EMA
EUROPEAN MEDICINES AGENCY

Challenges and opportunities in medicines and medical devices development

Introduction to the breakout sessions

EMA multistakeholder workshop

01/07/2026

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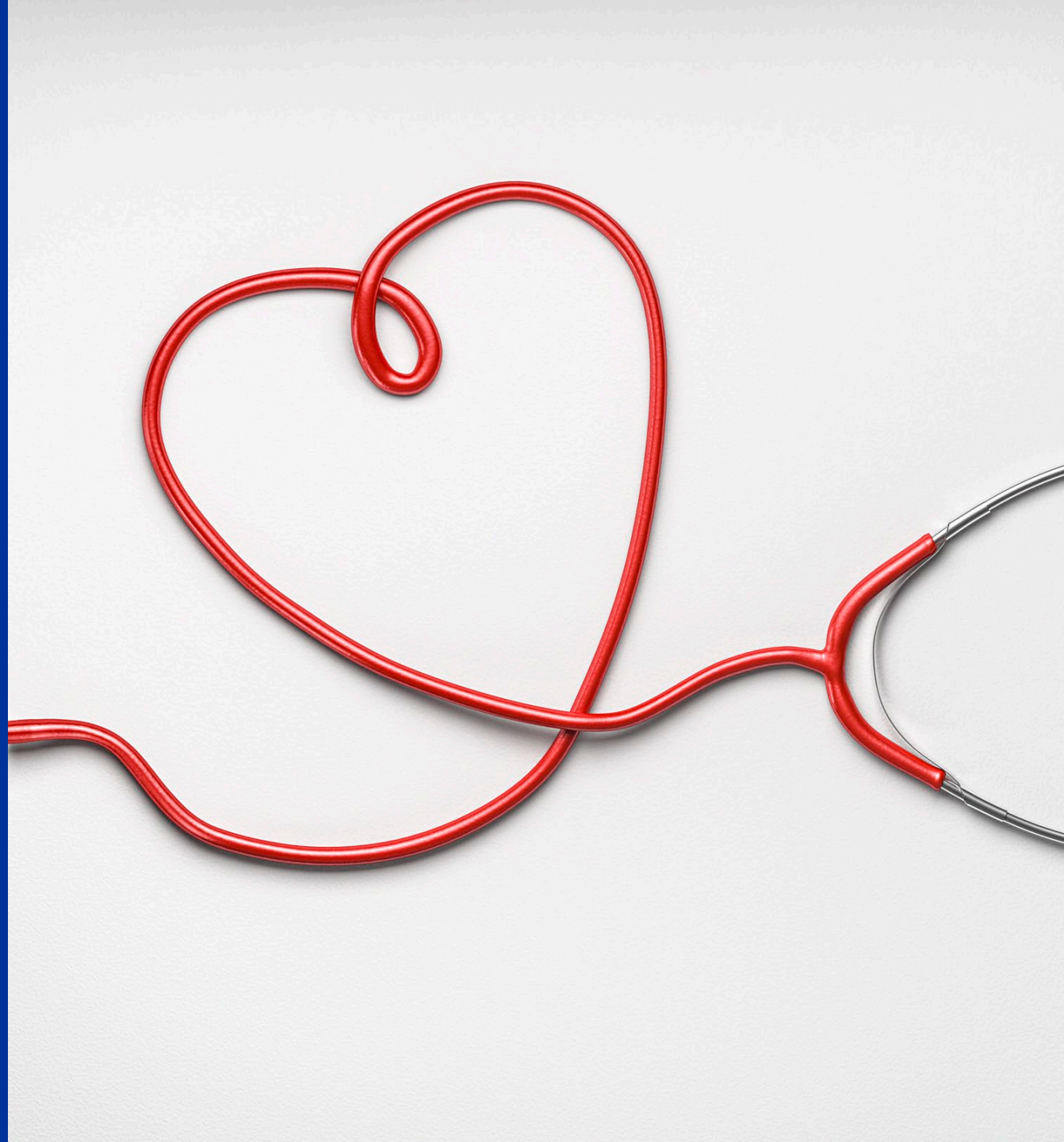
Expert Panels and Groups Office – Head of Office



Expert Panels activities on medical devices

- Provide an **opinion** on NB's clinical assessment of high-risk medical devices (CECP)
- Advise the Medical Device Coordination Group/European Commission on the **safety and performance** of medical devices and IVDs
- Advise **manufacturers of high-risk medical devices** on their clinical development strategy/clinical investigations
- Advise on **orphan device status** and support clinical development/clinical assessment (MDCG 2024-10)
- Advise on **breakthrough device status** and support the development/assessment (MDCG 2025-09)

CECP = Clinical Evaluation Consultation Procedure
PECP = Performance Evaluation Consultation Procedure

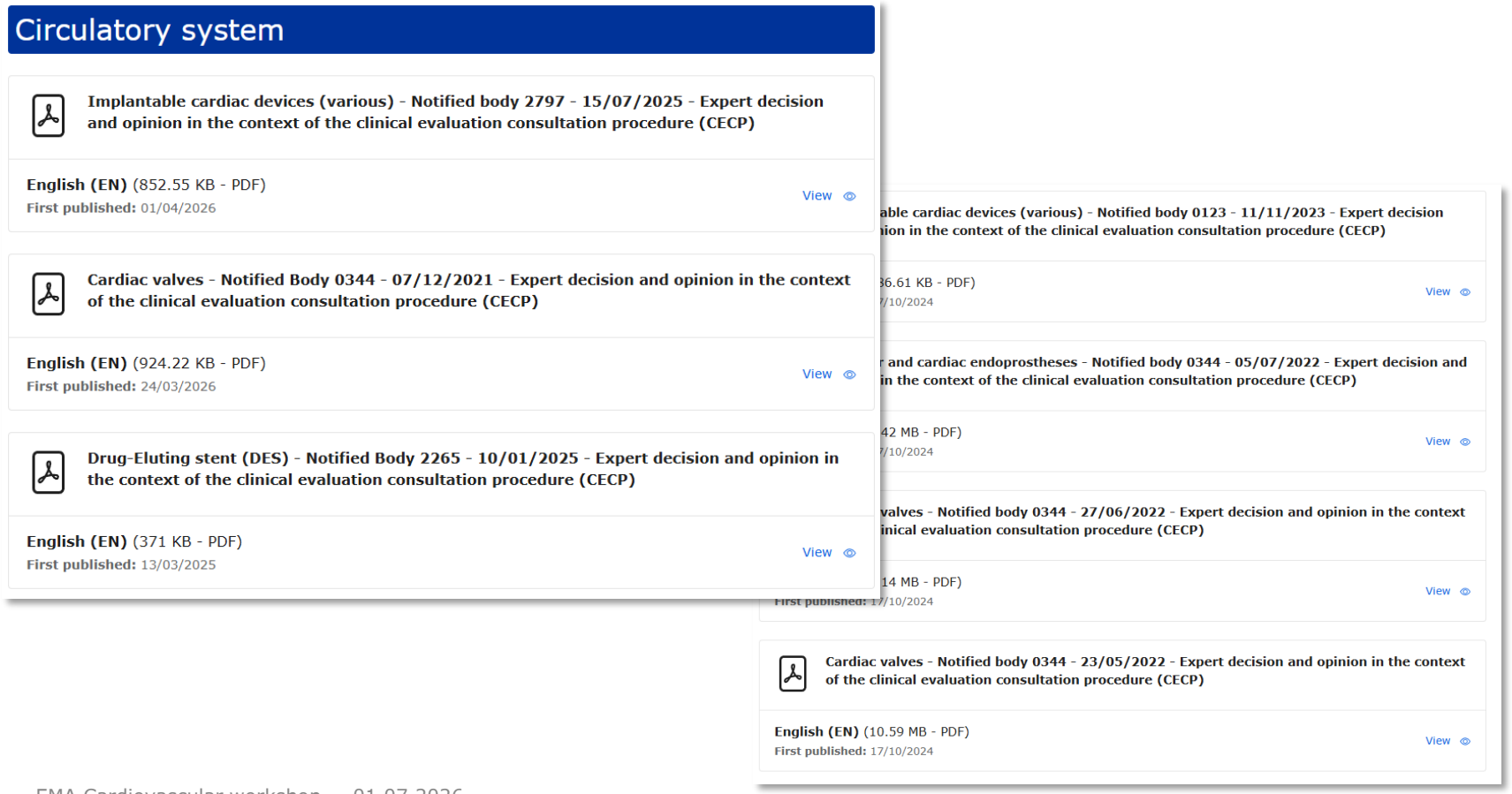
Clinical Evaluation Consultation Procedure

Submissions per clinical area: April 2021 – June 2026

Number of CECP/Opinions							
Year	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**Total**
CECP	9	29	50	74	119	47	338
Opinion	3	7	1	11	12	7	41

Clinical Evaluation Consultation Procedure

Cardiovascular system panel published opinions



[Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions | European Medicines Agency (EMA)]

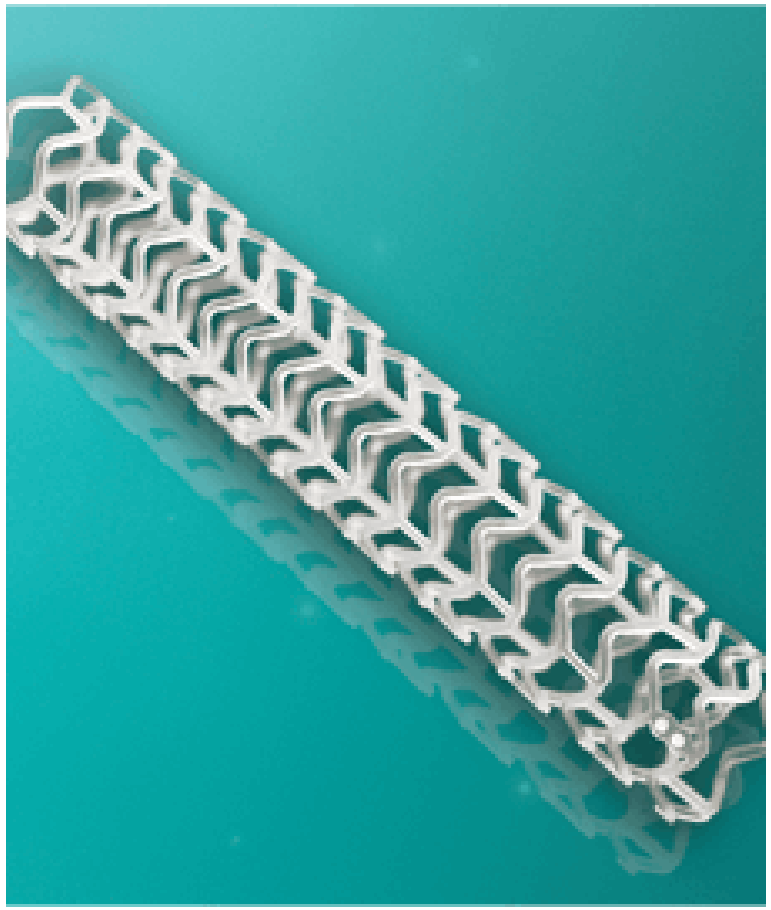
Clinical Evaluation Consultation Procedure

Cardiovascular system Opinions overview

- **Innovation is the most common criteria for decision for issuing an opinion**
- **Maturing oversight mechanism**
  - the CECP is an independent expert review for the clinical assessment of high-risk devices, supplementing the work done by Notified Bodies.
- **Alignment with NB assessments**
  - Generally, expert panels concurred with the Notified Body's benefit-risk conclusions.
- **Areas of shared focus for improvement:**
  - Extending the post-market follow-up period to better capture long-term outcomes for safety and clinical performance
  - Ensuring files are updated if new published clinical data becomes available
- **Patient safety for cardiovascular devices as the shared goal**

7 cardiovascular system opinions published

Advice to the MDCG



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05 August 2024
European Medicines Agency

Advice from the medical devices Expert Panels

Mandate[1] and Advice provided to the Medical Device Coordination Group (MDCG)

[1] According to the section 6.3 of the Rules of procedure of the European Commission expert panels on medical devices and in vitro diagnostic medical devices.

Advice on the use of **paclitaxel-coated devices** in **peripheral artery disease** and **potential association with higher mortality**

Request from the Medical Device Coordination Group

5 August 2024

Advice to medical device manufacturers

Expert panels can advise on intended clinical development strategies and clinical investigation proposals of:

- class III medical devices;
- class IIb active medical devices intended to administer or remove medicines from the body

Pilot launched in February 2023 and closed in Dec 2024, with regular advice service opened in February 2025.

Possibility of parallel advice with HTA bodies (Joint Scientific Consultation)

Source

Pilot advice expert panels report, February 2023–December 2024

ema.europa.eu/en/documents/report/pilot-advice-expert-panels-manufacturers-high-risk-medical-devices-interim-report-experience-pilot-february-2023-december-2024_en.pdf

Advice to medical device manufacturers

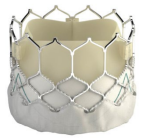
Thematic panel	# applications	%
Circulatory system	16	31
Orthopaedics, traumatology, rehabilitation, rheumatology	14	27
Neurology	7	14
General and plastic surgery and dentistry	6	12
Nephrology and urology	3	6
Gastroenterology and hepatology	2	4
Respiratory and anaesthetic devices, intensive care	1	2
Ophthalmology	1	2
Other	1	2
Total	51	100

Distribution of submissions per clinical area across all **3 submission phases**

Advice to medical device manufacturers

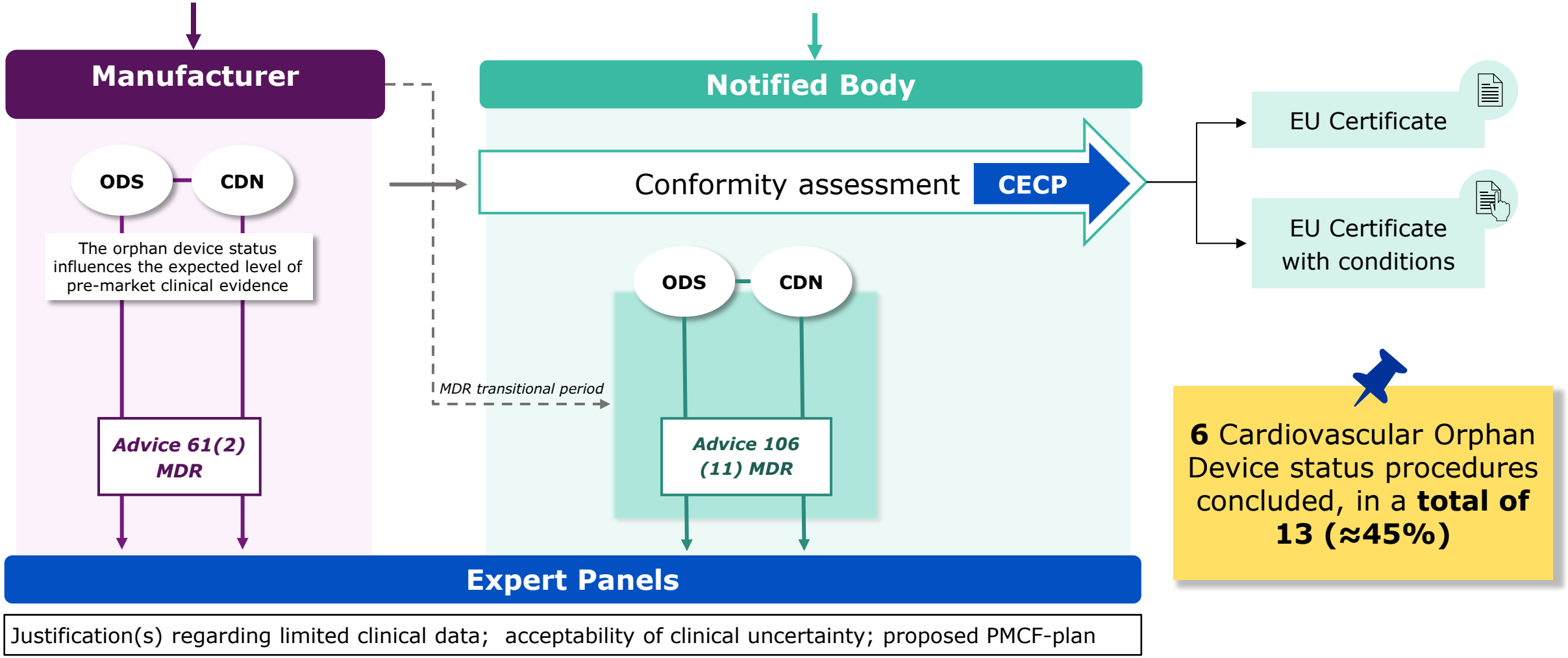
Thematic panel	# applications	%
Circulatory system	16	31

Category	Number of devices	Examples
C01: Arterio-venous system devices	2	E.g., Neurovascular angiography devices
J01: Cardiac functionality implantable devices	5	E.g., pacemakers, Ventricular Assist Devices (VADs)
P07: Vascular and cardiac prostheses	9	E.g., cardiac valves, vascular stents



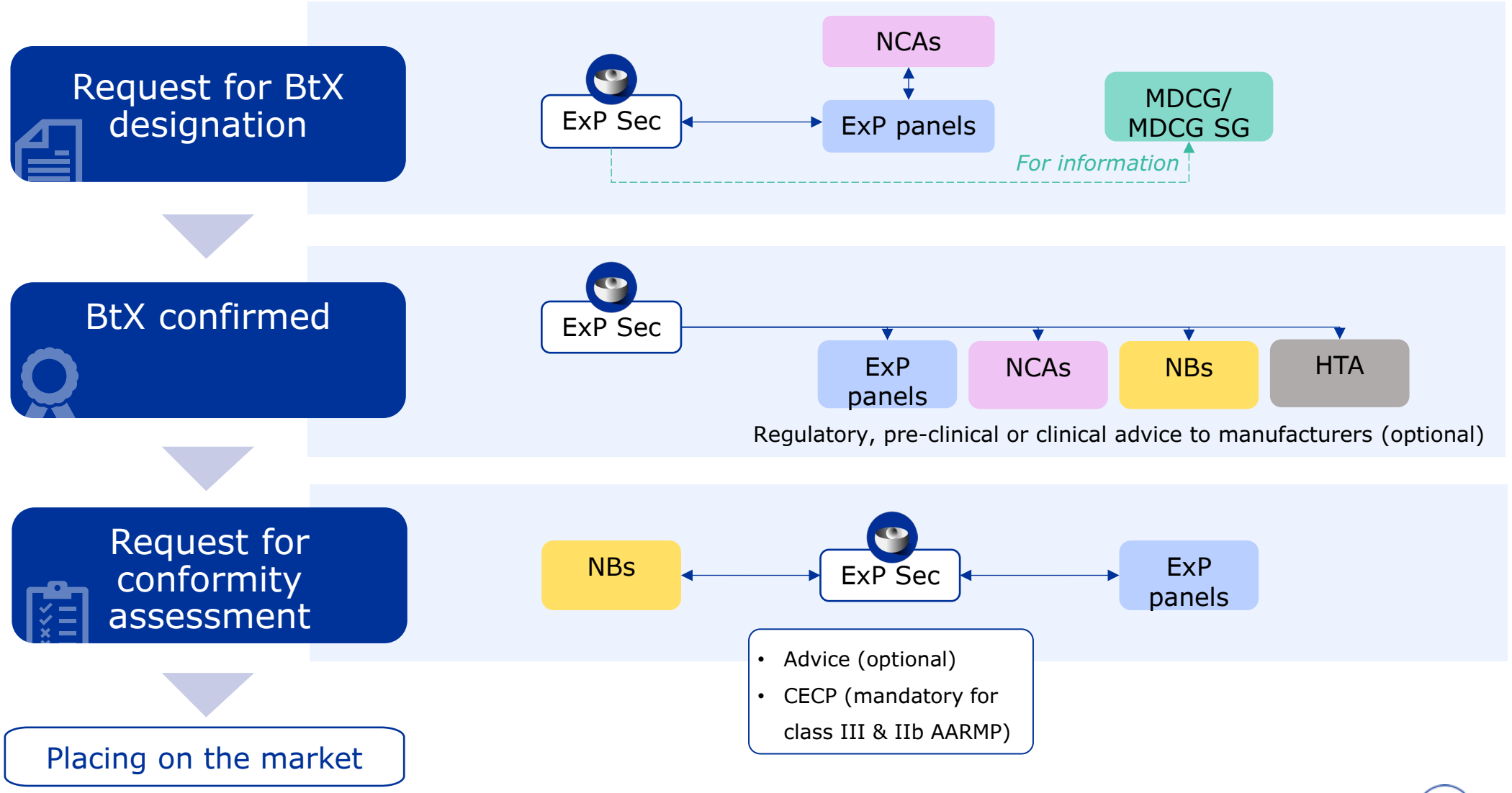
Orphan devices expert panels support

ODS – Orphan device status
CDN - Clinical data needed



6 Cardiovascular Orphan Device status procedures concluded, in a **total of 13 (≈45%)**

Breakthrough devices expert panels support



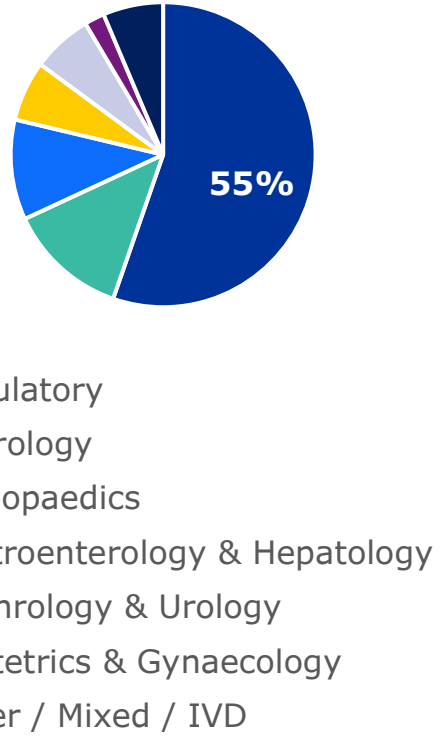
Procedures received for breakthrough designation (Phase Ia)

43 applications

Clinical Area	N.er applications
Circulatory	26
Neurology	6
Orthopaedics	5
Gastroenterology & Hepatology	3
Nephrology & Urology	3
Obstetrics & Gynaecology	1
Other / IVD	3

Note: Some procedures are counted in more than one clinical area when explicitly listed as multi-area (e.g., Circulatory + Neurology).

% applications per clinical area



Key questions for the breakout session

- Cardiovascular is the leading area in medical devices innovation and requests for support to clinical development, with the highest number of CECPs, advice to manufacturers and breakthrough proposals.
- Points to explore:
  - What are the main challenges and gaps in evidence generation (including clinical and real-world data), and how these could be addressed?
  - How the current role of the expert panels and their contribution could be further optimized?
  - Which are the key regulatory challenges for novel technologies and areas where additional clarity or guidance may be needed?
  - What are the main barriers to timely market access and uptake of innovative devices within the EU
  - How to foster coordination among regulators, notified bodies, HTA bodies, clinicians, and industry?
  - What could be priority actions to foster innovation, particularly in emerging areas such as digital and AI-based medical devices

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Thank you

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