SD/ABocconi SCHOOL OF MANAGEMENT



PRIVILEGED TALKS

EXCLUSIVE **CONVERSATIONS** WITH TOP EUROPEAN **POLICY MAKERS**



18.03.2025

9:00 • REGISTRATION

9:30 • WELCOME AND OPENING REMARKS

H. 9.00 - 13.00

ADOPTING A LIFECYCLE APPROACH TO ENHANCE ACCESS TO INNOVATIVE MEDICAL DEVICES: REGULATORY INSIGHTS AND FUTURE PERSPECTIVES **AMID THE ONGOING** TARGETED **EVALUATION**

SEDE: MILANO

SDA Bocconi Via Sarfatti, 10 • Milano

AUDITORIUM FERRERO

REGISTER HERE

9:40 • OVERVIEW OF THE MEDICAL DEVICE REGULATION (MDR): WHERE WE ARE AND NEXT STEPS

Flora Giorgio, Head of Unit, DG SANTE, European Commission

10:15 • THE NEED FOR REFORM: LESSONS LEARNED AND FUTURE DIRECTIONS

- Key challenges faced by manufacturers and regulators under MDR Andrea Rappagliosi, MedTech Europe Loris Chiusoli, TUV SUD
- Balancing safety, innovation, and access to medical technologies Alan Fraser, CORE MD Philip Collis, Patients Research Partner

11:15 • COFFEE BREAK

11:30 · ADOPTING A LIFECYCLE APPROACH: FROM EARLY FEASIBILITY TO ACCELERATED PATHWAY FOR INNOVATIVE TECHNOLOGIES: RETHINKING PATIENTS' ACCESS FOR MEDICAL DEVICES

- US vs. EU: 10 Years of Experience with EFS vs. a Program Starting to Emerge in Europe
 - Giuditta Callea, SDA Bocconi
- Overcoming the separation between pre- and post-market phases to adopt a circular approach. What could an "Accelerated Patients' Access Program" look like in the EU?

Rosanna Tarricone, SDA Bocconi

• HTAR at the starting line: What changes for medical devices? Marco Marchetti, co-chair HTACG, AGENAS

12:15 • NEXT STEPS: GUIDING THE FUTURE OF MEDICAL DEVICE ACCESS IN **EUROPE**

POLICY RECOMMENDATIONS AND STRATEGIC PATHWAYS FOR **REGULATORS, INDUSTRY, AND HEALTHCARE SYSTEMS**

Panel discussion moderated by **RosannaTarricone**, SDA Bocconi Philip Collis, Patients Research Partner Loris Chiusoli, TUV SUD Alan Fraser, CORE MD Flora Giorgio, Head of Unit, DG SANTE, European Commission Marco Marchetti, co-chair HTACG, AGENAS



FINAL REFLECTIONS & CLOSING REMARKS Flora Giorgio, Head of Unit, DG SANTE, European Commission Rosanna Tarricone, SDA Bocconi

13:00 · NETWORKING LUNCH