



AIRIS Incheon 2025 Outcome Statement

Building on the momentum of previous international efforts, including AIRIS Seoul 2024, AIRIS Incheon 2025 has further solidified its role as a global collaborative platform where diverse stakeholders from around the world, including academia, industry, WHO, and regulators, gather to discuss the latest applications of AI technology and regulatory innovations.

The AIRIS Incheon 2025 Outcome Statement emphasizes global efforts and continued collaboration to advance safe, responsible, inclusive, and actionable governance of artificial intelligence in health.

Under the AIRIS Incheon 2025 theme, '*Regulation for AI, Together for Tomorrow*', we share leading regulatory frameworks and best practices for the use of AI across the medical product lifecycle and encourage their appropriate application in accordance with national context and health system needs.

Recognizing the need for a lifecycle-based approach, including medical products development, clinical trials, manufacturing, regulatory evaluation, post-market surveillance, as well as benchmarking, we encourage a risk-proportionate regulatory approach that takes into account the characteristics of AI in establishing an AI regulatory strategy.

Emphasizing the importance of actively using AI systems, we ensure a balanced consideration of safety, ethical principles, equity, and accountability remain central from the design and development phase.

Recognizing the need to bridge cross-country gaps that hinder full participation in AI utilization and regulatory innovation, we encourage efforts to foster a responsible and trustworthy AI ecosystem through transparent, safe, and accessible mechanisms.

Recognizing the importance of leveraging governance mechanisms to address emerging challenges and opportunities in the evolving AI policy environment, together with diverse stakeholders worldwide (including academia, industry, international organizations, regulatory authorities, ICH, IMDRF and other relevant stakeholders), we look forward to continuing to strengthen sustainable and practical global governance, through AIRIS serving as a regular discussion platform.