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ICMR NIRDHDS
INDIAN COUNCIL OF
MEDICAL RESEARCH
National Institute for Research in Digital Health
and Data Science



HEALTH AI
The Global Agency for Responsible AI in Health

Panel Discussion

From Guardrails to Adaptive Governance in the Global South: Building a Joint Responsible Governance– HTA Framework to Deliver Safe Trusted, and Scalable AI in Health

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Report

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Concept Note

Introduction

Artificial Intelligence (AI) is increasingly being deployed across health systems, ranging from clinical decision support and diagnostics to operational optimization, wellness applications, and public health surveillance. These technologies hold the potential to improve efficiency, expand access, and strengthen health system performance, particularly in resource-constrained settings. At the same time, the rapid evolution of AI systems - especially self-learning and continuously updating algorithms - raises complex challenges related to safety, effectiveness, equity, accountability, and public trust.

Health systems today face a dual imperative: to accelerate the adoption of AI-enabled innovations while continuously demonstrating that these systems remain safe, effective, and equitable in real-world use. Existing regulatory approaches, largely anchored in hard-law instruments, provide essential guardrails but are often ill-suited to keep pace with fast-iterating algorithms and short product life cycles. Moreover, many AI applications used in health fall outside traditional medical device regulations, leaving gaps in oversight for operational, wellness, and public health AI.

In the absence of adaptive governance, these limitations heighten the risk of ethical drift, data bias, opacity, and the amplification of existing social and health inequities. Opaque or poorly governed AI systems may inadvertently reinforce inequality, exacerbate resource constraints, or deepen digital divides—particularly across the Global South.

Context: India and the Global South

India stands at a critical transition point in the governance of AI in health. Digital public goods such as the Ayushman Bharat Digital Mission (ABDM), data science initiatives led by the National Institute for Research in Digital Health and Data Science (NIRDHDS), and evolving regulatory pathways under the Central Drugs Standard Control Organisation (CDSCO) are converging with increasingly complex AI applications. Similar dynamics are unfolding across the Global South, where governments are experimenting with AI to strengthen health systems, often in advance of fully developed governance frameworks.

There is growing recognition that both India and other Global South contexts require governance models that go beyond static regulation. These models must retain regulatory rigor while enabling dynamic assessment, contextual evidence generation, and socio-technical considerations that reflect local priorities, capacities, and values.

Core Proposition: A Two-Track Adaptive Governance Model

This panel will discuss a pragmatic, two-track governance approach for AI in health:

- **Regulatory Guardrails Across the AI Total Product Lifecycle:** A robust regulatory foundation that evaluates and authorizes AI systems, enforces transparency and risk controls, and enables post-market monitoring and corrective action across the full lifecycle of AI—from development and deployment to real-world use and updating.
- **Contextual AI in Health Technology Assessment (AI-HTA):** A complementary, iterative assessment layer that embeds ethical, societal, and equity dimensions alongside traditional HTA considerations such as benefits, costs, utility, data protection, interoperability, and system impact. This layer explicitly integrates values such as fairness, accountability, inclusivity, and cultural alignment, and assesses AI performance against local health system priorities.
- Rather than operating in parallel silos, these two tracks are designed to intertwine—shaping evidence generation from concept through deployment and real-world use. Regulation establishes a rooted baseline for quality and safety, while HTA dynamically shapes trustworthiness through participatory, socio-technical assessment.

HealthAI Navigator: From Policy to Practice

As a keynote contribution, the panel will introduce the HealthAI Navigator, a policy-to-practice framework that operationalises this two-track governance model across the AI total product lifecycle. The HealthAI Navigator aligns regulatory processes with HTA workflows and economic evaluation approaches tailored to digital and AI technologies. It provides a structured way for policymakers, regulators, HTA bodies, and innovators to jointly assess safety, value, equity, and scalability over time.

Expected outcome

By bringing together regulators, HTA experts, policymakers, academia, and industry, this panel seeks to bridge policy, practice, and purpose—ensuring that AI in health is not only safe and trusted, but also just, inclusive, and responsive to the realities of the Global South.



Agenda

Time (IST)	Details
10:30 am – 10:35 am	Welcome Remarks Professor Sachin Kumar Sharma, Director General, RIS Context Setting Dr Monika Kochar, Advisor – Health, DAKSHIN, RIS
10:35 am – 10:40 am	Keynote Address Mr Rado Andriantsimiavona, Director-AI, HealthAI
10:40 am – 11:10 am	Panel Discussion Moderator: Mr Rado Andriantsimiavona, Director of AI, HealthAI Panelists Ms Vidushi Chaturvedi, Lead Architect, NITI Aayog Dr Ricardo Corpuz, HOD Basic Science, Senior Lecturer (Pathology), UPSM & HS, The University of Fiji, Fiji Dr Apoorva Dharmendra, Senior Editor, Lancet South-East Asia Mr Haitham Ali Ahmed El-Noush, Senior Advisor, Norad – Norwegian Agency for Development Cooperation
11:10 am – 11:20 am	Interactive Roundtable Q&A session with Panelists & Audience
11:20 am – 11:25 am	Way Forward Mr Rado Andriantsimiavona, Director-AI, HealthAI

Introduction

Artificial Intelligence (AI) is rapidly transforming the architecture of health systems worldwide. From clinical decision support and diagnostics to hospital workflow optimisation, surveillance, and public health planning, AI technologies are increasingly embedded in core health functions. However, while technological innovation is accelerating at unprecedented speed, governance frameworks often remain slow, static, and reactive.

For countries of the Global South, this divergence presents both a challenge and an opportunity. On one hand, regulatory capacity constraints, infrastructural gaps, and contextual diversity demand careful calibration of AI adoption. On the other hand, the absence of legacy systems in many settings creates the possibility of leapfrogging toward adaptive, context-sensitive governance models.

Against this backdrop, DAKSHIN – Global South Centre of Excellence at RIS convened a panel discussion in partnership with ICMR and HealthAI, to explore how countries of the Global South can move from conventional regulatory guardrails toward adaptive governance approaches that ensure AI in health remains safe, trusted, equitable, and scalable.

The session brought together policymakers, regulators, researchers, clinicians, development partners, publishers, and technology experts to deliberate on regulatory innovation, AI-specific health technology assessment (HTA), and South-South Collaboration.

Summary of Discussions by Speaker



"The Global South must shape its own governance frameworks rather than import them uncritically."

Professor Sachin Kumar Sharma

Director General, RIS

Professor Sharma opened the session by emphasising the transformative potential of AI across health systems. He noted that AI is already shaping diagnostics, health management systems, and broader public service delivery. However, he stressed that technological capability alone is insufficient; governance must evolve simultaneously.

He highlighted that the Global South faces distinctive challenges, including resource constraints, varying levels of digital readiness, and regulatory asymmetries. Therefore, AI governance models cannot simply be imported from other contexts and must be shaped locally.

Professor Sharma also underscored the role of DAKSHIN, established as a platform to amplify the voice of the Global South, foster knowledge exchange, and promote collaboration across developing countries. He encouraged participants to reflect on how AI can strengthen public health systems while remaining inclusive and equitable.



Dr Monika Kochar

Advisor - Health, DAKSHIN, RIS

Dr Kochar set the conceptual foundation for the discussion by articulating the dual imperative confronting health systems: enabling innovation while safeguarding safety, effectiveness, equity, and public trust.

She emphasised that AI systems are fundamentally different from traditional medical technologies. They are dynamic, adaptive, and continuously learning. Their product lifecycles are short, iterative, and frequently fall outside conventional medical device regulations.

"Innovation and trust are not opposing goals; they must evolve together."



"The total product lifecycle approach enables countries to align speed with safety."

Dr Kochar identified two key governance shifts:

- Moving from static, linear regulation toward lifecycle-based oversight across development, deployment, and post-market monitoring.
- Developing contextualised AI-specific health technology assessment frameworks that integrate ethics, social impact, and equity considerations alongside cost-effectiveness and interoperability.
- She warned that without adaptive governance, risks such as data bias, opacity, and amplification of inequities could undermine the promise of AI, particularly in settings where digital adoption is advancing faster than regulatory preparedness.

Mr Rado Andriantsimiavona

Director-AI, HealthAI

Mr Rado Andriantsimiavona addressed what he termed the "governance paradox." Digital health and AI technologies evolve faster than policy cycles, yet many countries hesitate to act while waiting for the "perfect" regulatory framework.

He argued that waiting is not a viable strategy. Instead, countries must adopt innovative governance approaches that are cyclical, iterative, and responsive.

He introduced HealthAI's Global Regulatory Network (GRN), which convenes governmental authorities to:

- Develop and strengthen national and regional validation mechanisms for responsible AI in health
- Establish global early warning systems to address AI-related adverse events
- Create public repositories of validated AI solutions
- Foster communities of practice and thought leadership

He further presented the HealthAI Navigator - a governance map that aligns dynamic AI total product lifecycle practices with regulatory processes and high-level governance requirements. This model allows countries to move faster without breaking trust, using regulatory sandboxes, AI-specific HTA frameworks, and partnerships to contextualise implementation.



Dr Apoorva Dharmendra

Senior Editor, Lancet South-East Asia

Dr Dharmendra brought an editorial and public health governance perspective to the discussion, emphasising that AI innovation in health must be anchored in evidence, accountability, and institutional integrity. She highlighted that technological advancement, while promising, cannot operate in isolation from regulatory frameworks, ethical safeguards, and systems-level oversight.

"Responsible AI is not simply about regulatory compliance; it is about aligning technology with measurable public value and long-term health system strengthening."

Drawing on her experience in scientific publishing, she underscored the importance of transparency, not only in algorithmic design but also in data provenance, validation processes, and real-world evaluation. As AI increasingly informs clinical and public health decisions, she stressed that rigorous peer review, reproducibility, and independent scrutiny are essential to maintaining trust.

Dr Dharmendra also emphasised that governance frameworks must clearly define responsibility across the AI lifecycle, from development to deployment and monitoring. Sustainable transformation, she noted, requires integration within existing health systems rather than fragmented pilot initiatives.

She concluded by reinforcing that responsible AI is not merely about regulatory compliance; it is about aligning innovation with measurable public value, equity, and long-term health system strengthening.



Mr Haitham Ali Ahmed El-Noush

Senior Advisor, Norad - Norwegian Agency for Development Cooperation

Mr El-Noush approached AI governance from the perspective of digital public infrastructure and national architecture design. He argued that governance frameworks must begin with clarity of purpose - what public value is AI meant to generate, and for whom?

He emphasised that India's experience with digital public infrastructure demonstrates that scale and inclusion can coexist when architecture is designed around principles of interoperability, openness, and citizen-centricity. In the context of AI, he highlighted

"The Global South must co-create standards rather than remain passive adopters."



"Governance begins with clarity of purpose-who benefits and how?"

that governance must embed values such as public trust, transparency, and inclusivity from the design stage itself.

He further reflected on the geopolitical concentration of AI development in the Global North, cautioning that Global South countries cannot remain passive adopters. Instead, they must co-create standards and governance norms that reflect their demographic realities, development priorities, and ethical frameworks. According to him, collaboration among Global South countries is not merely strategic but necessary to ensure that AI models are trained, validated, and deployed in ways that are contextually appropriate.

He concluded by emphasising that governance must be proactive rather than reactive - anticipating risks while enabling innovation.

Dr Ricardo Corpuz

HOD Basic Science, Senior Lecturer (Pathology), UPSM & HS, The University of Fiji, Fiji

Dr Corpuz provided a grounded clinical and academic perspective, particularly reflecting the realities of smaller island nations and resource-constrained environments. He described AI as a potentially transformative tool for streamlining patient triage, accelerating diagnostic interpretation, and reducing clinician workload.

He noted that in settings where healthcare professionals are overburdened, AI can serve as a decision-support partner, enabling doctors to spend more time on patient interaction and complex case management. However, he cautioned that AI outputs are inherently probabilistic and depend heavily on the quality of training data and user inputs.

Using a pedagogical analogy, he explained that AI systems are only as effective as the instructions and data they receive. Poorly framed prompts or non-representative datasets can produce misleading outputs. Therefore, clinician training, digital literacy, and continuous professional education are critical components of responsible AI integration.

He also highlighted infrastructural challenges such as unstable internet connectivity and limited technical support in some regions. These practical constraints must be addressed if AI is to function reliably in real-world clinical settings.



Ms Vidushi Chaturvedi

Lead Architect, NITI Aayog

Ms Chaturvedi brought a national policy and systems-design perspective to the discussion, focusing on how AI governance must be embedded within broader digital public infrastructure and regulatory strategy. She emphasised that responsible AI adoption in health requires clear institutional architecture, coordination across ministries, and alignment with national priorities.

She highlighted that governance frameworks must move beyond reactive regulation and instead anticipate future technological trajectories. In her view, policy design must incorporate flexibility to adapt to rapidly evolving AI capabilities while maintaining safeguards for safety, equity, and accountability.

Ms Chaturvedi underscored the importance of clearly defined roles across stakeholders, developers, deployers, regulators, and healthcare institutions to avoid fragmentation in implementation. She noted that strong governance is not only about setting standards but also about ensuring operational clarity, interoperability, and compliance mechanisms.

She further emphasised that India's digital public infrastructure offers an opportunity to build AI systems that are scalable, secure, and inclusive. However, this requires deliberate design choices that prioritise transparency, data governance, and public trust.

Her intervention reinforced the need for policy coherence, institutional preparedness, and forward-looking regulatory architecture to ensure that AI strengthens health systems rather than creating new systemic risks.

"AI governance cannot be reactive; it must be anticipatory, flexible, and embedded within national digital architecture."

Key Takeaways

Throughout the discussion, several overarching themes consistently emerged across speakers' interventions. These included concerns about geographically biased AI models trained on non-representative populations; the opportunity for the Global South to leapfrog legacy systems; the importance of South-South collaboration and collective agenda-setting; and the centrality of education, infrastructure, and institutional capacity in enabling responsible AI adoption. Trust, transparency, contextualisation, and lifecycle-based oversight were repeatedly identified as foundational principles.

- AI governance must be adaptive, iterative, and lifecycle-based rather than static and linear.
- AI-specific Health Technology Assessment (HTA) frameworks are essential for informed adoption, scaling, and reimbursement decisions.
- Contextualisation is critical. AI solutions must reflect local epidemiology, demographic realities, infrastructure constraints, and social values.
- Regulatory sandboxes, validation mechanisms, and early warning systems can enable innovation while maintaining safety and accountability.



- Capacity building, clinician training, digital literacy, and infrastructural strengthening are foundational to responsible AI integration.
- South–South collaboration and collective action are necessary to shape ethical standards and governance norms that reflect Global South priorities.

Conclusion

The deliberations throughout the session made it clear that governing AI in health is not merely a regulatory or technological challenge; it is a systemic and ethical responsibility. The Global South stands at a critical juncture: It can either passively import AI systems designed elsewhere or actively shape governance frameworks that reflect its own demographic realities, development priorities, and public values.

The discussions highlighted that adaptive governance anchored in lifecycle oversight, contextualised HTA frameworks, regulatory innovation, and strong partnerships, offers a viable pathway forward. Equally important is sustained investment in capacity building, infrastructure, research ecosystems, and South–South Collaboration.

Ultimately, the pathway to safe, trusted, and scalable AI in health will depend on balancing speed with safety, innovation with equity, and technological ambition with public accountability. By embracing collective action and people-centred design, the Global South can move from being a recipient of AI systems to becoming a co-architect of the global governance architecture for AI in health.



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RIS specialises in issues related to international economic development, trade, investment and technology. It is envisioned as a forum for fostering effective policy dialogue and capacity-building among developing countries on global and regional economic issues. The focus of the work programme of RIS is to promote South-South Cooperation and collaborate with developing countries in multilateral negotiations in various forums. Through its following centres/forums, RIS promotes policy dialogue and coherence on regional and international economic issues.



The word “DAKSHIN” (दक्षिण) is of Sanskrit origin, meaning “South.” The Hon’ble Prime Minister of India, Shri Narendra Modi, inaugurated DAKSHIN – Global South Centre of Excellence in November 2023. The initiative was inspired by the deliberations of Global South leaders during the Voice of the Global South Summits. DAKSHIN stands for Development and Knowledge Sharing Initiative. Hosted at the RIS, DAKSHIN has established linkages with leading think tanks and universities across the Global South and is building a dynamic network of scholars working on Global South issues.



AIC at RIS has been working to strengthen India’s strategic partnership with ASEAN in its realisation of the ASEAN Community. AIC at RIS undertakes research, policy advocacy and regular networking activities with relevant organisations and think-tanks in India and ASEAN countries, with the aim of providing policy inputs, up-to-date information, data resources and sustained interaction, for strengthening ASEAN-India partnership.



CMEC has been established at RIS under the aegis of the Ministry of Ports, Shipping and Waterways (MoPS&W), Government of India. CMEC is a collaboration between RIS and Indian Ports Association (IPA). It has been mandated to act as an advisory/technological arm of MoPSW to provide the analytical support on policies and their implementation.



FITM is a joint initiative by the Ministry of Ayush and RIS. It has been established with the objective of undertaking policy research on economy, intellectual property rights (IPRs) trade, sustainability and international cooperation in traditional medicines. FITM provides analytical support to the Ministry of Ayush on policy and strategy responses on emerging national and global developments.



BEF aims to serve as a dedicated platform for fostering dialogue on promoting the concept in the Indian Ocean and other regions. The forum focuses on conducting studies on the potential, prospects and challenges of blue economy; providing regular inputs to practitioners in the government and the private sectors; and promoting advocacy for its smooth adoption in national economic policies.



FIDC, has been engaged in exploring nuances of India’s development cooperation programme, keeping in view the wider perspective of South-South Cooperation in the backdrop of international development cooperation scenario. It is a tripartite initiative of the Development Partnership Administration (DPA) of the Ministry of External Affairs, Government of India, academia and civil society organisations.



FIRD aims to harness the full potential and synergy between science and technology, diplomacy, foreign policy and development cooperation in order to meet India’s development and security needs. It is also engaged in strengthening India’s engagement with the international system and on key global issues involving science and technology.



As part of its work programme, RIS has been deeply involved in strengthening economic integration in the South Asia region. In this context, the role of the South Asia Centre for Policy Studies (SACEPS) is very important. SACEPS is a network organisation engaged in addressing regional issues of common concerns in South Asia.



Knowledge generated endogenously among the Southern partners can help in consolidation of stronger common issues at different global policy fora. The purpose of NeST is to provide a global platform for Southern Think-Tanks for collaboratively generating, systematising, consolidating and sharing knowledge on South South Cooperation approaches for international development.



DST-Satellite Centre for Policy Research on STI Diplomacy at RIS aims to advance policy research at the intersection of science, technology, innovation (STI) and diplomacy, in alignment with India’s developmental priorities and foreign policy objectives.

— Policy research to shape the international development agenda —

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