ANNUAL REPORT

2024

HEALTH AI

The Global Agency for Responsible AI in Health

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Message from our CEO

"I am proud to be able to reflect on the **incredible progress we've made over the past year and share our excitement** for what lies ahead in 2025 and beyond."

Dr. Ricardo Baptista Leite
Chief Executive Officer

At the beginning of 2024, I told you about setting a new course for 'HealthAI - the Global Agency for Responsible AI in Health,' that aligned better with the needs of the countries and communities we serve to accelerate the development, equitable access, and adoption of responsible AI solutions that effectively improve health outcomes for all. I am proud to be able to reflect on the incredible progress we've made over the past year and share our excitement for what lies ahead in 2025 and beyond.

We took significant steps toward realizing our mission to advance the equitable development and adoption of Responsible AI solutions for health. We were proud to launch our HealthAI Strategy 2024-2026, which sets our path for the collaborative implementation of governance and regulatory mechanisms based on global guidelines for AI in health. This strategy is key to ensuring we can deliver on our vision where AI technologies are used ethically and effectively to improve health and well-being for all individuals and communities.

We achieved considerable progress in enhancing our internal capabilities to facilitate the execution of this strategy. A notable achievement was the successful recruitment of our executive management team. Additionally, we have secured financial commitments from eight government, philanthropic, and corporate partners, which enables us to further scale our initiatives and attain our objectives.

Our outreach and relationship-building efforts took us to **Angola, Austria, Brazil, Bulgaria, Chile, France, Germany, Indonesia, Italy, Japan, South Korea, Nigeria, the Philippines, Portugal, Rwanda, Singapore, South Africa, Tanzania, the UK, the UAE, the USA, Uruguay, and Zambia** where we discussed the governance of AI in health with various stakeholders.

These connections are vital as we work towards creating a Global Regulatory Network, a key initiative to bring countries together and ensure they are equipped to regulate AI in healthcare effectively.

We launched the HealthAI Community of Practice (CoP), bringing together 28 governments and approximately 200 institutions from over 50 countries. This milestone is a testament to our growing network and the collective commitment to shaping the future of AI in health. We also developed essential methodologies, toolkits, and training materials to serve as knowledge sources and blueprints in the coming years. As part of these efforts, we published a report on Mapping AI Governance in Health: From Global Regulatory Alignments to LMICs' Policy Developments.

Looking ahead, we will deepen the strong relationships built with our partners. In particular, we look forward to selecting the ten pioneer countries that will form the inaugural Global Regulatory Network. These countries will be early adopters of the HealthAI approach, and we will work closely with them to establish and strengthen government-led regulatory mechanisms for validating AI technologies in health. Additionally, we are actively working towards establishing crucial tools such as a Global Repository of validated AI solutions, an Early Warning System, and an intuitive self-assessment tool called the Navigator.

The CoP has initiated its first working group to develop and validate a HealthAI portal for community engagement and knowledge resources. Furthermore, we will hold our inaugural in-person event, the HealthAI Global Governance Forum, which offers a unique opportunity to enhance collaborations and foster meaningful discussions within our community.

Finally, we announced the launch of the inaugural Funders' Council in 2025. This advisory body will serve as a platform for our donors to engage directly with our work, promote transparency, offer strategic insights, and foster global cooperation in the AI for health space.
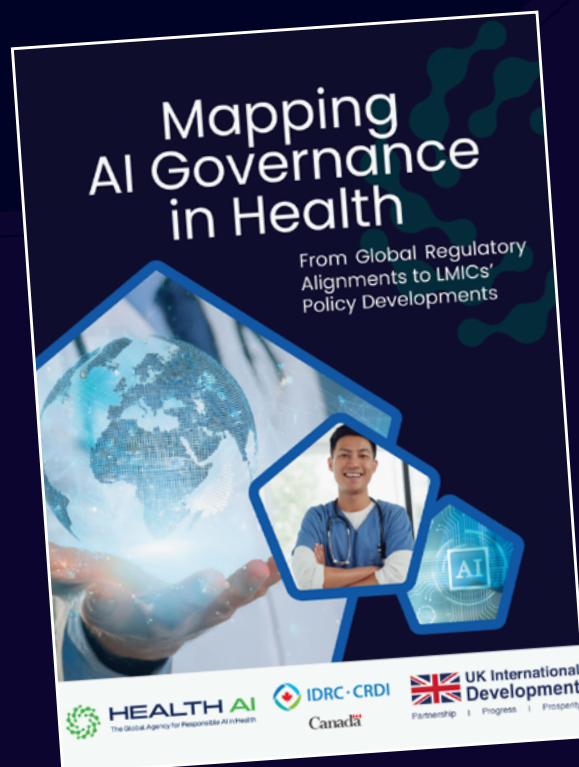
Indeed, 2024 has been a year of significant milestones for our organization. None of this would have been possible without our team members, board, donors, and partners, to whom I express my heartfelt thanks for their unwavering support, collaboration, and commitment to advancing responsible AI in health. Together, we will continue to work daily to improve every citizen's health, no matter where they may be in the world.

**Thank you,
Ricardo**

Milestones

Mapping AI Governance in Health Report

The report on "**Mapping AI Governance in Health: From Global Regulatory Alignments to LMICs' Policy Developments**" represents a first step in our implementation of national and regional regulatory mechanisms to form a Global Regulatory Network. It not only raises awareness of existing AI for health governance frameworks but also demonstrates our commitment to not leaving the low-resourced countries behind and to push for decentralization of regulatory processes to cultivate local innovation and trust.

This report examined global AI governance policies developed by key international institutions through an interoperability lens. Interoperability of AI governance refers to a shared understanding, interpretation, and implementation of cross-border governance mechanisms for AI.

It aims to foster a cooperative environment where **different governance models can coexist, communicate, and function effectively** despite their inherent differences.

The report also explored influential world regions setting global regulatory trends and expectations and presented country-specific analyses of four countries representing different regions, namely Africa, Latin America, Middle East and Asia, to offer diverse perspectives on the challenges and progress in the governance of AI in health. In particular,

we noted that LMICs face unique challenges in establishing regulatory mechanisms for AI in health that can adequately address local needs while attempting to align with global standards. Such an approach has allowed us to capture both global trends and local nuances, providing a comprehensive landscape of AI regulations in health.

Moving forward, this report will provide the basis for a living knowledge base for HealthAI's Community of Practice Knowledge Portal. We will co-create new content and versions of the report with our international partners. We will also use the landscape knowledge to develop training materials to increase regulators', policymakers', researchers', and innovators' awareness of, adherence to, and application of AI regulations in health.

Country Implementation Visits

In December 2024, the HealthAI team, represented by our Chief Regulatory Officer, Chief Scientist, and Country Implementation Manager, visited Zambia and Tanzania as part of our pioneer country implementation efforts. At HealthAI, we believe engaging with stakeholders on the ground is important to have an accurate understanding of the processes, systems, and local contexts. These visits to the countries aim to establish a strong foundation for the partnerships as well as to develop a contextual understanding of AI governance in the health landscape. Before the visits, we conducted a desktop review to understand the current state of AI governance in health in Zambia and Tanzania. With this baseline knowledge, the team then visited these two countries to validate and expand on the desktop review, as well as to obtain buy-in

and forge stronger relationships with key local stakeholders. For each country, a two-day agenda was planned, with bilateral meetings, focus group discussions and participatory activities.

In Zambia, representatives from diverse stakeholder groups participated, including the Ministry of Health, Ministry of Technology and Science, Zambia Medicines Regulatory Authority, Zambia Information and Communications Technology Authority, SMART Zambia Institute, and research and public health institutes. We were encouraged by the strong support and collaboration among the local partners, as well as their active commitment to participate in our workshops. Besides gaining a deeper understanding of the local landscape for AI in health, the trip also helped forge a deeper

bond, not just between HealthAI and the local stakeholders, but also amongst the local stakeholders themselves. The gathering of various stakeholders in the same room to discuss these issues was a first for them, and they acknowledged and reiterated the need for such an opportunity and platform.

In Tanzania, HealthAI met with representatives from the Ministry of Health and Tanzania Medicines and Medical Devices Authority (TMDA). We observed the strength of TMDA's medical devices regulatory team and their commitment to advancing responsible AI in healthcare within the country, as they shared their journey and strategy around medical device regulations, as well as the current state of AI applications in health in Tanzania and its regulation. This laid the ground for an in-depth discussion on the experiences and challenges, as well as their current capacity and capabilities to regulate AI solutions in health.

This was an important step in establishing HealthAI as a thought leader in this field among key local stakeholders in Zambia and Tanzania. Overall, the visits to the countries were a crucial first step for HealthAI to work collaboratively with them to strengthen the local regulatory teams' capacity and capabilities to regulate AI solutions in health

"During our in-person discussions on AI applications, the current regulatory landscape for AI in health, as well as ethics and responsible AI in health, **we shared our perspectives and knowledge of the domain, which resonated well with the local teams**".

Building Capacity and Community to Shape the Global Conversation on
Responsible AI in Health

Launch of the HealthAI Community of Practice

2024 saw the launch of the HealthAI Community of Practice (CoP), a collaborative platform that facilitates knowledge sharing and supports the equitable and coherent evolution of AI governance in health across the globe, with members representing diverse sectors and geographies.

The creation of this community directly aligns with HealthAI's strategic goals, driven by the belief that bringing diverse stakeholders together can foster meaningful partnerships and knowledge exchange. This is especially important as AI in health evolves rapidly, requiring international and regional coordination and multi-stakeholder participation to shape governance and policy frameworks effectively. These efforts range from raising awareness and expanding knowledge among stakeholders to consulting representatives from civil society organizations, research institutions, and beyond. HealthAI believes these exchanges will ultimately build greater trust between society and the AI solutions being governed.

"We were happy with the strong interest the community has attracted since applications opened, reinforcing the need for a space to exchange at the intersection of Health, Responsible AI, and Governance".

North America
19.1 %

Europe
28.5 %

Middle-East
3 %

Asia-Pacific
19.6 %

Africa
25.5 %

South America
4.3 %

"Our ambition for 2025 is twofold: to continue growing, with more members and a greater diversity of perspectives, and to **solidify the community's relevance by introducing new ways for members to engage**".

Our CoP Members

The creation of the CoP attracted great interest within the community and as a result, we launched in December of 2024 with over 170 member organizations from more than 50 countries. These include both leaders in the field and newer organizations looking to develop AI governance structures in their respective environments. Participants come from government agencies, international organizations, research institutions, civil society organizations, and private companies,

all with the same goal: to advance AI governance in health. A complete list of the CoP members is available here .

Within the CoP, an invite-only Leadership Group was created with 24 governmental institutions to provide a safe space for governments and regulators to discuss governance structures, regulations, approaches, and policies for Responsible AI in health.
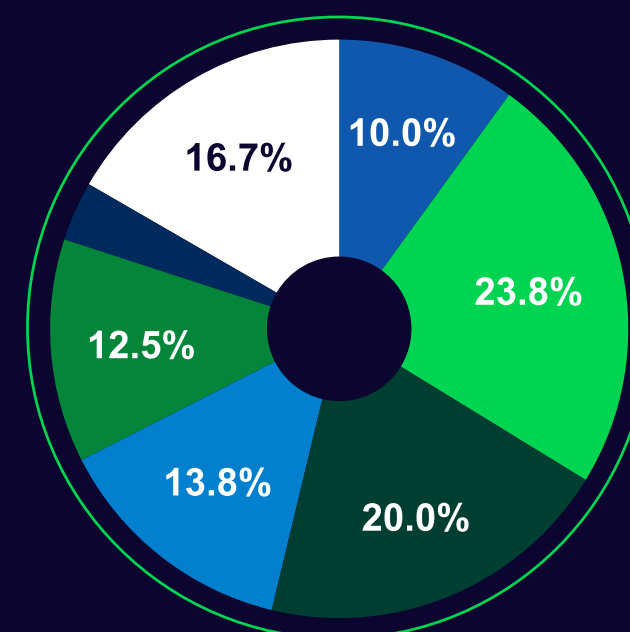
10.0%
23.8%
20.0%
13.8%
12.5%
16.7%

- ● Civil Society Organisation
- ● Private Sector Company
- ● Research institution
- ● International Organisations
- ● Healthcare
- ● Government
- ● Other

Work starts on Global Public Repository

In May 2024, with the appointment of HealthAI's Chief AI Officer, the organization initiated the development of the Global Public Repository of Validated AI Solutions—a landmark initiative aimed at increasing transparency and accessibility in AI regulation for health.

The repository's first version, slated for launch in 2025, will feature validations from national stringent authorities already engaged in evaluating software as medical device solutions. This beta platform will serve as a foundation for future iterations, enabling countries within the HealthAI Global Regulatory Network to showcase their validated solutions.

As we move forward, HealthAI's focus will be on finalizing the budget for the repository's development and launch, refining the roadmap based on valuable stakeholder input, and establishing formal agreements with pioneering countries to ensure a robust and diverse initial dataset.

With these strategic steps in place, HealthAI remains on track to launch this transformative repository in 2025, marking a significant leap forward in our commitment to advancing responsible AI in global healthcare

Key Achievements in 2024:

1. **Repository Specifications:** We developed comprehensive specifications for version 1 of the repository, focusing on aggregating data from existing country databases to provide stakeholders with holistic insights into AI solution authorization and regulatory frameworks.

2. **Stakeholder Engagement:** Key stakeholders were identified and engaged, ensuring that the repository's development aligns with the needs of the global healthcare AI community.

3. **Roadmap Development:** A detailed roadmap for the repository's development and deployment in 2025 was created, outlining key milestones and objectives

"This initiative underscores HealthAI's **dedication to fostering transparency, collaboration, and innovation** in the rapidly evolving field of AI-driven healthcare solutions".

"We extend our heartfelt appreciation to **all our funders for their trust, vision, and commitment** to shaping the global governance of AI for Health".

Mobilizing Resources for Implementation:

One of HealthAI's key priorities in 2024 was mobilizing the resources needed to implement its strategic vision and drive meaningful impact in the near term. Thanks to our funding partners' generosity and commitment, we have secured essential funds to implement our work.

We are deeply grateful for the support of eight government, philanthropic, and corporate partners who recognized the urgency and importance of our work. Their contributions have been instrumental in enabling HealthAI to accelerate its strategy implementation and realize the key milestones outlined in this annual report. As of the end of 2024, our confirmed funders include: **the International Development Research Centre, Ottawa, Canada, UK International Development, the Ministry of Health of New Zealand, the Norwegian Agency for Development Cooperation (Norad), the Ministry of Health of Singapore, Foundation Botnar, the Patrick**

J. McGovern Foundation, and Merck. In parallel, many more prospective partners were approached, with whom we look forward to continuing and formalizing our conversations in 2025.

Another significant milestone in 2024 was the approval by the Board of the Terms of Reference for the inaugural HealthAI Funders' Council. This Council will serve as a key advisory body, providing our funders with a structured platform to engage with HealthAI's leadership and contribute to shaping the organization's strategic direction. The Council will strengthen collaboration and alignment around our shared mission by fostering meaningful dialogue between funders and HealthAI's independent governing structures. The inaugural Funders' Council is set to launch in 2025, marking an important step toward building a sustainable and engaged funding ecosystem for HealthAI's future.

Trust
Respect
Integrity
Dedication
Accountability

Organizational **Update**

Strengthening Operations and Leadership:
HealthAI's Organizational Transformation in 2024

In 2024, HealthAI embarked on a transformative journey to optimize its organizational structure and enhance operational capabilities, laying the groundwork for sustainable growth and increased impact.

This strategic rightsizing initiative resulted in the addition of eleven new team members, bringing our total workforce to 15 by December 31, 2024. While we bid farewell to some colleagues pursuing new opportunities, this transition ensured we had the right talent to support our expanding mission.

Leadership Renewal: Building a Strong Senior Management Team

A pivotal achievement was the formation of a revitalized Senior Management Team, with three out of four senior leaders—excluding the CEO—joining during the year.

This leadership renewal brought fresh expertise and diverse perspectives, enabling HealthAI to better navigate the complexities of AI governance in healthcare. The strengthened team fosters agility, innovation, and alignment with strategic goals, ensuring HealthAI remains at the forefront of responsible AI adoption.

Defining Strategic Objectives and Core Values

In December 2024, HealthAI convened its entire team for a retreat and strategy meeting. This collaborative effort culminated in the establishment of clear Objectives and Key Results (OKRs) to guide our long-term vision. The four strategic objectives identified are:

- Enhancing operational efficiency to support sustainable growth.
- Implementing AI solutions in 10 pioneer countries to advance responsible adoption.
- Strengthening HealthAI's reputation as a global authority on technical and regulatory excellence in AI for health.
- Positioning HealthAI as the primary global convener in AI governance for health.

Additionally, 2024 marked a defining moment in shaping HealthAI's organizational culture. We identified five Core Values, embedded in our newly deployed Code of Conduct ensuring ethical leadership across all operations and serving as the foundation for our work.

Looking Ahead

As HealthAI continues its journey into 2025, these strategic developments position us for greater impact through stronger partnerships and enhanced leadership in global AI governance.

Events, Activities
& Outreach

Events

HealthAI was represented at the following major events:

- AI X Summit, Zurich, Switzerland
- Africa Health Tech Summit, Kigali, Rwanda
- CoRE Scientific Conference 2024: Regulating the future of health
- European Health Forum, Gastein, Austria
- Forbes Portugal, HealthCare Summit 2024
- G20 Health Working Group, Salvador, Brazil
- GCC eHealth Workforce Development Conference, Dubai, UAE
- 14th GDHP Summit 2024, Auckland, New Zealand
- GI-AI4H regulatory group meeting, Singapore
- Global Symposium on Health Systems Research, Nagasaki, Japan

- Health Transformation Summit, Amsterdam, The Netherlands
- IMAGINE AI, Singapore
- OSCE (Organization for Security and Co-operation in Europe) Parliamentary Assembly at the National Parliament in Portugal
- United Nations General Assembly 2024, New York City, USA
- World Bio Summit, Seoul, South Korea
- World Health Summit 2024, Berlin, Germany
- Workshop on Research for Development in ASEAN, Jakarta, Indonesia

Media Coverage

HealthAI was represented at the following major events:

Health: A Political Choice – Enhancing Resilience and Trust. A Global Governance Project Publication - 2024 - Page 80

- **Ensuring Ethical AI Implementation:** HealthAI Launches Global Community of Practice Health Policy Watch - Global - Apr. 04, 2024

- **Ensuring Ethical AI Implementation:** HealthAI Launches Global Community of Practice. Medicus Mundi - Switzerland - Apr. 2024

- **Interview:** "Machine learning can help us re-conquer compassion and humanisation of healthcare." Ricardo Baptista Leite, HealthAI and UNITE Parliamentarians Network for Global Health - Health Tech News - Global - Jan. 29, 2024

- **The Regulator's Dilemma.** About Digital Health - Online - Apr. 25, 2024

- **Healthcare delivery:** FG, PharmAccess, others advocate modern policie Vanguard News - Nigeria - Oct. 10, 2024

- **Transforming Healthcare:** HFN, PharmAccess Propel Collaborative Policy Discussions in Landmark Dialogue The Sun - Nigeria - Oct. 12, 2024

- **Why AI adoption in healthcare demands regulation in Nigeria,** other African countries Vanguard News - Nigeria - Oct. 12, 2024

- **Eyes on Nigeria to develop framework for AI adoption.** Business Day - Nigeria - Oct. 14, 2024

- **From Pandemics to AI:** Unpacking the Forces Shaping Global Health Policies Health Policy Watch - Global - Feb. 17, 2024

- **Artificial Intelligence Opens a New Era of Patient Care...** "Need to Establish Global Governance" eToday - South Korea - Nov. 11, 2024

GLOBAL, INTERNATIONAL, NP

Interview: "Machine learning can help us re-conquer compassion and humanisation of healthcare" Ricardo Baptista Leite, HealthAI and UNITE Parliamentarians Network for Global Health

January 29, 2024 8:20 am

We recently sat down for a chat with Ricardo Baptista Leite about the potential and considerations for artificial intelligence, key learnings from his career and his thoughts on the digital health landscape in Portugal.

Along with his background as a medical doctor, Ricardo has experience in a number of settings including current roles as CEO at HealthAI, global agency for responsible AI and health; founder and president of UNITE Parliamentarians Network for Global Health; national spokesperson for health in Portugal's Democratic Party; and guest lecturer at NOVA Medical School in Lisbon.

The Regulator's Dilemma

Dr. Ricardo Baptista Leite is the CEO of HealthAI—a global nonprofit for responsible AI in health
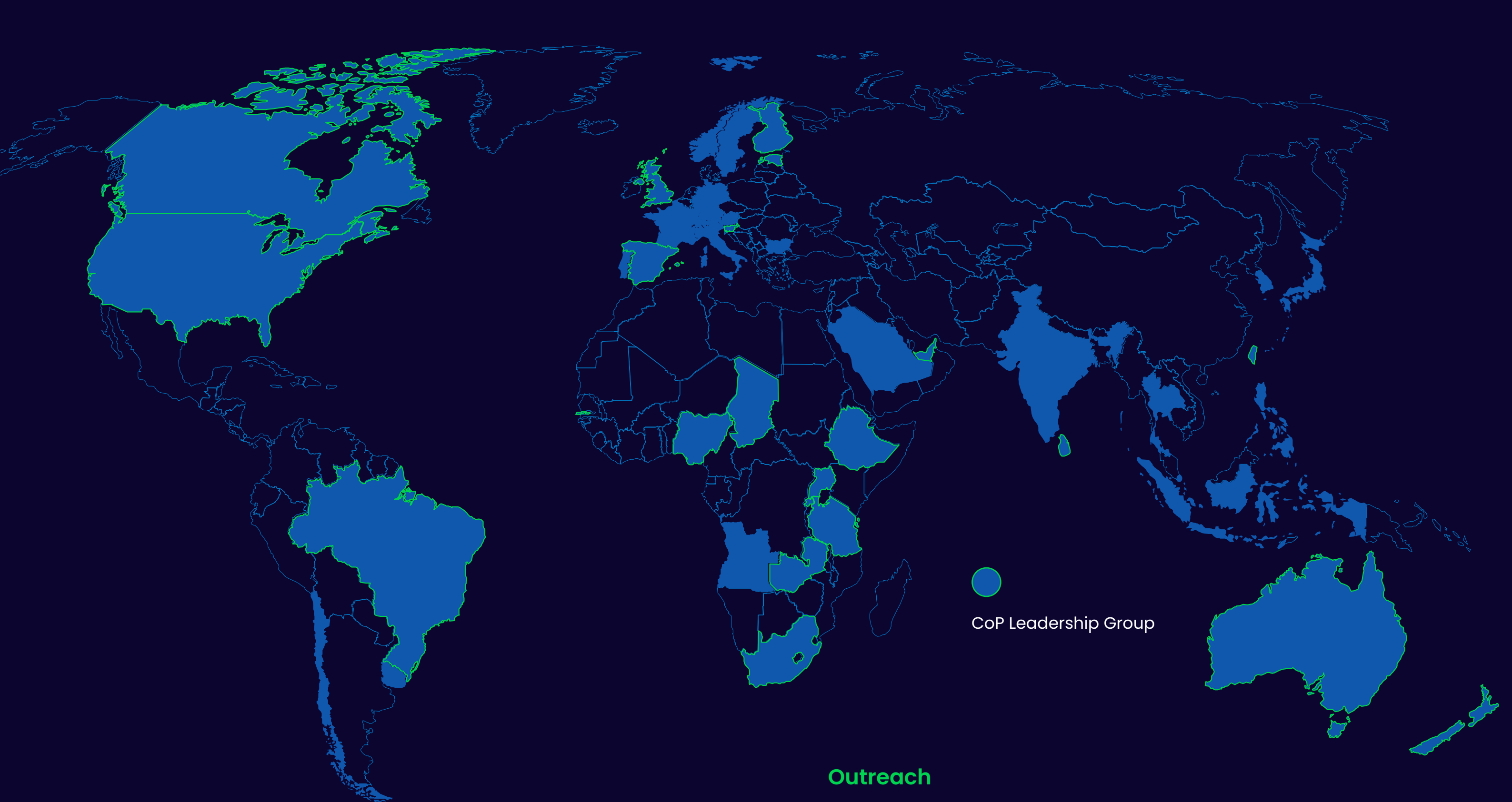
Ensuring Ethical AI Implementation: HealthAI Launches Global Community of Practice

Medical Innovation   09/04/2024 · Maayan Hoffman

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CoP Leadership Group

Outreach

In 2024, HealthAI engaged with officials in more than 30 countries to foster strategic partnerships and advance the development of the Global Regulatory Network—a key pillar of the HealthAI strategy.

Future Outlook: 2025 and Beyond

As we look ahead to 2025, HealthAI is poised for significant advancements in operational efficiency, global implementation, technical credibility, and its role as the leading convener in AI governance for health. Our strategic objectives and key results (OKRs) outline a comprehensive roadmap for the organization's growth, impact, and sustainability.

OBJECTIVE 1: Initiating Implementation in 10 Pioneer Countries

HealthAI will take decisive steps in working with national governments to advance AI governance in health. We will establish a qualification model endorsed by key stakeholders and develop regulatory maturity profiles for 10 pioneer countries. The selection and signing of Memoranda of Understanding (MoUs) with these countries will mark a significant milestone, enabling public announcements and hiring in-country consultants.

By the end of 2025, we will have completed in-depth training in five pioneer countries and initiated training in the remaining five, ensuring tangible capacity-building for regulatory frameworks.

OBJECTIVE 2: Launching Transformative AI Governance Tools

In 2025, the organization will introduce a series of groundbreaking tools to enhance AI governance in healthcare. The **Public Profile Page** (Portal), launching in Q2/2025, will serve as the central access point for all resources. Concurrently, the **Knowledge Hub** will be deployed as a curated library of research, guidelines, and policy tools to support responsible AI adoption. Also in Q2, the **Global Public Repository** (Beta Version) will be established as a public good, consolidating AI validation data from national regulatory authorities. In Q3, the organization will launch the **Navigator**, an intuitive self-assessment tool designed to guide policymakers and regulators in evaluating AI solutions. By Q4, the **Community Portal** will provide an interactive space for global stakeholders to collaborate and share expertise. Finally, in Q1/2026, the **Global Early Warning System** (Version 1.0) will be introduced to proactively identify and address emerging risks in AI governance.

These initiatives will significantly contribute to the responsible deployment of AI in health by equipping stakeholders with essential knowledge, assessment frameworks, and early risk detection capabilities.

Artificial intelligence has the potential to accelerate the transformation of health systems, ultimately leading to the **equitable improvement of citizens' health outcomes at a global scale.**

OBJECTIVE 3: Solidifying HealthAI's Reputation for Technical Credibility

Our technical leadership will be reinforced by launching and enhancing digital platforms and knowledge-sharing tools. The HealthAI Portal, Repository Beta, and Navigator Beta will be introduced, providing valuable resources for policymakers and regulators.

In parallel, we will launch a Global Early Warning System Beta to track and anticipate emerging challenges in AI governance.

Training and capacity-building will remain a priority, with new curricula developed and delivered to support regulatory frameworks in partner countries.

Thought leadership will be strengthened through policy analyses, institutional assessments, and key publications.

Additionally, we will cultivate strategic relationships with leading think tanks and governance organizations, further positioning HealthAI as a global authority in AI and health regulation.

OBJECTIVE 4: Establishing HealthAI as the Leading Global Convener in AI Governance for Health

HealthAI will reinforce its role as the premier platform for dialogue and collaboration on AI governance in health.

The Community of Practice will expand by 40%, with targeted outreach in Latin America and the MENA region. Member engagement will be prioritized, with satisfaction rates exceeding 85% through enhanced feedback mechanisms.

Our media presence will be amplified through strategic campaigns positioning HealthAI as the central convener in the field.

The annual CoP event will serve as a key moment for thought leadership, with active participation and dissemination of insights. Furthermore, we will drive engagement on our digital platforms, ensuring 10 active members on the repository and early warning system while tracking visits and downloads from the HealthAI portal.

OBJECTIVE 5: Building Operational Efficiency for Sustainable Growth

HealthAI will solidify its financial and operational foundations to ensure long-term impact. We will finalize the legal structure for revenue-generating service provision and launch a detailed business plan.

Our fundraising efforts will intensify with the launch of the inaugural Funders Council, securing at least 50% confirmed funding for 2026. By the end of the year, we aim for 100% confirmed funding, supported by repeat and new funding proposals, donor engagement, and a more robust pipeline.

Operationally, we will streamline critical processes, including travel reimbursement and procurement, while ensuring compliance with Swiss labor laws in HR matters. Additionally, we will implement a CRM system to enhance donor tracking and finalize a Gift Acceptance Policy to uphold transparency in fundraising.
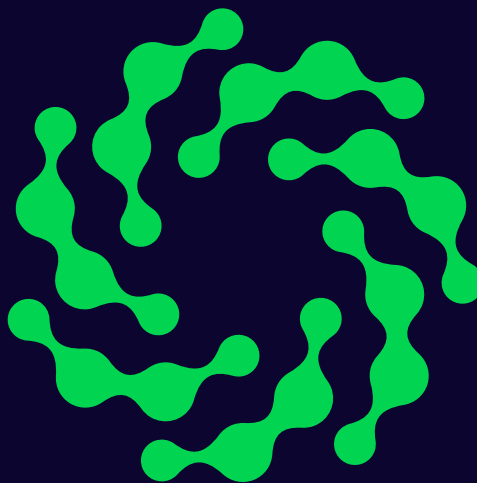
Conclusion:
2025, a pivotal year

As we move from strategic planning to concrete implementation, 2025 represents a pivotal year for HealthAI.

By strengthening our operational base, deepening country engagements, advancing technical solutions, and amplifying our convening power, we will take decisive steps toward shaping the future of AI governance in health.

Our collective efforts will reinforce HealthAI's position as a trusted leader, ensuring the responsible and effective use of AI to improve health systems worldwide.

Digital Health

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