EMA
EUROPEAN MEDICINES AGENCY

Breakthrough Medical Devices Pilot

Information session

Friday, 24 April 2026, 15:00 - 17:00

Teams Webinar

Participation etiquette

Please note that this event is being recorded. For information on the processing of personal data, please refer to the General EMA Privacy Statement and the EMA Privacy Statements on the organisation of meetings and events.

Please note that **only speakers** will be able to switch on the camera and unmute themselves.
The speakers are kindly asked to switch on their cameras before speaking, if possible.

Part I and II will be followed by a **Q&A session** to clarify points further to the presentations, address questions received in advance of the meeting and receive feedback.

Participants will be able to submit questions via **Slido**, with the option of remaining anonymous.

In case of **any technical issues**, please try to connect again or contact virtualmeetings@ema.europa.eu.

EMA
EUROPEAN MEDICINES AGENCY

Welcome and opening remarks

Chairperson: Silvy Da Rocha Dias, EMA-EPG

Agenda

1.	Welcome	5’
	PART I: Guidance on Breakthrough Devices – General considerations	
2.	Overview of the breakthrough devices guidance	20’
3.	European Commission’s perspective and expectations	10’
4.	Industry’s perspectives on practical implications	15’
	PART II: Launch of the pilot, Expert Panels and Notified Bodies role	
5.	Role of the expert panels in the breakthrough devices framework and launch of the pilot • Assessing medical device innovation: past and future contributions of expert panels • Pilot on breakthrough devices: overview and procedural considerations	30’ 15’ 15’
6.	Notified body’s activities and responsibilities	15’
	PART III: Q&A, conclusions, next steps	
7.	Q&A	20’
8.	Conclusions and next steps	5’

Submit your questions on Slido

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ID: #2042156
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What would you like to learn in today's webinar on breakthrough devices?

What do you see as the biggest challenge for bringing breakthrough devices to the EU market?

PART I: Guidance on Breakthrough Devices – General considerations

Speakers:

- *Donal O'Connor (HPRA), Mariana Madureira (INFARMED)*
- *Nada Alkhayat (EC-DG SANTE-D3)*
- *Jana Russo (MedTech Europe), Johanna Sorsa (COCIR)*

Overview of breakthrough devices guidance

Donal O'Connor (HPRA)
Mariana Madureira (INFARMED)

Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746 MDCG 2025-09

Overview of BtX device criteria and pre-clinical and clinical evaluation considerations

Information session on the pilot for BtX medical devices

24 April 2026

MDCG 2025-9

Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746

December 2025

Purpose

- Provide a **structured framework** for early regulatory support
- Assist manufacturers of breakthrough technologies in navigating MDR/IVDR
- Improve **clarity and consistency** in regulatory interactions
- Support innovation **without introducing regulatory derogations**

MDCG TF on BtX composition

Co-Chairs:

European Commission

EUROPEAN MEDICINES AGENCY

Member state members/respondents to consultations:
AT,ES, DE, DK, FI, FR, NL, PL, PT, SE.
Notified bodies: NBCG-Med / Team NB.
Industry: MedTech Europe, COCIR, MPP, EFPIA.
Clinical: ESC, Biomedical Alliance
Other: ESIP, EU4HS.

Contents overview: MDCG 2025-09- Guidance on Breakthrough Devices (BtX) under Regulations 2017/745 & 2017/746

European Commission

BtX device criteria

'BtX' if the following criteria are met:

1. **Novelty**

The device introduces a high degree of novelty with respect to the device technology, the related clinical procedure, and/or the application of the device in clinical practice,

AND

2. **Positive clinical impact**

The device is expected to provide a significant **positive clinical impact** on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by **either** of the following:

- o Offering a significant positive clinical impact on patients or public health compared to available alternatives and the state of the art, **OR**
- o Fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.

Considerations - **Degree of Novelty**

Technology

- **materials**, including their composition, **chemical, physical and biological characteristics**, duration of contact of materials with human tissues or body fluids, or changes in the **release characteristics of substances**,
- **design**, including new or modified specifications and properties,
- manufacturing **process, sustainability, circularity, durability, reusability or environmental** impact of materials, design or manufacturing process,
- incorporated technologies or components that are integral to the functioning of the device, e.g., **biomarkers, analytes, test platform, or combination/integration with other devices**,
- technologies including medical device artificial intelligence (**MDAI**), devices with nanotechnology or advanced materials, or devices for precision medicine.
- [.....]

Clinical procedure/application in clinical practice

- **intended purpose or indication**, for example for IVDs detection/measurement of biomarkers to a different/new clinical condition
- **intended user,** e.g., level of public access, application of the device to lay users,
- **mode of application**, e.g., novel procedural approach or deployment methods, early detection/prediction/screening, monitoring/disease management,
- or **application of existing technologies in a novel context**,
- **interface or interaction of patients or users with the device**, including control, maintenance, and adjustment.

European Commission

Considerations – **Clinical Impact**

Patient health: effects on an individual level

Clinical impact on patient health is understood, in this context, as **the totality of benefits, harms and related risks at the individual level**. Clinical impact on patient health refers to a MD or IVD's expected or potential impact on:

- diagnosis, treatment, management, or prevention of a **life-threatening** or **irreversibly debilitating** disease or condition,
- clinical outcomes, for example differences in safety and/or clinical performance **compared with state of the art and alternatives** (if any) leading to **changes in**: mortality, morbidity, health-related quality of life, burden of treatment, […], etc.
- provision of care to individuals or specific groups of patients, e.g**.: differences in mode of administration, procedural efficiency, or cost-effectiveness,** resulting in clinical benefits or **advantages to patients** compared with state of the art,
- risks related to **specific groups of patients**, with a focus on **vulnerable populations**. [….]

Public health: effects on a population level

Clinical impact on public health is understood as the **net potential benefits and risks stemming from the clinical impacts on a population level**. Clinical impact on public health refers to a MD or IVD's expected or potential impact on:

- individual patient health, **cumulatively expressed on a population level**,
- prevention, diagnosis, management, and treatment of **serious public health threats** and **condition**s associated with significant risk to public health,
- response to and management of diseases and conditions that represent local, regional, national, European, and/or international **health emergencies**,
- **system-level benefits**, for example, by enabling clinically accepted treatment pathways to be delivered in a **significantly more cost-effective, efficient, scalable, and/or simplified manner with a greater capacity compared with state of the art**,

Considerations – **Life-threatening or irreversibly debilitating disease or condition**

Life-threatening disease or condition

- Highly likely to result in death **without major medical intervention**
- Typically associated with limited treatment options
- Requires significant medical intervention to interrupt disease progression

Irreversibly debilitating disease or condition

- Causes morbidity with **substantial and lasting impact** on:
  - Day-to-day functioning, and/or
  - Quality of life (individual, population, or subpopulation)
- Short-lived or self-limiting conditions are generally excluded
- Persistent or recurrent conditions may qualify where impact is ongoing

Illustrative examples

- Cancer, Neurodegenerative diseases, etc.

Considerations – **Available alternatives and state of the art**

Description of the state of the art

- Manufacturers must describe current EU clinical practice for the disease or condition
- Assessment must consider whether **relevant alternatives** exist on the EU market

Available alternatives may include: existing medical devices, IVDs, medicinal products, biological products, combination products, clinical or surgical procedures

Key guidance principles

- Focus on alternatives reflecting the **current state of the art**
- Exclude obsolete or rarely used options unless still clinically relevant
- Consider alternatives for the **same specific indication and disease stage**

Sources informing the state of the art

- relevant scientific standards and guidance, clinical practice guidelines, recommendations from authoritative scientific bodies, other reliable information reflecting current EU clinical practice

Guidance overview

Clinical Evaluation Considerations

European Commission

PART A - Pre-clinical, Clinical, and Performance Evaluation Considerations

- General considerations including acceptability of uncertainty and limitations in pre-market clinical data
- Considerations for IVD and MDAI

- Non-clinical data
  - Biological safety evaluation
  - Bench testing
  - In silico modelling and simulation
  - Usability aspects
  - Novelty in manufacturing aspects & validation
  - Analytical performance studies
  - Software validation

Clinical Investigations & Performance Studies

General principles include;

- MDR/IVDR rules on clinical investigations and performance studies apply unchanged
- Premarket studies may focus on safety and short- and medium-term performance
- Premarket data should be supplemented by post market investigations or other PMCF/PMPF activities
- Appendix provides further considerations on:
    - Study design
    - Objectives
    - Endpoints
    - Choice of comparator/control

Post market surveillance and PMCF/PMPF

- Increased reliance on timely post-market clinical data collection
- Need for detailed, structured, milestone-based PMCF plan
- PMCF / PMPF critical for breakthrough technologies, particularly relevant where:
  - Pre-market evidence may be more limited
  - Uncertainty of long-term effects
- Post-Market Surveillance:
  - Should consider enhanced PMS for BtX
  - Importance of PMCF / PMPF planning at early stage
  - Post-market data may contribute significantly to overall evidence base
- Methods
  - PMCF investigations and other activities, Registries, Real world data

Thank you

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European Commission's perspective and expectations

Nada Alkhayat (EC-DG SANTE-D3)

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Industry’s perspectives on practical implications

Jana Russo (MedTech Europe)

MedTech Europe
from diagnosis to cure

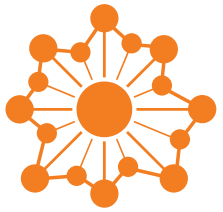
Breakthrough pathway: MedTech Europe perspective

24 April 2026

MedTech Europe
from diagnosis to cure

The European trade association for the medical technology industry including diagnostics, medical devices and digital health

145+ multinational corporations*



50 medical technology associations

*medical devices, diagnostics and digital health

Breakthrough initiatives

- Welcome 👏 👏 👏
- Big picture:
  - Successful IVDR/MDR simplification reform
  - Annex VII implementing act

Source: https://www.medtecheurope.org/resource-library/the-future-of-europes-medical-technology-regulations/

Putting MDCG 2025-9 into practice: pilot and beyond

- ‘Early dialogue’
- Enhanced coordination between expert panels and NBs
- Conditional certificates
- Expand expert panels’ expertise to technical & regulatory

- MedTech Europe Special Pathways position paper

- **A concrete timeline end to end; measure performance**

Incentives & predictability

Absence of **concrete timeline for process end to end: predictability?**

Incentives to support breakthrough manufacturers?

MedTech Europe
from diagnosis to cure

Thank you

Industry’s perspectives on practical implications

Johanna Sorsa (COCIR)

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Breakthrough pathway

COCIR Perspective

April 24, 2026

Dr. Johanna Sorsa, COCIR representative for breakthrough technologies
Senior manager clinical and regulatory affairs at Siemens Healthineers AG

Manufacturers' needs: Predictability to Enable Market Entry and Adaptation of BtX

Legal and regulatory compliance framework

Adaptive regulatory sandboxes

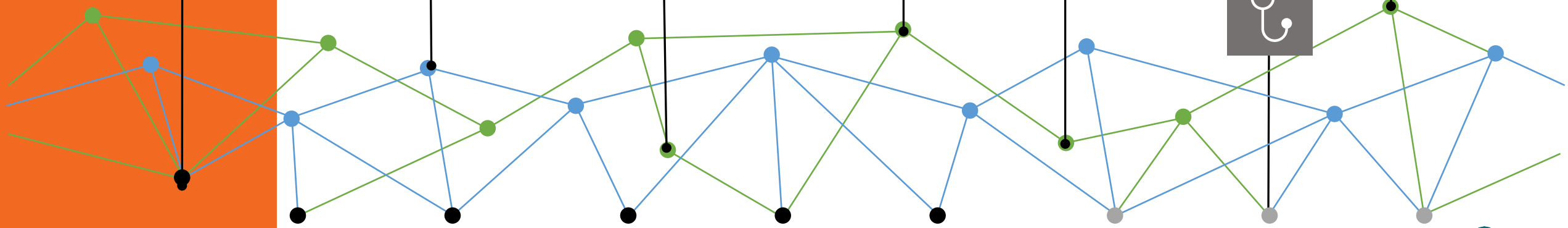
Regulatory convergence in major markets

Health economic value /payment models /reimbursement

Adaptive technical standard framework

Adaptive evidence framework

Funding on research on new technologies and clinical application fields



Manufacturers' needs: Predictability to Enable Market Entry and Adaptation of BtX

Close aligment with multiple stakeholders is essential for bringing BtX to the EU market.

Manufacturer

Notified body(s)

Expert panel(s)

Authority(s)

Product specifications

Project specifications

Market entry specifications

Market adaptation specifications

Framework must enable predictability in planning and investment.

COCIR
Advancing Healthcare

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PART II: Launch of the pilot, Expert Panels and Notified Bodies role

Speakers:

- *Tom Melvin (Expert panels)*
- *Miguel Antunes (EMA-EPG), Cécile Henrot (EMA-EPG)*
- *Richard Holborow (BSI NL), Ashleigh Batchen (TÜV SÜD), Sebastian Fischer (TÜV SÜD)*

Role of the expert panels in the breakthrough devices framework and launch of the pilot

Assessing medical device innovation: past and future contributions of expert panels

Tom Melvin (Expert panels)

Ollscoil na Gaillimhe
University of Galway

An Institiúid do Thrialacha Cliniciúla
Institute for Clinical Trials

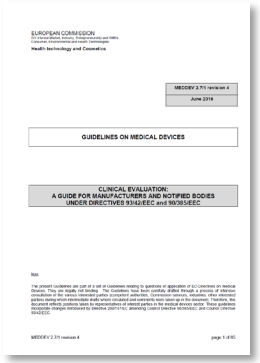
Assessing medical device innovation: past and future contributions of expert panels

Tom Melvin
Medical Devices Expert Panels, Screening Panel Representative

University *of* Galway.ie

Evolution of Regulation and Policy for Expert Panels and Breakthrough devices

2016



Annex A8 – Devices for unmet medical needs & Breakthrough Devices

2017

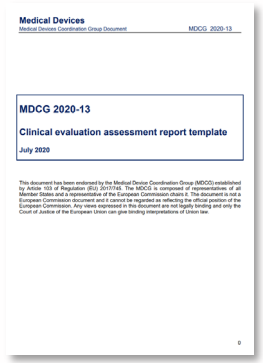
Publication of the MDR 2017/745

2019

Joint Research Centre established as secretariat for Expert Panels

11 thematic panels + Screening panel established

2020



Clinical Evaluation Assessment Report template published

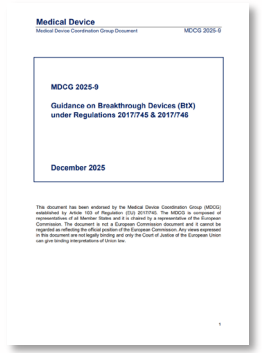
2021

Application of the MDR 2017/745 begins

2022

EMA take over secretariat for Expert Panels from JRC

2025



MDCG Breakthrough Device Guidance published

2026/2027

MDR Revision with new provisions for Breakthrough devices

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University of Galway

Overview of expert panel Work

Coordination committee

Chairs & Vice Chairs of 10 MDR panels + IVD panel and representatives of screening panel.

1. Screening panel

Thematic expert panels

2. Orthopaedics, traumatology, rehabilitation, rheumatology *
3. Circulatory system *
4. Neurology *
5. Respiratory system, anaesthesiology, intensive care
6. Endocrinology and diabetes
7. General and plastic surgery and dentistry *
8. Obstetrics and gynaecology, incl. reproductive medicine
9. Gastroenterology and hepatology
10. Nephrology and urology
11. Ophthalmology
12. In vitro diagnostic devices
13. Paediatrics and rare diseases

* Further organised into specialised subgroups

Central list of available experts

Temporary assignment of experts to panels.

Reserve list for appointments.

Expert panels activities

- Provide an **opinion** on NB's clinical assessment of high-risk medical devices (CECP)
- Provide a **view** on the performance evaluation of class D IVDs (PECP)
- 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)

Clinical trial requirements in EU and US for breakthrough devices

	510(k)	De Novo	PMA
United States	*Often none*. Frequently relies on bench & usability data; clinical data required only when predicate comparison is insufficient.	Usually requires **clinical evidence** tailored to risk	**Yes—mandatory**, with well-controlled, often multi-centre pivotal trials
European Union	**Clinical data providing sufficient clinical evidence** **Typically an observational clinical study** with **short to medium** term follow-up **Adaptive** and **sequential** designs can be acceptable for market access		

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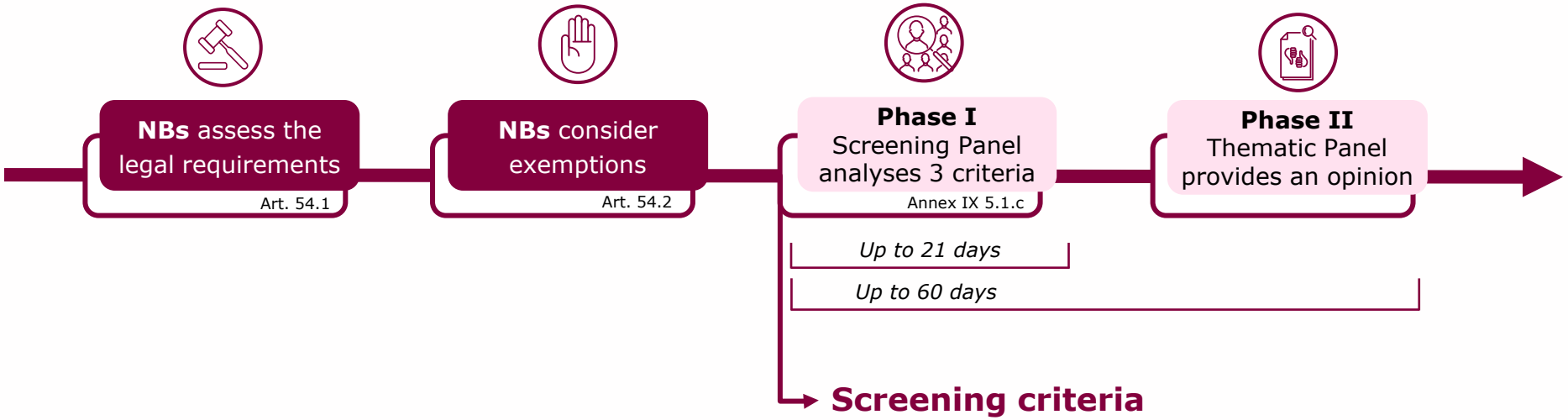
CECP phases and screening criteria



Screening criteria

1. Novel and major clinical/health impact

- Procedure- and device-related novel aspects to be evaluated
- Clinical and health impact are assessed in relation to the identified novelty

2. Adverse change of B/R of a group of devices due to scientifically valid health concerns

3. Significant increase of rate of serious incidents as per Art. 87 for a relevant group of devices

More detail on how these criteria should be interpreted can be found in Commission guidance c/2020/5264

Novelty under the CECP

Novelty is relevant only when linked to a possible **major clinical or health impact**; novelty alone does not trigger a scientific opinion.

What novelty means

Limited experience with the device, its features, or the related clinical procedure, with no similar devices—or insufficient experience with similar devices—to support straightforward appraisal of real-world safety and performance.

Assessment basis

The panel can assess novelty directly from the CEAR and accompanying documents, particularly the manufacturer's CER; for modifications, post-market information may also be relevant.

Decision logic

Potential impacts not linked to a novel device, novel feature, or novel procedure do not trigger a scientific opinion; the link between novelty and impact is essential.

Novelty under the CECP

Procedure-related dimensions

- Novel clinical or surgical procedure.
- Change in mode of use or treatment option.
- New or changed device-patient interface, including maintenance and adjustment.
- New interaction and control context, including a new interface or way of application.
- Novel deployment methods.

Device-related dimensions

- Novel medical purpose, including new intended purpose, clinical setting, disease stage, body site, or target population, with particular attention to paediatrics.
- Novel design, including specifications, physicochemical properties, shape, size, energy characteristics, or integral software algorithms.
- Novel mechanism of action, including new or modified physical or chemical properties.
- Novel materials, coatings, surface treatments, release characteristics, degradation products, or leachables; novel site of application for an established material.
- Novel components or novel manufacturing process, for example additive manufacturing, bio-printing, or sterilisation processes.

Significance

Clinical impact

At individual level, the assessment covers benefits, hazards, and risks, including effects on mortality, morbidity, quality of life, burden of treatment, re-intervention, adverse events, incompatibility with other devices, vulnerable patient groups, and foreseeable misuse or dysfunction.

Health impact

At population level, experts consider cumulative effects, exposed population, duration of effects, probability of serious public health threats, and whether innovation could lead to high market penetration and therefore greater aggregate harm.

Uncertainty

Novel devices may have limited real-world data. High uncertainty may justify requesting a scientific opinion even when novelty or resulting negative impact is not clearly major, provided the panel explains the remaining uncertainties and associated risks.

What to focus on

- Focus on negative impacts: hazards, harm, and risks.
- Consider possible outcomes even without direct evidence if they could realistically occur in real-world use.
- Estimate severity: public health risk, side effects, life-threatening conditions, and impact on safety or delivery of care.

Trigger threshold

- No scientific opinion is typically required when novelty is low and there is no major potential negative clinical or health impact.
- A scientific opinion is required when a major negative clinical or health impact is anticipated, irrespective of the degree of novelty.

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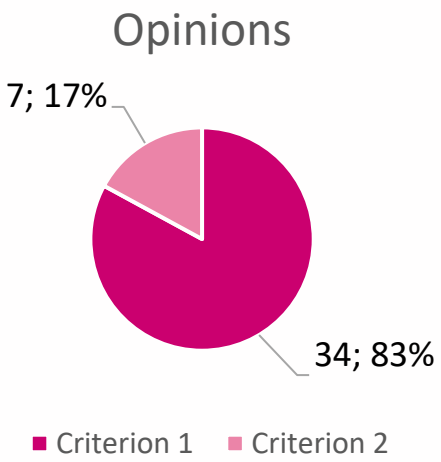
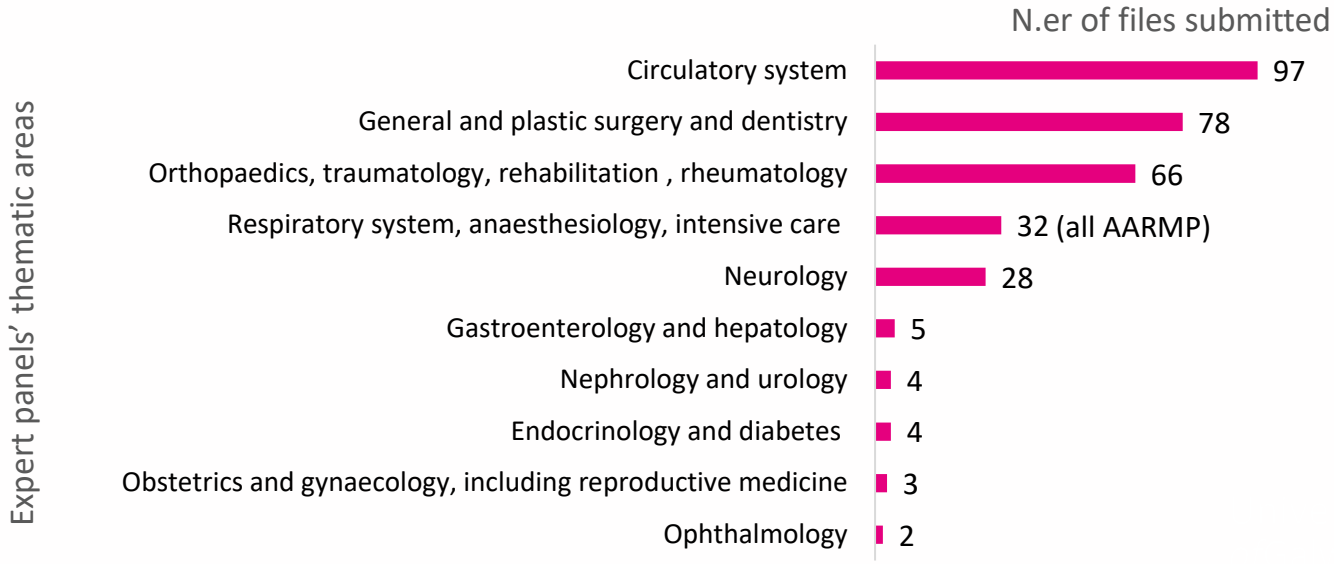
University of Galway

Update on the CECP number: 21/04/2021 – 20/04/2026

Number of CECP/Opinion/PECP

Year	2021	2022	2023	2024	2025	2026	Total
CECP	9	29	50	74	119	38	319
Opinion	3	7	1	11	12	7	41
PECP	15	1	2	3	0	0	21





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University of Galway

What will change for breakthrough devices?

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University of Galway

For designation opinions - these were offered by **EMA or notified bodies for orphan devices**. For **breakthrough**, it will be **EMA only**

Orphan devices had c. 13 designation assessments, breakthrough devices will be **much greater** in number

Providing advice to **National Competent Authorities** on **clinical investigations** is a new and time bound process – building an agile approach for interaction will be necessary

Support for Expert Panel members on the advice process to manufacturers will need greater support to manage the '**higher level of uncertainty**' and '**more limited pre-market clinical evidence**' suggested by MDCG guidance

What methodological approaches can empower the pathway?

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University of Galway

Standard **templates** for sponsor and Expert Panels will be needed to document granular criteria and rationale for designating / not designating a candidate technology

A **methodological approach** to support the balance of ‘acceptable uncertainty’ versus lack of alternative available treatment options will empower the Expert Panels

Early interaction with National Competent Authorities who require advice will be needed to meet clinical investigation assessment timelines

Resource planning will be needed for the high-throughput clinical areas – cardiology, orthopaedics, neurology

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Thank *you*

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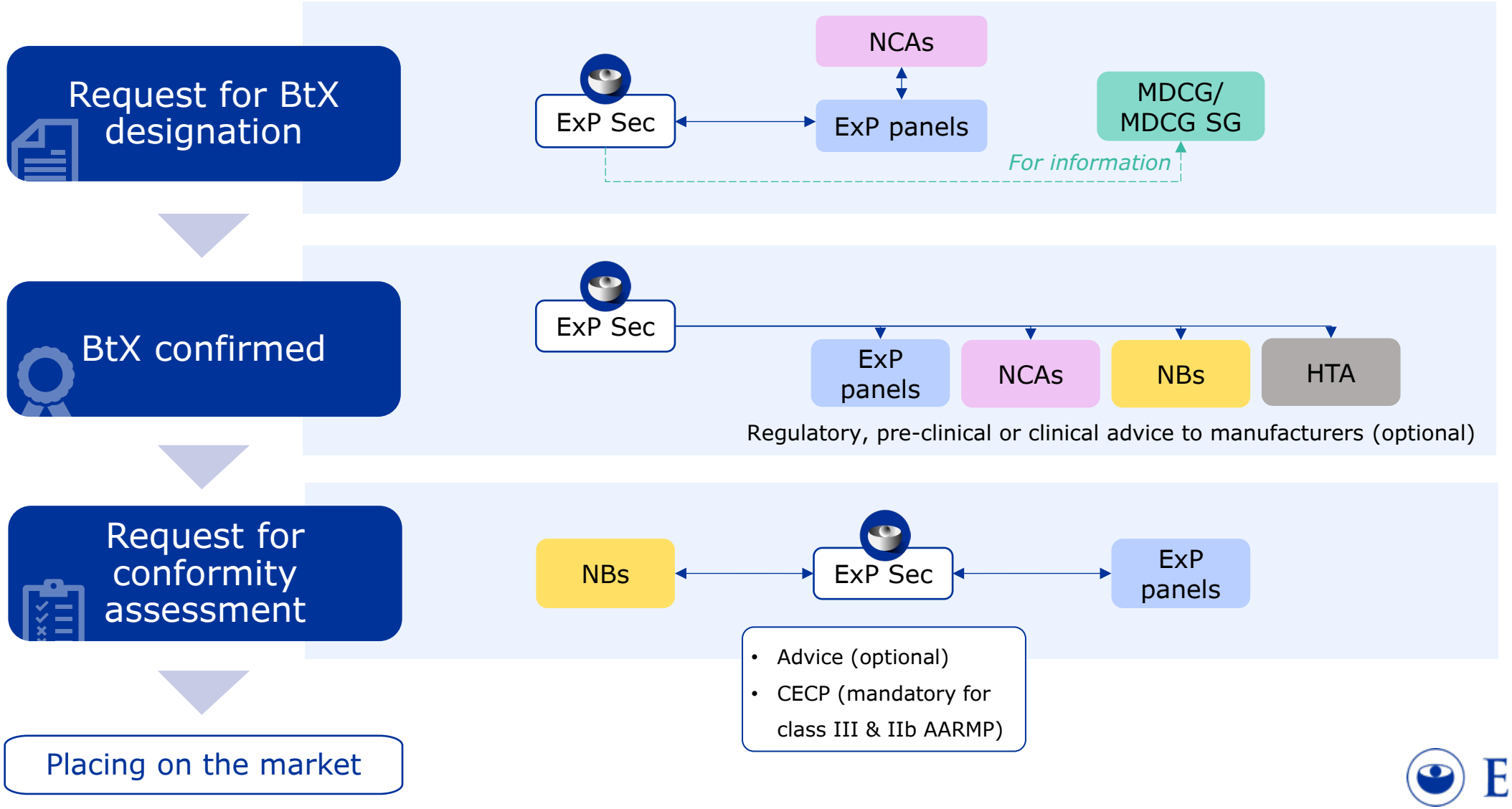
Role of the expert panels in the breakthrough devices framework and launch of the pilot

Pilot on breakthrough devices: overview and procedural considerations

Miguel Antunes (EMA-EPG)
Cécile Henrot (EMA-EPG)

Expert panels support to breakthrough devices



HTAR Joint Scientific Consultation (JSC) request periods 2026

Number of JSC defined in 2026 Annual Work Programme of the HTACG - 2-5 JSC medical devices

- **Four request periods defined for 2026**

OPEN

Second request period for 2026 currently open for medicinal products and medical devices

Available consultation slots to apply for in the **second request period 01 to 29 April 2026**:

- Briefing document submission by 06 July 2026
- Briefing document submission by 31 August 2026
- Briefing document submission by 28 September 2026

Third request period for 2026 – 03 June to 01 July for medicinal products and medical devices

- Briefing document submission by 26 October 2026
- Briefing document submission by 23 November 2026
- Briefing document submission by TBC December2026

What can scientific advice be provided for:

- **MD class III implantable / class IIb** active device, **administer/remove a medicinal product (ARMP) / IVD class D**
- **Studies which are in scope are: MD Post-market clinical investigations[1]/ IVD performance studies[2]** not yet certified or **Post-market clinical investigations[1] / performance studies[2]** for a **JCA update** or where **new evidence is required** from initial JCA report.

1. Article 2(45) of the MDR 2. Article 2(42) of the IVDR 3. Annex XIV PART B of the MDR 4. Annex XIII PART B of the IVDR

Pilot structure

April 2026 — *Q3 2026* — *Q1 2027* — *Q3 2027*

Phase Ia

Expert panels + CAs
+ 1 NB **(for the advice step)**

Medical devices:
- Class III
- Class IIb AARMP

5 applications selected
- 1 per manufacturer
- 1 manufacturer ready for conformity assessment

Prioritisation criteria:
- Cardiovascular area
- Paediatric population
- Different types of devices
- Different stages of development (TRLs*)

Phase Ib

Expert panels + CAs
+ NBs **(for the advice step)**

Medical devices:
- Class III
- Class IIb AARMP

Phase II

Expert panels + CAs
+ NBs **(for the advice step)**

Medical devices:
- All classes

Phase III

Expert panels + CAs
+ NBs **(for the advice step)**

Medical devices:
- All classes

IVDs:
- All classes

*Technology Readiness Levels

Timeline and next steps for Phase I

	Months	Dates
	April	**24/04** Info session for manufacturers **28/04** Opening of submissions for designation **(Ia)**
	May	**22/05** Closing of submissions for designation **(Ia)** **29/05** End of selection **(Ia)**
Designation assessments	June	**12/06** Deadline for submission of designation briefing document **(Ia)** **15/06** Start of the assessment **(Ia)**
1,5 months	July	**31/07** End of designation assessment **(Ia)**
	August	
	September	**01/09** Opening of submission for advice **(Ia)** **15/09** Closing requests for advice **(Ia)** **15/09** Opening of submissions for designation **(Ib)**
Expert panels advice on clinical strategy/investigations	October	**15/10** Deadline for submission of advice briefing document **(Ia)** **16/10** Start of the advice **(Ia)**
	November	
2 months	December	**15/12** Deadline for delivery of advice **(Ia)**

Application structure

1. Letter of interest

- Information on the device
  Description, risk class, EMDN type, clinical area, intended purpose, development history, regulatory status, other advice from regulatory authorities
- Type of advice requested
  BtX status or clinical advice for device already designated breakthrough
- Description of the **targeted condition** / population
  Justification for its life-threatening or irreversibly debilitating nature
- **Novelty**
  Device technology, related clinical procedure, application in clinical practice
- Significant **positive clinical impact** on patient or public health
- **Prioritisation criteria**
  Cardiovascular area, paediatric population

Application structure

2. Briefing document

https://www.ema.europa.eu/en/expert-panel-support-breakthrough-medical-devices-pilot-programme

Pilot application templates

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Application structure

2. Briefing document


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date>

Request for advice from the Expert Panels pursuant to MDCG 2025-9 guidance[1], for a device designated as breakthrough

https://www.ema.europa.eu/en/expert-panel-support-breakthrough-medical-devices-pilot-programme

Pilot application templates

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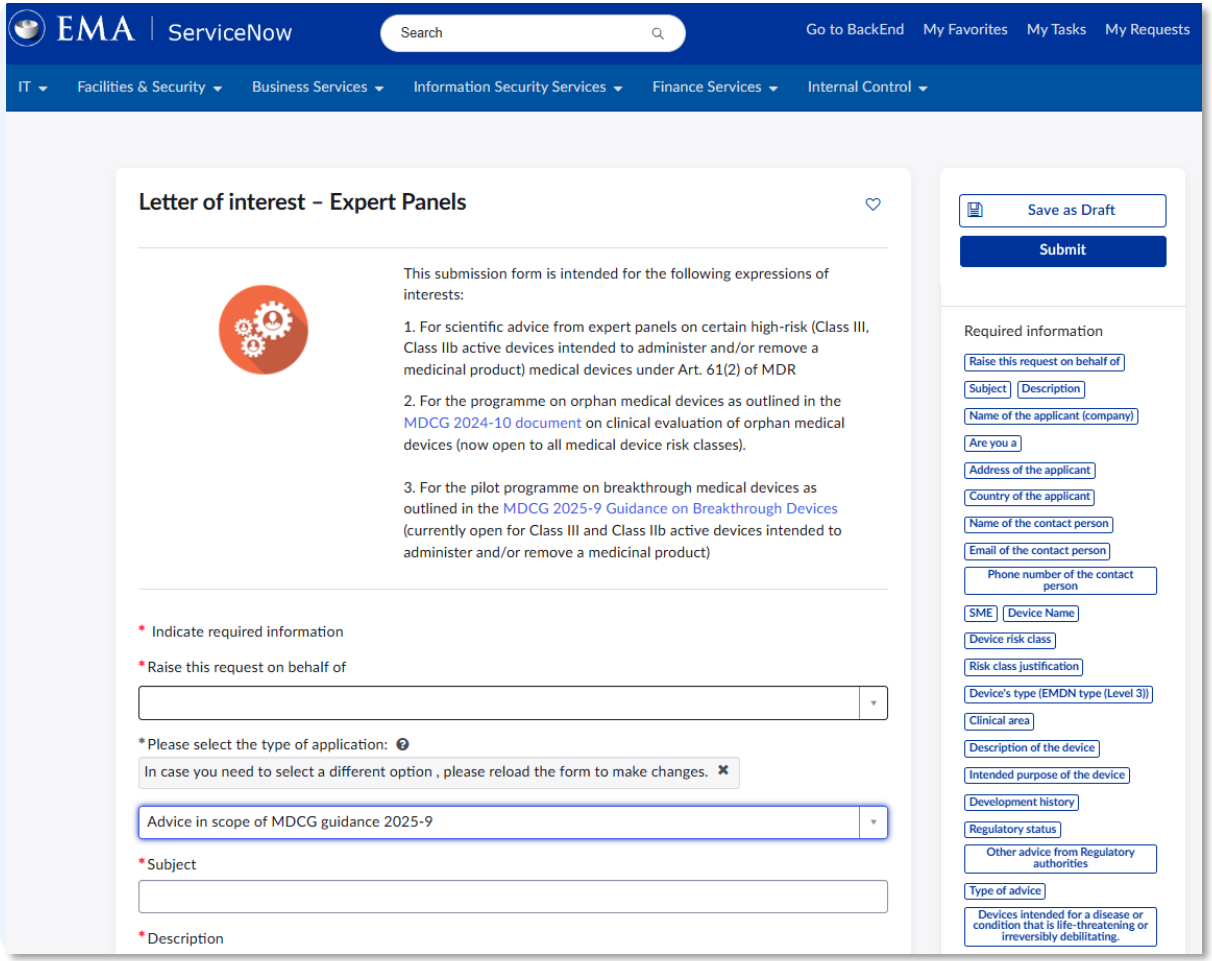
How to apply

The letter of interest can be accessed via the link below:

Letter of interest – Expert Panels



An EMA account is necessary to access the webform. EMA accounts are created by self-registering on the EMA homepage: https://register.ema.europa.eu/

Interactions with the applicant

Designation

Exploratory meeting

- High level discussion on the device and procedure

Pre-submission meeting

- Voluntary participation
- Aim: provide feedback on draft briefing document and discuss needed revisions prior to submission of final version

Discussion meeting

- Aim: experts ask questions or express major disagreements prior to finalisation of the breakthrough status assessment

Advice

Pre-submission meeting

- Voluntary participation
- Aim: provide feedback on draft briefing document and discuss needed revisions prior to submission of final version

Discussion meeting

- Aim: experts ask questions or express major disagreements prior to finalisation of the advice

Submit your questions on Slido

www.slido.com

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Passcode: bkhsgj

Notified body's activities and responsibilities

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Notified Body Activities and Responsibilities

Breakthrough Medical Devices – EMA Information Session

NBCG-Med, 2026-04-24

Notified body activities and responsibilities
Introduction

- Notified Bodies welcome the BtX Pilot and were involved in the drafting process from the beginning.
- Scope: Pilot only
- Learning for future processes and policies.

Notified body activities and responsibilities
Prioritisation of BtX and access to structured dialogue

Structured Dialogue

- Clarify questions and issues *early*
- Discuss possibilities to expedite TD assessment

Prioritisation of BtX designated devices

- Early resource planning
- Ensuring smooth and fast certification

Coordination with Expert Panels

- Special pathways for alignment and input to expert panel opinions under discussion

Notified body activities and responsibilities
Certification with Specific Conditions or Provisions

- Comprehensive pre-clinical submission
  - E.g. Modelling and simulation
- Limited clinical evidence
- Risk-proportionate approach for imposing conditions

→

- Earlier market entry
- Enhanced follow-up and surveillance activities

Notified body activities and responsibilities
Examples for Specific Conditions or Provisions

- PMCF/PMPF
- Enhanced surveillance and monitoring, e.g. milestone reporting
- User/patient information: BtX status in label, IFU, etc.
- Reduced validity of certificates
- Controlled release strategy
- User training obligation
- Providing information to EMA/MDCG about market access (→ BtX dashboard/register)

Notified Body **Expectations and Caveats** for BtX designated devices

Completeness and high-quality of technical documentation
- Extensive support in development phase → apply when ready! -

Appropriately resourced QARA departments
- We prioritise; you do so as well. -

A BtX Designation is not a pre-approval.
- Conformity with GSPRs must be demonstrated. -

Notified body activities and responsibilities
Conclusions and Outlook

- Expect Notified Body Work Instructions on BtX
  → **Harmonised approach across NBs**

- **Engage early on with a Notified Body to fully benefit from a BtX Designation**

- **We are looking forward to participate and contribute to the BtX Pilot Phase!**

Thank you!

Any questions?

PART III: Q&A, conclusions, next steps

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Conclusions and next steps

- **28/04:** Opening of submissions for designation (Phase Ia)
- The letter of interest is available via the EMA ServiceNow portal
- Any questions not addressed during this webinar will be answered in a Q&A document, which will be made available on the EMA website

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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