Considered
in relation
to context
Reawaken
other thoughts
New Facts/
Events
Compared
to prior/old
Seen before
Compare/
contrast
Repeat/
Iterate

Artificial Intelligence: Evolution

Two Broad Paths

1. Computer programs, Algorithms solving (repetitive) tasks

Faster

Need to define all the components, issues, variables

2. Iterative Learning approaches

Decide, fail, correct, learn

Slower

Predictive Analytics

The process of using data to forecast future outcomes.

The process uses data analysis, machine learning, artificial intelligence, and statistical models to find patterns that might predict future behavior. One can use historic and current data to forecast trends and behaviors seconds, days, or years into the future, often with great precision.

Predictive Analytics

A statistical model is formulated, trained, and modified to generate predictions.

1. **Define the problem: Thesis/set of requirements**
   e.g. flood w severe weather, infection w VAD

2. **Acquire and organize data**

3. **Pre-process data – organized, cleaned**

4. **Develop predictive models – machine learning, regression models, and decision trees**

5. **Validate and deploy results**

The key is the model

Predictions

"I think there is a world market for maybe 5 computers"

Thomas Watson 1943
President of IBM

"Its tough to make predictions, especially about the future"

Yogi Berra

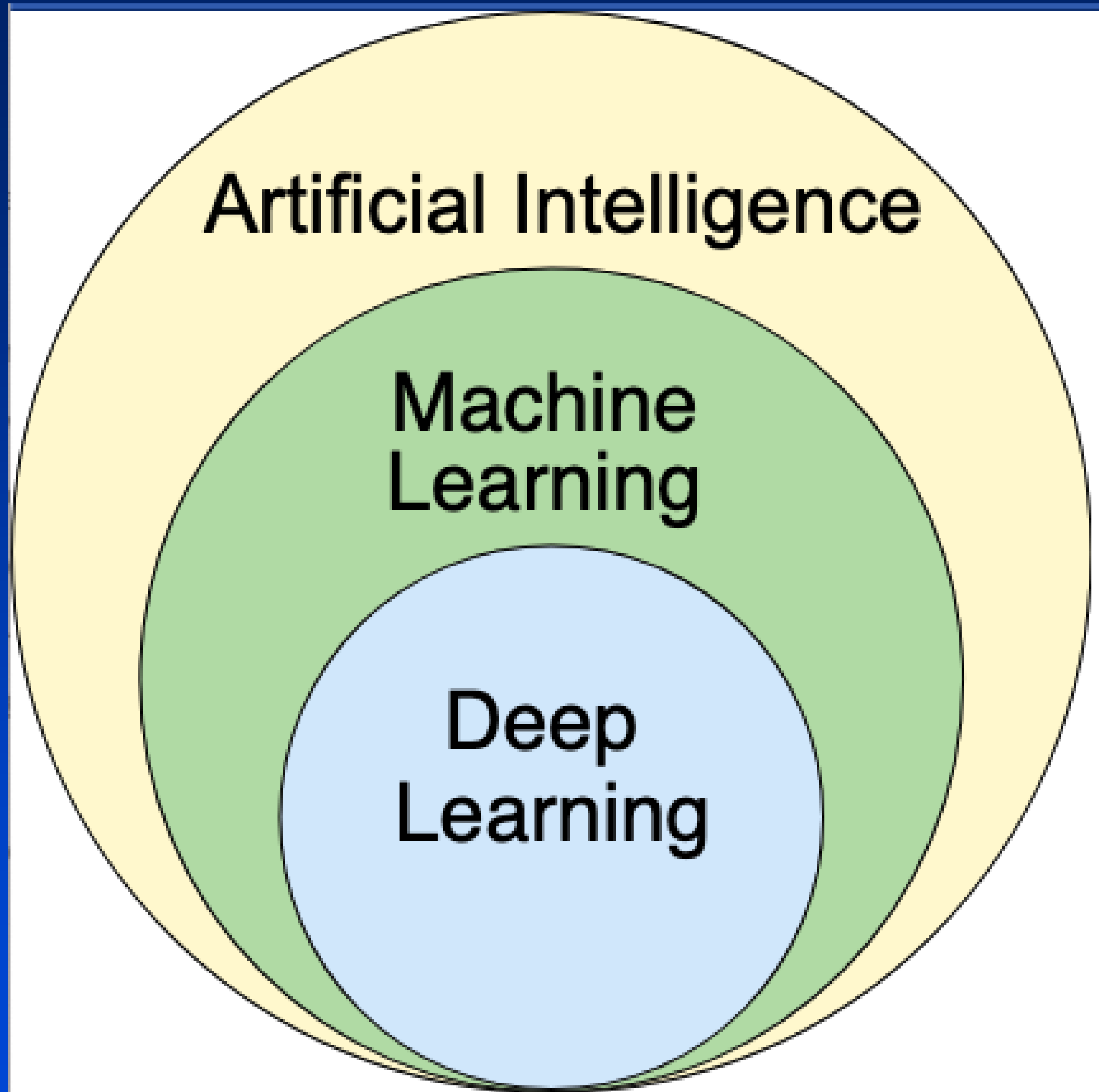
Machine Learning

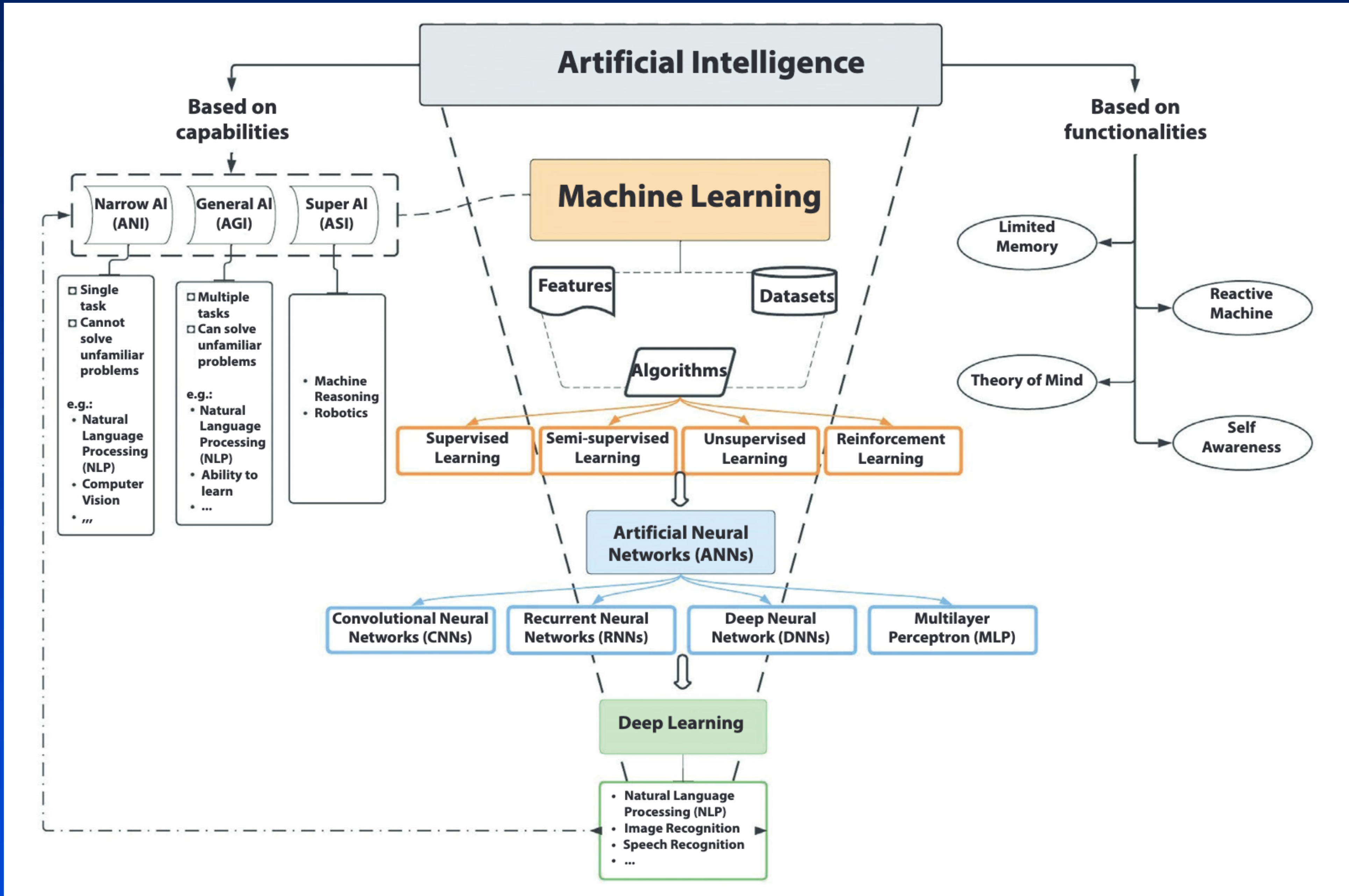
Arthur Samuel
1950

"the field of study that gives computers the ability to learn without explicitly being programmed."

letting computers learn to program themselves through experience

1. Descriptive – use data to explain what happened
2. Predictive - use data to predict what will happen
3. Prescriptive - use data to make suggestions about what action to take


Artificial Intelligence
Machine
Learning
Deep
Learning



Bellini et al. Acta Biomed 2022; Vol. 93, N. 5: e2022297

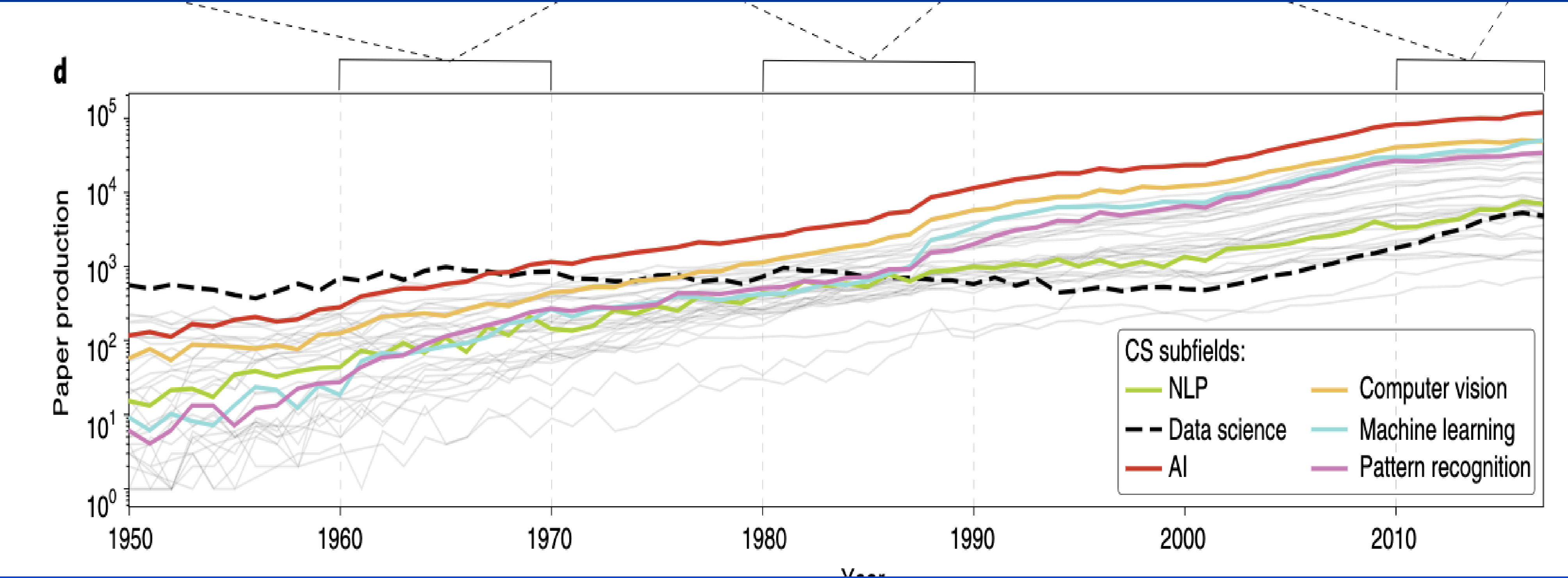
nature machine intelligence

PERSPECTIVE

https://doi.org/10.1038/s42256-019-0024-5

The evolution of citation graphs in artificial intelligence research

Morgan R. Frank[1], Dashun Wang[2,3], Manuel Cebrian[1] and Iyad Rahwan[1,4,5*]



Artificial Intelligence - NLP

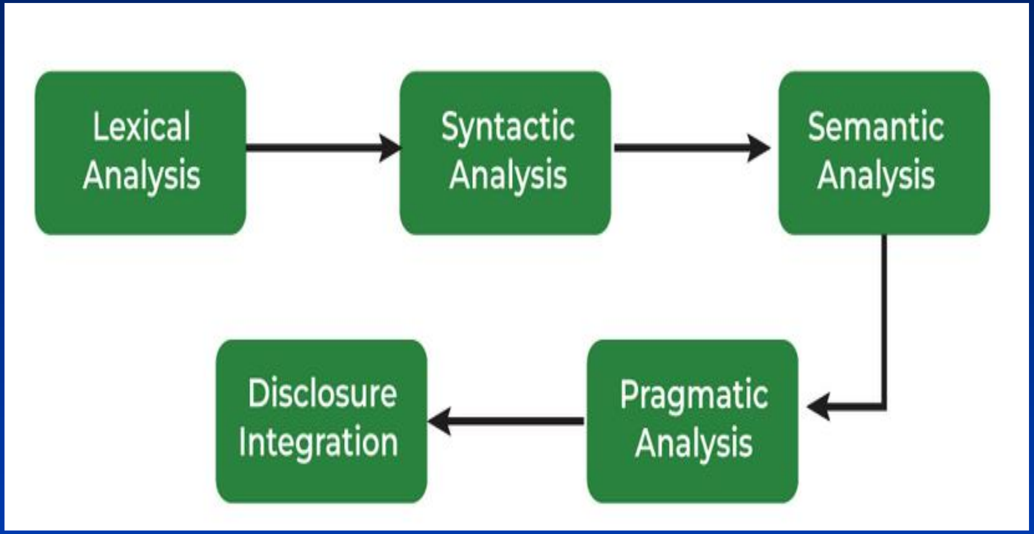
Interdisciplinary subfield of computer science and linguistics

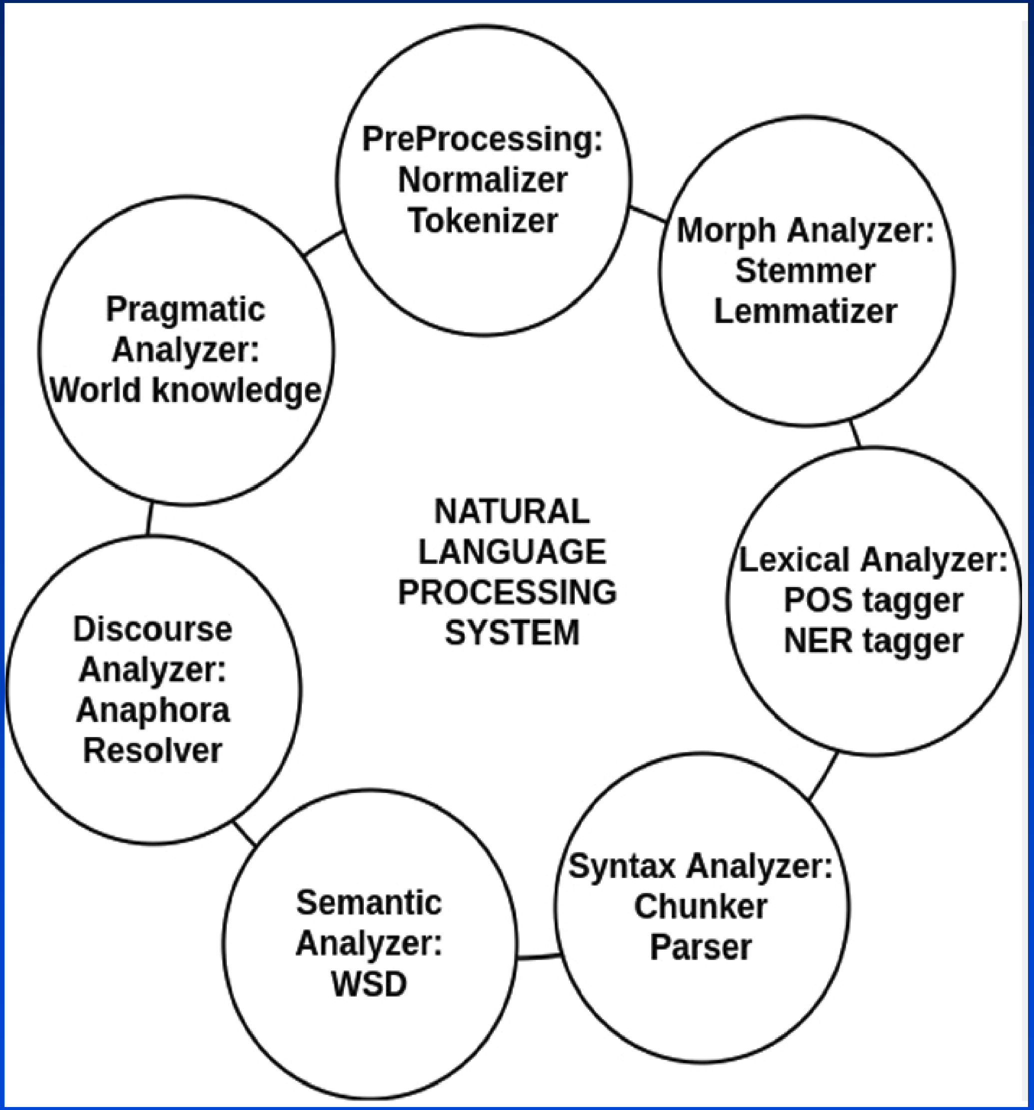
Computers support and manipulate human language.

Process natural language datasets, such as text corpora or speech corpora, using either rule-based or probabilistic (i.e. statistical and, most recently, neural network-based) machine learning approaches.

Goal: Computer capable of "understanding" the contents of documents, including the contextual nuances of the language within them. The technology can then accurately extract information and insights contained in the documents as well as categorize and organize the documents themselves.

Artificial Intelligence - NLP





Sentiment

Artificial Intelligence: ChatBots

A chatbot is a computer program that simulates human conversation with an end user.

Not all chatbots are equipped with artificial intelligence (AI)

modern chatbots increasingly use conversational AI techniques like natural language processing (NLP) to understand the user’s questions and automate responses to them.

https://www.ibm.com/topics/chatbots

Artificial Intelligence – Digital Assistants

A digital assistant = predictive chatbot

An advanced computer program able to converse with people, typically over web.

Digital assistants use advanced artificial intelligence (AI), natural language processing, natural language understanding, and machine learning to learn as they go and provide a personalized, conversational experience.

Digital assistants can answer complex questions, provide recommendations, make predictions, and even initiate conversations.

AI as Agent

Artificial Intelligence – LLMs
Large Language Models

A computer program with contained algorithms /models allowing for general purpose language generation and understanding.

LLMs acquire these abilities by learning from computationally intensive self-supervised or semi-supervised training processes.

LLMs are **artificial neural networks** built with a **decoder transformer-based architecture**. Some are based on **recurrent neural networks** and **Mamba** (State space model)

GPT = Generative Pre-trained Transformer

Artificial Intelligence – LLMs
Large Language Models

ChatGPT 4o, 4o mini
Chat GPT 3.5

BARD (Gemini)

BERT
Claude
Cohere
Ernie
Falcon 40B
Galactica

Lamda
LlaMA
Orca Palm
Phi-1
Stable LM
Vicuna 33B
Deep Seek R1

https://www.techtarget.com/whatis/feature/12-of-the-best-large-language-models

Artificial Intelligence: GenAI Companies and Offerings

OpenAI
GPT, DALL-E, Codex, Sora

Google
Gemini, Gemma

Meta
LlaMA (partial)

Microsoft
CoPilot

Anthropic
Claude

■ Open Source

AI: Top 25 Companies 2025

Anthropic
Rossum
Phenom
Scale AI
Central Reach
Minimax
Glean
LinkSquares
Helsing
Joveo
Ada
Prezent

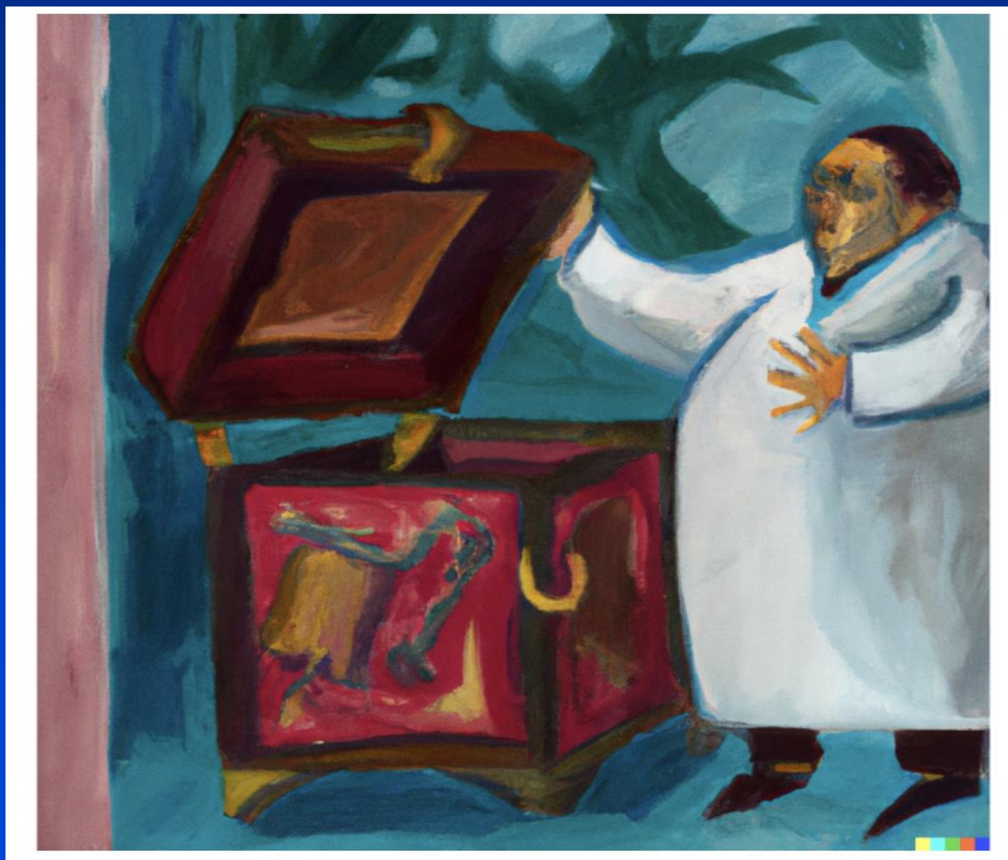
Adept
Stellar Cyber
Axelera AI
Together.AI
Harvey
Perpelxity AI
Inflection AI
Mistral AI
Poolside
World Labs
Liquid AI
Hugging face
Moonshot

https://www.thesoftwarereport.com/the-top-25-ai-companies-of-2025/

JOURNAL OF MEDICAL INTERNET RESEARCH Májovský et al

Original Paper

Artificial Intelligence Can Generate Fraudulent but Authentic-Looking Scientific Medical Articles: Pandora's Box Has Been Opened



AI easily generated fradulent, convincing medical paper

Matisse emulated style

Painting generated based on prompts

Fully AI generated

Majovsky et al. J Med Internet Res 2023 | vol. 25 | e46924 | p. 1

Generative AI: “Under the Hood”

Large Language Models

The **key to AI** is knowing what is under the hood

The **key to safe and effective AI** is knowing what’s under the hood

The **key to equitable AI** is knowing what’s under the hood

AI in Medicine - Today

Artificial Intelligence – Medicine

Big Data – Defining associations, patterns

Predictive Analytics – Diagnosis, Outcome predictions, Txic Predictions, Prognosis

Machine Learning – Refined efficacy of algorithms

Neural Networks – Enhanced performance of ML

Deep Learning – further ML performance/insight

Natural Language Processing – Voice/Text extraction, Syntax, Semantics (meaning), Sentiment (emotional tone)

Large Language Models – topic specific use

Generative AI - synthesis of information for Dx, Tx, reporting/EHR, pt interface, education, research

Associative Generative AI – further Information synthesis

360 BB emails
Sent per day

500 MM
Tweets (X) per day

400 Terabytes of
Data uploaded daily

40% Growth in Global
Data generated per Year

21 Petabytes of Data
Collected by US
Lib of Congress
(in April 2022)

460 Exabytes (2.5×10^{18})
of data are created daily

Tera 10^{12}
Peta 10^{15}
Exa 10^{18}

Memory unit	Description
Kilo Byte	1 KB = 1024 Bytes
Mega Byte	1 MB = 1024 KB
Giga Byte	1 GB = 1024 MB
Tera Byte	1 TB = 1024 GB
Peta Byte	1 PB = 1024 TB
Exa Byte	1 EB = 1024 PB
Zetta Byte	1 ZB = 1024 EB
Yotta Byte	1 YB =1024 ZB
Bronto Byte	1 Bronto Byte = 1024 YB
Geop Byte	1 Geo Byte = 1024 Bronto Bytes

10^x

3
6
9
12
15
18
21
24
27
30

$1024 = 2^{10}$

Convergence:

Communication, Data Dispersion and Data Processing

Written word

Letter

Printed word

Copying

Telegram

Telephone

Faxing

Radio

Mainframe Computing

Analog

Digital

TV

Broadband

Internet

WWW

Cell phone

Personal Computing

Tablet

Sensors

Internet of Things

Data warehousing

Decision support

Predictive Analytics

Social, Operational and Commercial Trends that Emerged

Connectivity

Voice, Text, Tweet (X)

Peer-to-peer communication

Web life

Bz to consumer Website
Consumer to consumer – eBay and Amazon
Bz to Bz to consumer – Amazon

Social/Bz networks

Facebook, SnapChat
Linked-in, Tik Tok

All generate available capturable, interpretable Data

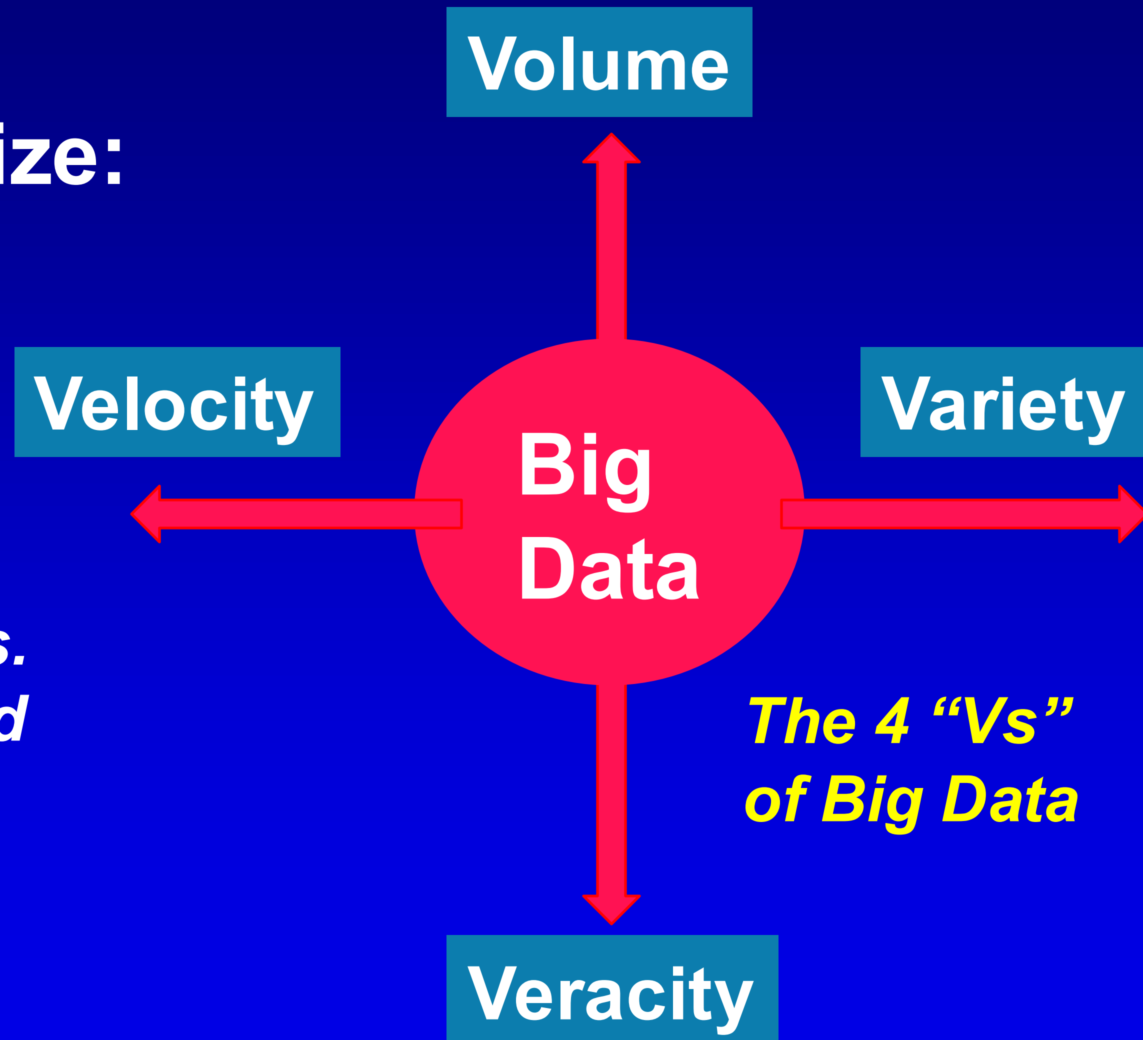
Power of the Crowd

→ **Sensors – Machine, Device, Personal**

Big Data: Characteristics

Not just about data size:

- *Complexity*
- *Heterogeneity*
- *Noise*
- *Structure vs.*
  Semi-structured vs.
  Unstructured
- *Relational vs*
  Non-relational



The 4 "Vs" of Big Data

Big Data: Elements in Health Care

The Medical Encounter – History and Physical

Family Hx, Medication Hx

Laboratory Data

Imaging Data – Xray, CT, MRI, PET, Nuclear Medicine

Functional Testing – Spirometry, Stress Test

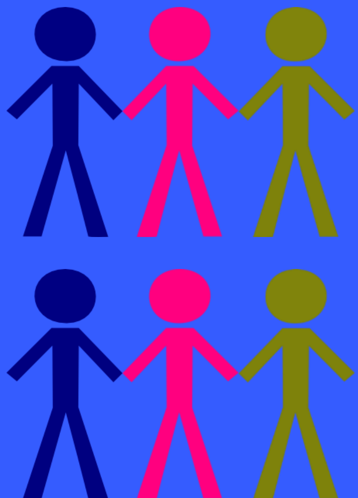
Diagnoses – Specific medical, ICD-10, DRG’s

Compliance Data – Office visits, Rehab

Social data – family, care environment, smoking/Rx use

Financial Data – Insurance, Medicare/Medicaid

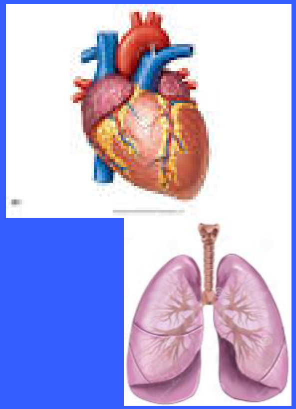
Big Data: All A Matter of Scale



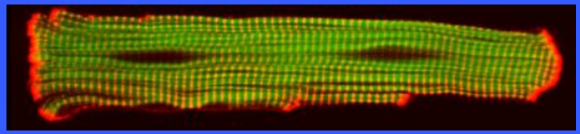
Society

Group

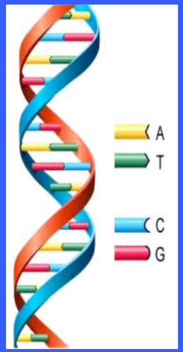
Man



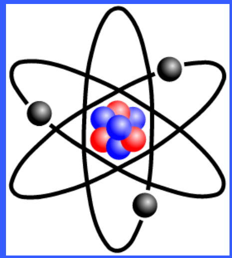
Organ



Cell



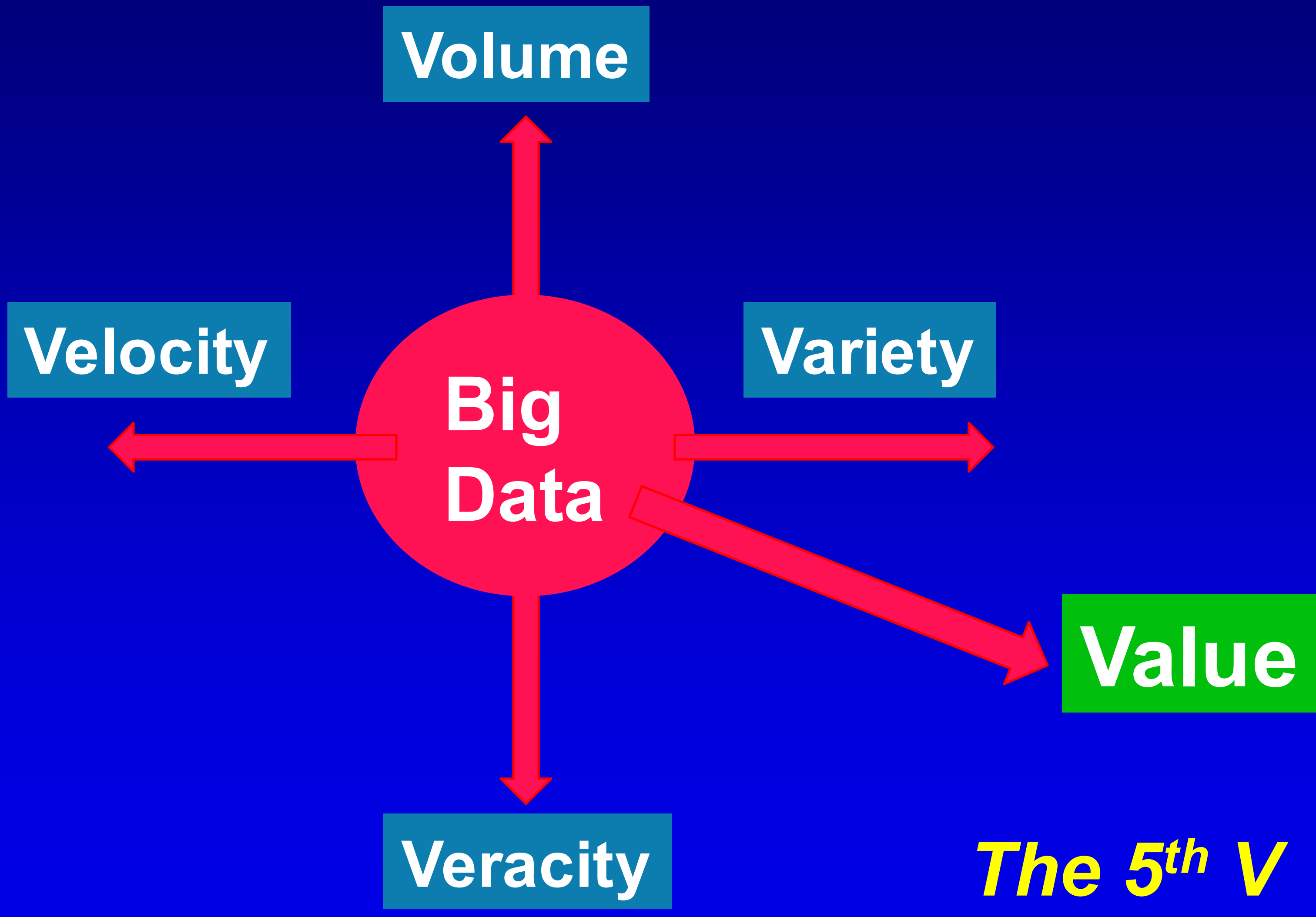
Molecule



Atom

Big Data has always existed

Big Data + Innovation



The 5th V

DATA ⟷ KNOWLEDGE

Insight

AI

Big Data in Healthcare: Opportunities

Pattern Recognition

Trends

Model building and Hypothesis Generation

- ***Mechanisms of Disease***
- ***Precipitants of Clinical Events***
- ***Understanding Disease Progression***
- ***Medical errors***
- ***Disease recurrence***
- ***Readmission***
- ***Mortality***

AI Lifecycle

1

- Engage stakeholders to define the problem & perform root-cause analysis
- Identify solution & plan future state
- Gather business requirements
- Assess feasibility, potential for impact, & prioritization
- Make procure/build/partner decision

2

- Select/understand model task & architecture
- Capture design & technical requirements or determine best solution to meet business requirements
- Design solution application & system workflow according to human-centered design principles
- Design deployment strategy with end users
- Design risk management, monitoring & reporting plan

3

- Access data
- Prepare data
- Develop data management plan
- Train & tune model

4

- Conduct installation qualification (when applicable)
- Validate local system performance (when applicable)
- Execute prospective, silent evaluation
- Establish risk management plan
- Train end users
- Test usefulness
- Ensure compliance with applicable healthcare regulations & standards

5

- Implement small-scale pilot to assess real-world impact
- Execute and update risk management plan
- Educate & train users on AI application reporting
- Assess usefulness and adoption

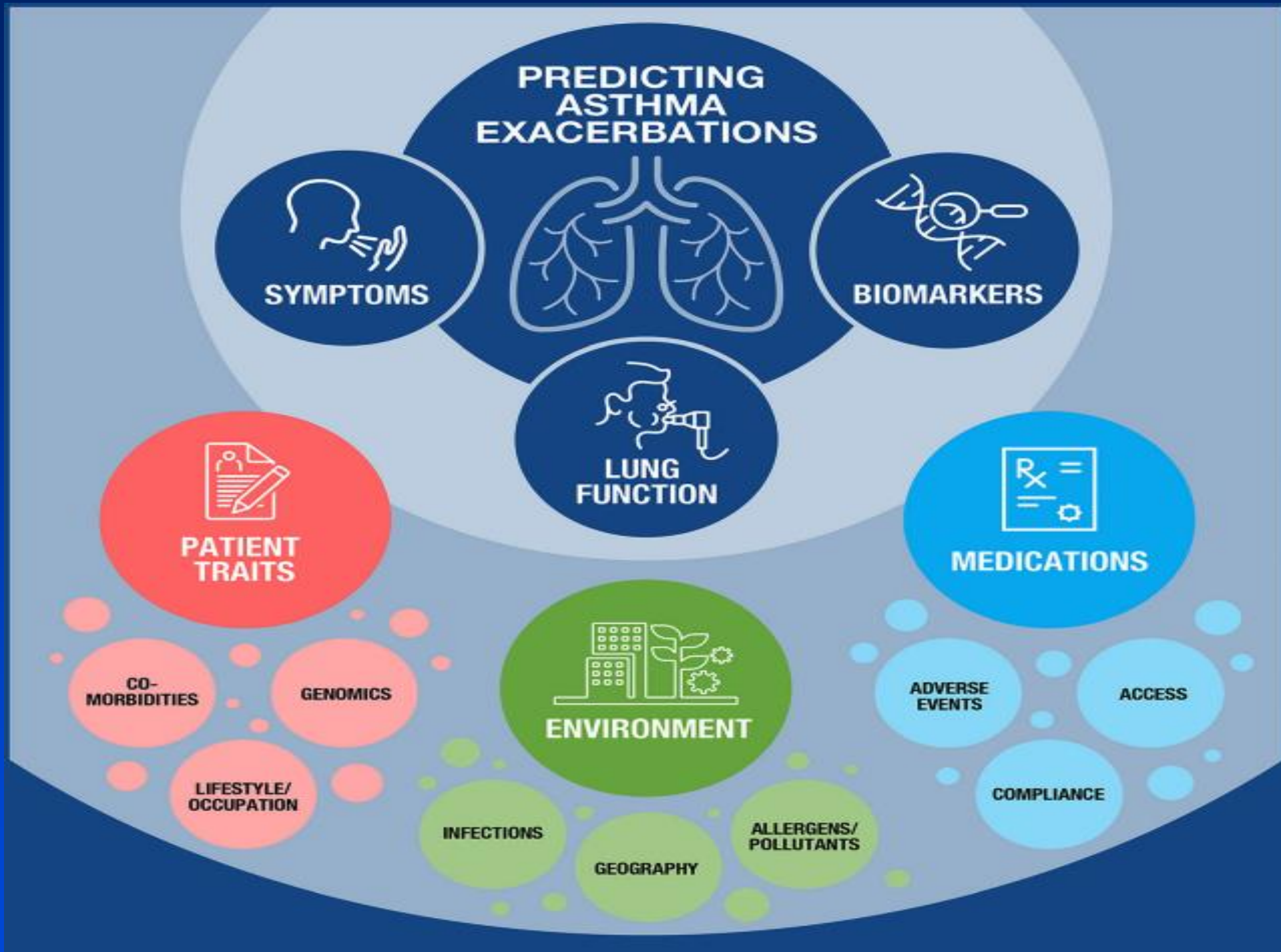
6

- Deploy at a larger scale on a general population
- Audit AI system to inform whether to maintain, refine or sunset
- Conduct ongoing risk management

AI in Medicine Today – Example Use cases

1. **Predictive EHR Risk Use Case**
   Pediatric Asthma Exacerbation
2. **Imaging Diagnostic Use Case**
   Mammography
3. **Generative AI Use Case**
   EHR Query and Extraction
4. **Claims-Based Outpatient Use Case**
   Care Management
5. **Clinical Ops & Administration Use Case**
   Prior Authorization with Medical Coding
6. **Genomics Use Case**
   Precision Oncology with Genomic Markers

Pediatric Asthma Exacerbation



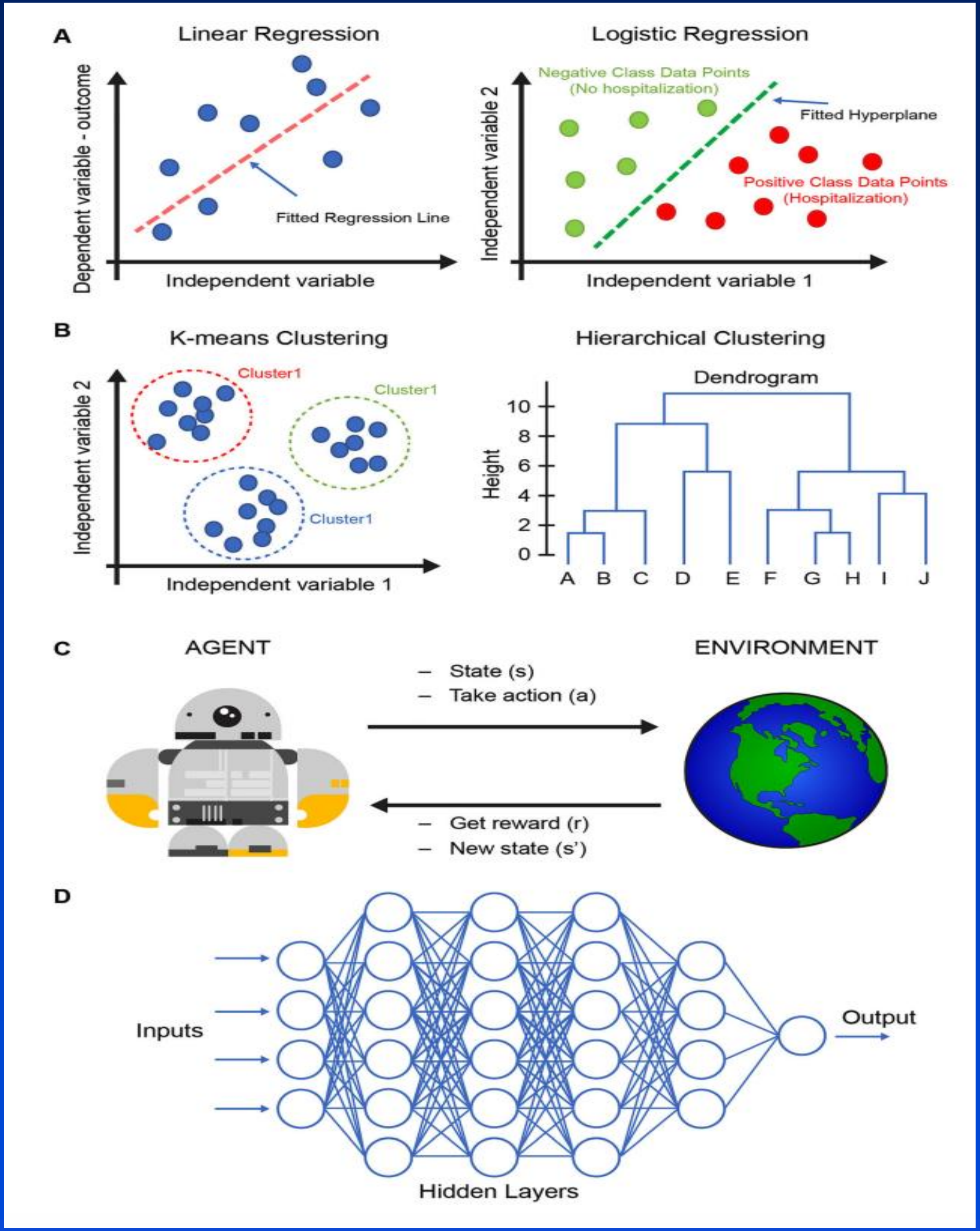
Molfino et al. Adv Ther (2024) 41:534–552 https://doi.org/10.1007/s12325-023-02743-3

Supervised learning

Unsupervised learning

Reinforcement learning (trains agent)

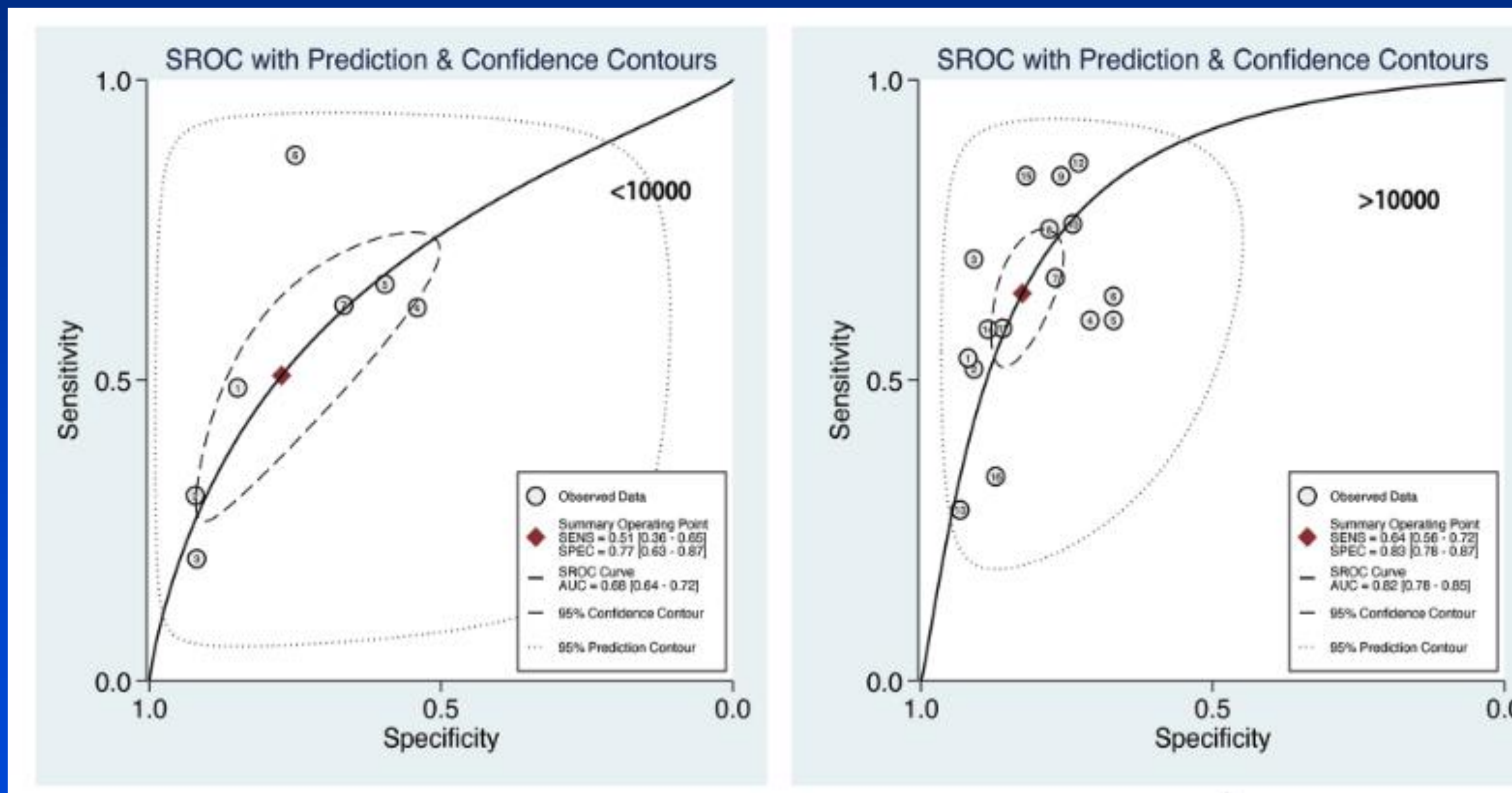
Deep learning
Multiple layers of neural networks



Machine learning for prediction of asthma exacerbations among asthmatic patients: a systematic review and meta-analysis

10434 papers reviewed, 23 ML prediction models
Linear regression, Random forest, neural networks

<u>Key variables:</u>
systemic steroids, short-acting beta2-agonists, age, ED visit, asthma diagnosis number, exacerbation history, race, BMI, duration, blood eosinophils, and smoking.



Sample size < 10,000 **Sample size > 10,000**

Xiong et al. BMC Pulmonary Medicine (2023) 23:278 https://doi.org/10.1186/s12890-023-02570-w

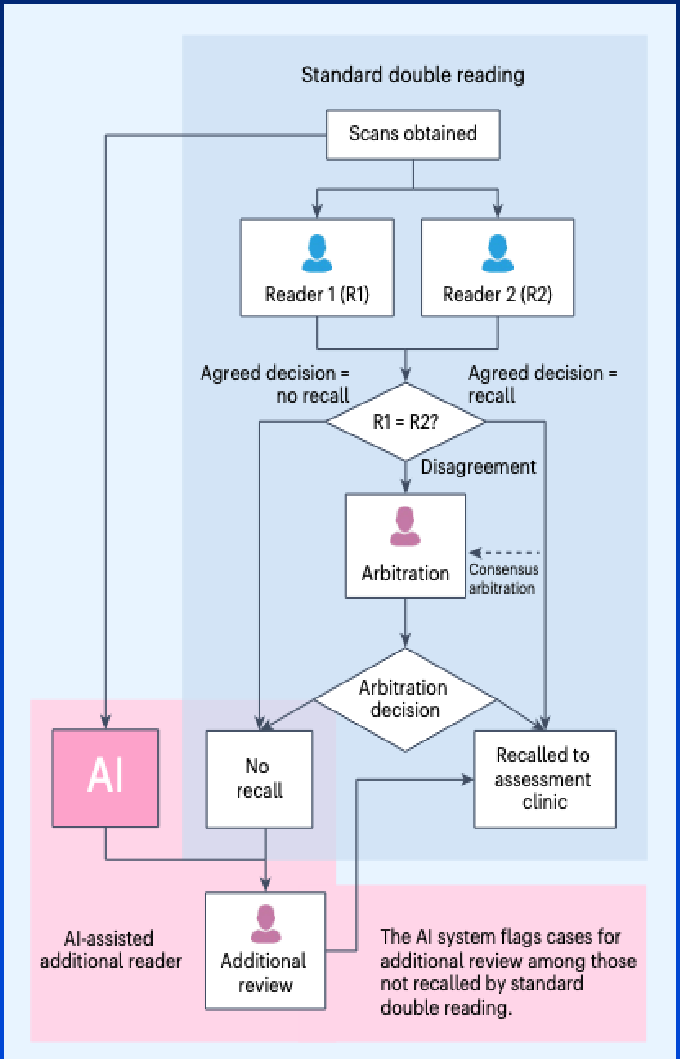
How AI Transformed Pulmonary Embolism Care at Cedars-Sinai: 5 Key Takeaways From the 10th Annual PERT Symposium

1. Faster Time to Activation, Faster Intervention
2. Shorter Stays, Improved Outcomes
3. Substantial Cost Savings
4. AI Expanding Beyond PE – stroke, trauma
5. A Growing Case for Mechanical Thrombectomy in PE – intermediate risk PE

https://www.aidoc.com/learn/blog/5-takeaways-cedars-pert-symposium/?utm_campaign=FY25_Connection_Oct_Unengaged&utm_medium=email&_hsenc=p2ANqtz-9lkT7zPCg5dq7xCwtugXqQTnfJI1atiGbABCVvehFPCKc-3H8t3VQI0C6fQp74EELdBuE4waiaInq92E89SErxD3L2wg&_hsmi=329278458&utm_content=329278458&utm_source=hs_automation

nature medicine

Prospective implementation of AI-assisted screen reading to improve early detection of breast cancer



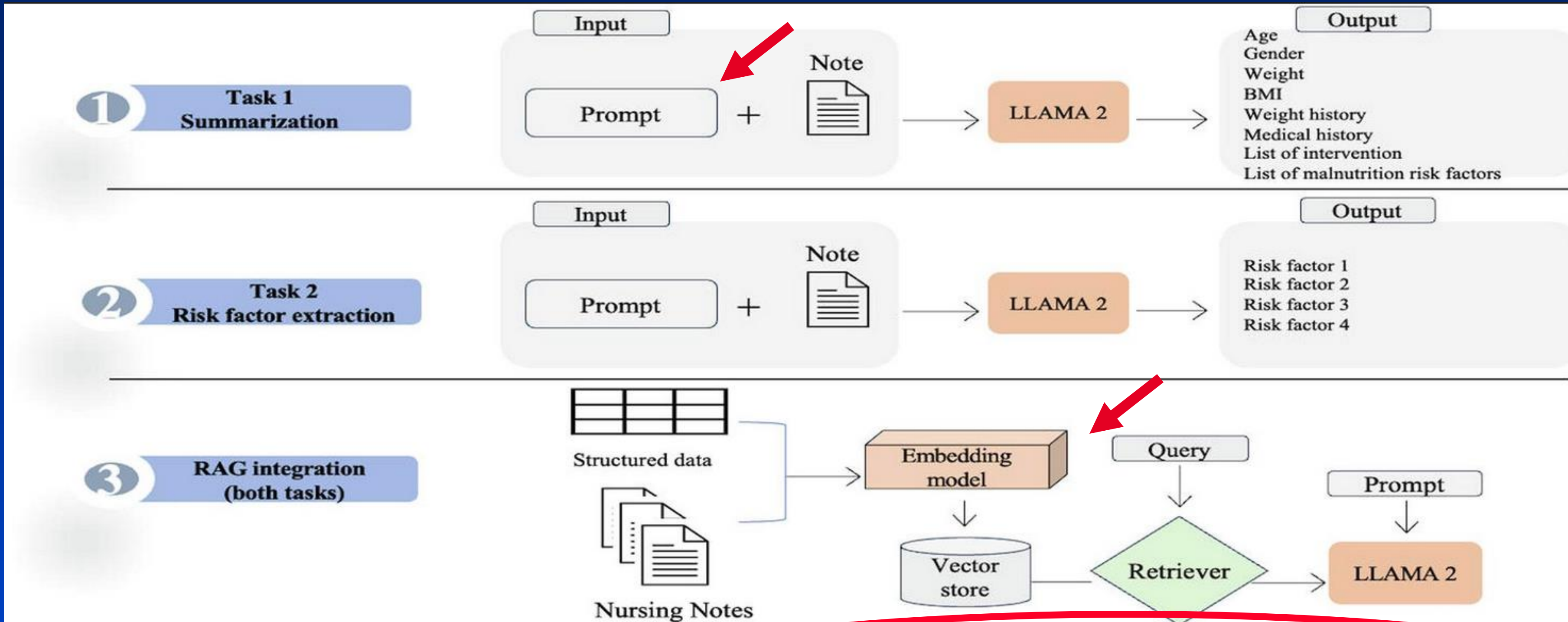
16,000 cases studies (3 phases)

showed that, compared to double reading, implementing the AI-assisted additional-reader process could achieve 0.7–1.6 additional cancer detection per 1,000 cases, with 0.16–0.30% additional recalls, 0–0.23% unnecessary recalls and a 0.1–1.9% increase in positive predictive value (PPV) after 7–11% additional human reads of AI-flagged cases (equating to 4–6% additional overall reading workload). The majority of cancerous cases detected by the AI-assisted additional-reader process were invasive (83.3%) and small-sized (≤10 mm, 47.0%). This evaluation suggests that using AI as an additional reader can improve the early detection of breast cancer with relevant

5-13% overall increase in cancer detection rate with AI-assisted reads

Ng et al. Nature Medicine | Volume 29 | December 2023 | 3044–3049

Applying generative AI with retrieval augmented generation to summarize and extract key clinical information from electronic health records



2474 notes
Nutritional status

Alkhalaf et al, *Journal of Biomedical Informatics 156 (2024) 104662*

...erative AI ...t nutritional status of RACFs' clients. The generated summaries provided concise and accurate representation of the original data with an overall accuracy of 93.25%. The addition of RAG improved the summarization process, leading to a 6% increase and achieving an accuracy of 99.25%. The model also proved its capability in extracting risk factors with an accuracy of 90%. However, adding RAG did not further improve accuracy in this task. Overall, the model has shown a robust performance when information was explicitly stated in the notes; however, it could encounter hallucination limitations, particularly when details were not explicitly provided.

Association between claims-based setting of diagnosis and treatment initiation among Medicare patients with hepatitis C

Data Sources and Study Setting: Medicare enrollment and claims data from 2014 to 2019.

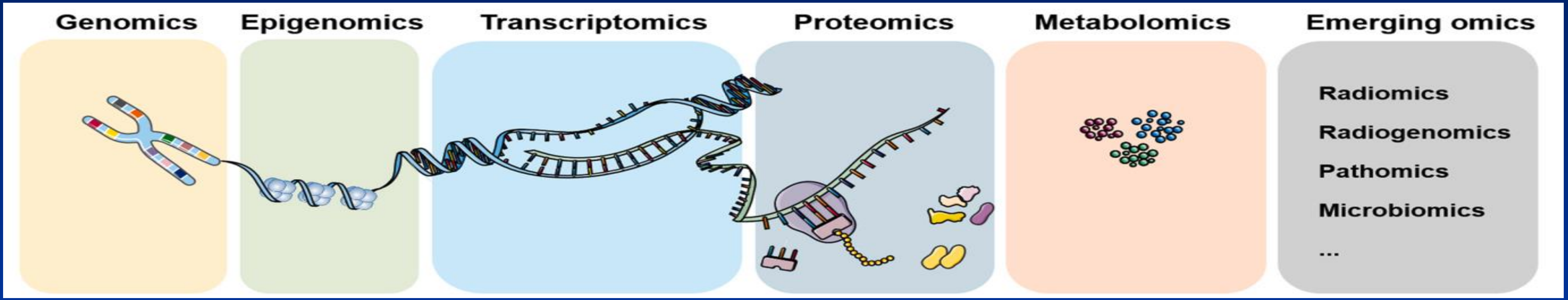
Study Design: We developed a claims-based algorithm using facility indicators, revenue center codes, and place of service codes to identify settings where HCV diagnosis first appeared. When the first appearance was in a laboratory, we attempted to

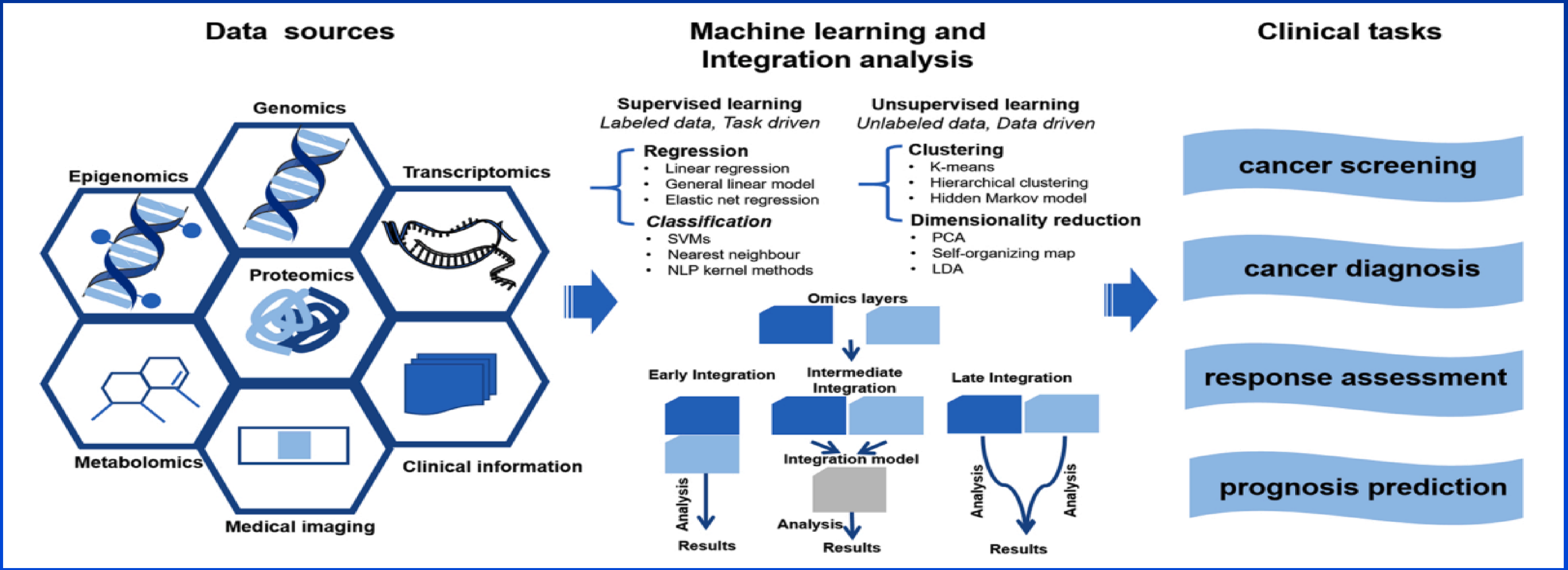
Principal Findings: Among 104,454 patients aged 18–64 and 66,726 aged ≥65, 70.1% and 69%, respectively, were diagnosed in outpatient settings, and 20.2% and 22.7%, respectively in laboratory or unknown settings. Logistic regression revealed significantly lower odds of treatment initiation after diagnosis in emergency departments/urgent cares, hospitals, laboratories, or unclassified settings, than in outpatient visits.

Conclusions: The algorithm identified the setting of HCV diagnosis in most cases, and found significant associations with treatment initiation, suggesting an approach that can be adapted for future claims-based studies.

Zhang et al. Health Serv Res. 2024;59:e14330.

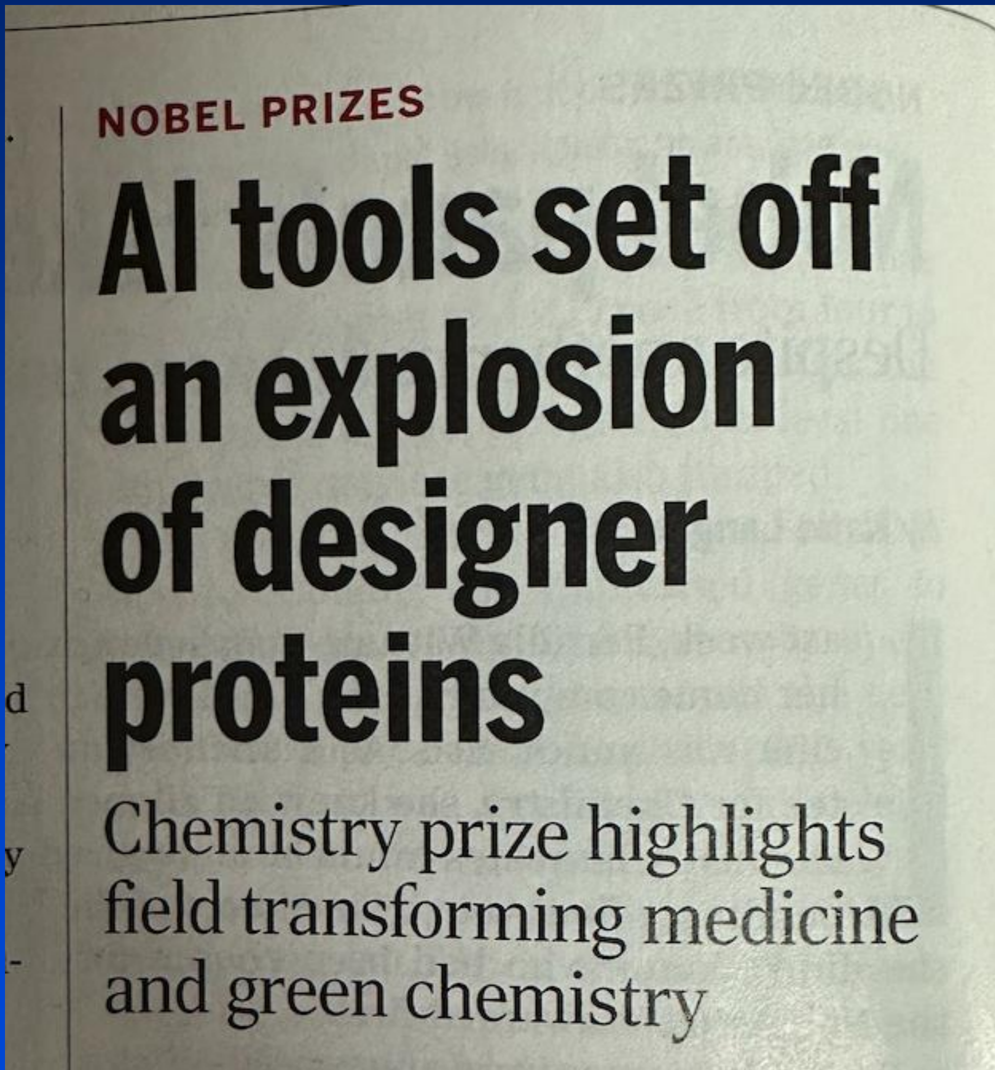
Artificial intelligence-based multi-omics analysis fuels cancer precision medicine





He at al. Seminars in Cancer Biology 88 (2023) 187-200

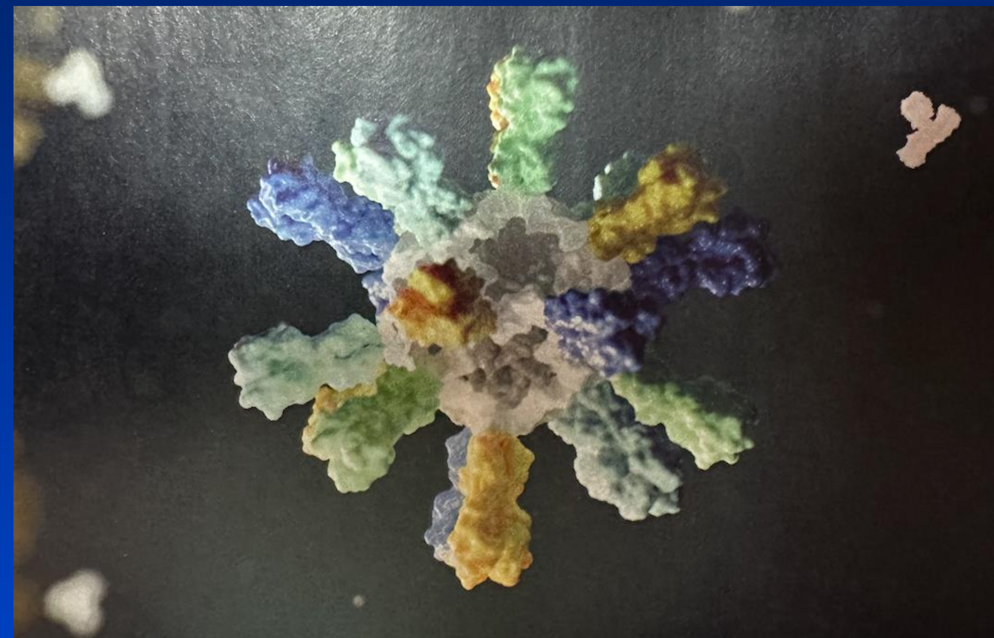
AI in Basic/Fundamental Research



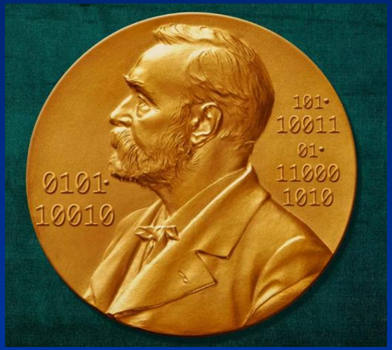
NOBEL PRIZES

AI tools set off an explosion of designer proteins

Chemistry prize highlights field transforming medicine and green chemistry



AI in Basic/Fundamental Research



Nobel Prize in Physics 2024

Geoffrey Hinton and John Hopfield
Artificial Neural Networks

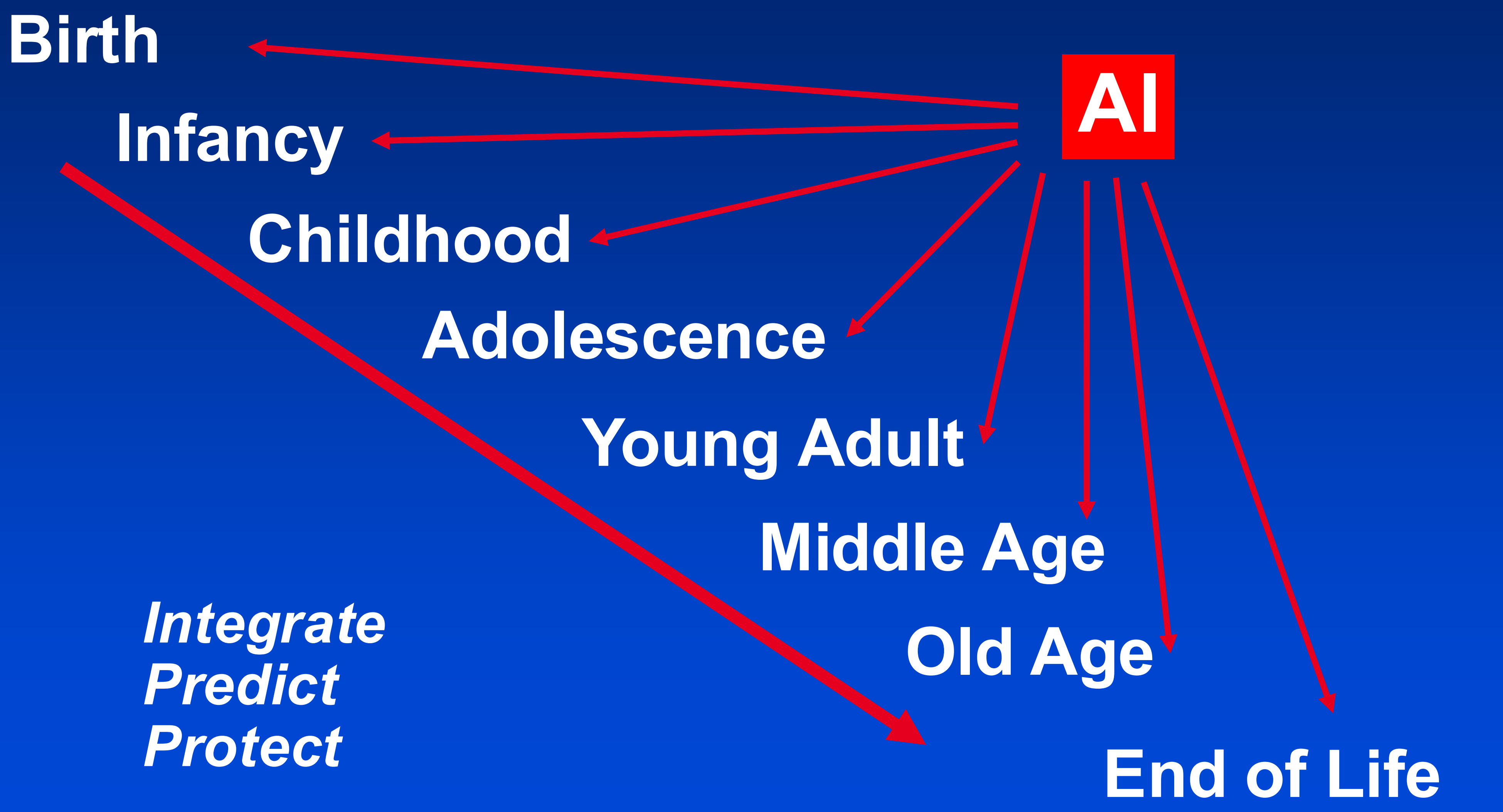
Nobel Prize in Chemistry 2024

Demis Hassabis and John Jumper – Google Deep Mind
Alpha fold – primary folding of proteins

David Baker – U Washington
Rose TTA Fold – function driven protein
structural design

AI – in Medicine – Analytical/Application Framework

AI Across the Patient Lifespan/Health Journey



Disease Natural History

Disease

Symptoms
Signs → Diagnosis (Dx) Preliminary/ Confirmatory → Therapy (Tx) → Tx → Tx → Cure / Chronic / Death

Biochemical
Cellular
Changes/markers

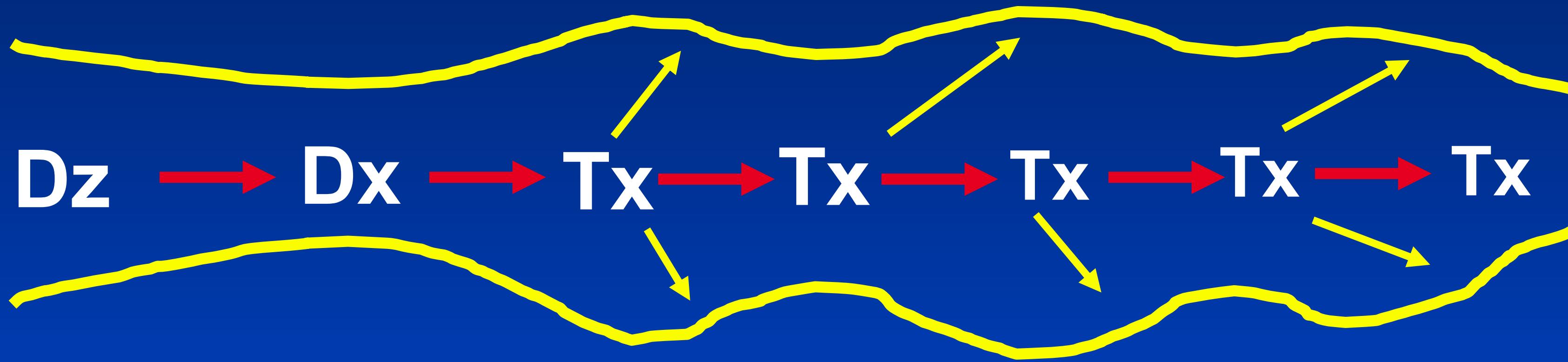
AI

Dx/Tx Assistant
Tx/Care Facilitator
Tx/Care Actor?

Disease Natural History

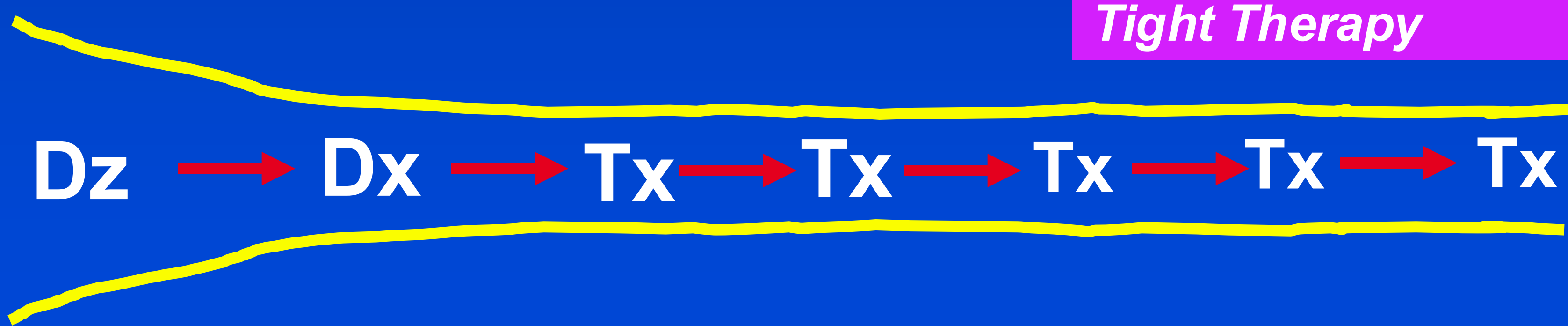
Traditional Care

Significant inter-visit intervals
Therapeutic deviations



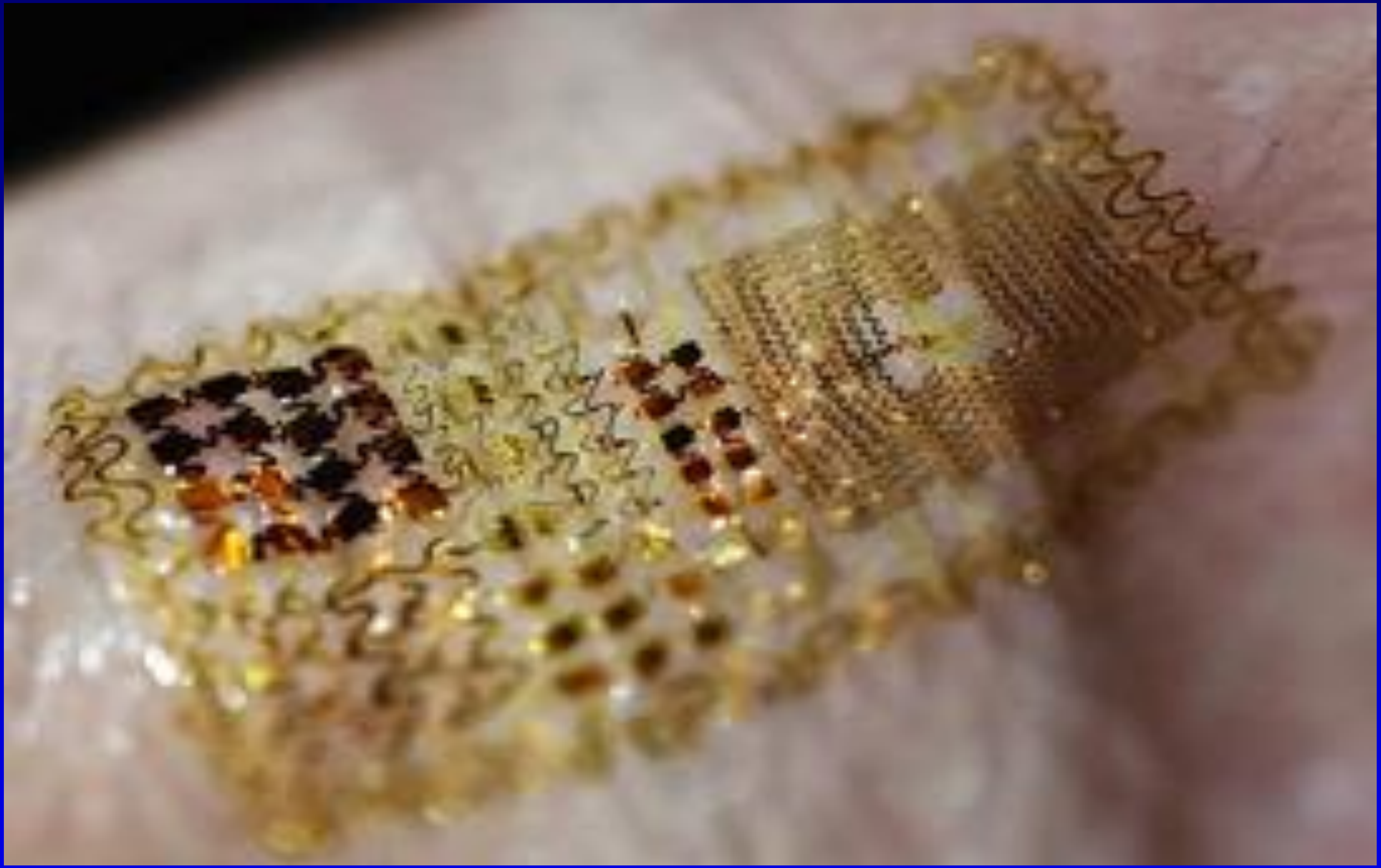
POC/Sensor + AI Augmented Care

Reduced inter-visit intervals
Tight Therapy



AI and Point-of-Care

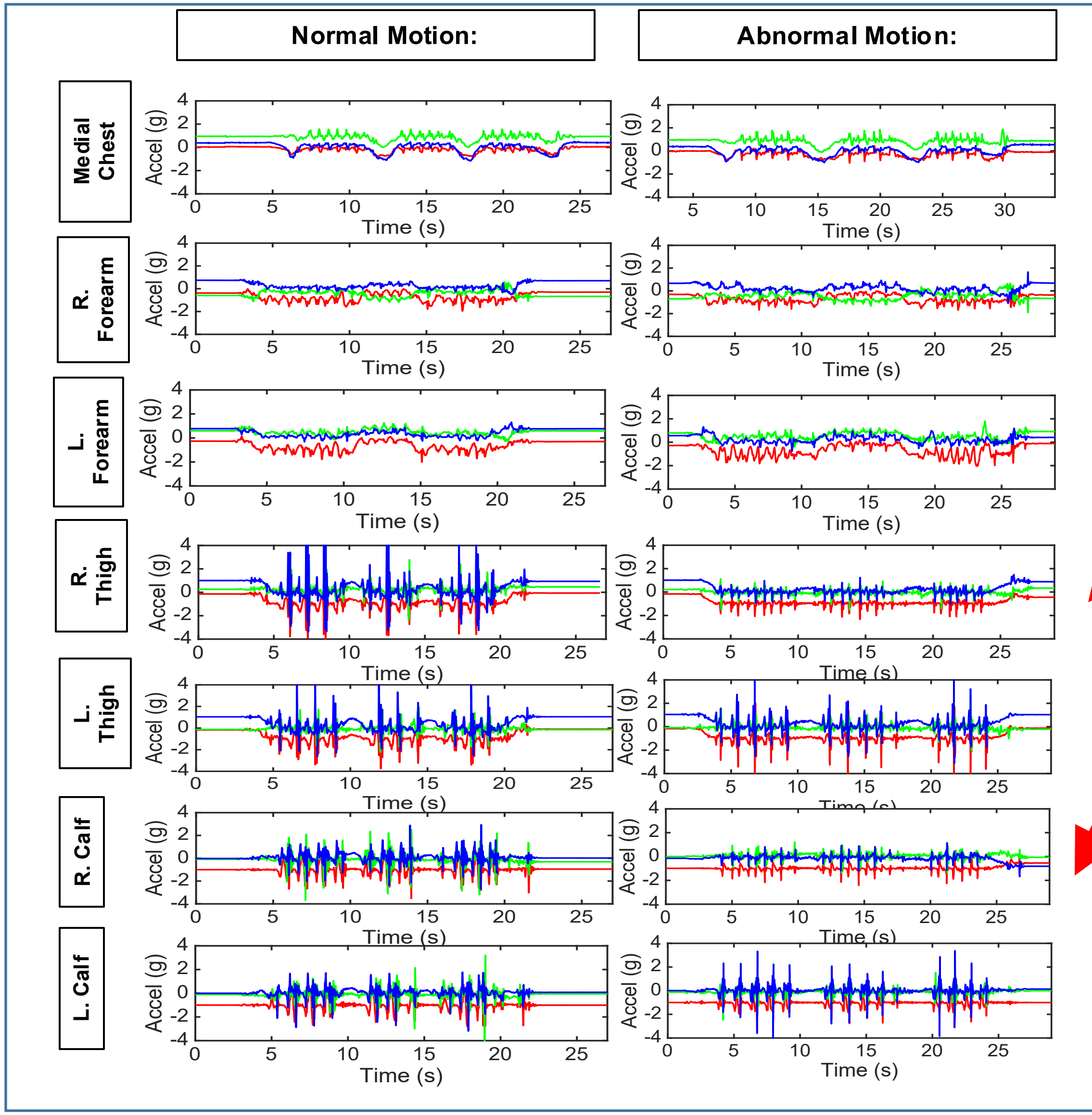
Amplification
Refinement
Guardrails
Insight
New Digital Biomarkers
Safety
Efficacy
Economy
Equity
Equality



BioStamp

mc10
reshaping electronics

Wearable Sensor Network:



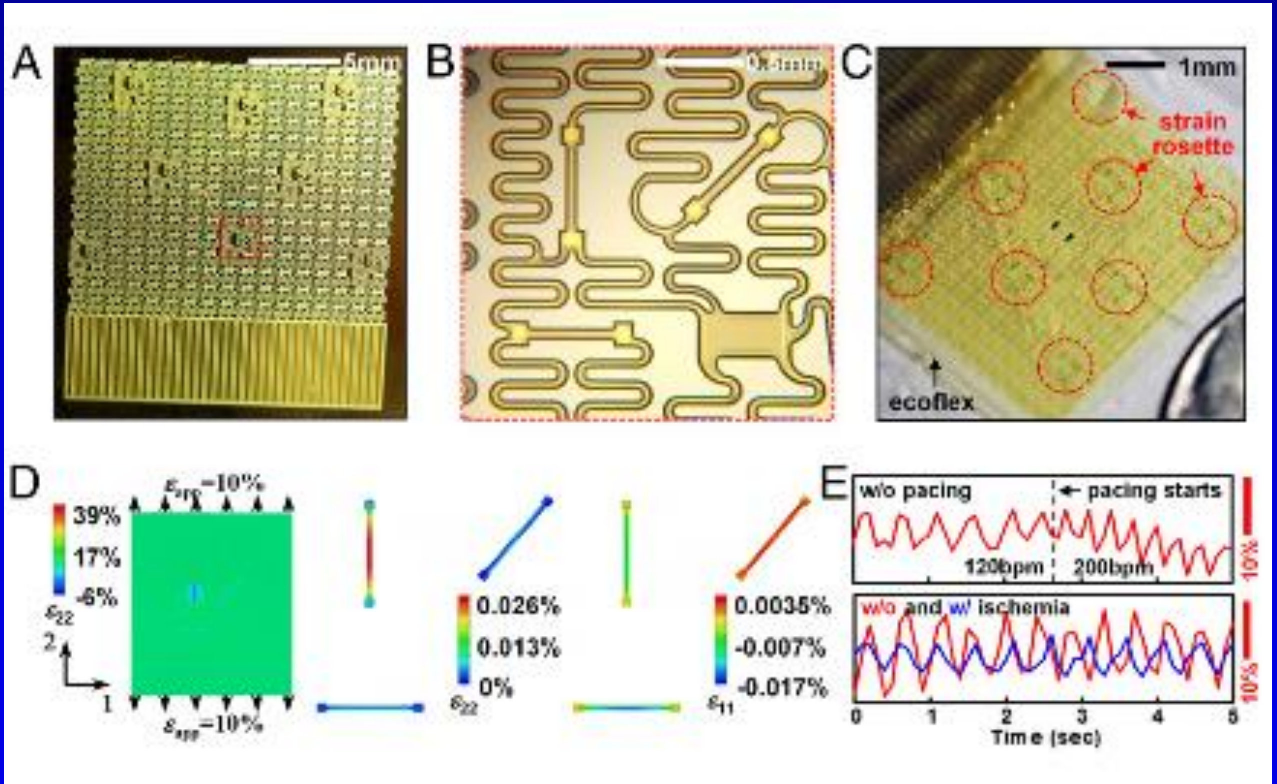
Affords detection of regional dysfunction

Advantages

- *Regional motion capture*
- *Tracking*
- *Alteration of component*
- *of envelope*
- *Targeted rehabilitation*
- *Targeted augmentation*
- *Integration with robotics*

Electronic sensor and actuator webs for large-area complex geometry cardiac mapping and therapy

Dae-Hyeong Kim[a,1], Roozbeh Ghaffari[b,1], Nanshu Lu[c,1], Shuodao Wang[d,1], Stephen P. Lee[b], Hohyun Keum[e], Robert D'Angelo[b], Lauren Klinker[b], Yewang Su[d,f], Chaofeng Lu[d,g], Yun-Soung Kim[e], Abid Ameen[e], Yuhang Li[d,h], Yihui Zhang[d,f], Bassel de Graff[b], Yung-Yu Hsu[b], ZhuangJian Liu[i], Jeremy Ruskin[j], Lizhi Xu[e], Chi Lu[e], Fiorenzo G. Omenetto[k], Yonggang Huang[d], Moussa Mansour[j], Marvin J. Slepian[l], and John A. Rogers[e,2]



Sensor arrays on sheets

Conformal to epicardium

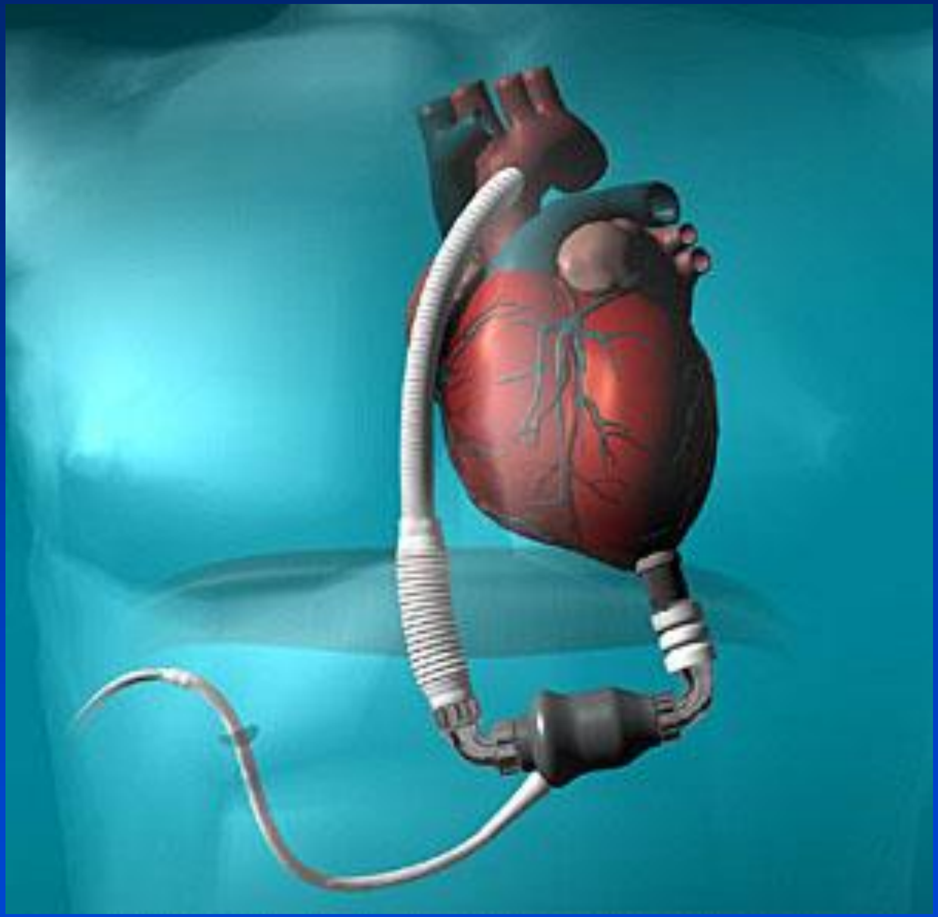
Measure:

Electrical activity
Temperature
Mechanical strain
Pressure
Physical contact

Kim et al ***PNAS*** **109:19910, 2012**

Mechanical Circulatory Support

Catheter
Pumps



Ventricular
Assist Devices

Total
Artificial Heart

Artificial Intelligence - MCS

AI empowered MCS systems and care

1. Design optimization
2. Sensors/Physio control
3. Patient selection
4. Device implantation
5. Patient management
6. Med Adjustment/Adjunctive Tx
7. Recovery detection
8. End of life

Artificial Intelligence in MCS

Deconstruct the "MCS" process

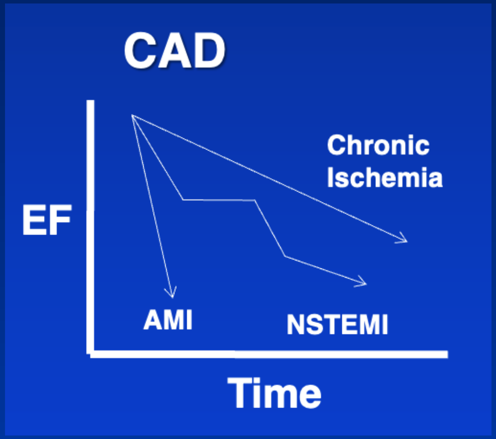
Time: Define the **Patient Journey** and apply

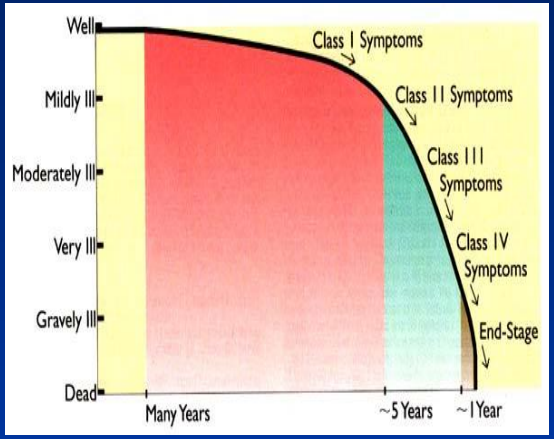
Level: Operating at what **"scale,"** outcome goals

Application: Device, adjunctive Tx, enterprise

Inter-connectedness: Systems Biology/
Precision Medicine, Integrated care,
whole patient experience

Time: Impella Natural History





AI

*

*

Integrate with 300K + pts experience

* Pre- Implant

* Implant

* Weaning

* Post-Implant

Patient screening
Device selection
Adjunctive Rx
optimization

P level (RPM)
Positioning
Escalation
CP to 5.5
Add RP
5.5 to VAD

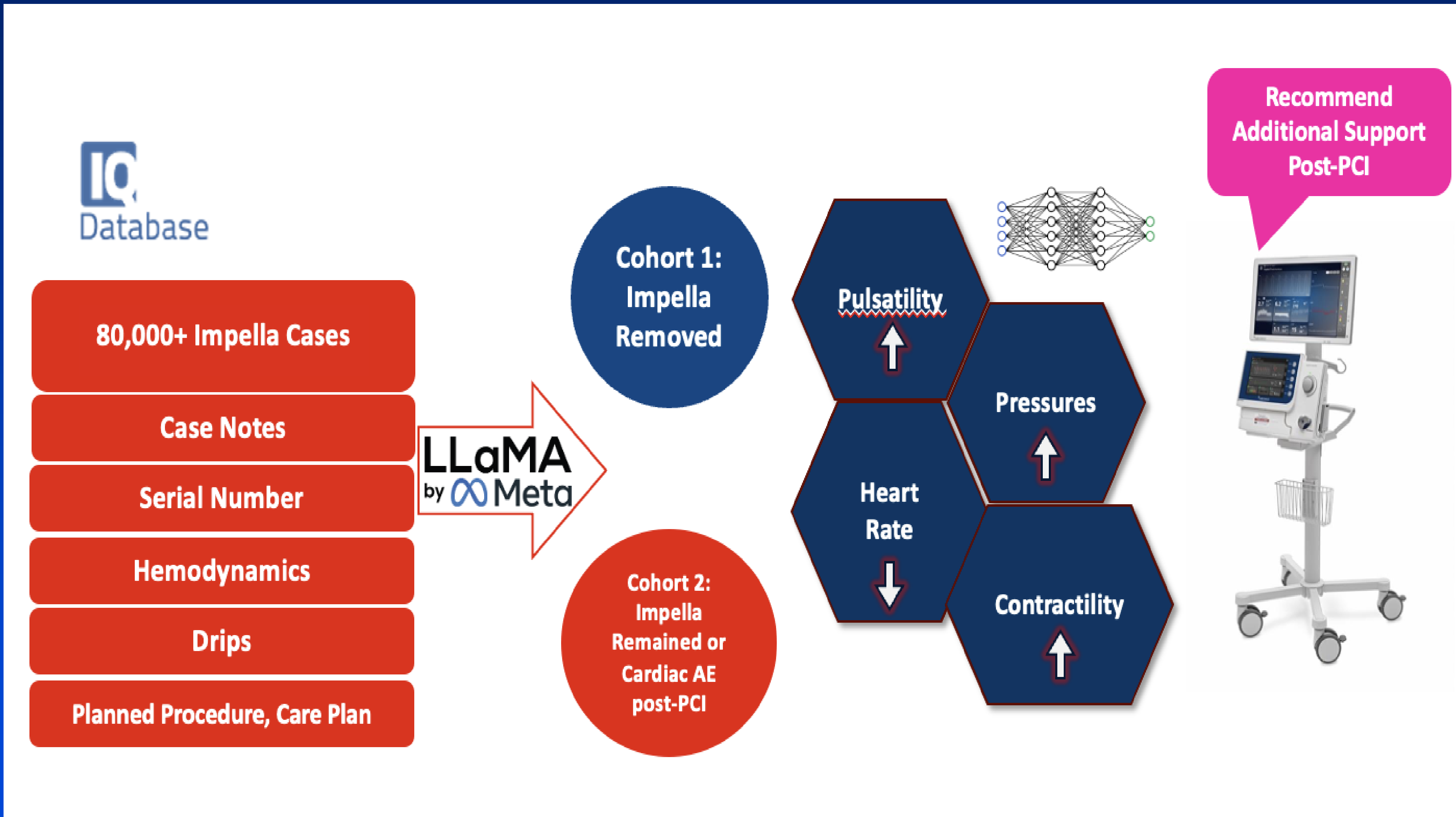
Cath lab
ICU/CCU
Recovery
detection

Recovery
Rehab

Utility of AI Algorithms/Smart Systems in MCS

Which patients will benefit most?
When is the time to initiate use?
How should use be modulated while in place?
When is RV support needed, How long?
How should adjunctive pharmacology be managed?
How will adjunctive pulmonary/fluid/renal/metabolic management affect performance? And heart and organ function?
When and how should support be de-escalated
Can on pump end-points predict long-term outcomes?
Can Impella serve as enhanced theragnostic platform?

Cath Lab Impella Weaning



Escalation Strategies

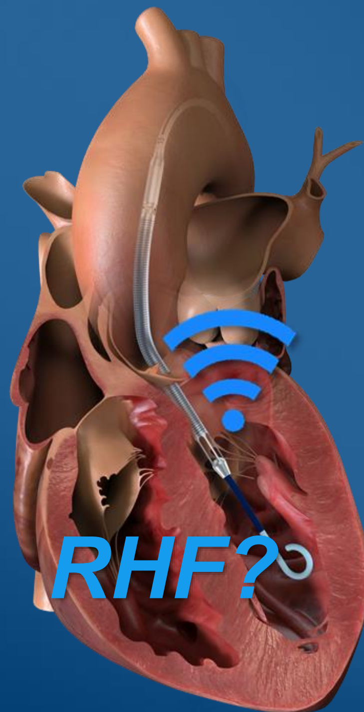
If CP at P9 at TOTAL CO = 3.5 = Concern!
Is LV systolic < AO Systolic = No AV opening

- **Anticipate** these from **AI modeling**
- Develop **signatures**
- Develop **test wean routines** (auto test wean)
- Feedback for gathered **collective patient experience**
- Escalate to Greater = 5.5 or beyond

RV support

Identifying Right Heart Failure from Left Heart Impella Signals

RHF Dashboard



RHF AI Prediction

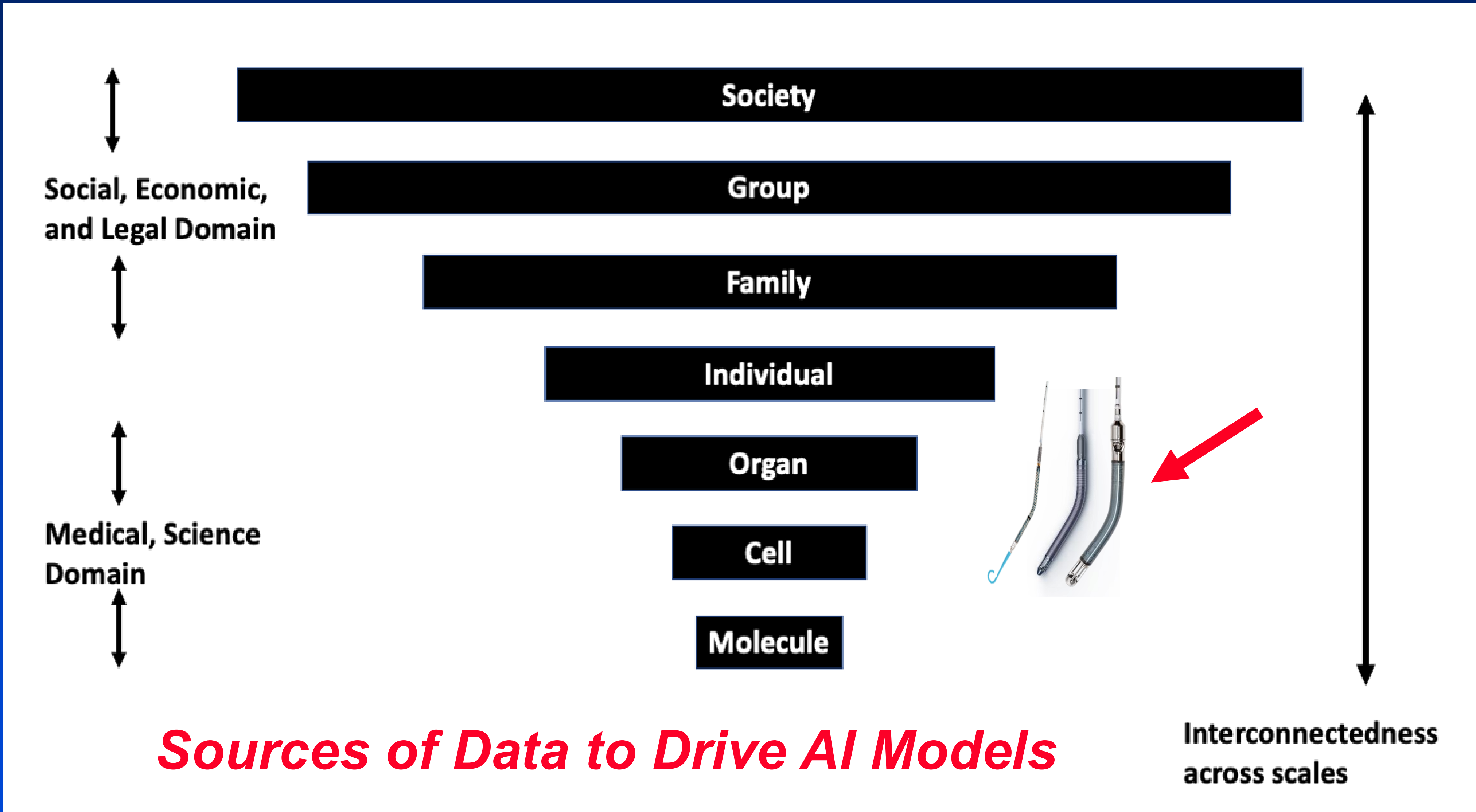
AI will assist with enhanced outcome measures

Survival
Net systemic perfusion
Left and R heart integrated performance
Organ perfusion
Organ/vascular function
Cellular metabolism
Cellular longevity/Recovery
Inflammatory and other markers
Molecular /Biomarker signatures

Reverse/
?Future order

Doing the best
for our patients
vs. CMS window

Multi-Scale Thinking and AI



Slepian MJ, Synergistic Approaches of Cross-Fertilization and Feedback Together Driving and Advancing Health for All. in K. Ramos, ed. *Comprehensive Precision Medicine*, Elsevier 2024.

Integrated Electronic Biomaterial Systems

Externals

Catheter

Sheet/Array

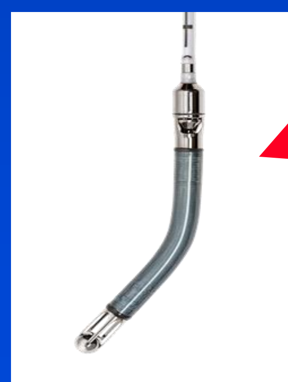
PPM

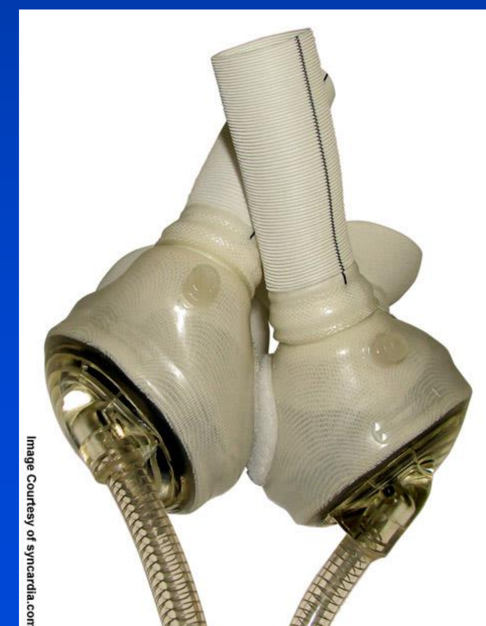
ICD

Smart Stent

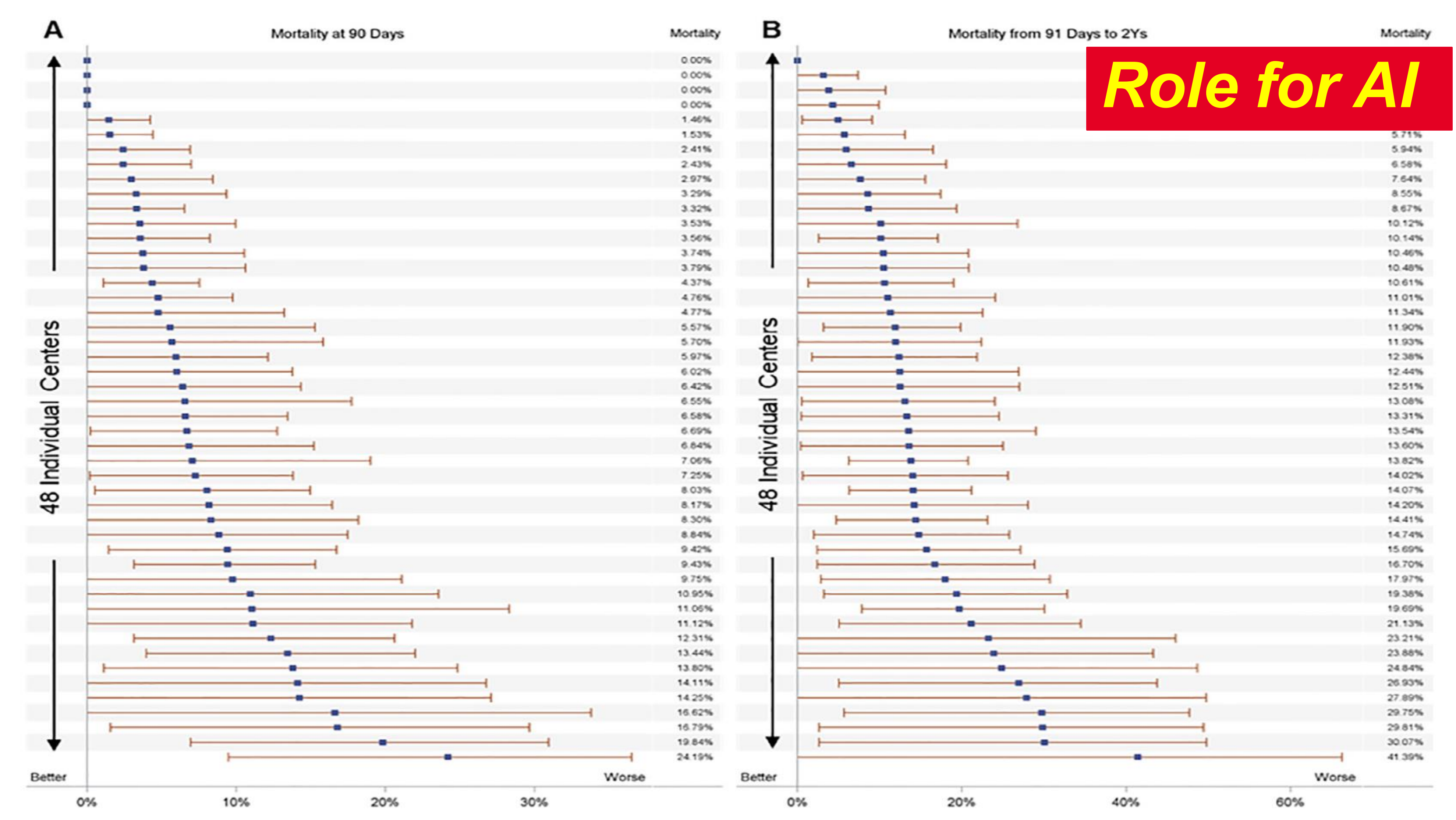
Catheter pump

VAD/TAH



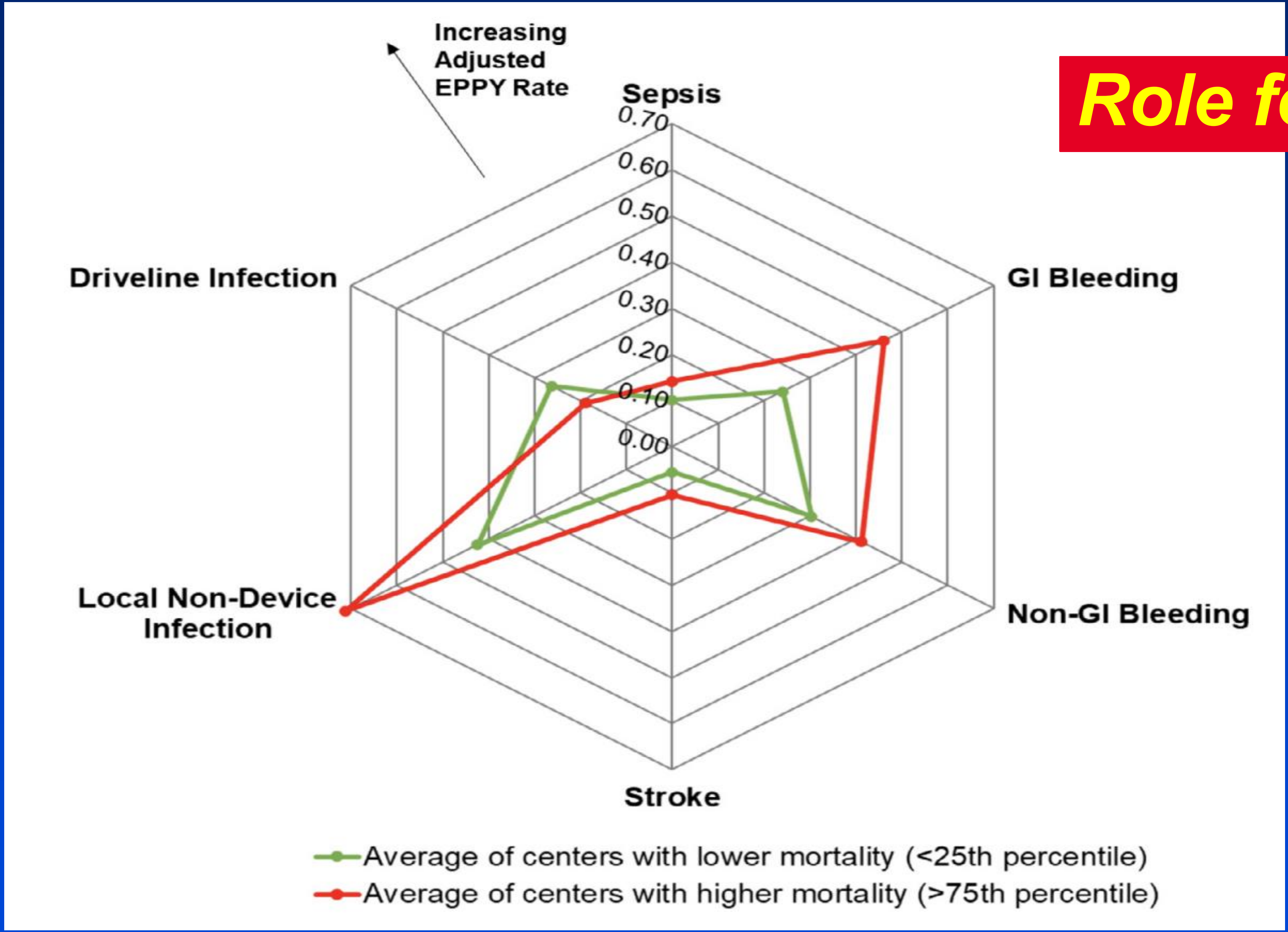


Center Variability in Patient Outcomes Following HeartMate 3 Implantation: An Analysis of the MOMENTUM 3 Trial



Kanwar et al J Cardiac Failure 28:1158, 2022

Center Variability in Patient Outcomes Following HeartMate 3 Implantation: An Analysis of the MOMENTUM 3 Trial



Role for AI

Kanwar et al J Cardiac Failure 28:1158, 2022

Slepian/ACABI studies

PLOS DIGITAL HEALTH

Diverse patients' attitudes towards Artificial Intelligence (AI) in diagnosis

2 parts:

1. **Structured interviews**, diverse patients to pretest materials
2. **Randomized, blinded survey experiment in factorial design**

N=2675, oversamples minorities

Question:

1° EPV = patient preference AI clinic vs. Human MD

Two clinical vignettes – Leukemia vs Sleep apnea

Eight variables including AI accuracy, AI personalization, Racial/Ethnic bias, PCP promise to explain/incorporate AI

Robertson…Slepian PLOS Digital Health |
https://doi.org/10.1371/journal.pdig.0000237 May 19, 2023

PLOS DIGITAL HEALTH

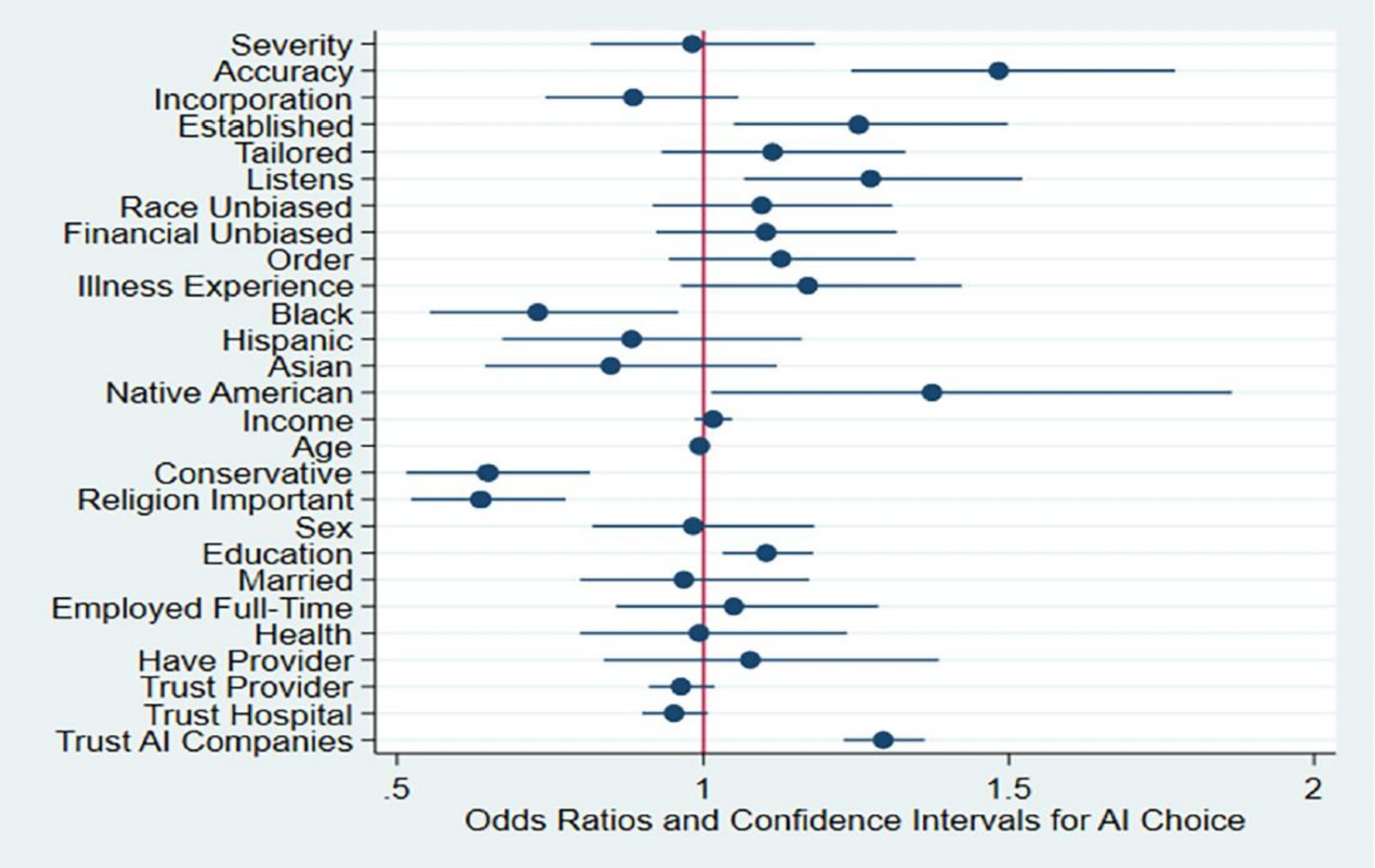
Diverse patients' attitudes towards Artificial Intelligence (AI) in diagnosis

Results: Respondents were split:

52.9% chose Human Doctor vs 47.1% AI clinic

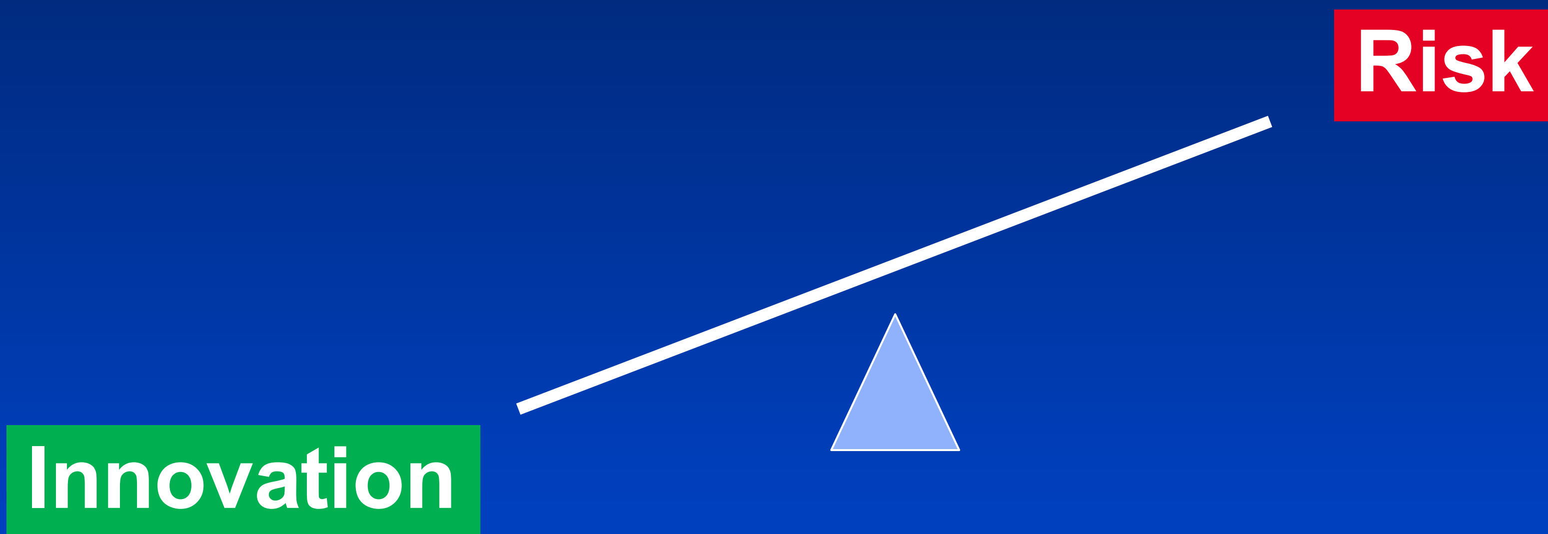
	Odds Ratio
PCP explanation AI superior	1.48
PCP nudge to AI	1.25
Reassurance AI "will listen"	1.27
Black v White	0.73
Native American v White	1.37

Robertson…Slepian PLOS Digital Health https://doi.org/10.1371/journal.pdig.0000237
May 19, 2023



Robertson…Slepian PLOS Digital Health | May 19, 2023

Regulation



AI Takeover

Theoretic vs real risk
AI is human developed
Need transparency of systems
Guidelines
Guardrails
Regulations

Human diligence
    Engagement
    Watchdog

AI: Threats/Concerns

Inaccuracy
Truth(fullness)/Veracity
Trustworthy
Misinformation
Disinformation
Reliance - for critical decision making
Impact on education and research
Impact on Originality – “authorship”
Job Loss
Independent actor

Lack of control
Lack of oversight/
Absence of Regulation

Research Letter | Health Informatics

Perspectives on Artificial Intelligence–Generated Responses to Patient Messages

3,769,023 Patient Medical Advice Requests in EHRs, 1089 clinical questions and included 59 messages

Table. Satisfaction of AI and Clinician Responses and Association With the Length of Responses

	AI[a]					Clinicians				
				Satisfaction and the length of response					Satisfaction and the length of response	
Division	Assessments, No.	Satisfaction estimate (SE)[b]	No. of characters, mean (SD)	Standardized β[c]	*P* value	Assessments, No.	Satisfaction estimate (SE)[b]	No. of characters, mean (SD)	Standardized β[c]	*P* value
Overall	213	3.96 (0.09)	1470.77 (391.83)	0.10	.16	195	3.05 (0.09)	254.37 (198.85)	0.23	.002
Cardiovascular	78	4.09 (0.14)	1559.04 (424.83)	0.068	.58	75	3.25 (0.14)	306.36 (221.09)	0.29	.02
Internal medicine	87	3.82 (0.13)	1314.72 (347.11)	0.037	.72	78	2.94 (0.14)	146.31 (109.43)	0.0056	.96
Endocrinology	48	4.00 (0.19)	1610.19 (330.87)	0.25	.08	42	2.90 (0.20)	362.21 (200.79)	0.31	.09

with the clinician-determined information quality and empathy. For example, satisfaction was highest with AI responses to cardiology questions while information quality and empathy were highest in endocrinology questions. Interestingly, clinicians' response length was associated with satisfaction while AI's response length was not. The findings suggest that the extreme brevity of responses could be a factor that lowers satisfaction in patient-clinician communication in EHR.

JAMA Network Open. 2024;7(10):e2438535.
doi:10.1001/jamanetworkopen.2024.38535

October 16, 2024

The New York Times

9 © 2024 The New York Times Company THURSDAY, SEPTEMBER 26, 2024

Some Worry No One Will Catch Mistakes by Doctor's A.I. Helper

By TEDDY ROSENBLUTH

Every day, patients send hundreds of thousands of messages to their doctors through MyChart, a communications platform that is nearly ubiquitous in U.S. hospitals.

They describe their pain and divulge their symptoms — the texture of their rashes, the color of their stool — trusting the doctor on the other end to advise them.

But increasingly, the responses to those messages are not written by the doctor — at least, not entirely. About 15,000 doctors and assistants at more than 150 health systems are using a new artificial intelligence feature in MyChart to draft replies to such messages.

Many patients receiving those replies have no idea that they were written with the help of artificial intelligence. In interviews, officials at several health systems using MyChart's tool acknowledged that they do not disclose that the messages contain A.I.-generated content.

The trend troubles some experts who worry that doctors may

Continued on Page A21

Some Worry About Doctor's A.I. Helper

From Page A1

not be vigilant enough to catch potentially dangerous errors in ...

some of the country's largest aca-

demic medical centers were eager to adopt it.

Instead of starting each mes-

innovation officer.

Patients have generally accepted the new technology, he

MYCHART

MyChart, a widely used patient portal, now has a tool powered by A.I. that doctors can use to write to patients.

Brent Lamm, chief information officer for U.N.C. Health, said this addressed complaints from doctors: "My personal voice is not coming through" or "I've known this patient for seven years. They're going to know it's not me."

Health care administrators often refer to Art as a low-risk use of A.I., since ideally a provider is always reading through the drafts and correcting mistakes.

The characterization annoys researchers who study how humans work in relation to artificial intelligence. Ken Holstein, a professor at the human-computer interaction institute at Carnegie Mellon, said the portrayal "goes against about 50 years of research."

Humans have a well-documented tendency, called automation bias, to accept an algorithm's recommendations even if it contradicts their own expertise, he said. This bias could cause doctors to be less critical while reviewing A.I.-generated drafts, potentially allowing dangerous errors to reach patients.

And Art is not immune to mistakes. A recent study found that seven of 116 A.I.-generated drafts contained so-called hallucinations — fabrications that the technology is notorious for conjuring.

Dr. Vinay Reddy, a family medicine doctor at U.N.C. Health, recalled an instance in which a patient messaged a colleague to check whether she needed a hepatitis B vaccine.

The A.I.-generated draft confidently assured the patient she had gotten her shots and provided dates for them. This was completely false, and occurred because the model didn't have access to her vaccination records, he said.

A small study published in The Lancet Digital Health found that GPT-4, the same A.I. model that underlies Epic's tool, made more insidious errors when answering hypothetical patient questions.

Physicians reviewing its answers found that the drafts, if left unedited, would pose a risk of severe harm about 7 percent of the time.

What reassures Dr. Eric Poon, chief health information officer at Duke Health, is that the model produces drafts that are still "moderate in quality," which he thinks keeps doctors vigilant about catching errors.

On average, fewer than a third of A.I.-generated drafts are sent to patients unedited, according to Epic, an indication to hospital administrators that doctors are not rubber-stamping messages.

"One question in the back of my mind is, what if the technology got better?" he said. "What if clinicians start letting their guard down? Will errors slip through?"

Epic has built guardrails into the programming to steer Art away from giving clinical advice, said Garrett Adams, a vice president of research and development at the company.

Mr. Adams said the tool was best suited to answer common administrative questions like "When is my appointment?" or "Can I reschedule my checkup?"

But researchers have not developed ways to reliably force the models to follow instructions, Dr. Holstein said.

Dr. Anand Chowdhury, who helped oversee deployment of Art at Duke Health, said he and his colleagues repeatedly adjusted instructions to stop the tool from giving clinical advice, with little success.

"No matter how hard we tried, we couldn't take out its instinct to try to be helpful," he said.

Three health systems told The New York Times that they removed some guardrails from the instructions.

Dr. Longhurst at U.C. San Diego Health said the model "performed better" when language that instructed Art not to "respond with clinical information" was removed. Administrators felt comfortable giving the A.I. more freedom since doctors review its messages.

Beyond questions of safety and transparency, some bioethicists have a more fundamental concern: Is this how we want to use A.I. in medicine?

Unlike many other A.I. health care tools, Art isn't designed to improve clinical outcomes (though one study suggested responses may be more empathetic and positive), and it isn't targeting strictly administrative tasks.

Instead, A.I. seems to be intruding on rare moments when patient and doctors could actually be communicating with one another directly — the kind of moments that technology should be enabling, said Daniel Schiff, co-director of the Governance and Responsible A.I. Lab at Purdue University.

"Even if it was flawless, do you want to automate one of the few ways that we're still interacting with each other?"

Artificial Intelligence in Healthcare: Ethics

Ethics
Expectation of Doctor-patient 1:1 engagement
Compassion
Care
Concern
Human soft skills engagement
Focus
Dedication
Personalization
Context/Family/Work/Social situation
Operate within the “envelope of trust”

AI in Healthcare: Transparency and Notice

Pro vs Con

Notice
Fully informed
Defined expectations

Fear of NO human/provider involvement
Impression of lack of concern
Sense of betrayal
Risk of dissatisfaction
Concern of accuracy
Loss of patient from health system

NATIONAL ACADEMY OF MEDICINE

Health Care Artificial Intelligence Code of Conduct

Toward a Code of Conduct Framework for Artificial Intelligence in Health, Health Care, and Biomedical Science

"aimed at providing a guiding framework to ensure that AI algorithms and their application in health, health care, and biomedical science perform accurately, safely, reliably, and ethically in the service of better health for all."

The FDA classifies software-based medical devices into **two main** categories:

1. **Software in a Medical Device** (SiMD): Software embedded within a medical device.

2. **Software as a Medical Device** (SaMD): Software intended for medical purposes but functioning independently of any hardware device.

950 such AI-based medical devices to date

Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices

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

Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis

THE LANCET Digital Health

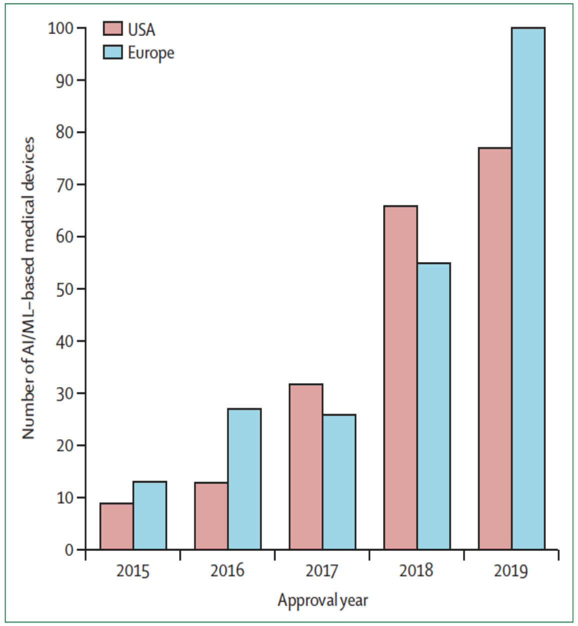
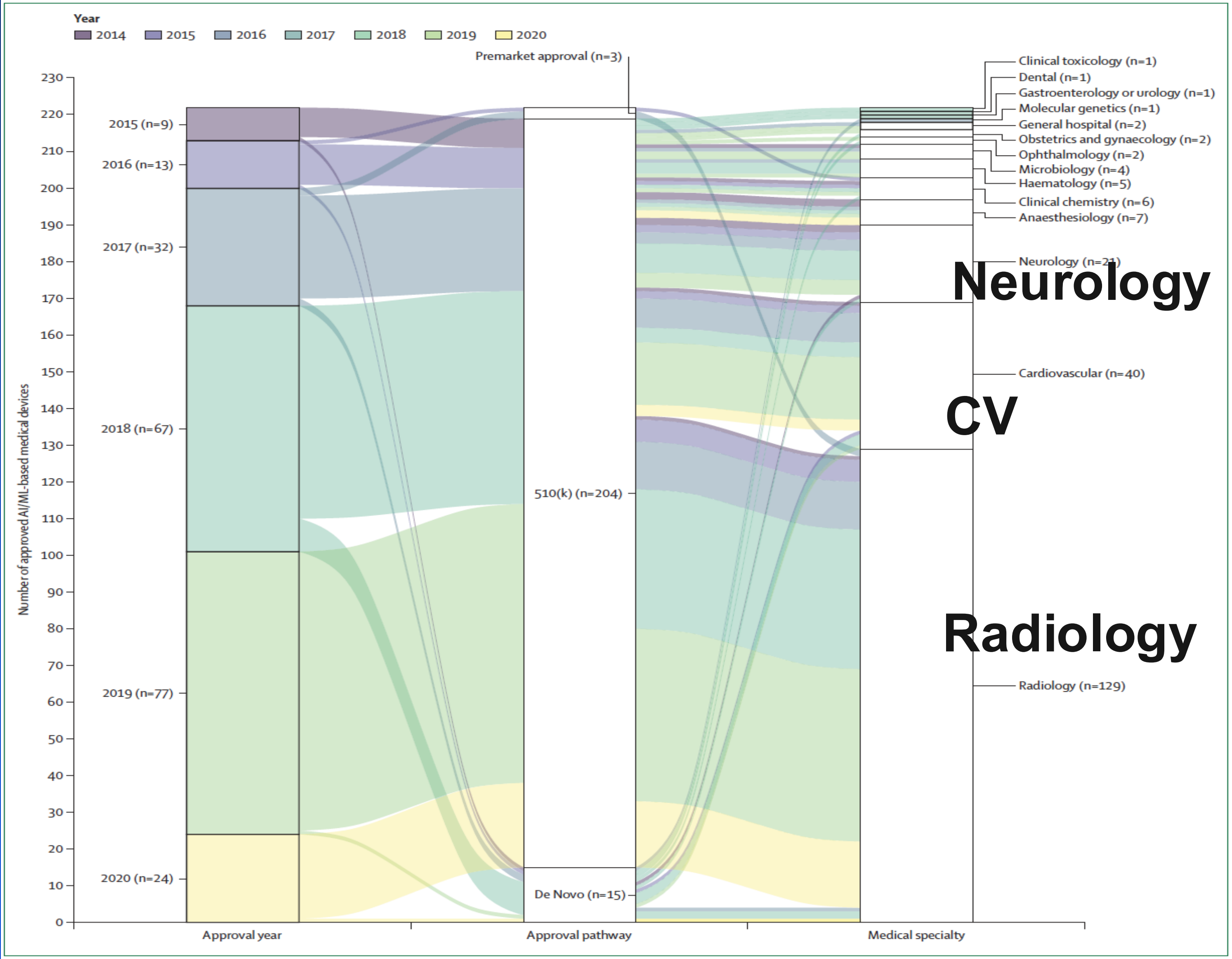


Figure 2: Number of approved (USA) and CE-marked (Europe) AI/ML-based medical devices between 2015 and 2019
The CE-mark year is considered the approval year for devices in Europe. AI/ML=artificial intelligence and machine learning. CE=*Conformité Européenne*.



Muehlematter, et al
www.thelancet.com/digital-health Vol 3 March 2021

comment

Check for updates

How medical AI devices are evaluated: limitations and recommendations from an analysis of FDA approvals

A comprehensive overview of medical AI devices approved by the US Food and Drug Administration sheds new light on limitations of the evaluation process that can mask vulnerabilities of devices when they are deployed on patients.

Eric Wu, Kevin Wu, Roxana Daneshjou, David Ouyang, Daniel E. Ho and James Zou

Medical artificial-intelligence (AI) algorithms are being increasingly proposed for the assessment and care of patients. Although the academic community has started to develop reporting guidelines for AI clinical trials[1–3], there are no established best practices for evaluating commercially available algorithms to ensure their reliability and safety. The path to safe and robust clinical AI requires that important regulatory questions be addressed. Are medical devices able to demonstrate performance that can be generalized to the entire intended population? Are commonly faced shortcomings of AI (overfitting to training data, vulnerability to data shifts, and bias against underrepresented patient subgroups) adequately quantified and addressed?

In the USA, the US Food and Drug Administration (FDA) is responsible for

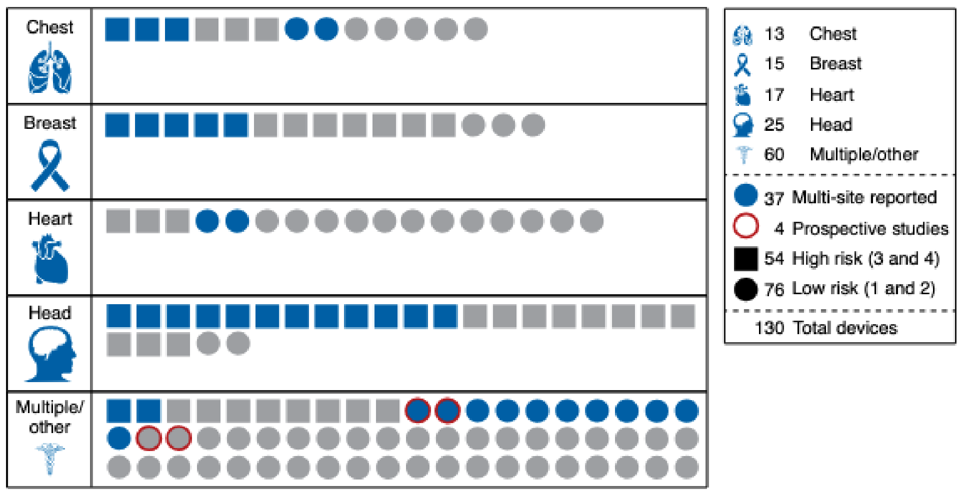


Fig. 1 | Breakdown of 130 FDA-approved medical AI devices by body area. Devices are categorized by risk level (square, high risk; circle, low risk). Blue indicates that a multi-site evaluation was reported; otherwise, symbols are gray. Red outline indicates a prospective study (key, right margin). Numbers in key indicate the number of devices with each characteristic.

126/130 devices evaluated retrospectively

No significant prospective studies

Number of evaluation sites not reported

Most reported cases involve only 1 or 2 sites

Issues:

Generalizability

Bias

Overfitting of training data

Nature Medicine | VOL 27 | AprilL 2021 | 576–584 | www.nature.com/naturemedicine

U.S. FOOD & DRUG
ADMINISTRATION

FDA-Approved AI based Algorithms

HealthCCS	Zebra Medical Vision Ltd.	coronary artery calcification algorithm	K172983	510(k) premarket notification
RayCare 2.3	RaySearch Laboratories AB	Medical charged-particle radiation therapy system	K191384	510(k) premarket notification
KardiaAI	AliveCor, Inc	six-lead smartphone ECG	K181823	510(k) premarket notification
FibriCheck	Qompium NV	Cardiac Monitor	K173872	510(k) premarket notification
Current Wearable Health Monitoring System	Current Health Ltd.	Monitoring vital signs	K191272	510(k) premarket notification
BioFlux	Biotricity Inc.	detecting arrhythmias	K172311	510(k) premarket notification
MindMotion GO	MindMaze SA	software with rehabilitation exercises for the elderly	K173931	510(k) premarket notification
Cognoa ASD Diagnosis Aid	Cognoa, Inc	Software aid in the diagnosis of Autism Spectrum Disorder	DEN200069	de novo pathway
Loop System	Spry Health, Inc.	Monitoring vital signs	K181352	510(k) premarket notification
Quicktome	Omniscient Neurotechnology Pty Ltd	Digital brain mapping platform	K203518	510(k) premarket notification
Embrace	Empatica Srl	wearable for seizure monitoring	K181861	510(k) premarket notification
ACR | LAB Urine Analysis Test System	Healthy.io Ltd	Urinary tract infection diagnosis	K182384	510(k) premarket notification

https://medicalfuturist.com/fda-approved-ai-based-algorithms/

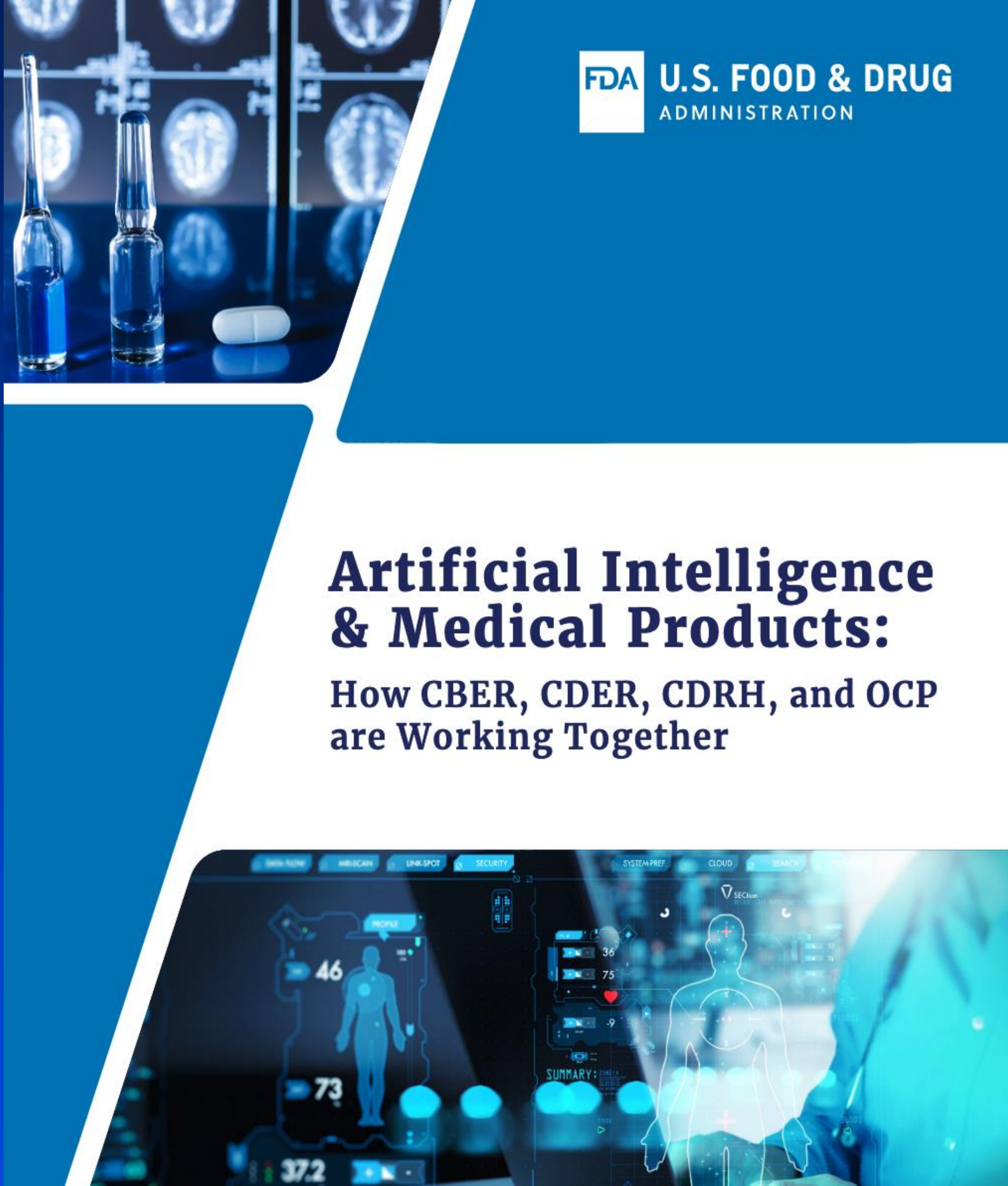
How about Adaptive AI??

"traditional" pathways of FDA approval of software as either medical device (SAMD) or in a medical device (SIMD) do not apply to adaptive AI

The device/system is changing from the time of submission - they improve and make modifications in real time based on real-world usage.

FDA published "Good Machine Learning Practice for Medical Device Development: Guiding Principles"

A dynamic area for regulation evolution


FDA U.S. FOOD & DRUG ADMINISTRATION
Artificial Intelligence & Medical Products:
How CBER, CDER, CDRH, and OCP are Working Together


Foster Collaboration to Safeguard Public Health
Advance the Development of Regulatory Approaches that Support Innovation
Area of Focus
Promote the Development of Harmonized Standards, Guidelines, Best Practices, and Tools
Support Research Related to the Evaluation and Monitoring of AI Performance

March 2024

VIEWPOINT

AI IN MEDICINE

Health Care Privacy Risks of AI Chatbots

Privacy

Chat GPT and Medical Notes, Encounter Summaries

"Clinicians may not realize that by using ChatGPT, they are submitting information to another organization, OpenAI, the company that owns and supports the technology. In other words, the clinical details, once submittedbthrough the chat window, have now left the confines of the covered entity and reside on servers owned and operated by the company. Given that OpenAI has likely not signed a business associate agreement with any health care provider, the input of PHI into the chatbot is an unauthorized disclosure under HIPAA."

Kanter. JAMA 330:311 2023

The Times Sues OpenAI and Microsoft Over A.I. Use of Copyrighted Work

Millions of articles from The New York Times were used to train chatbots that now compete with it, the lawsuit said.

Privacy and Ownership in Training Material

December 27, 2023

EU AI Act

A legal framework governing the sale and use of artificial intelligence in the EU

Purpose - to ensure the proper functioning of the EU single market by setting consistent standards for AI systems across EU member states

First comprehensive regulation addressing the risks of artificial intelligence through a set of obligations and requirements that intend to safeguard the health, safety and fundamental rights of EU citizens and beyond

Covers AI systems that are “placed on the market, put into service or used in the EU. = US Products too

THE WHITE HOUSE

OCTOBER 30, 2023

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

BRIEFING ROOM ▸ PRESIDENTIAL ACTIONS

October 30, 2023

uspto UNITED STATES PATENT AND TRADEMARK OFFICE

USPTO announces new Public Advisory Committee members to help advise agency and advance core mission of fostering and protecting innovation across America

2023

UNITED STATES
PATENT AND TRADEMARK OFFICE

Inventing AI

Tracing the diffusion of artificial intelligence with U.S. patents

AI and Invention
USPTO issued 4 Guidance documents in 2024

Inventorship Guidance for AI-Assisted Inventions

A Notice by the Patent and Trademark Office on 02/13/2024

Guidance on Use of Artificial Intelligence-Based Tools in Practice Before the United States Patent and Trademark Office

A Notice by the Patent and Trademark Office on 04/11/2024

2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence

A Notice by the Patent and Trademark Office on 07/17/2024

Directors Guidance on Applicability of Existing Regulations on Party and Practitioner Misconduct Related to the Use of AI

Patent Public Advisory Committee
2024 ANNUAL REPORT

uspto UNITED STATES PATENT AND TRADEMARK OFFICE

Regulatory Incongruity by Virtue of Varied Definition/Coverage: FDA vs USPTO

Software as Medical Device (SAMD)
- **FDA – considered device**
- **USPTO = not patentable**

Therefore less incentive for industry to fund studies, trials, data sets to train/improve AI

Dilemma

Software in Medical Device (SIMD)
- **FDA – component of device**
- **USPTO – patentable**

Better incentive for industry funding for enhanced studies/refinement of device for improved AI

AI Regulation/Legislation

Colorado - Law
Utah - Law
California – 5 Bills pending

Establish a **"Duty of Care"** on **Developer** and **Deployer** to protect consumer from known or reasonably forseeable risk

Define risk
Design out the risk
Upfront disclosure
Notice

Datasets used to train models
Algorithm transparency
How model tested/validated

Tort Law
Negligence
Joint and Several Liability

The New York Times

The A.I. Revolution Will Change Work. Nobody Agrees How.

The tally of how many jobs will be "affected by" world-changing technology is different depending on who you ask.

Oxford study
Predicted 47% of U.S. jobs affected

June 10, 2023

GPTs are GPTs: An Early Look at the Labor Market Impact Potential of Large Language Models

Abstract

We investigate the potential implications of large language models (LLMs), such as Generative Pre-trained Transformers (GPTs), on the U.S. labor market, focusing on the increased capabilities arising from

Our findings reveal that around 80% of the U.S. workforce could have at least 10% of their work tasks affected by the introduction of LLMs, while approximately 19% of workers may see at least 50% of their tasks impacted. We do not make predictions about the development or adoption timeline of such LLMs.

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with higher recent productivity growth. Our analysis suggests that, with access to an LLM, about 15% of all worker tasks in the US could be completed significantly faster at the same level of quality. When incorporating software and tooling built on top of LLMs, this share increases to between 47 and 56% of all tasks. This finding implies that LLM-powered software will have a substantial effect on scaling

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the economic impacts of the underlying models. We conclude that LLMs such as GPTs exhibit traits of general-purpose technologies, indicating that they could have considerable economic, social, and policy implications.

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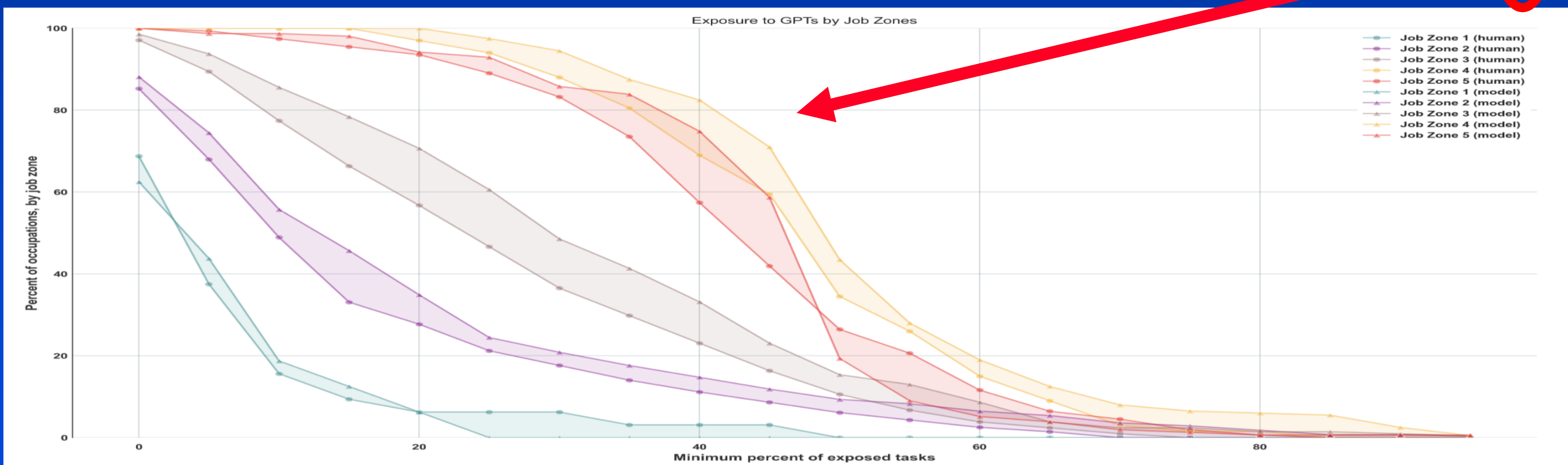
Job Zone	Preparation Required	Education Required	Example Occupations	Median Income	Tot Emp (000s)	H α	M α	H β	M β	H ζ	M ζ
1	None or little (0-3 months)	High school diploma or GED (otional)	Food preparation workers, dishwashers, floor sanders	\$30,230	13,100	0.03	0.04	0.06	0.06	0.09	0.08
2	Some (3-12 months)	High school diploma	Orderlies, customer service representatives, tellers	\$38,215	73,962	0.07	0.12	0.16	0.20	0.24	0.27
3	Medium (1-2 years)	Vocational school, on-the-job training, or associate's degree	Electricians, barbers, medical assistants	\$54,815	37,881	0.11	0.14	0.26	0.32	0.4	0.51
4	Considerable (2-4 years)	Bachelor's degree	Database administrators, graphic designers, cost estimators	\$77,345	56,833	0.23	0.18	0.47	0.51	0.71	0.85
5	Extensive (4+ years)	Master's degree or higher	Pharmacists, lawyers, astronomers	\$81,980	21,221	0.23	0.13	0.43	0.45	0.63	0.76



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Broad strategies are needed to allow AI to interact, integrate, and empower all aspects of Society from the individual to the family, group and beyond

Done lawfully with respect, fairness, free of bias and discrimination, with broad access, equity and equality

Conclusion

The aspiration of computer systems to humanly think, demonstrating "intelligence" has been ongoing with fits and starts for >70 years.

Advances in chip design, processing power, programming and data science have generated a range of technologies collectively termed "Artificial Intelligence." ?Machine Intelligence"

Of AI systems, Predictive/Prescriptive AI offers great opportunity for Medicine/MCS.

Advance of AI in CS/MCS will accelerate via defining the touchpoints AI integration in terms of: 1. patient time/natural history, 2. level/scale, 3. application/purpose, 4. Interconnectedness – device, Rx, systems and scale. *Goal improved care – lives saved*

Generative AI offers even more disruption for Medicine, CS/MCS, and <u>Society</u>. BUT needs continued refinement, training and system transparency. We need to embrace this, yet provide insightful guidance as to how best steward this forward.

ACABI = Arizona Center for Accelerated BioMedical Innovation

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