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 proposes a pragmatic, two-track governance approach for AI in health:

1. **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.

2. **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.

Closing Note

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.