



Luca Pani

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Bio:

Luca Pani, MD, holds dual Italian and American citizenship and serves as Professor of Clinical Psychiatry and Medical Director of Continuing Education Programs at the University of Miami, USA, as well as Full Professor of Clinical Pharmacology at the University of Modena and Reggio Emilia, Italy. He is the former Director-General of the Italian Medicines Agency (AIFA, 2011–2016) and previously held key roles at the European Medicines Agency (EMA), including membership on the Board of Directors, the Committee for Human Medicinal Products (CHMP), and the Scientific Advice Working Party (SAWP).

With 228 peer-reviewed scientific publications and 26 books, Dr. Pani is widely recognized for his expertise in basic and clinical pharmacology, regulatory science, and the integration of artificial intelligence (AI) and machine learning (ML) in R&D, clinical and health technology assessments. His work focuses on leveraging clinical datasets to inform innovative regulatory frameworks, approval pathways, and negotiation strategies.

Currently, Dr. Pani coordinates **FACILITATE** (Framework for Clinical Trial Participants' Data Reutilization for a Fully Transparent and Ethical Ecosystem), the final IMI-2 project funded by the European Commission (January 2022–December 2025). FACILITATE aims to establish a patient-centered, data-driven platform that creates a new ethical, legal, and regulatory framework for returning clinical trial data to participants and healthcare professionals in compliance with GDPR.

Dr. Pani is the pro-tempore President (2024–2026) of the International Society for CNS Clinical Trials and Methodology (ISCTM). He also serves as Chief Advisor at Relmada Therapeutics, USA, and Chief Regulatory and Innovation Officer at Netramark, Canada.