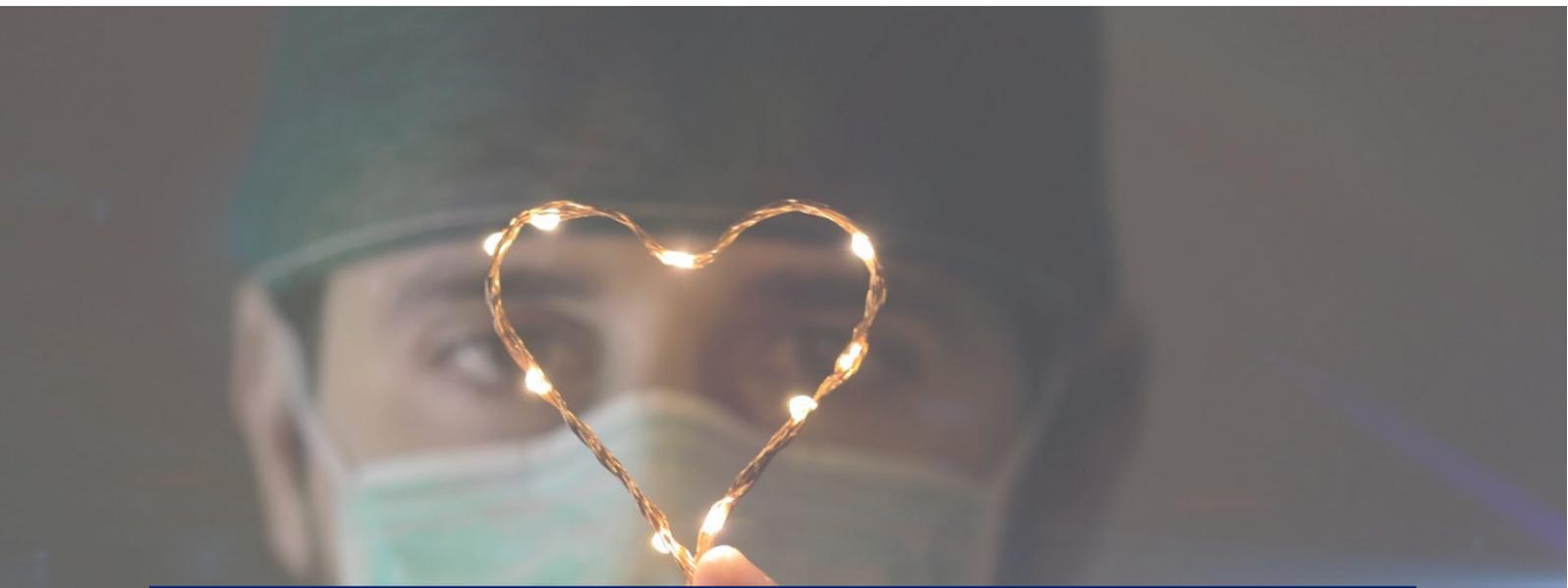




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Supporting innovation in cardiovascular medicines and medical devices in the EU

EMA's contributions to the Safe Hearts Plan

EMA multistakeholder workshop

01-02 July 2026

Hybrid meeting

Background and objectives

Cardiovascular diseases (CVD) account for a high burden in morbidity and mortality rates in the EU, with a considerable impact on EU healthcare systems. More actions are required to leverage the current opportunities to support research, innovation and personalised approach to address the gaps in current available therapeutic options for patients. In line with the ambition of the EU Cardiovascular (CV) Health Plan: the Safe Hearts Plan, greater focus is also needed on the prevention of CVD to reduce disease burden and long-term healthcare costs.

This multistakeholder workshop will bring together patients, healthcare professionals, academia, regulators, and industry to discuss opportunities to bring together the medicines and devices under the

EMA's umbrella and leverage the scientific expertise of the Cardiovascular Working Party (CVSWP) and the Circulatory System medical devices panel in this area.

These interdisciplinary discussions will cover a range of important topics including clinical gaps, development challenges and regulatory strategies, advancing CV prevention and treatment in the overlapping fields of diabetes, obesity and lipid disorders, the role of real-world data, and digitalisation and AI in CV innovation.

The overall objective of the workshop is to enhance understanding among stakeholders on the interplay of regulation and innovation in medicines and medical devices.

Expected outcomes of the workshop

- Identify priority areas in research and innovation for CV prevention and treatment;
- Improve understanding of scientific and regulatory gaps hindering CV research and innovation;
- Identify strategic recommendations to support development and timely access to safe and effective medicines and safe and performant medical devices for CV health;
- Provide foundations for follow-up actions, activities and initiatives.

Participation in this multistakeholder event will be by invitation only, but all those interested are welcome to follow the live broadcast. A video recording will be published after the event.

EMA Multistakeholder Workshop: Supporting innovation in cardiovascular medicines and medical devices in the EU – Agenda

Day 1 – 1 July 2026, 13:00 – 18:25 (CEST)

12:45 **Joining and technical checks**

13:00 **Welcome and opening speech**

Opening remarks from EMA Executive Director **10'**

Outline of the day and objectives **10'**

13:20 **Session 1: Setting the scene**

Lived experience in unmet need **15'**

Clinical challenges and opportunities **15'**

EU Cardiovascular Health Plan: The Safe Hearts Plan **15'**

Recent developments in medicines and medical devices for cardiovascular indications **30'**

14:35 **Q&A**

Questions from the audience **15'**

14:50 **Session 2: Opportunities in prevention and treatment**

Cardiometabolic diseases: tackling the unmet need in CV risk reduction **30'**

Challenges and opportunities in medicines and medical devices development - introduction to breakout sessions **10'**

15:30 **Coffee break**

15:45 **Breakout sessions**

17:15 **Coffee break**

17:30 **Reporting from breakout sessions**

Breakout session on medical devices **10'**

Breakout session on medicines **10'**

Plenary discussion: from prevention to intervention – the interplay between medicines and medical devices **25'**

18:15 **Closing remarks**

Wrap up **10'**

18:25 **End of day 1**

Day 2 - 02 July 2026, 09:00 – 16:00 (CEST)

08:45 **Joining and technical checks**

09:00 **Welcome and opening remarks**

Recap from day 1 and outline of the day **10'**

09:10 **Session 3: How can real-world data (RWD) support innovation and decision-making in CV**

Experience gained and lessons learned from recent and ongoing initiatives **20'**

Panel discussion **50'**

10:20 **Coffee break**

10:50 **Panel discussion (cont.) and Q&A**

Panel discussion and questions from the audience **60'**

11:50 **Lunch**

13:00 **Session 4: Foster innovation in cardiovascular diseases with digitalisation and AI**

Presentation - Industry **15'**

Presentation - Academia **15'**

Presentation - Regulators **30'**

14:00 **Coffee break**

14:30 **Q&A and discussion**

Questions from the audience **60'**

