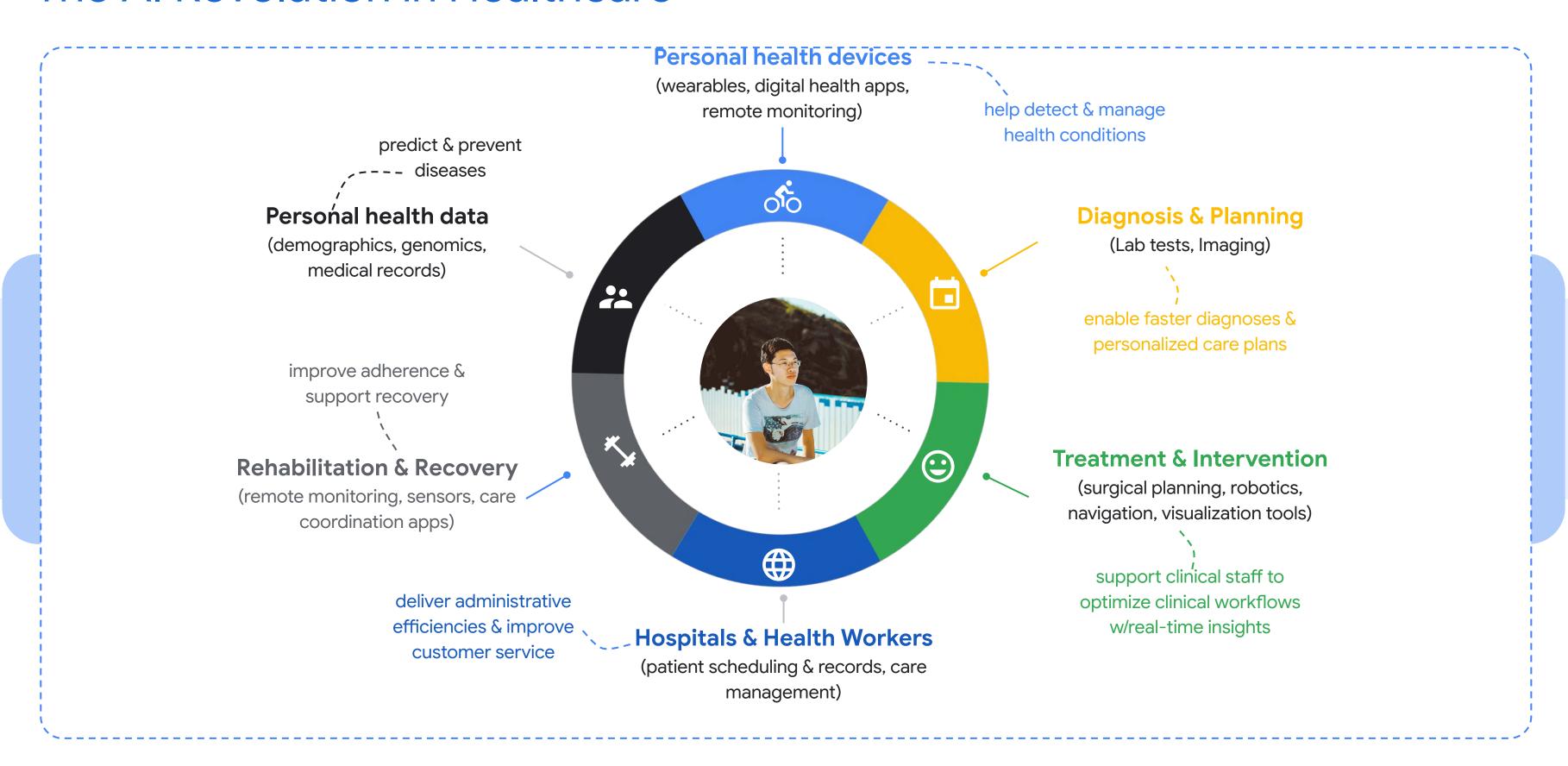


The Al Revolution in Healthcare





Responsible Al is

Privacy

Al governance

Accountability

Safety and Security

Sociotechnical

Fairness

Explainability

Trustworthy

Robustness

Transparency

Interpretability

Socially beneficial

Human-centered and human controlled



Google's Approach: Responsible Al in Practice

Govern

- Principles and policies
- Decision Making
- Transparency and Accountability

Map

- Risk Identification
- External Expertise
- Risk Taxonomy

Measure

- Rigorous Evaluation
- Multi-layered Red Teaming
- Al-assisted auto-raters

Manage

- Risk Mitigation
- Phased launches
- User Understanding
- Exosystem Enablement





US FDA Approach to Al Regulation

- Treating medical purpose AI/ML models as medical devices
- PCCP: Allowing for algorithms to be updated while maintaining safety and effectiveness
- TPLC + GMLP: Emphasizing quality and consistency in development
- Public list of Al-enabled medical devices, and PCCP approved devices









Global Efforts in Al Governance

Mainly Focused on Traditional ML

EU AI Act

- Risk-Based Framework
- Pre-market Compliance
- Broad Scope including General Purpose Al System
- Penalties

SK AI Bill 🕵

- Balance of Promotion and Regulation
- Targeting "High-Impact" Al
- Transparency and Accountability

US FDA

- Focus on Software as a Medical Device (SaMD)
- Total Product Lifecycle (TPLC) Approach
- Emphasis on Safety,
 Transparency, and Bias

JP AI Promotion Bill

- Innovation-First Approach
- Voluntary Guidelines
- International Leadership

World Health Organization (WHO): "Global Initiative on Al for Health"

Ethics and Governance

Standards and Evidence

Global Collaboration



Collaborative Efforts for Al Governance



- Developing standards for trustworthiness in health Al
- Focus on safe and reliable technology



- Developing an Al Code of Conduct (AICC) for ethical Al in medicine
- Establishing responsible development guidelines



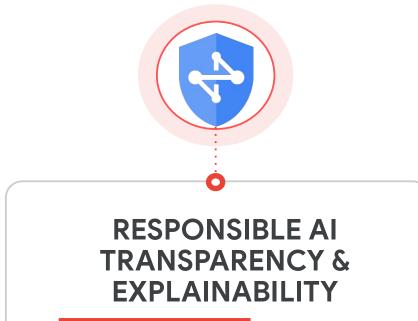
- Advocating for a risk-based, sectoral approach.
- Tailoring regulations to specific AI applications and risks



Common Themes Observed



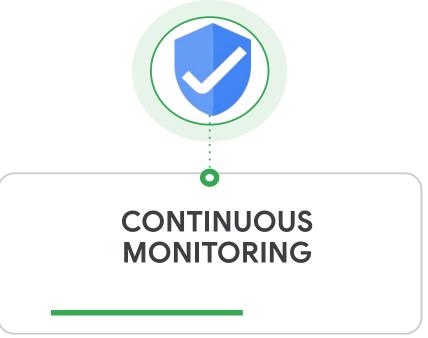
High-quality, diverse, and unbiased data is critical for safe and effective Al in healthcare.



Al algorithms to be **transparent and explainable** for users and regulators as well



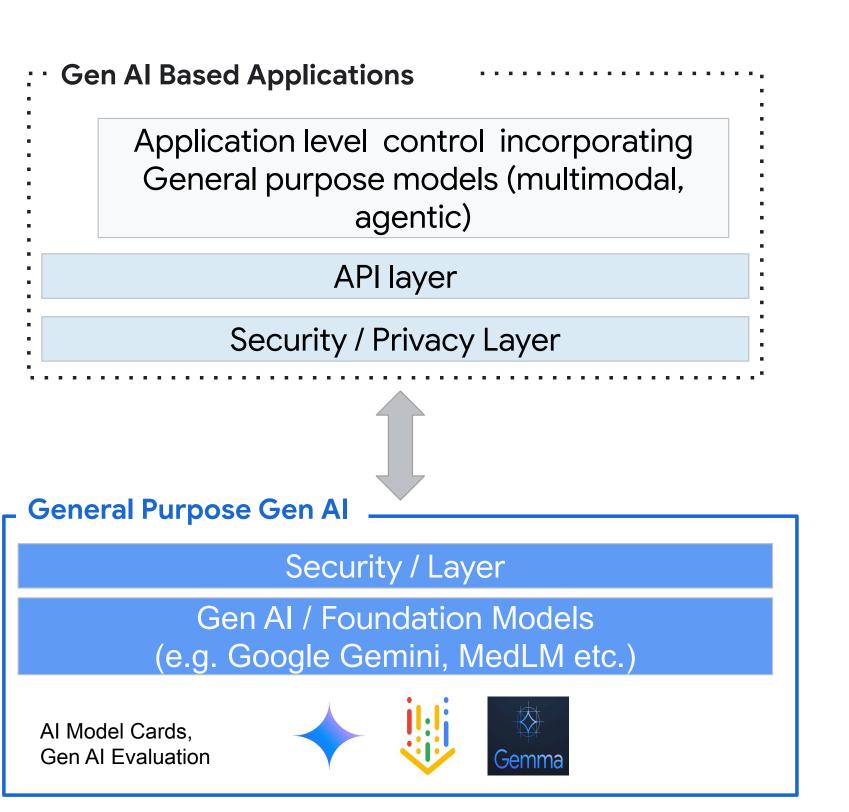
Robust Cybersecurity and compliance to be in place such as ISO 27001, 27017/18, HIPAA, Japan's APPI etc.



Al models require continuous post deployment performance monitoring and regular updates for new data or clinical practice changes.

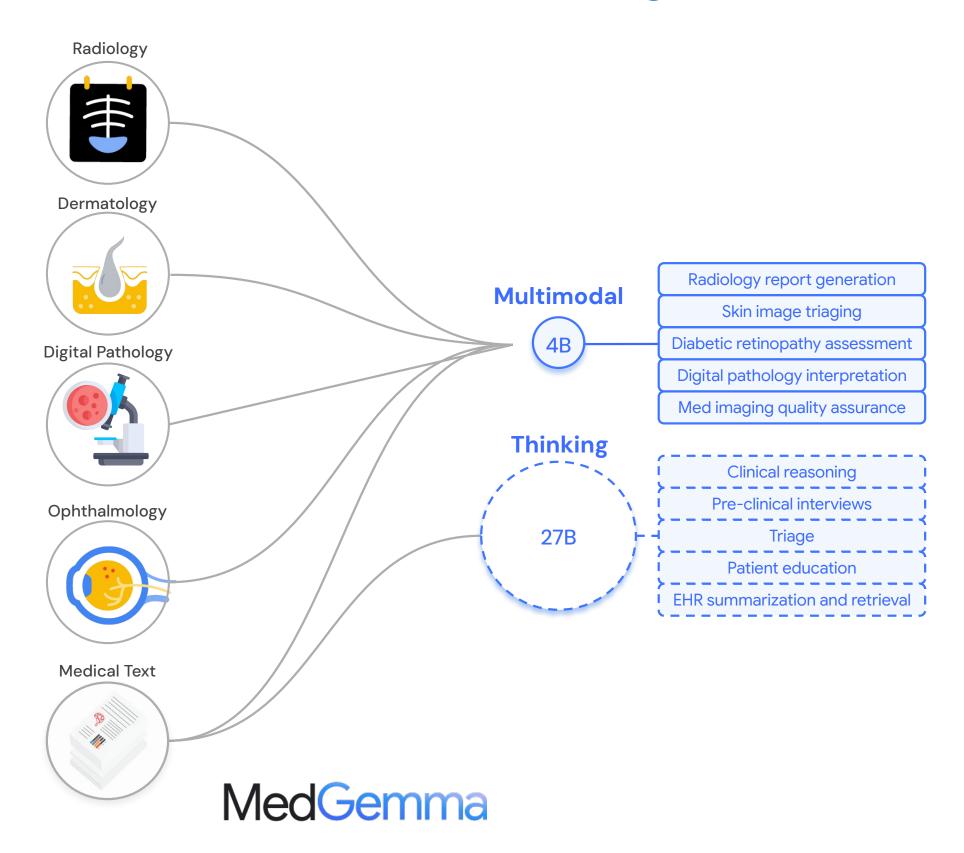
Use of General Purpose Models in Applications

General Purpose GenAl Based Applications Gen Al (GPAI) Broad, diverse training Governance of Data data, difficult to define **Application** specific Governance unified governance data Can be more "black box": difficult to **Transparency** explainable for the explain outputs specific use case **Overall model security Security &** including cloud Client level security **Privacy** technologies and controls + rely on GPAI certificates **Overall model** Monitor for application **performance** against specific **Model drift** in **Monitoring** global benchmarks (e.g. the real world MedQA)





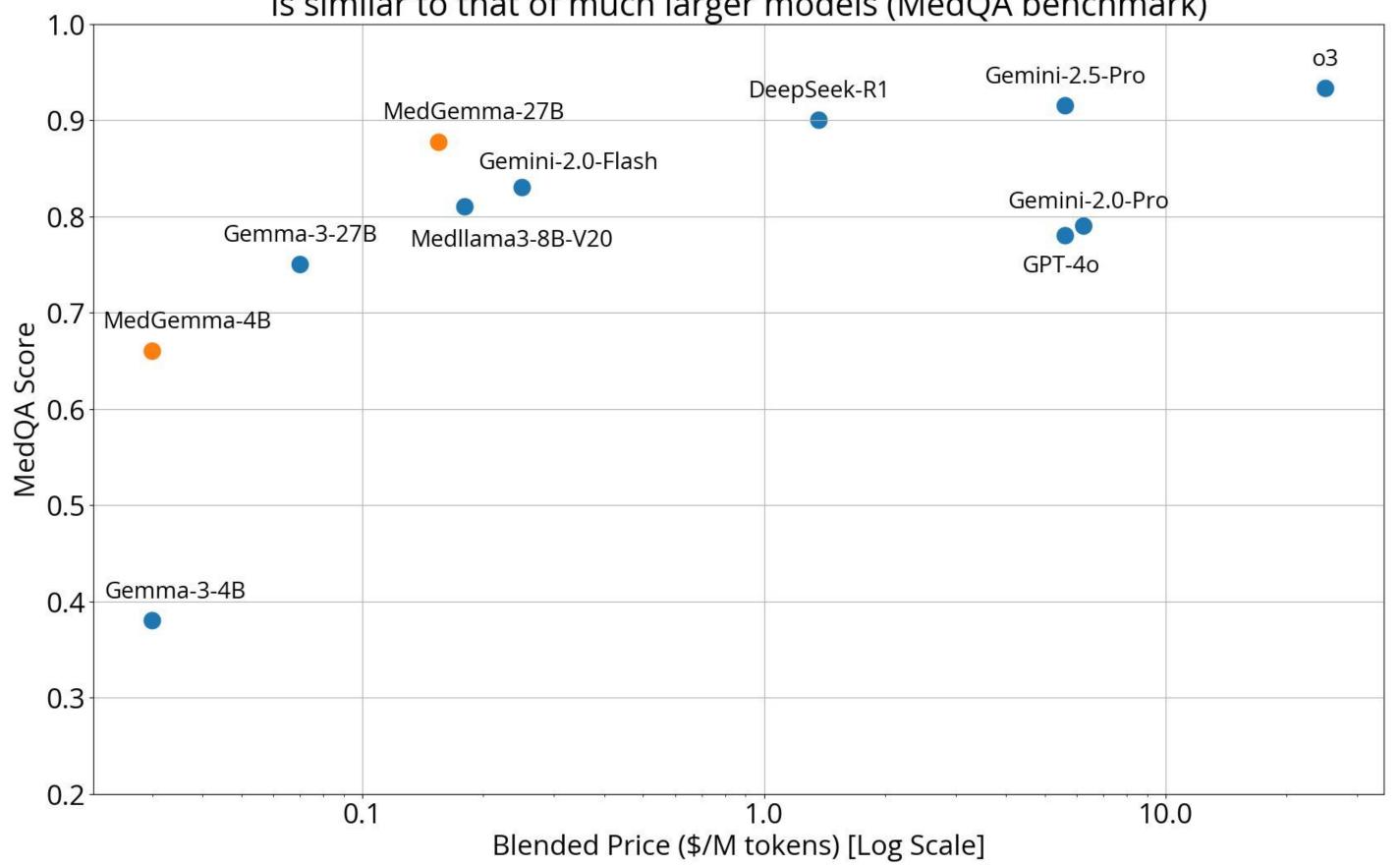
Al Innovations - Open Weight Models



Model cards for transparency

- Information about how the model was developed
- Datasets used for training and evaluation
- Performance results
- An intended use statement
- Known limitations

MedGemma's baseline performance on clinical knowledge and reasoning is similar to that of much larger models (MedQA benchmark)





Major Challenges

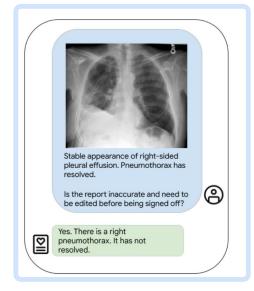


Conventional AI (e.g. CNN, RNN)

Closed General purpose models
Open source /

open weights models

Gen AI - LLMs



Fine-Tuned GenAl Applications

Data Governance: Ensuring privacy, security, and appropriate use of sensitive health data







Algorithmic Bias: The risk of Al models perpetuating or even amplifying existing health disparities



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The "Black Box" Problem: Understanding and explaining how complex Al models make decisions

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Accountability & Liability: Defining responsibility when Al systems are involved in patient care







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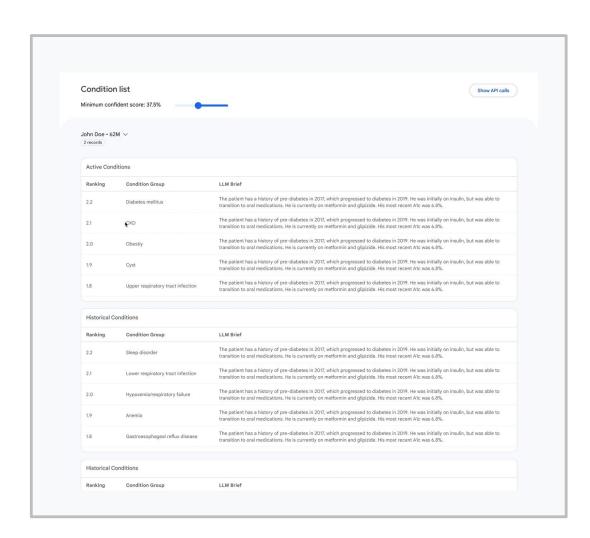


How we innovate together - customer stories

Partnering to turn inventions into innovations that have a real impact for the world, at scale

Care Delivery Transformation

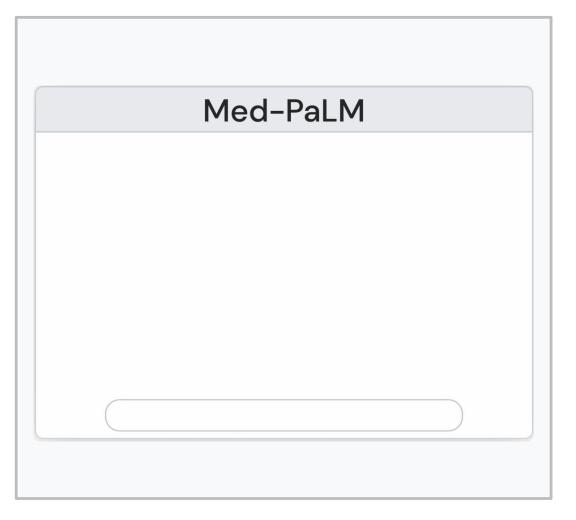
Search in Healthcare context



Diagnostics, Therapy Planning



Nurse hand off, Ambient doc (e.g. in ER)





Value-based Care: Transforming healthcare in Taiwan

Al an enabler for personalisation and value-based care



Use of Al-on-DM risk classification model



Individual Risk Rating

Assigned based on clinical history



Personalis ed Care:

Delivered under flagship Family physician program



Al Agent Guidance:

Health Agent sitting in National Health App

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Value based Care

Al-on-DM model enables transition to value based care



Ongoing Support

Bundled payments include fully subsidised digital therapeutics

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Benefit Analysis

Supporting delivery team with Health impact and economic assessment





Call to Action



Focused

- Regulate real-world effects, not scientific progress
- Identify and address regulatory gaps
- Focus on the outputs
- Consider a sectorally-based, hub-and-spoke governance architecture
- Encourage effective techniques to identify Al-generated content



Aligned

- Prioritize international coherence and interoperability
- Look to international standards and benchmarks



Balanced

- Risk-based frameworks centered on use cases
- Clear and differentiated obligations for the respective actors in the AI ecosystem
- Avoid regulatory burdens for research and development, and promote access to open data to enable fair learning
- Ensure that transparency requirements are balanced and feasible
- Weigh the trade-offs between AI tools and human alternatives



Out with the old!

- Existing approaches are no longer effective
- New strategies are essential for future success
- Traditional methods hinder progress and innovation
- Embrace change for sustained growth





