

Medical Devices expert panels (MD) update

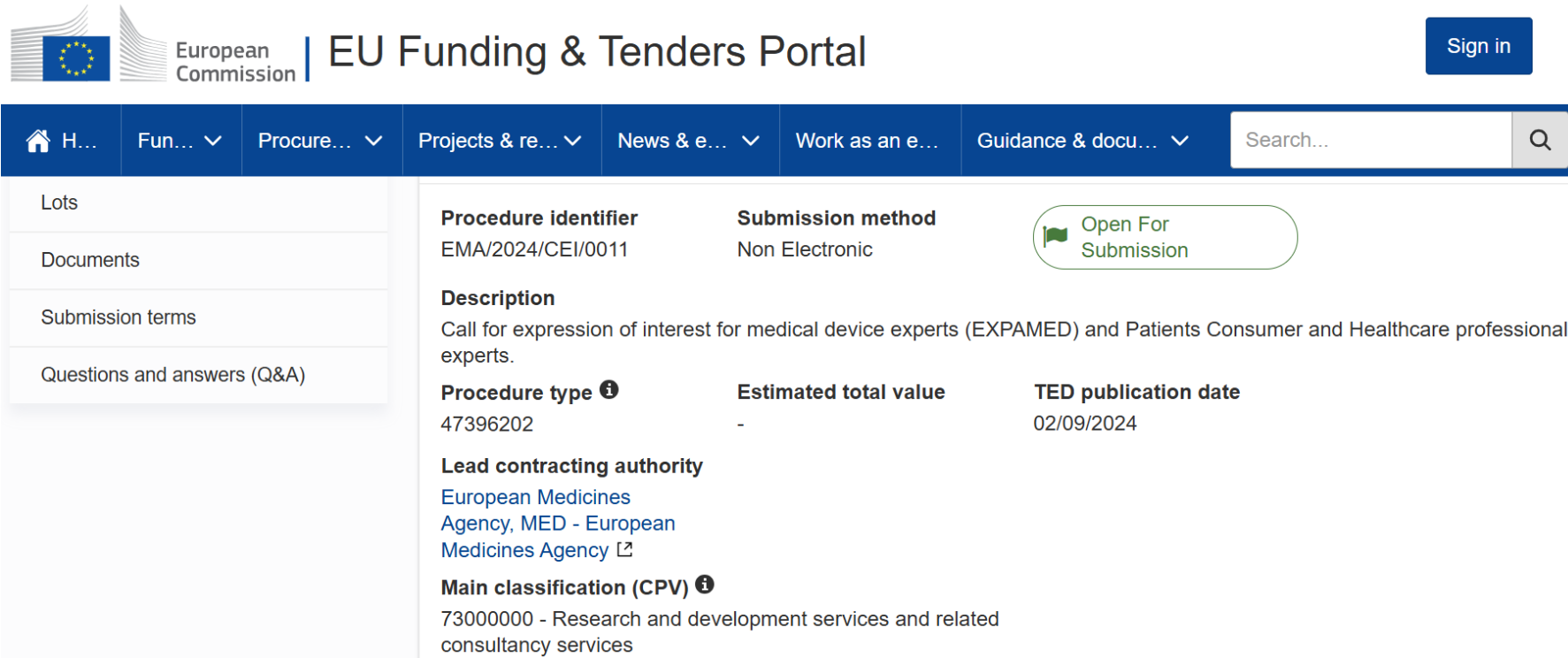
ISG meeting – 29/06/2026

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EMA-EPG Office



Updated call to experts



The screenshot displays the EU Funding & Tenders Portal interface. At the top left is the European Commission logo. The main header reads "EU Funding & Tenders Portal" with a "Sign in" button on the right. Below the header is a navigation bar with menu items: Home, Functions, Procurement, Projects & results, News & events, Work as an expert, and Guidance & documents. A search bar is also present. The main content area shows details for a specific call to experts:

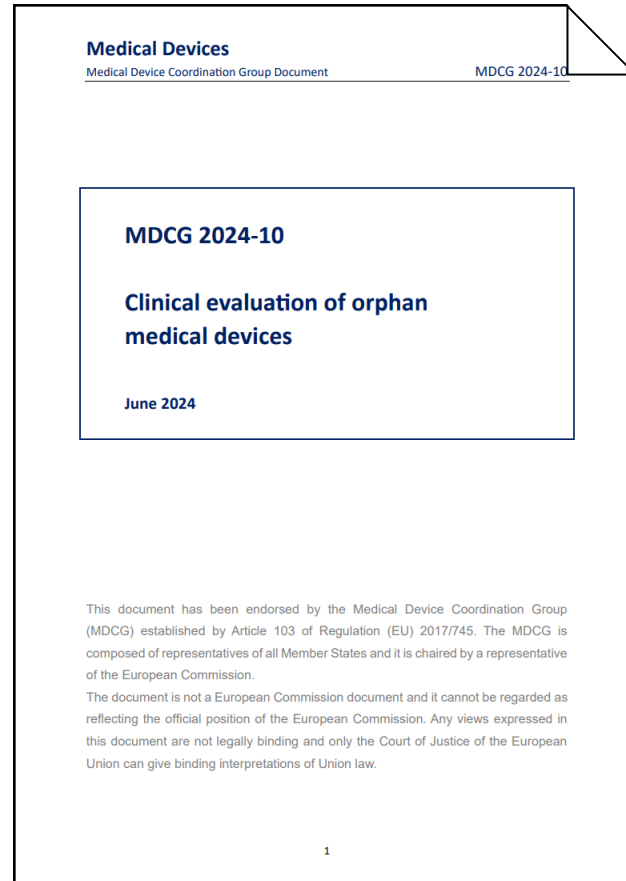
- Procedure identifier:** EMA/2024/CEI/0011
- Submission method:** Non Electronic
- Status:** Open For Submission (indicated by a green flag icon)
- Description:** Call for expression of interest for medical device experts (EXPAMED) and Patients Consumer and Healthcare professional experts.
- Procedure type:** 47396202
- Estimated total value:** -
- TED publication date:** 02/09/2024
- Lead contracting authority:** European Medicines Agency, MED - European Medicines Agency
- Main classification (CPV):** 73000000 - Research and development services and related consultancy services

Published on both the EU Funding & Tenders portal and the EMA website:

[EU Funding & Tenders Portal](#)

[Procurement | European Medicines Agency \(EMA\)](#)

Background: pilot on orphan medical devices



A pilot programme ran from **August 2024** until **March 2026**

open to:

Class III

Class IIb AARMP

prioritisation criteria

Life-threatening conditions / permanent impairment

Paediatric devices

Novel with potential major clinical benefit

Procedures concluded in the pilot programme

Thematic Panel	Orphan status procedures	Orphan advice procedures
Circulatory system	7	1
Neurology	3	1
Orthopaedics, traumatology, rehabilitation, rheumatology	1	0
Gastroenterology and hepatology	1	0
Respiratory and anaesthetic devices, intensive care	1	0
Ophthalmology	0	0
Endocrinology and diabetes	0	0
General and plastic surgery and dentistry	0	0
Obstetrics and gynaecology, including reproductive medicine	0	0
Nephrology and urology	0	0
In vitro diagnostic medical devices	0	0

13 designation procedures

2 advice procedures

Conversion to regular service



Since 1 April 2026

Class III, IIb → **all classes**

No prioritisation criteria

Fixed timetable for submission of final briefing document

Final Briefing Document Submission	Start of the Procedure	List of Questions (if required)	Discussion Meeting with the Applicant (if required)	Advice Letter
20-Apr-26	04-May-26	Week of 01-Jun-26	Week of 15-Jun-26	03-Jul-26
18-May-26	01-Jun-26	Week of 29-Jun-26	Week of 13-Jul-26	31-Jul-26
15-Jun-26	29-Jun-26	Week of 27-Jul-26	Week of 10-Aug-26	28-Aug-26

New panel

13. Paediatrics and rare diseases

- GEWILLIG Marc, [CV](#), [Declaration of interest](#)
- KOPYTA Ilona Anna, [CV](#), [Declaration of interest](#)
- MALAGON CALLE Jose Ignacio, [CV](#), [Declaration of interest](#)
- NATERA DE BENITO Daniel, [CV](#), [Declaration of interest](#)
- PAPAIOANNOU Eleni, [CV](#), [Declaration of interest](#)
- SANGIORGI Luca, [CV](#), [Declaration of interest](#)
- TRKA Jan, [CV](#), [Declaration of interest](#)
- TUESHAUS Ludger, [CV](#), [Declaration of interest](#)
- VAN DEN BERG Gert, [CV](#), [Declaration of interest](#)



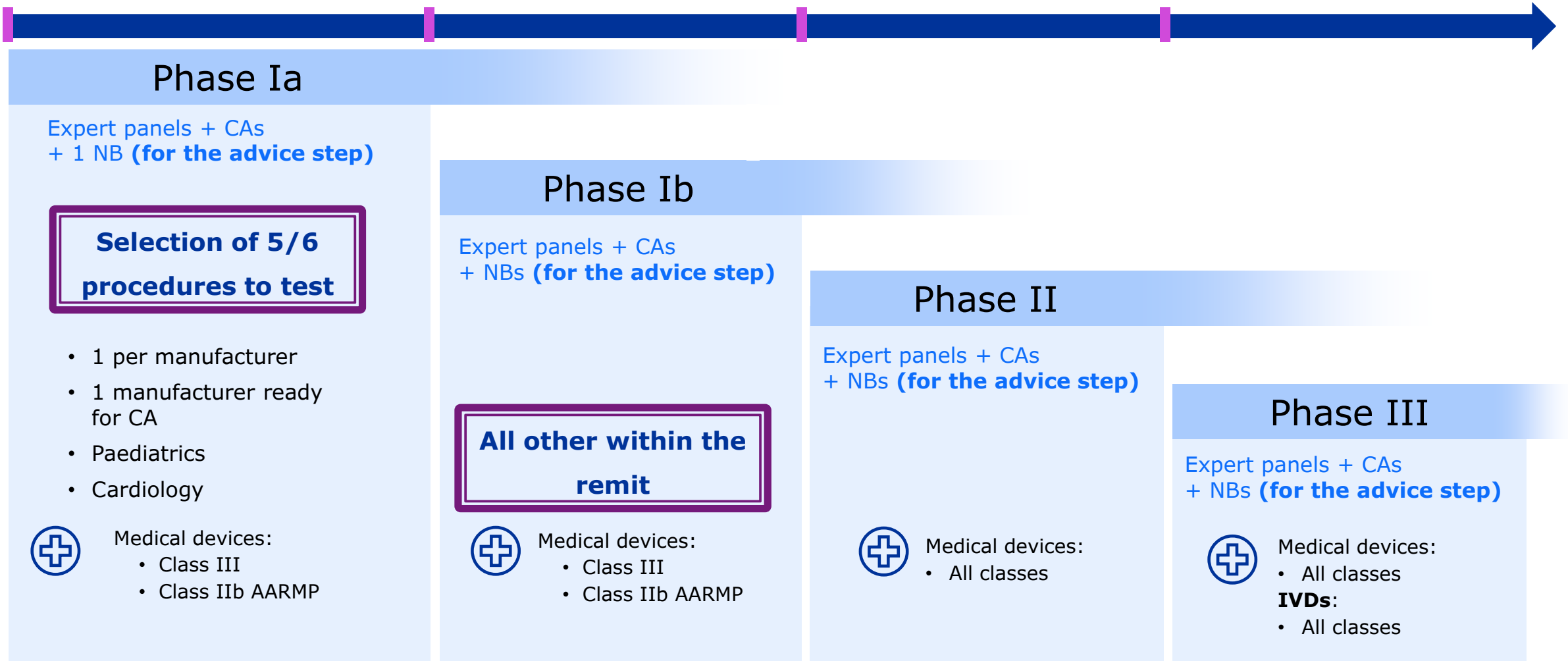
Breakthrough devices pilot structure

April 2026

Q3 2026

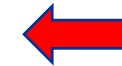
Q1 2027

Q3 2027



Timeline and next steps for Phase I

		Phase Ia (5 test cases)	
	Month	Day	
Designation assessments <i>1,5 months</i>	April	24	Info session for manufacturers
		28	Opening for designation LoI
	May	22	Deadline for designation LoI
		29	End of selection
	June	1	Opening for designation BD
		12	Deadline for designation BD
15		Start of the designation assessment	
July	31	End of designation assessment	
August			
	September	1	Opening for advice LoI
		15	Deadline for advice LoI
		16	Opening for advice BD
Exp advice on clinical strategy <i>2 months</i>	October	15	Deadline for advice BD
		16	Start of the advice
	December	15	End of advice (delivered)



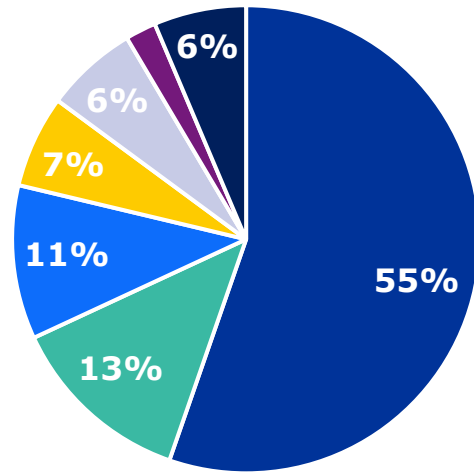
Phase Ib
(all class III/AARMP)
Opening for designation LoI

LoI: Letter of interest
BD: Briefing document

Summary of the applications received

43 applications

% applications per clinical area



- Circulatory
- Neurology
- Orthopaedics
- Gastroenterology & Hepatology
- Nephrology & Urology
- Obstetrics & Gynaecology
- Other / Mixed / IVD

Risk Class	N.er applications
Class III	36
Class IIb non-AARMP	5
Class I	1
Class C (IVD)	1

Manufacturer size	N.er applications
Big MedTech	10 (≈25%)
SME	29 (≈70%)
Academia	3 (≈5%)

Procedures selected for Ia (summary)

Device	Area	Regulatory status	NB involvement?
1	Cardiovascular	Early clinical development (end of pre-clinical)	-
2	Cardiovascular	Early development (pre-clinical ongoing)	Yes. NB A
3	Cardiovascular	Ready for conformity assessment	-
4	Orthopaedics	Conformity assessment started	Yes. NB B
5	Orthopaedics	Early clinical development (end of FIH)	-
6	Nephrology + Hepatology	CE marked; under review for new indication	Yes. NB C

**After application of
the prioritisation
criteria**



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Thank you

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