



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Information session on the pilot for expert panels' scientific advice to manufacturers of certain high-risk medical devices

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Expert Panels and Groups Office  
25 January 2023

An agency of the European Union





# Welcome to this Webinar

## Housekeeping rules

- Please make sure your microphone is muted when not speaking.
- Speakers are asked to switch on their camera. Other participants are invited to switch on the camera when they are taking the floor.
- Please raise your hand when you want to take the floor.
- Please indicate your name and affiliation when taking the floor.
- In case of an urgent technical issue (e.g. connection problems, etc...) please contact [esther.cozar@ema.europa.eu](mailto:esther.cozar@ema.europa.eu)
- Please **participate** in the discussions this is meant to be a working environment!.





## General information about this information session



60 min  
Session



30 min Q&A



Mics muted



Questions  
during Q&A



Recorded



Will be published  
on EMA webpage



# Outline

- Commission proposed measures to ensure the continued availability of safe devices
- EMA's role in medicines and medical devices
- Session 1: Background to the Scientific Advice from the Expert Panels
- Session 2: Introduction to the pilot on Scientific Advice from the Expert Panels
- Session 3: Submission Portal for the Scientific Advice from the Expert Panels
- Q&A Session



# Commission measures for continued availability of safe medical devices

## pilot scientific advice to manufacturers

Paul Piscoi  
DG SANTE D.3 Medical devices

January 2023

# Expert panels - functions

- Mandatory functions:
  - Clinical Evaluation Consultation Procedure (CECP)
  - Performance Evaluation Consultation Procedure (PECP)
- *Ad hoc* functions:
  - For manufacturers - may provide advice with respect to manufacturer's intended clinical development strategy and proposals for clinical investigation prior to certification.
  - For EU Commission and the MDCG - may contribute to the development of guidance and common specifications, standards at international level, identification of concerns and emerging issues on the safety and performance of specific high-risk medical devices.
  - For Member States - may provide advice in various fields upon request, including on the safety and performance of medical devices.
  - For notified bodies - may advice on the criteria for appropriate data set for the assessment of medical devices.

# Current overall context - main concerns

- Risk of shortage of medical devices due to expiring certificates
- Overall capacity of notified bodies not sufficient
  - 36 notified bodies designated under MDR (Jan. 2023)
  - 1.990 MDR certificates issued vs 22.793 (AI)MDD certificates valid (October 2022)
  - 3.509 (AI)MDD certificates expired (May 2021 to December 2022)
- Low numbers of manufacturers' applications to notified bodies
  - 8.120 MDR applications (October 2022)

# Addressing these concerns - guiding principles

- Ensure patient access to wide range of safe devices
- Aim at full application of MDR
- Identify measures under the current legislative framework
- Give more time to manufacturers who aim to transition to MDR
- Avoid unnecessary disposal of safe devices in the supply chain



# Legislative action

- Commission proposal of COM(2023)10 of 6.1.2023
- Extension of transition period – staggered and conditional
- Extension of validity of (AI)MDD certificates – only if conditions are met
- Application of certain MDR requirements during transition period – same as in current Article 120(3) MDR (post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices)
- Derogation for class III implantable custom-made devices
- Removal of 'sell-off' date in MDR and IVDR, i.e. no withdrawal of devices

# Non-legislative actions

- Financial support actions under EU4Health Programme
  - Market survey to monitor implementation progress
  - Grant for capacity-building of notified bodies, facilitated access of SMEs to notified bodies and increased preparedness of manufacturers
  - Joint Action on market surveillance
  - Orphan devices support programme, focussed on devices for children
  - Support for stronger coordination of the Notified Bodies Coordination Group
  - Study on innovation and governance

# Non-legislative actions

- Ongoing implementation of actions to enhance notified body capacity and ensure availability of medical devices (MDCG position paper 2022-14)
- Uniform application of Article 97 MDR as temporary bridging measure regarding expired certificates (MDCG position paper 2022-18)
- Gaining momentum in designation process of notified bodies
- Ongoing work of MDCG taskforce on orphan devices (seek tailored solutions)
- Targeted support for SMEs through Enterprise Europe Network
- Pilot project on scientific advice for clinical development strategies for high-risk devices (focus on orphan devices and SME manufacturers)
- Support to research consortia for generation of methodology on clinical data generation – CORE – MD project + new call

# Non-legislative actions

The pilot project on scientific advice to manufacturers is a very important non-legislative measure undertaken in close cooperation with the EMA Secretariat of the expert panels for medical devices, with a focus on orphan devices and SMEs

Pilot entirely funded from the EU4Health budget

# Thank you



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# EMA's role in medicines and medical devices

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Presented by Silvy da Rocha Dias - Expert Panels and Groups Office  
25 January 2023

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The mission of the European Medicines Agency (EMA) is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU)

- Enabling **timely patient access** to new medicines
- Support scientific committees to provide **independent recommendations** on medicines for human and veterinary use, based on a comprehensive **scientific evaluation of data**
- Monitor the **safety of medicines** across their life cycle
- Publish **clear and impartial information** about medicines and their approved uses

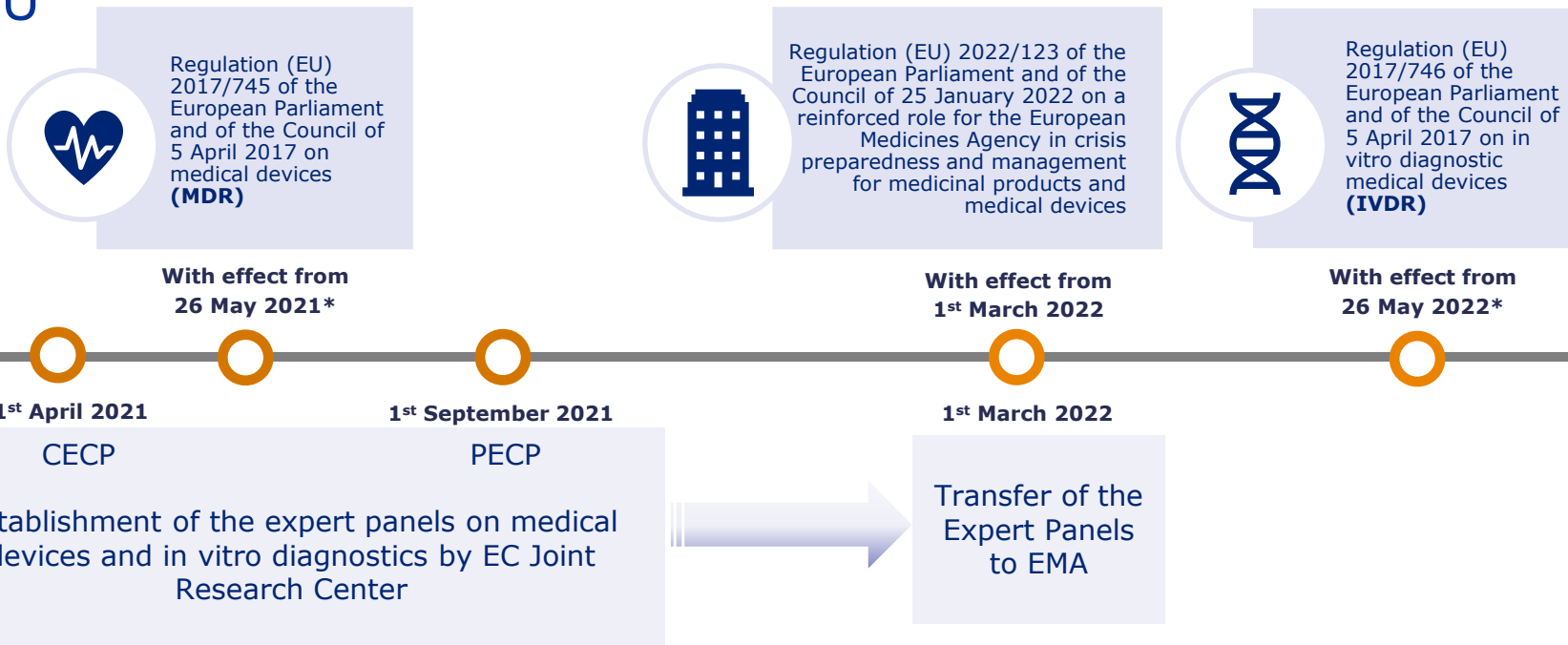


## EMA's role in supporting a European regulatory network on medicines and certain medical devices

- EMA brings together the best-available scientific expertise in the EU for the regulation of medicines
- EMA plays a role in consultation procedures for Notified Bodies' conformity assessments:
  - Medicinal products in combination with a medical device
  - Medical devices with an ancillary medicinal substance
  - Companion diagnostics
  - Medical devices made of substances that are systemically absorbed
  - Expert Panels on Medical devices



# The new Medical Device Regulation (MDR) and the Extended Mandate have strengthened the regulation of medical devices in the EU





## Expert Panels – Activities

- Activities of the Expert Panels on medical devices started with the implementation of the **mandatory consultation procedures**
  - Clinical Evaluation Consultation Procedure (CECP) in April 2021
  - Performance Evaluation Consultation Procedure (PECP) in September 2021
- In addition to the CECPs and PECPs, the Medical Device Regulation (MDR) foresees for the Expert Panels **ad hoc activities** depending on needs, that include Scientific Advice (SA) to manufacturers



## Scientific Advice to support manufacturers' development of medical devices

- Expert panels' activities focused first on the mandatory consultation procedures while *ad hoc* activities were to be gradually implemented depending on needs and resources
- Stakeholders feedback highlighted the need for scientific support from the Expert Panels on the clinical development of medical devices => **early pilot for scientific advice** for manufacturers in 2023
- The pilot will help shape the future scientific advice procedure in 2024
- This activity will foster **innovation development** in Europe and promote **faster access** to safer and more effective devices to EU patients



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# Session 1 - Background to the Scientific Advice from the Expert Panels

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Presented by Leslie Pibouleau - Expert Panels and Groups Office  
25 January 2023

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1. Legal basis
2. Format of the pilot
3. Timelines
4. Evaluation of the pilot



- **Article 61(2) MDR:** For all class III devices and for the class IIb active devices intended to administer and/or remove medicinal product(s), the manufacturer may, prior to its clinical evaluation and/or investigation, consult an expert panel with the aim of reviewing the **manufacturer's intended clinical development strategy and proposals for clinical investigation**. The manufacturer shall give due consideration to the views expressed by the expert panel. Such consideration shall be documented in the clinical evaluation report.

- **Objective of the pilot:** to build an efficient SA process for 2024 adapted to the specificities of the medtech sector, including adjusted timelines and costs
- **Format of the pilot**
  - **Period:** February 2023 to Q1 2024
  - **Applicants:** manufacturers/authorised representatives established in the EU
  - **Financing:** no fees for the applicants during the piloting phase
  - **Number of procedures:** 10 SA in 2023 organised in 2 rounds of 5 applications
    - Limited number to ensure availability of experts for CECs



- **In case the number of requests exceeds the capacity of the expert panels** for running the pilot, the expert panels will select applications so as to cover a large enough spectrum of types of requests:
  - Various types of devices -> prioritisation criteria to cover current identified needs of the medical device system
  - Various medical areas
  - SME representation to be taken into consideration
- **Selection process**
  - Experts in the clinical field
  - Possibility to submit several proposals but only one can be selected per company
  - Proposals not selected at the 1<sup>st</sup> round will automatically be considered for the 2<sup>nd</sup> round



## The following criteria will be considered – No priority order

- **Devices intended to benefit a relatively small group of patients** in the treatment or diagnosis of a disease or condition (e.g. “orphan devices” and devices for paediatric use)

-> *Description of the target population of patients and quantitative estimate of this population in the EU*

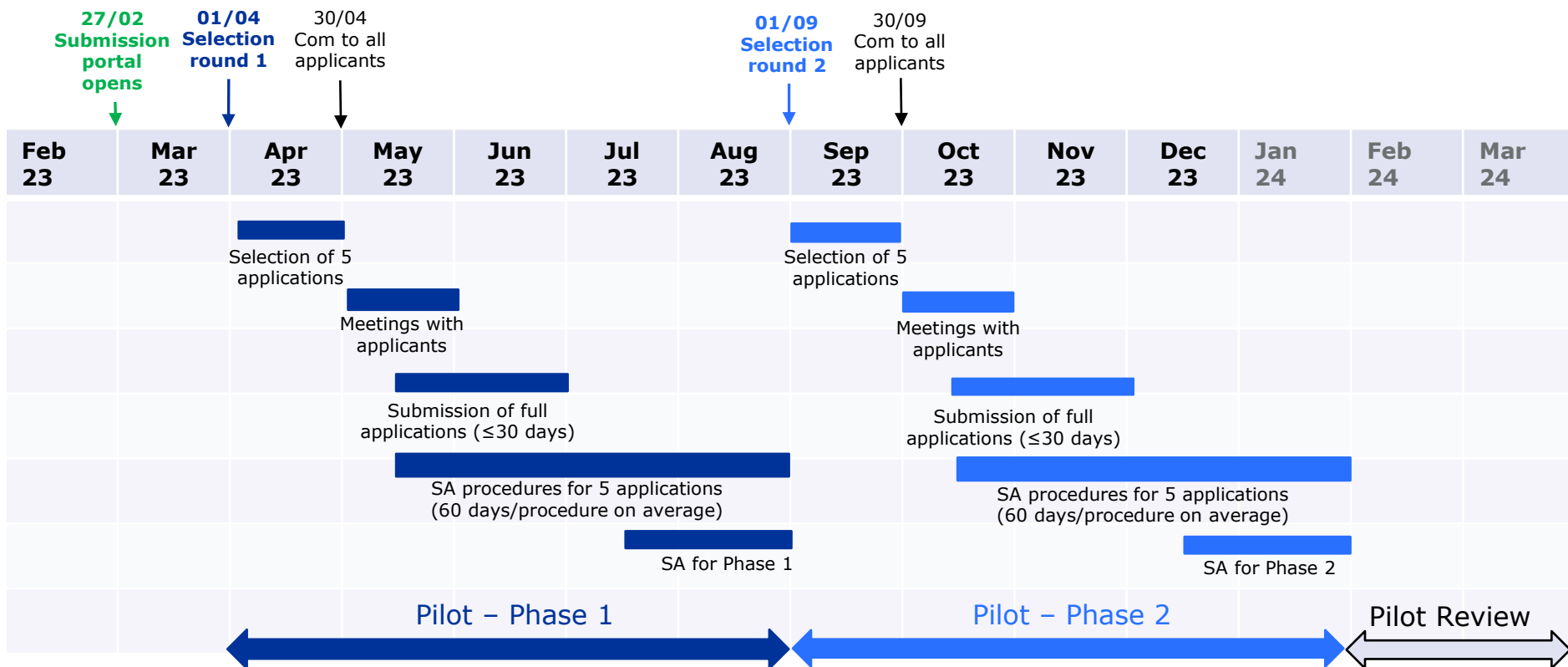
- **Devices for unmet medical needs** i.e., devices for medical conditions that are life threatening or cause permanent impairment of a body function AND for which current medical alternatives are insufficient or carry significant risks (see definition of “breakthrough devices” in [MEDDEV 2.7/1 rev.4](#), Appendix 8 )

-> *Description of the disease(s)/condition(s) and the current standard medical treatments or diagnosis*

- **Novel devices with a possible major clinical or health impact**

-> *Assessment of the novelty of the device and the expected clinical and/or health impacts resulting from that novelty cf. EC guidance for the medical device expert panels on the consistent interpretation of the decision criteria in the clinical evaluation consultation procedure*

# Pilot Scientific Advice – Timeline (tentative)



- Timeline subject to experts' availabilities (priority given to CECs)
- Some complex applications could require > 60 days

- **Outcomes to be assessed**
  - Satisfaction with the process (applicants and experts)
  - Time needed for the different steps and adequacy
  - Application form
  - Workload for the experts and internal workload -> estimation of actual costs
- **Meeting with stakeholders** to discuss potential changes to be implemented in the design of the SA process
- **Survey of manufacturers** end of 2023 to estimate their needs in terms of SA and plan resources in the expert panels



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## Session 2 - Introduction to the pilot on Scientific Advice from the Expert Panels

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Presented by Miguel Antunes - Expert Panels and Groups Office  
25 January 2023





1. Nature of the process
2. Structure of the process
3. Content of the application
4. Timeline overview

- The Expert Panels will provide guidance and support on the applicant's clinical development strategy and/or proposals for clinical investigation
- Their advice is given based on what is considered to be the most adequate scientific solution(s). However, scientific advice is **prospective** in nature
- The Expert Panels **do not perform any type of pre-assessment** of data or of study results. The advice is based on the scientific strategy under discussion, not the results
- "The manufacturer may not invoke any rights to the views expressed by the expert panel with regard to any future conformity assessment procedure". (Art. 61(2) of the MDR)

- Only the selected proposals will need to develop a **full application**
- Each SA full application will be reviewed and assessed by a **group of clinical experts** in that field
- There is always a **Pre-Submission Meeting (PSM)** between the experts and the applicant. This takes place at least **30 days** before the start of the procedure
- The procedure will take on average **60 days**
- Before the final advice is delivered, there is a **discussion meeting** with the applicant
- The **final advice** is delivered to the applicant at the end of the procedure

1. Orthopaedics, traumatology, rehabilitation, rheumatology
2. Circulatory system
3. Neurology
4. Respiratory system, anaesthesiology, intensive care
5. Endocrinology and diabetes
6. General and plastic surgery and dentistry
7. Obstetrics and gynaecology, including reproductive medicine
8. Gastroenterology and hepatology
9. Nephrology and urology
10. Ophthalmology



## 1. Pre-Submission Meeting (PSM)

- 30 days before the final submission, the expert group and the secretariat have a meeting to ensure the applicant gets the maximum benefit of the procedure
- The draft submission is reviewed, including the suitability of the questions and the comprehensiveness of the applicant's position. Suggestions are given on how to prepare the final submission

## 2. Discussion meeting

- Before issuing the final advice, the expert group discusses with the applicant its main conclusions and may ask for clarification. The applicant should be able to discuss and clarify the proposals presented for the procedure

## First part: Letter of interest

## Second part: Application

- **“Question and Answer”** format. The applicant presents its clinical development strategy or proposal for clinical investigation, identifies questions and possible solutions. The advice from the Expert Panels is based on the proposals presented
- Each **question** is followed by a corresponding, separate **Applicant’s position** including a comprehensive justification of the chosen approach
- The applicant’s position should be **clear and detailed** to allow the experts to easily understand the rationale behind
- **Back-up information** presented in Annex (e.g., scientific publication, interim study reports)

- The final advice is provided in the same template that is used for the application. For each section of question and applicant's position, there is a section called “**Draft Expert Panels answer to question**”

Question {X}

Does the Expert Panel agree that/with...?

Applicant's position

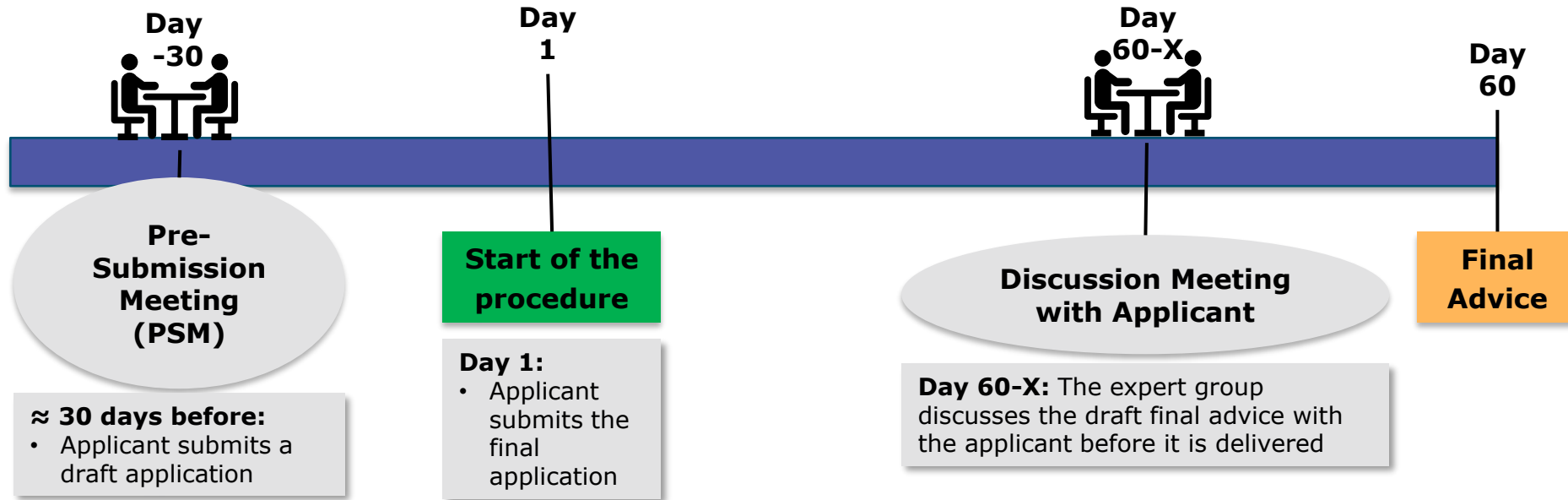
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Draft Expert Panels answer to Question {X}

*Scientific discussion*

*Conclusion*

- The advice delivered in this pilot phase will **not be published**
- The proposals made in the advice need to be addressed in the **Clinical Evaluation Report (CER)** of the manufacturer



\* The submission timeline may vary slightly, depending on expert's availability and the nature of the request



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## Session 3 - Submission Portal for the Scientific Advice from the Expert Panels

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Presented by Michael Vogl - Expert Panels and Groups Office  
25 January 2023

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1. Prerequisites
2. Information required
3. Demo



- Access to the submission form is depended on an EMA Account
- EMA Accounts are created by self registering on the EMA homepage ([EMA Account Management](#) [europa.eu](#))
- After registration, you can access the submission portal

**EMA - Self-service Registration Form**

Submit the following form to register.

**First Name \***

This is used to create your username and to address you in email correspondence.

**Last Name \***

This is used to create your username and to address you in email correspondence.

**Email \***

We require a valid/active email address to create an EMA Account.

**Password \***

Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.

**Confirm Password \***

**Country Code**

**Mobile (optional)**

This is an optional field. We will only use this information for security messages or alerts in relation to your account. Please include the international dialling code in front of your mobile number.

User Agreement

- Personal information about the user is already present through the registration with the EMA Account management
- The following applicant information needs to be provided additionally to the personal user information
  - Name, address and general contact details of the company
  - SME Status



- The following information on the device needs to be provided as part of the letter of interest
  - Name
  - Risk Class and a justification why this risk class was chosen
  - EMDN Code (Level 3)
  - Clinical area of the device
  - Description of the device
  - Development history and regulatory status



- If applicable, the information in relation to the prioritisation criteria needs to be provided:
  - Device intended to benefit a relatively small group of patients in the treatment or diagnosis of a disease or condition (e.g., orphan devices and devices for paediatric use)
  - Device for unmet medical need
  - Novel device with a possible major clinical or health impact





# Any questions?

## Further information

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