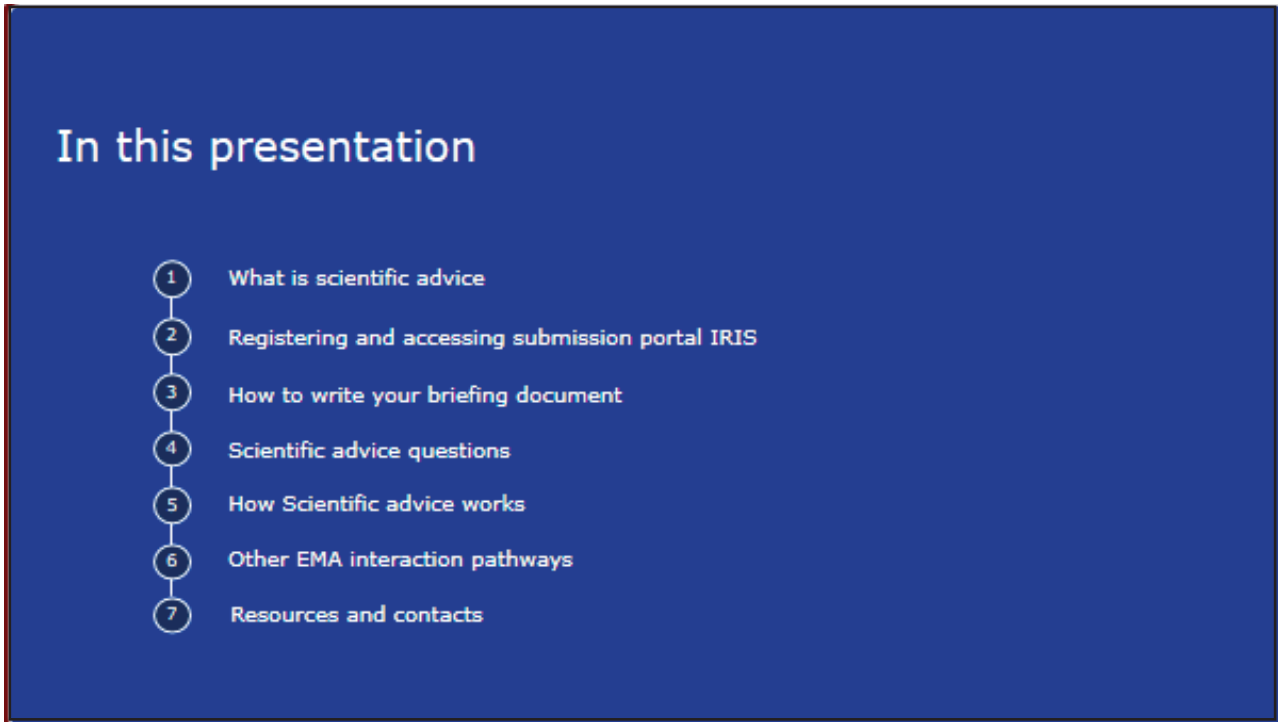
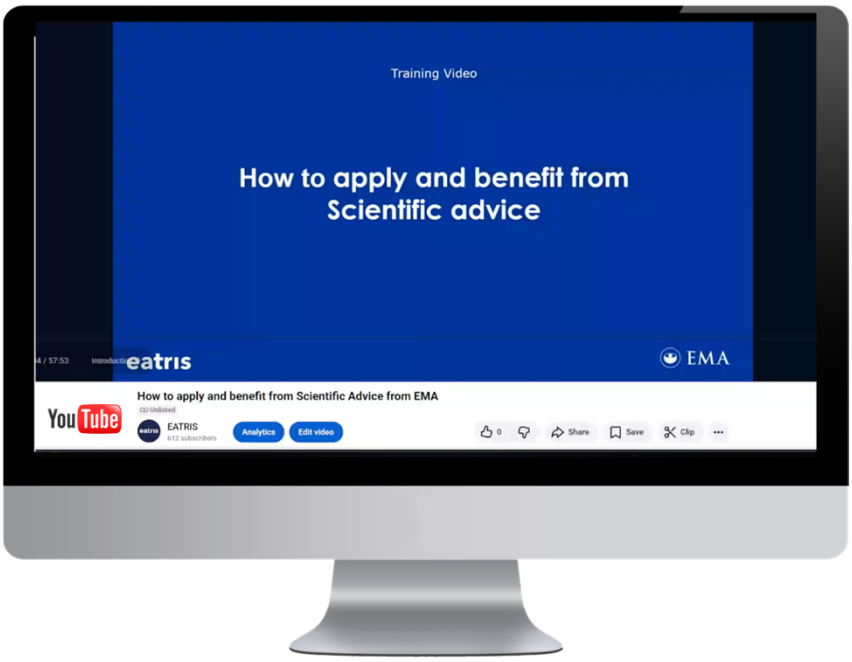

Welcome to this video tutorial on the **Scientific Advice process at the European Medicines Agency (EMA)**. This tutorial is designed specifically for academic medicine researchers and developers who are seeking advice on the most appropriate way to generate robust evidence to support their development.




In this video, we will:

- Explain what Scientific Advice is, and how it can support your medicine development.
- Walk you through the steps of the process to get scientific advice — from initial registration and accessing the IRIS platform, to preparing your application and submitting it.
- Guide you on how to write a strong Briefing Document, including how to formulate your questions and applicant positions.
- Help you understand the Scientific Advice process, prepare for an optional discussion meeting, and how to interpret and use the responses you receive.
- Introduce the various support tools offered by EMA, such as Protocol Assistance, Qualification of novel methodologies, Academia Briefing Meetings, and the Innovation Task Force (ITF) briefing meetings.

And finally, point you to key resources and contacts that can support your medicine development strategy from early planning to regulatory submission.

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Chapters have been included in this video to make navigation easier and to allow viewers to jump directly to the sections most relevant for their work; these appear as markers on the video's progress bar, and the respective timestamps for each section are shown here on the slide and in the video description below.


In this section, we will explain what Scientific Advice is, who can Apply, what the benefits of Scientific Advice are and when is it most useful and lastly we will discuss Fee waiver & procedural steps.

## What is Scientific Advice and why should you use it

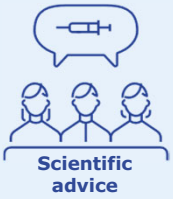
**For a medicine to be authorised**

Medicine developers have to demonstrate

- Effective
- Safe
- High quality
- Positive benefit–risk balance

EMA guidance on

- Quality aspects
- Preclinical studies
- Clinical trial designs




**Can be requested at any stage of development** (human & veterinary)

**Not retrospective** – advice must be sought before critical stages, not mid-trial

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**What is Scientific Advice and why should you use it?**

For a medicine to be authorised, medicine developers have to demonstrate that it is effective, safe and of good quality. In other words, a medicine has to demonstrate a positive benefit-risk balance. During a medicine's development, a developer can request guidance from EMA on quality aspects, such as the manufacturing process of the medicine, on preclinical studies and on clinical trial designs to generate robust evidence on how well a medicine works and how safe it is. This is known as scientific advice.

Scientific Advice can be requested at any stage of development and for both human and veterinary medicines. It's important to note, though, that scientific advice is not meant to retrospectively validate plans when it's already too late to make meaningful changes — for example, during an ongoing clinical trial. Seeking advice early helps ensure that your development stays on track without compromising its integrity.

## What is Scientific Advice

- Does not replace the requirement to seek trial authorisation under the Clinical Trials Regulation, ethics review, or other procedures.
- Share with your collaborators, ethics committee and national competent authority for initiating a study
- Recommendations are non-binding but help generate robust and complete data

EMA gives scientific advice by answering developers' questions

- Developers present how they plan to develop the medicine.
- They formulate questions on issues where guidance is needed.
- They propose their preferred approaches to these issues.
- EMA provides advice on the developers' proposals.

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At the same time, scientific advice does not replace the requirement to seek trial authorisation under the Clinical Trials Regulation, ethics review, or other procedures. However, you can share the scientific advice from EMA with your collaborators, with the ethics committee and with the national competent authority as a part of the clinical trial application prior to initiating a study.
Scientific advice provides you with recommendations. These recommendations are non-binding and help researchers to ensure the planned studies designs, methodologies and quality measures are more likely to generate robust and complete data that meet regulatory standards, increasing the likelihood of a smooth medicine approval process.
EMA gives scientific advice by responding to specific questions posed by developers on the development of a particular medicine.
The developers of a medicine present the way they plan to develop the medicine, formulate questions on issues where guidance is needed and propose their preferred approaches to the issues. EMA then gives advice on the developer's proposals.

## Who is involved in Scientific Advice

### Dozens of experts are involved

- CHMP (Committee for Medicinal Products for Human Use)
- SAWP (Scientific Advice Working Party)
- CAT (Committee for Advanced Therapies) or Paediatric committee acts as a peer reviewer
- CVMP (Committee for Medicinal Products for Veterinary Use)
- ETF (Emergency Task Force)

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**Who's involved in providing scientific advice?**

Dozens of experts from a range of disciplines are involved in responding to the questions asked. At EMA, the Committee for Medicinal Products for Human Use (CHMP) is responsible for assessing marketing authorisation applications. One of its tasks is also to support research and development by providing scientific advice. This task is assigned to EMA's Scientific Advice Working Party (SAWP), which is composed of experts nominated by national competent authorities and other delegates.

For advanced therapy or paediatric medicinal products, an expert from the Committee for Advanced Therapies (CAT) or Paediatric committee acts as a peer reviewer in the process. The answers to the questions asked by the developer are elaborated by the SAWP, and then the final advice is formally adopted and issued by the CHMP.

The EMA also can give scientific advice to developers on the appropriate tests and studies in the development of veterinary medicines. For veterinary medicines, EMA's Committee for Medicinal Products for Veterinary Use (CVMP) provides scientific advice at the recommendation of the veterinary Scientific Advice Working Party (SAWP-V).

Scientific advice for developments of new medicines that could address a public-health emergency is channeled through the Emergency Task Force (ETF).

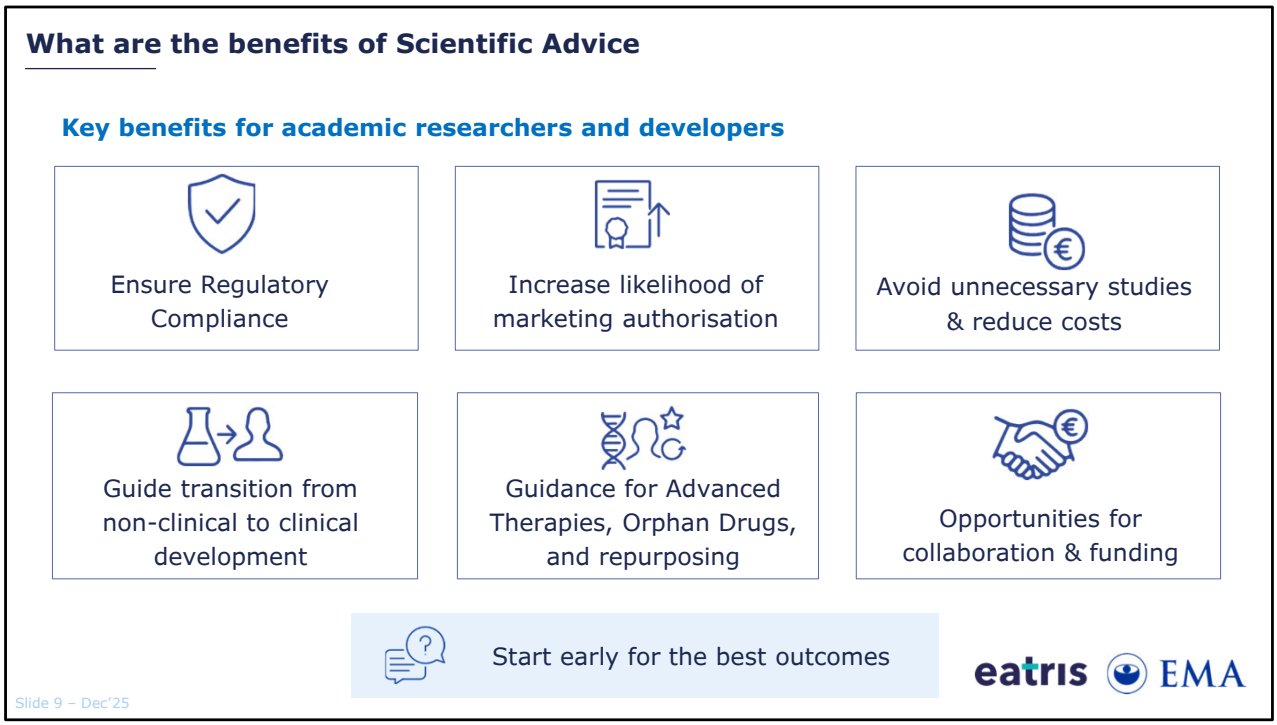

**Who can apply ?**

Any medicine developer can apply for Scientific Advice, this includes academic institutions, research organisations, and individual scientists.

Scientific Advice is not just for pharmaceutical companies and Small and Medium-Sized Enterprises (SMEs). In fact, scientific advice and other regulatory procedures are also welcoming researchers and developments from the academic sector, from which many promising medicines originate.

However, academic researchers often struggle with the regulatory complexities involved in advancing their solutions and bringing them to patients.

By engaging with EMA's experts early, academics can ensure their research is aligned with regulatory requirements, avoiding unnecessary research activities and obstacles later on.




**What are the benefits of SA**

Seeking Scientific Advice from EMA offers significant advantages, especially for academics who may not have experience navigating regulatory processes

Ensure regulatory compliance

EMA guidance helps medicines developers choose appropriate technical approaches, scientific methods and study designs to generate robust data on a medicine's efficacy and safety and to produce a product of good quality.

Increase the likelihood of receiving marketing authorisation but it does not guarantee it.

Applications for marketing authorisations following Scientific Advice had a higher success rate than those that do not.

Avoid unnecessary studies & reduce costs

By getting expert feedback early, you can avoid unnecessary studies, reduce costs, and streamline your research strategy

Guide transition from non-clinical to clinical development

Scientific Advice helps academics transition their lab research to first in human trials and later clinical trials more efficiently, ensuring they collect the data needed for future approval.

Guidance for Advanced Therapies, Orphan Drugs and drug repurposing

If you're working on gene therapy, cell therapy, tissue-engineered product or rare disease treatments, Scientific Advice provides essential guidance on unique regulatory requirements. For researchers exploring new uses for existing medicines, Scientific Advice provides input on the additional evidence that needs to be generated

Opportunities for collaboration & funding

Using regulatory procedures and obtaining scientific advice increase the value of the asset and the confidence of funders, partners, and investors in the project, with positive advice further strengthening this.

Start early for the best outcomes

The earlier you seek advice, the better. Addressing quality and nonclinical issues in a scientific advice before moving into clinical research will save time and improve your chances of approval.

## When is Scientific Advice most useful

### Key situations where guidance adds value

- Choosing to deviate from scientific guidelines
- Developing an innovative medicine with no or limited EU/international guidance available
- Developing new or repurposed medicines for (re)emerging pathogens with unmet medical need

### Can be requested during initial development or in the post-authorisation phase

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**Scientific advice is particularly useful to medicine developers when:**
you choose or need to deviate in your development plan from scientific guidelines that are available from EMA and other regulators;
you are developing an innovative medicine and there appears to be no or insufficient relevant detail in EU guidelines or international guidance documents, or in Pharmacopoeia monographs, including draft documents or monographs released for consultation;
you are developing new or repurposed medicines targeting (re)emerging pathogens for which there is an unmet medical need but insufficient or no guidance is available.
Medicine developers can request scientific advice repeatedly and at any stage, during the initial development of a medicine before submission of a marketing authorisation application or later on, during the post-authorisation phase.


**Regulators are in a unique position to provide Scientific Advice**

Scientific advice is grounded in the comprehensive experience of regulators, including with more than 700 advices per year. They also review all new medicines for which a marketing authorisation has been requested, including those that don't lead to authorisation—giving regulators a broad view of what works and what doesn't.

Over the decades, regulators have built deep expertise, especially with highly-innovative medicines and methods. Their knowledge comes from evaluating a wide range of development strategies and trial designs.

At the same time, regulators continue to learn from new scientific and technological developments. Scientific Advice is therefore not a one-way process, but a mutual exchange where both developers and regulators gain insights.

Importantly, regulators aim to be enablers of progress—supporting innovation that benefits patients and public health.

So there are many reasons. That's why academic researchers are strongly encouraged to seek Scientific Advice—so they can access and benefit from this expertise early in development.

# Fee waiver for Scientific Advice

To eligible 'Entities Not Engaged in an Economic Activity'

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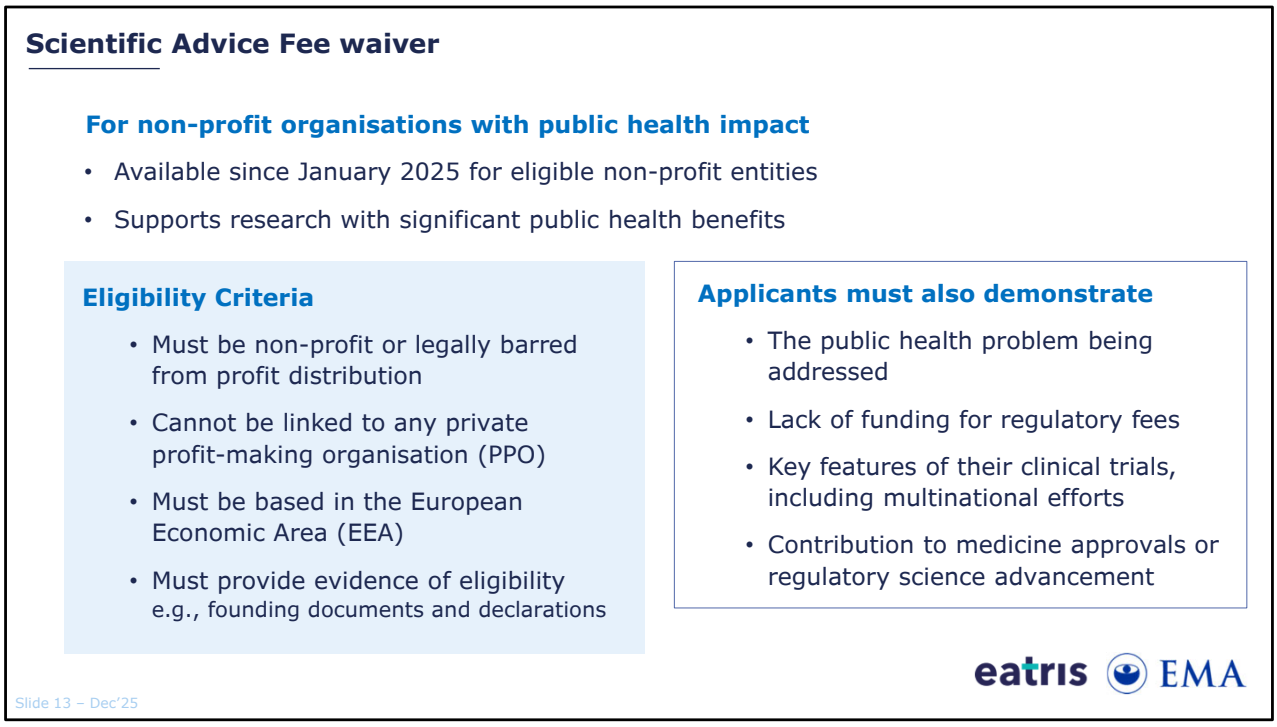


Since January 2025, the EMA is offering a **fee waiver** for Scientific advice to certain not for profit organisations. This fee waiver supports research with a strong public health impact.
An organisation must meet the following conditions:

- It must be non-profit or legally obligated not to share profits with owners, shareholders, or members.
- It cannot be owned, controlled by, or have certain agreements with any private profit-making organisation (PPO) for sponsoring or participating in the specific research project.
- It must be located in the European Economic Area (EEA).

The organisation needs to provide proof of these points, such as founding documents and declarations.

Additionally, applicants must explain how the advice they seek will positively impact their research and contribute to public health. Depending on their research, they should explain:

- The public health problem being addressed.
- Lack of funding to cover regulatory fees.
- Key aspects of their clinical trials, including multinational efforts.
- How their work supports future medicine approvals or develops tools to improve regulatory science and medicine evaluation.

For more information, please refer to the fee regulation. We encourage to get in touch with EMA to discuss this fee waiver and other incentives that are available for medicine development.

# Procedural steps

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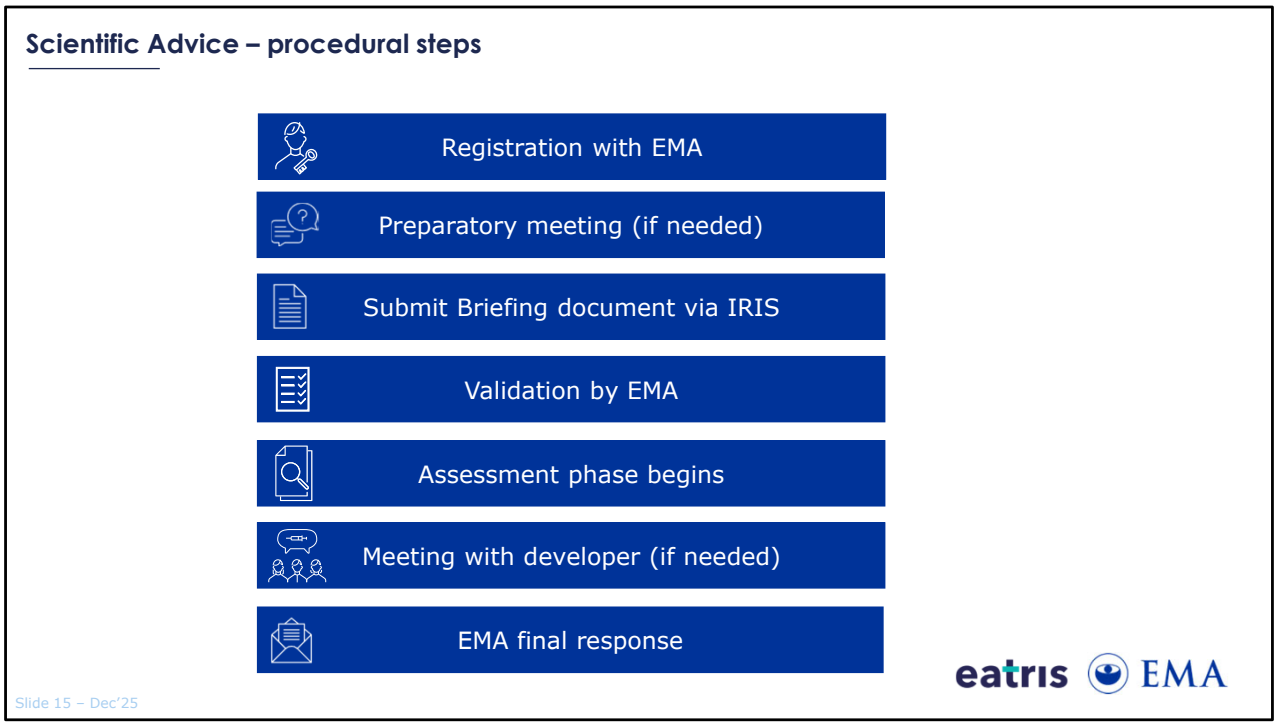



**Steps of the process**

Understanding the procedural steps for Scientific Advice can facilitate a smoother interaction and enhance the quality of your medicinal product development.

The Scientific Advice process begins with registration—developers must newly create or use existing records that identify themselves, their organisation and the medicinal product in EMA's systems.

In the system, developers can ask for a preparatory meeting to be arranged, and is highly recommended, particularly for newcomers or complex development cases.

The developer then submits a request via the IRIS portal, including a well-structured Briefing Document outlining scientific questions, development plans, and supporting data.

EMA reviews the submission to validate its completeness and the suitability of the questions, and then sets a timetable for the procedure.

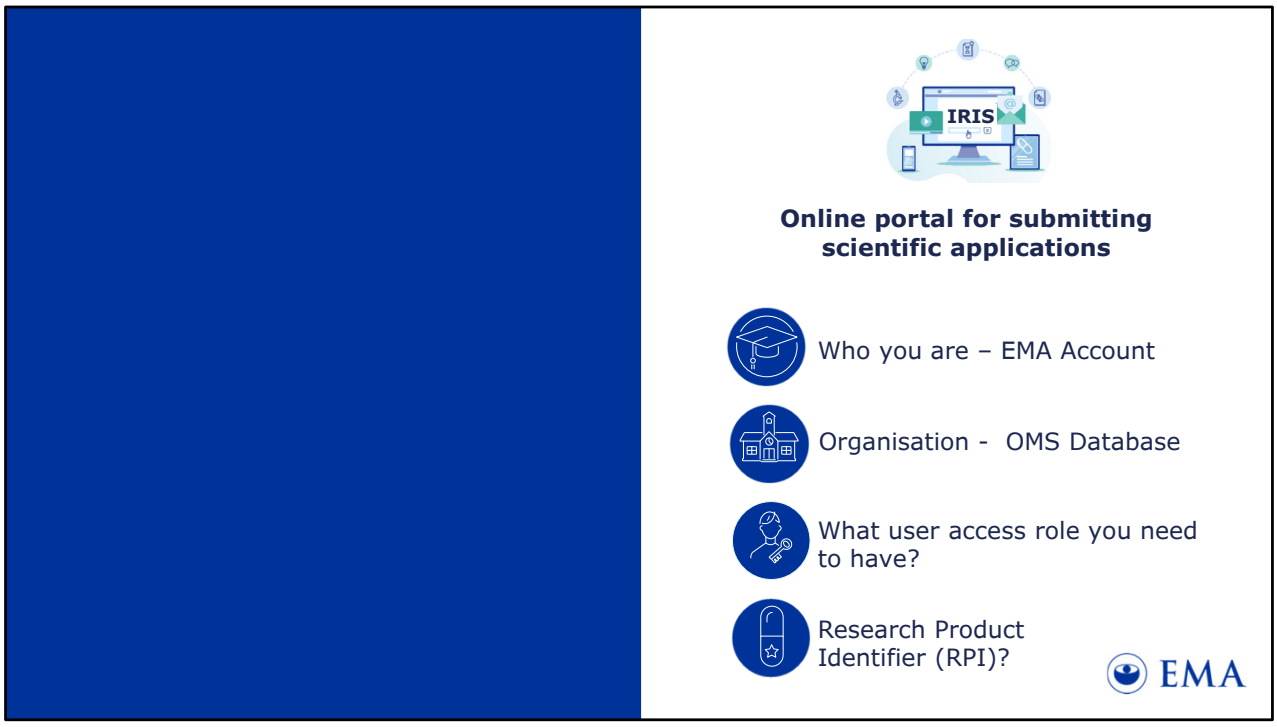
Once validated, the request moves into the evaluation phase, where two coordinators from the SAWP are appointed to lead the scientific assessment.

If needed, a discussion meeting with the developer may be scheduled later in the process to explore key issues further.

The procedure concludes with the adoption of a final written report containing the EMA's advice on the submitted questions.

1. What is scientific advice
2. **How to access IRIS?**

   **The Regulatory & Scientific Information Management Platform**
3. How to write your briefing document
4. Scientific advice questions
5. How Scientific advice works
6. Other EMA interaction pathways




The Regulatory & Scientific Information Management Platform (IRIS) is the online secure portal for sponsors to submit scientific applications to the Agency and is connected to various databases that are managed by EMA. Before being able to access and use IRIS, the platform needs to know:
Who you are – and your identification is managed through your EMA account
Do you represent an organisation, and which is it? Representatives of your organisation are managed by your organisation in EMA's Organisation Management System (OMS) database
What user access role you need to have?
Furthermore, to submit a scientific advice request and other procedures such as Orphan designation, you need a valid Research Product Identifier (in short RPI) and this will be explained in more detail later.

## Access to IRIS – EMA Account Management

IRIS guide to registration and RPIs

**You need an EMA Account to submit an application**

As individual or organisation

- Many organisations are already registered in the Organisation Management System (OMS)
- Individual Account Management
  - Provides individuals with EMA accounts
  - Obtain required user roles

**Applying as an individual or organisation**

- Registered in Organisations Management Service (OMS)
- Request appropriate IRIS user access role 5- 10 days
- Request access to IRIS

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**EMA Account Management**

You need to have an account in the EMA Account management system. Using your EMA account, you can submit an application as an individual or as part of an organisation. Many organisations, including universities and hospitals, are already registered in the Organisation Management System (OMS), and you can see these directly in the IRIS portal. EMA Individual Account Management is a user registration system that provides individuals with EMA accounts. Via those accounts the users access the applications that are managed by EMA, IRIS included. IRIS users will use Individual Account Management to obtain appropriate profiles with roles needed for their work in IRIS.
You can affiliate yourself with an organisation in OMS.
Even if you have been granted a fee reduction, you also need to have a financial account with EMA. And this may exist already with your organisation.
There is a step-by-step guide and a flow chart can in the "IRIS guide to registration and RPIs" with which you can find out how to proceed in your particular situation:
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf

**Applying as an individual or organisation**

You will need to consider whether you want to apply for Scientific Advice as an individual or as part of an organisation. In case of the latter, your organisation must be registered through the Organisations Management System (OMS) otherwise you will not be able to affiliate yourself to an organisation and request the appropriate IRIS user role. Registration of a new organisation takes from 5-10 working days. Once you have registered your organisation, the next step is to request access to IRIS, which is done via the EMA account management Portal.

## Access to IRIS – IRIS roles and login

### IRIS Roles

- You must have a 'Manager role'
- Through EMA Account Management
- Service Desk Request + Required documentation 2 days
- Applying as an individual is simpler
  - Automatically have the right IRIS role (IRIS individual user)
  - Allow to created and submit applications

### IRIS login

- Using your EMAusername@id.ema.europa.eu
- EMA account password

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In order to create an application for SA in the IRIS portal on behalf of an organisation, you must have already registered and been granted a 'Manager'' role through the EMA Account Management portal. For this create a Service Desk request and attach the required documentation. Approval can take up to 2 working days.
Applying as an individual is simpler as you will automatically have the right IRIS role assigned, IRIS Individual User" which allows to create and submit applications as an individual.

**IRIS**

Once your EMA account has been generated, you can login in IRIS using your EMA username followed by "@id.ema.europa.eu" and your EMA account password. You are now ready to use the platform.

## Access to IRIS – Research Product Identifier

### Research Product identifier (RPI)

- Track medicines through pre-authorisation procedures
- Connect submissions, procedures and entitlements for the same development entity
- Request a new RPI via the IRIS platform
  - Active substance needs to be already present in the EMA public list of all substances (IRIS)
    → Register "new active substance" via EMA Service Desk request 5-days

### Helpful guidance and training videos available

- How to use the IRIS platform
- How to submit scientific application (ODD)


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EMA uses research product identifiers (RPIs) to track medicines through / across interactions / procedures, to connect submissions, and entitlements for the same development entity. Companies and individuals that approach EMA for the first time with a new medicinal product and do not have a previously assigned RPI, will need to request a new RPI via the IRIS platform. To do so, you need the active substance in the product to be already present in the EMA public list of all substances. You can check if your substance is already registered by opening the substance list available on IRIS (link) In case your "active substance" is not registered you will need to raise an EMA Service Desk request to register a new "Substance" in the public list, which may take up to 5 working days.
The request for a new RPI for an active substance from the list will be validated by EMA staff and it may take a day or two for the validated RPI to appear in the portal for you to use when creating the draft of your Scientific advice submission. So it is a good idea to prepare the RPI well in advance of the advice. The EMA has helpful guidance and training videos to show applicants how to use the IRIS platform and how to submit scientific application, including one on orphan designation (https://iris.ema.europa.eu/homenews/additional-guidance/)
Now that you have gone through those preparatory steps, you should be ready to proceed with your submission of a scientific advice request.

# Preparatory meeting

Optional

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## Preparatory meetings with EMA

**An opportunity for applicants to**:

- Present your development programme and receive initial feedback
- Get feedback on question phrasing and applicant positions
- Identify additional issues to include in your request
- Learn more about the Scientific Advice and Protocol Assistance procedures
- Ask regulatory questions outside the scope of Scientific Advice
- Allow EMA to determine if there is a need for additional expertise
- Especially valuable for first-time users, SMEs, and complex cases

- EMA views are individual, not final SAWP/CHMP opinions
- Provides applicants with bullet point list of recommendations for the briefing document

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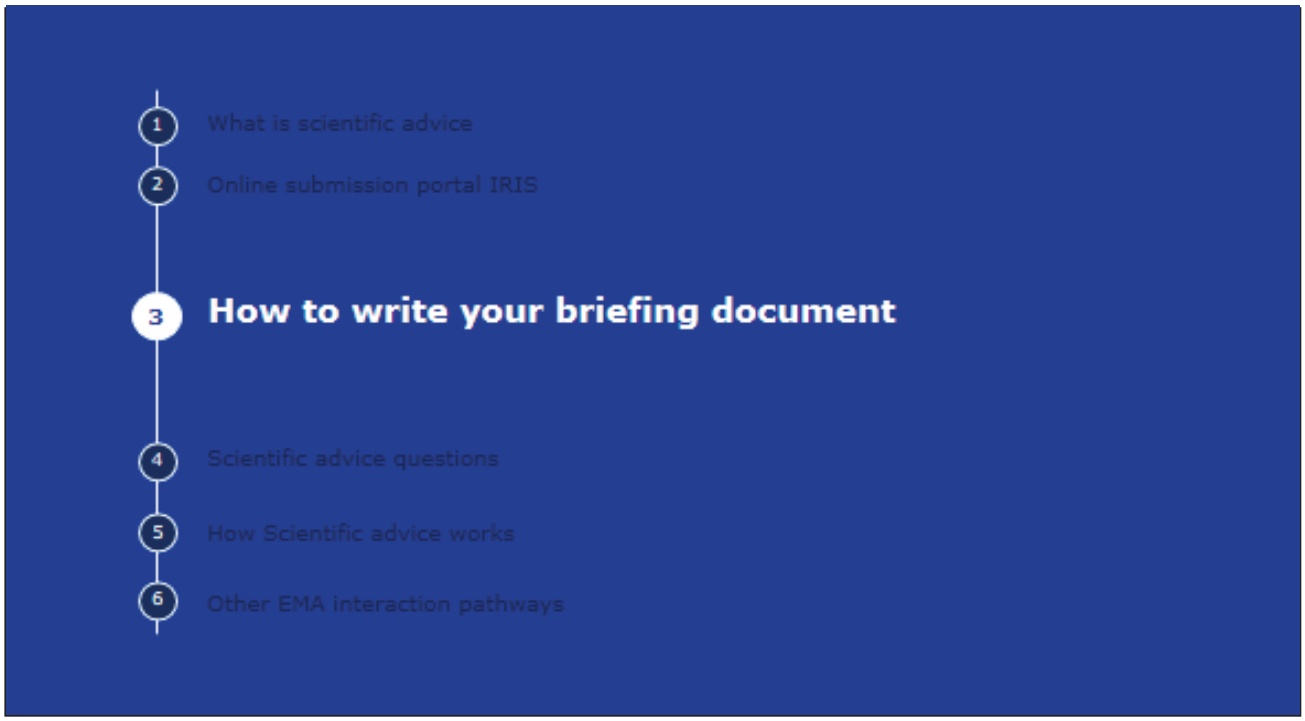
The Agency offers assistance applicants for drafting the briefing document through preparatory meetings. These meetings are free of charge and held via teleconference.

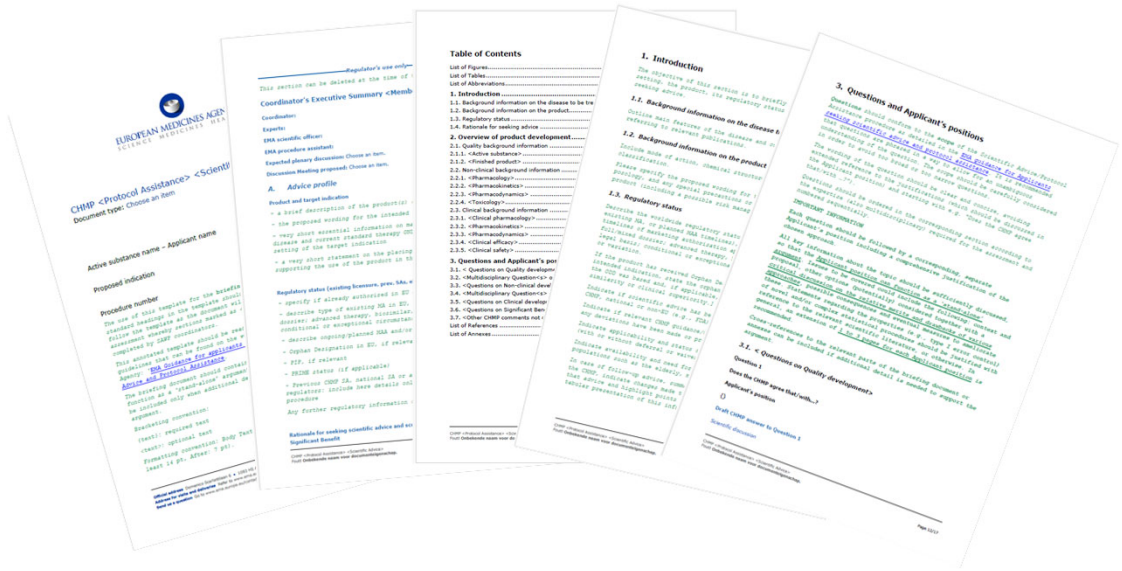
Preparatory meetings are an opportunity for applicants to introduce their proposed development programme and receive feedback from Agency scientific staff on the scope of advice that would be important at the stage, such as on the domains of quality, non-clinical or clinical research;

- Receive feedback on the type and wording of the questions to be included in the briefing document as well as feedback on how to include the applicant's position and explain it in the document for obtaining satisfactory answers;
- Identify additional issues to be included in the request for scientific advice;
- obtain more detailed information concerning the procedure for obtaining scientific advice or protocol assistance;
- Ask regulatory questions that are outside the scope of scientific advice, such as which legal basis for authorisation may be chosen;
- The meetings also allow EMA to determine if there is a need for additional expertise at an earlier stage in the procedure.
- Preparatory meetings are particularly important for first-time users of these procedures, for SMEs, and for applicants seeking general advice on specific types of medicinal products or therapies.

The information provided by the applicant forms the basis for the preparatory meeting. The opinions expressed by E.M.A. participants represent their individual views and do not represent the final opinion of the Scientific Advice Working Party or Committee for Medicinal Products for Human Use. After the preparatory meeting, the agency officers will provide applicants with a bullet point list of recommendations for the briefing document and advice procedure.


1 What is scientific advice
2 Online submission portal IRIS
3 How to write your briefing document
4 Scientific advice questions
5 How Scientific advice works
6 Other EMA interaction pathways

## Briefing document - template

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Applicants must upload a draft briefing document introducing the medicine under development and outlining their questions and positions in IRIS at the time of application, using the CHMP scientific advice briefing document template.


The first part of the briefing document template is designated exclusively for regulators' internal use and should not be completed, modified, or deleted by applicants. It provides a space for EMA coordinators and experts to summarise the request, prepare for plenary discussion, and draft preliminary positions.

The remainder of the template is to be completed by the applicant and forms the core of the scientific advice request. It is structured into four main sections

- The introduction
- The overview of product development
- Questions and Applicant's Positions and
- References and annexes

The Introduction Provides background on the disease, the product, and its regulatory status.
The Overview of Product Development Covers key information on quality, non-clinical and clinical studies.
Questions and Applicant's Positions – The central part of the request, where specific scientific questions are presented to the CHMP. And finally the References & Annexes section where Supporting materials and literature are provided

Each section of the template features green text that gives applicants specific guidance on how to describe the details expected in that part

## Briefing document - Introduction

### Disease summary

- Brief description of the disease
- Prevalence and burden
- Current treatments

### Product overview

- Mechanism of action (MOA)
- Formulation and pharmacological class (e.g. ATC classification)
- Proposed indication and dosage

### Risk Management

Precautions or risk mitigation strategies if any


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This section provides background on the disease, the product, its regulatory status, and the reasons for seeking advice.

- Background on the Disease
  - Provide a concise summary of the disease the product is intended to treat.
  - Describe prevalence, burden, and current treatment options.
  - Reference treatment guidelines and relevant publications where applicable.
- Background on the Product
  Explain the mechanism of action, formulation, and pharmacological classification. This can be based on widely used systems such as the WHO Anatomical Therapeutic Chemical (ATC) classification.
  The aim is to explain the product within its pharmacological context, making clear how it compares to existing medicines in terms of mechanism of action and therapeutic use. Clearly state the proposed indication and dosage regimen.
- And mention any special precautions or recommendations for use of the product, including a possible risk management strategy

**Briefing document - Introduction**

## Regulatory Status

- Brief Approval status (EU/other regions)
- Type of approval (full, conditional, etc.)
- Planned submissions & timelines
- Key Designations: ODD, PIP, PRIME inclusion & Impact on development
- Previous interactions: Summary of CHMP, FDA, or other agency feedback and modifications made
- Guideline deviation: Clearly state & justify any deviations

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**Regulatory Status**

This section should outline the product's current regulatory status, including approvals, special designations, and prior regulatory interactions, in the EU or beyond.

If the product is already authorised in the EU or other regions, the type of approval (e.g., full, conditional, hybrid) and any post-approval commitments should be specified. If not yet authorised, the planned submission strategy and timelines should be stated.

Key regulatory designations, such as Orphan medicine Designation, Paediatric Investigation Plan agreements, or PRIME inclusion, should be highlighted, along with their impact on development.

Any prior scientific advice from CHMP, national competent authorities for medicines or health technology agencies in EU Member states, or international regulators such as the FDA, MHRA, PMDA or SwissMedic should be summarized, especially how it has influenced the current approach.

If there are parallel advice procedures ongoing or planned with other organisations (e.g., FDA, HTA bodies), these should also be mentioned. If the development deviates from EMA or ICH scientific guidelines, a clear rationale should be provided in this section and the concerned question.

For follow-up advice requests, previous CHMP recommendations and any resulting modifications to the development plan should be briefly summarized.

Providing a clear regulatory status ensures that scientific advice is well-informed and aligned with the product's approval strategy.

**Briefing document - Introduction**

## Rationale for seeking advice

- Clearly state the reasons for requesting scientific advice
- Specify whether the advice is related to quality, non-clinical, clinical aspects
- Regulatory pathways if scientific
  - planned studies adequate to support a conditional marketing authorisation or under exceptional circumstances.
  - Not for data pre-assessment

**Questions of a purely regulatory nature are outside the scope**
→ preparatory meeting
→ academia office (academia@ema.europa.eu)
→ ASK EMA

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**Rationale for Seeking Advice**

In this section, clearly state the specific reasons for requesting scientific advice. Specify whether the advice is related to quality, non-clinical or clinical aspects. Scientific advice may also cover questions related to regulatory pathways, provided they relate to scientific considerations.

For example, applicants can ask whether the planned studies and anticipated efficacy/safety evidence are adequate to support a *conditional* marketing authorisation or an authorisation under exceptional circumstances.

However, it is not possible to use scientific advice for obtaining a data pre-assessment in view of such types of marketing authorisations.

Questions of a purely regulatory nature are outside the scope of Scientific Advice and can instead be raised during the preparatory meeting or via the academia office (academia@ema.europa.eu). Another way is to raise your question via AskEMA, which we will explain in more detail later.

## Briefing document - Overview of Product Development

*1.4. Rationale for seeking advice*

*Describe the scope of the questions and the rationale for the advice request (e.g., clinical/non-clinical/quality/significant benefit/similarity/conditional approval/exceptional circumstances).*

**2. Overview of product development**

*This section should give a comprehensive scientific overview of the product development program, providing relevant systematic information in sufficient detail, together with a critical discussion. However, it should be kept in mind that any information essential for the justification of a given question should also be sufficiently discussed in the corresponding Applicant's position. The proposed list of subsections is not meant to be exhaustive nor mandatory, since the relevance or applicability of each subsection may vary depending on the scope of the advice request. In this respect, the potential direct or indirect relevance of the information covered in relation to the questions posed should be considered. It is strongly recommended to address all elements outlined below related to the area (quality, nonclinical, clinical) of the scientific advice. For areas not within the scope of the advice, it is acceptable to include only high-level information. The briefing document should contain all necessary information and function as a 'stand-alone' argument. Cross-references to annexes can be included only when additional detail is needed to support the argument. The use of tabulated overviews and graphs is encouraged.*

*2.1. Quality background information*

*This section should provide an overview of the following aspects in addition to the Applicant's position to quality/GMP questions: Active substance (AS) definition and structure, manufacture sites and process flow chart. AS and finished product (FP) specifications, stability, FP composition and primary packaging.*

*If a medical device is proposed, it should be described and the status of compliance with the Medical Devices Regulation (EU) 2017/745 mentioned.*

*Novel manufacturing approaches (e.g., decentralised manufacturing approaches, advanced manufacturing approaches, digitalisation in manufacturing), where used as part of the manufacturing process, and innovative technologies such as nanomaterials or genome editing should be described.*

Provide a clear scientific overview of the medicinal product in development

- Consider how quality, non-clinical and clinical information may relate to the questions asked
- Include full summaries for the areas that are the focus of the advice request
- For areas outside the main focus, high-level context is sufficient—no need for unnecessary detail

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In the 'Overview of Product Development' section, applicants should provide a clear scientific overview of the medicinal product in their development.
When preparing the overview, applicants should think about how each area — quality, non-clinical, and clinical — may be directly or indirectly relevant to the questions they are asking.
It is best practice to provide full summaries for the area that is the focus of the scientific advice request.
For areas that are outside this focus, it is acceptable to include only high-level information, giving enough context without going into unnecessary detail.


In the Quality Background Information section, begin by describing the Active Substance —include details on its molecular structure, how it is manufactured, and the methods used for quality control.

For the Finished Product section, outline the product's full composition, key specifications, stability data, and proposed packaging format.
This is also the place to highlight any major changes or plans concerning the pharmaceutical quality of the medicinal product, such as modifications to the manufacturing process, formulation or control strategy.

If your product includes a medical device component, be sure to indicate this and explain how it complies with the Medical Devices Regulation (EU) 2017/745.
The same applies for *in vitro* diagnostics such as certain biomarkers and companion diagnostics, and how they are developed under Regulation (EU) 2017/746.
Guidance on both is available from the EMA website and the https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

The goal is to present in this section a coherent, scientifically grounded overview of your product's development status.

## Briefing document - Non-Clinical Background Information

Product development | **Non-clinical** | Clinical

| Study No. | Domain | GLP Status | Study Status | Animals (Sex, N) | Study Groups & Dose | Endpoints Measured | Key Findings / Outcome |
|---|---|---|---|---|---|---|---|
| **NC-PHARM-001** | Pharmacology | GLP | Completed | Rat (M/F, n=20) | Control, Low, Mid, High | Receptor binding, functional activity | Confirmed selective binding to target receptor; dose-dependent PD response observed |
| **NC-PK-002** | Pharmacokinetics | GLP-like | Ongoing | Dog (M, n=6) | Single dose (IV, Oral) | ADME profile, plasma levels | Absorption ~60% oral bioavailability; extended t½; ongoing tissue distribution assessment |
| **NC-PD-003** | Pharmacodynamics | GLP | Planned | Mouse (F, n=24) | Vehicle, Low, High | Biomarker response, exposure-response | To evaluate concentration-biomarker correlation for target engagement |
| **NC-TOX-004** | Toxicology | GLP | Completed | Rat (M/F, n=80) | Vehicle, 10, 30, 100 mg/kg | Clinical signs, hematology, organ histopathology | No observed adverse effect level (NOAEL) at 30 mg/kg; mild hepatotoxicity at 100 mg/kg |
| **NC-TOX-005** | Toxicology | Non-GLP | Completed | Rabbit (F, n=12) | Repeated dermal exposure | Local irritation, systemic absorption | Minimal local irritation; no systemic toxicity detected |

Provide detailed information for domains in scope, high-level context for others, and include full study protocols (or a clear narrative description) where available

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### Non-Clinical Background Information

In the non-clinical section, applicants should provide a structured summary of all non-clinical studies in a tabulated format and mention whether the studies are completed, ongoing or planned. The table should include for each study: the study number, the Good Laboratory Practice (GLP) adherence status (whether it is GLP, non-GLP, or GLP-like), and key design features. These features include number and sex of animals, study groups and dosing regimens, endpoints measured, and key outcomes.

If GLP-like, describe the measures taken to ensure quality. Literature-based data may be used, particularly in repurposing cases, if adequately supported by scientific references.

Each study should be categorized under one of the following domains:

Pharmacology: Mechanism of action and key pharmacodynamic effects

Pharmacokinetics (PK): Absorption, distribution, metabolism, and excretion

Pharmacodynamics (PD): Relationship between drug concentration and effect, including biomarker response where applicable

Toxicology: Summary of toxicology findings, major safety signals, and tolerability profile

Applicants should provide detailed summaries for the domains relevant to the advice being sought, while for domains not in scope, a high-level overview is sufficient to provide context. Where available, include the full study protocol as an annex. If the protocol is not available, ensure a detailed narrative description is included in the main text to enable clear understanding of the study design, rationale, and findings.

**Briefing document - Clinical Background Information**



Product development



Non-clinical

**Clinical**

Summarize all ongoing/planned trials—design type, endpoints, patient groups, assessment timelines

| Study No. | Phase | Design | Target Population | Status | Patients / Arm | Geographic Scope | Endpoints |
|---|---|---|---|---|---|---|---|
| **CL-101** | Phase 1 | Open-label, dose-escalation | Healthy volunteers | Completed (Q1-2024) | 8 per cohort (3 cohorts) | Single-site (NL) | Primary: Safety, tolerability Secondary: PK profile |
| **CL-201** | Phase 2a | Randomised, double-blind | Adults with moderate disease X | Completed (Q3-2024) | 50 treatment, 50 placebo | EU-wide (6 countries) | Primary: Change in symptom score Secondary: Biomarkers, QoL |
| **CL-202** | Phase 2b | Adaptive, double-blind | Adults with disease X, biomarker+ | Ongoing | 80 per dose group (3 arms) | Multinational (EU + US) | Primary: Efficacy (response rate) Secondary: Dose-response |
| **CL-301** | Phase 3 | Single-arm, open-label | Patients with rare subtype Y | Planned (Q1-2026) | 120 total | Global (EU, US, Asia) | Primary: ORR (objective response rate) Secondary: PFS, safety |
| **CL-401** | Phase 1b/2 | Basket trial (open-label) | Tumour-agnostic population with mutation Z | Planned (Q2-2026) | 25 per basket (4 baskets) | Europe + North America | Primary: Safety (Phase 1b), Efficacy (Phase 2) Secondary: PK/PD |

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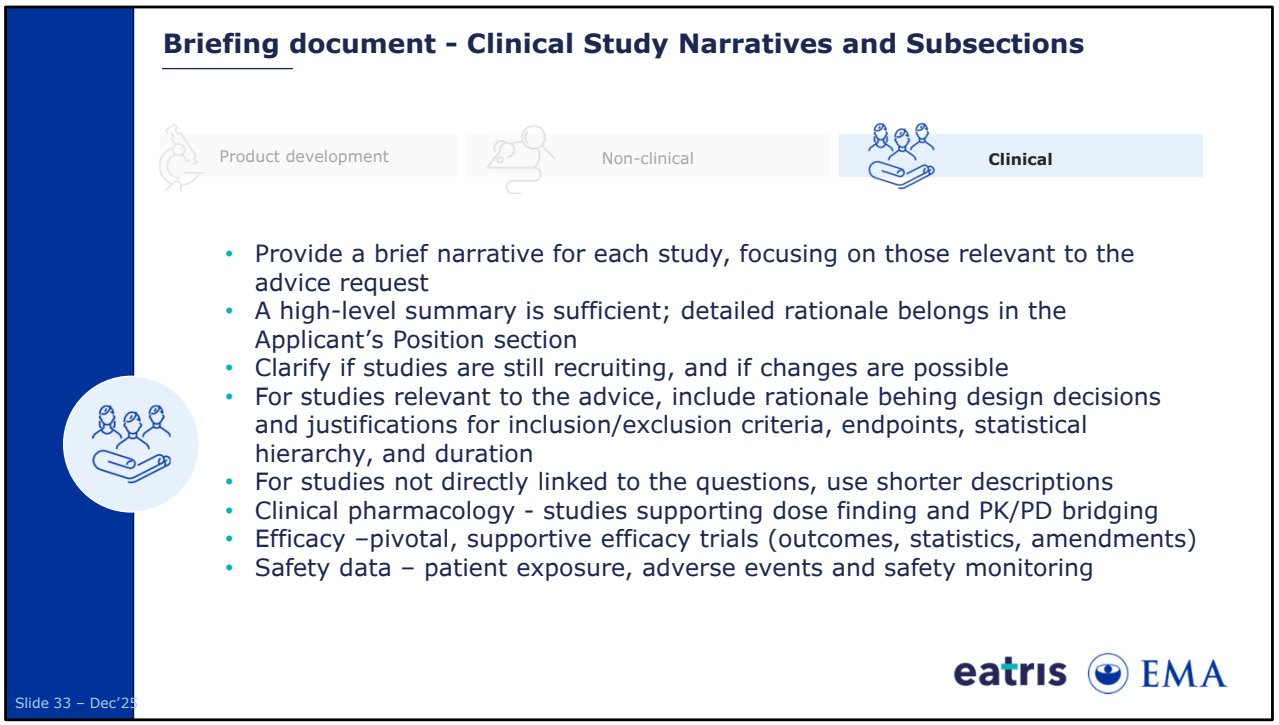
## Clinical Background Information

This section should provide a comprehensive overview of all clinical trials and other clinical research as relevant to the development of the product. Begin with a diagram that visually outlines the key elements of the study design(s) for all trials that are ongoing or planned and are the subject of one or more Scientific Advice questions.

The diagram should show whether the trial is randomized or single-arm, the number of patients per group, the primary and secondary endpoints, and the time points for assessments.

Include a table summarizing each study. This should feature the study number or identifier, trial phase, study design (such as adaptive or open-label), target population, status (planned, ongoing, or completed including approximate dates), number of enrolled patients, geographic location if relevant, and any unique methodological aspects.




Following the table, provide a narrative for each study, especially those for which you are seeking scientific advice. A high-level summary is sufficient here; detailed rationale and justification for design choices should instead be presented in the Applicant's Position section where relevant questions are asked. Clarify if the study is already recruiting or if there is flexibility for modifications.

For studies relevant to the questions in the advice, include the main rationale behind design decisions as well as key justifications for inclusion and exclusion criteria, proposed endpoints, statistical hierarchy and study duration. This allows assessors to understand your reasoning, consider possible alternatives, and provide targeted feedback.

For studies not directly linked to your questions, a shorter description may be sufficient.

Subsections should include as relevant based on the advice sought:

Clinical Pharmacology: Describe studies supporting dose finding, exposure-response relationships, and PK/PD bridging.

Efficacy: Summarize pivotal and supportive efficacy trials, highlighting outcomes, statistical considerations and protocol amendments.

Safety: Discuss the safety dataset, including total patient exposure, nature and frequency of adverse events, serious adverse events, adverse events of special interest and any dose-limiting toxicities. Describe safety monitoring protocols and any risk mitigation measures.

1. What is scientific advice
2. Online submission portal IRIS
3. How to write your briefing document
4. **Scientific advice – what kind of questions can I ask?**
5. How Scientific advice works
6. Other EMA interaction pathways

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## Scientific Advice Questions

### Scope and structure

- Present specific questions to CHMP as the foundation of your request
- Questions may cover

**Quality**

- Manufacturing
- Chemical testing
- Pharmaceutical
- Biological testing

**Non-clinical**

- Toxicological,
- Pharmacological tests

**Clinical/ methodological**

- Study design
- Endpoints (estimands)
- Statistical tests
- Modelling and simulation
- Post-authorisation activities

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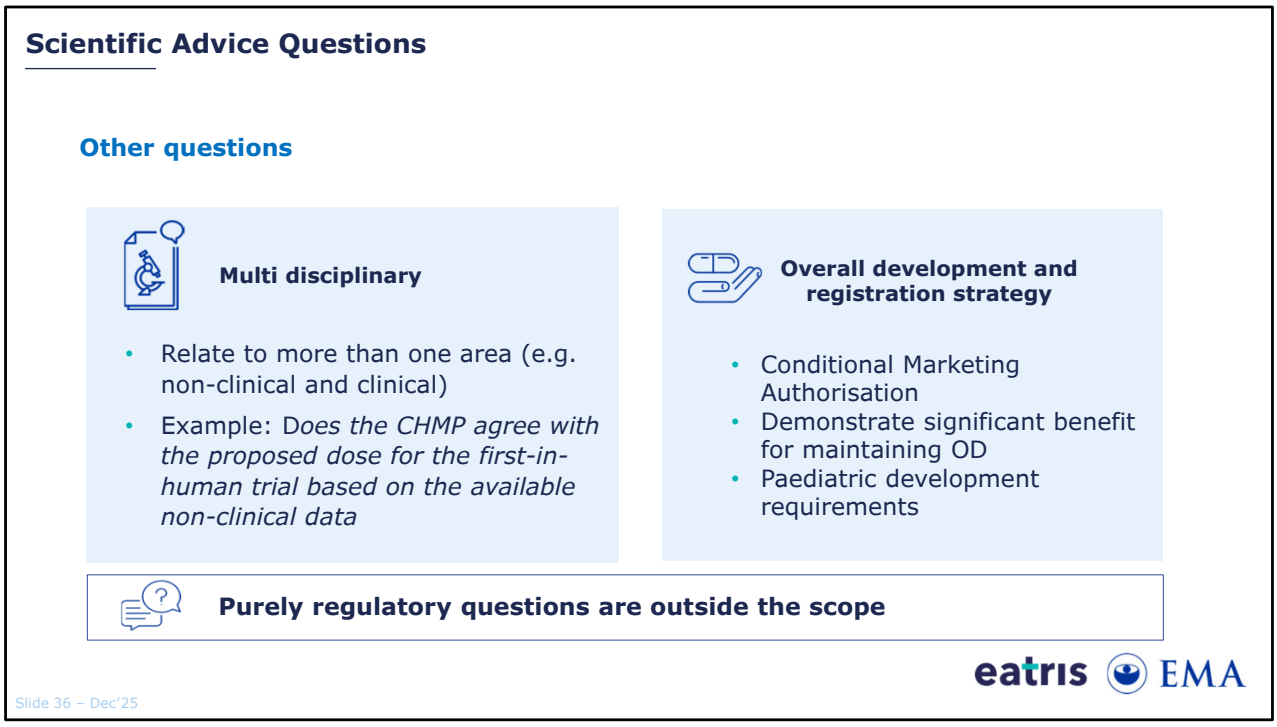
The section with the questions and the Applicant's position forms the core of the scientific advice briefing document, and it is in this section where the applicant presents their specific questions and concerns to the CHMP. Questions during scientific advice can either relate to:

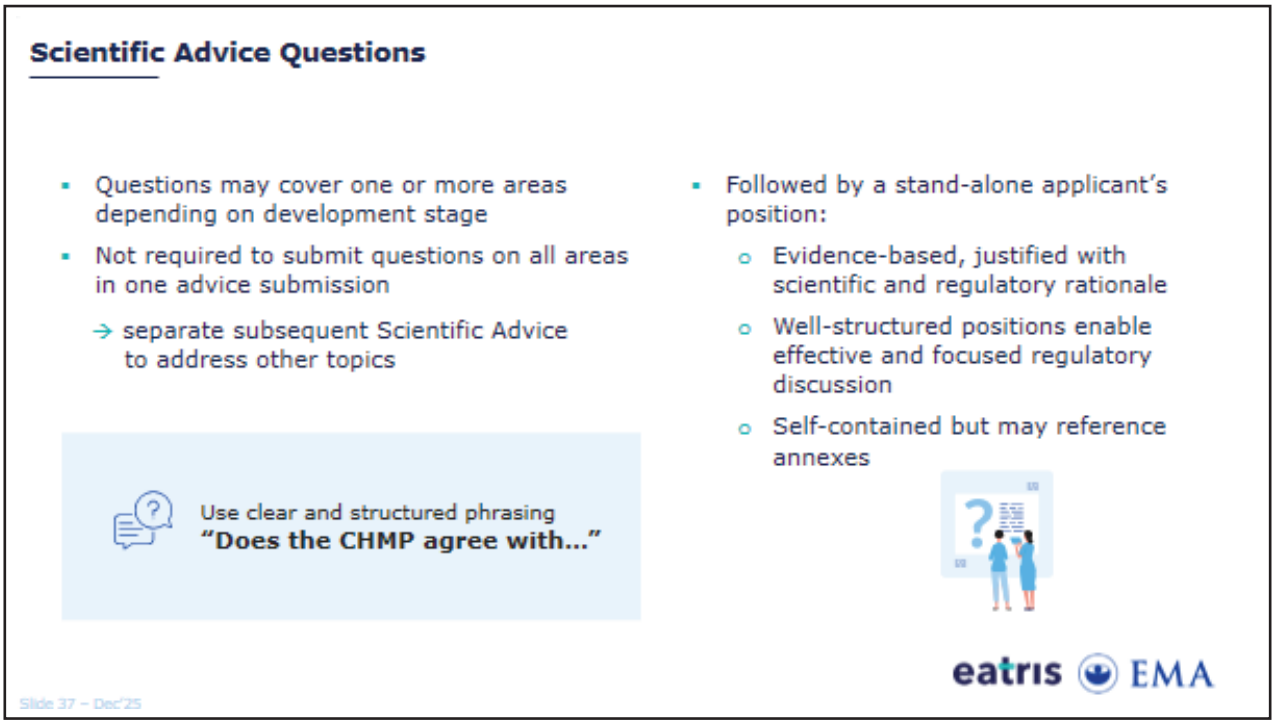
- Quality aspects (manufacturing, chemical, pharmaceutical and biological testing of the medicine), or to
- Non-clinical aspects (toxicological and pharmacological tests designed to show the activity of the medicine in vitro or in vivo), or to
- Clinical and methodological aspects (appropriateness of study design elements, e.g. randomized/controlled vs single-arm design, choice of comparator, inclusion/exclusion criteria, selection of primary & secondary endpoints and described using the estimand framework, statistical tests to use, statistical analysis plan, use of modelling and simulation, or post-authorisation activities including risk management plans).




There is also the possibility to ask **multidisciplinary questions**, questions that relate to more than one area of advice. For example, a multidisciplinary question on non-clinical and clinical development could be: Does the CHMP agree with the approach for either unilateral or bilateral administration of the product to the eye, based on the available non-clinical and preliminary clinical data? Does the CHMP agree with the proposed dose for the first-in-human trial based on the available non-clinical data?

Applicants may also raise questions about the overall development and registration strategy for their product— for example, how their proposed studies could support Conditional Marketing Authorisation, demonstrate significant benefit for maintaining orphan designation, or address paediatric development requirements.

It is important to note that purely regulatory questions (e.g. formal eligibility for Conditional Marketing Authorisation) are outside the scope of Scientific Advice. When including such a question, applicants are advised to explain how their product meets the criteria for the proposed pathway, and to provide a sound scientific justification to support their request for advice.




In a single submission for scientific advice, you can ask questions in any single area quality, non-clinical, clinical and multi-disciplinary or together, because the area of questions should depend on the current stage and needs of your development. In other words, you are not required to submit questions on all areas in one advice submission—for example, one can submit non-clinical questions in a first scientific advice and in a separate, subsequent scientific advice address quality or clinical topics.

How do I write clear questions and positions?
Each question should be clearly formulated (e.g., *"Does the CHMP agree that/with…?"*), and followed by a stand-alone applicant's position that provides a comprehensive, evidence-based justification and supported by relevant scientific and regulatory rationale. Ensuring each applicant's position is well-structured and self-explanatory will facilitate a clearer, more effective regulatory discussion. The applicant's positions should include enough data and information to be assessed without having to refer to other sections of the briefing document, though cross-references to annexes may be included for additional data.

## Scientific Advice – Applicant's position

**Each position should cover**

**Context and Proposal**

Statement of the issue and proposed approach

**Scientific & Regulatory Justification**

Support with data, guidelines, literature, or past advice

**Alternative Approaches**

Explain why other options were not pursued (if relevant)

**Implications**

Clarify expected impact on development and approval path.

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Each position should cover:

- Context and Proposal – A clear statement of the issue and proposed approach.
- Scientific and Regulatory Justification – Supporting data, relevant guidelines, literature, or prior regulatory advice.
- Alternative Approaches – If applicable, a rationale for rejecting other approaches.
- Implications – The potential impact on development and approval.

## Scientific Advice – Applicant's position

### Common issues observed in clinical background section

- Unclear timelines and missing justification for key design elements (endpoints/estimands, comparator, criteria, sample size, multiplicity, safety)
- These issues often arise when advice is requested too early or when design choices and alternatives are not adequately explained
- Ensure questions are supported by sufficient data and a clear scientific rationale
- Clearly state study status (planned, ongoing, completed) and whether changes are still possible
- Use a visual study design diagram and a clear programme narrative to support assessment

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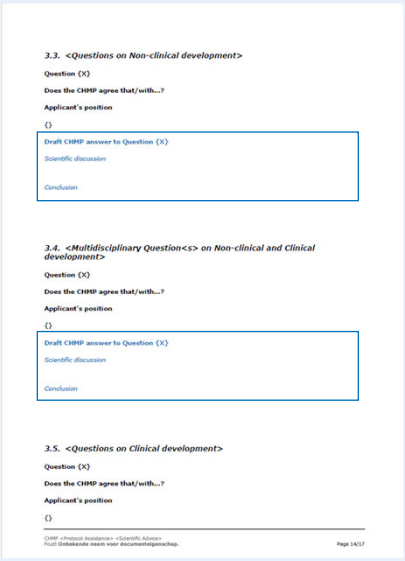
Common issues observed in Applicant's positions in clinical questions include unclear study timelines and missing justifications for key study design elements, such as primary endpoints or estimands, choice of comparator, inclusion/exclusion criteria, sample size, multiplicity control and safety monitoring strategies. These problems often occur when Scientific Advice is requested too early, before enough data are available to well inform the next step, or when applicants do not explain the reasoning behind their design choices or do not discuss possible alternatives.
To avoid this, make sure your questions are supported by sufficient data, and always provide a clear rationale for your decisions. Also, be explicit about the status of each study (planned, ongoing, completed), and whether modifications are still feasible in case of ongoing studies. A visual diagram summarizing the trial design together with a clear narrative of the overall programme will help assessors quickly understand your plan and provide more valuable feedback.

## Scientific Advice Questions – CHMP Answer



*3.3. <Questions on Non-clinical development>*

**Question {X}**

**Does the CHMP agree that/with...?**

**Applicant's position**

{}

**Draft CHMP answer to Question {X}**

*Scientific discussion*

*Conclusion*

*3.4. <Multidisciplinary Question<s> on Non-clinical and Clinical development>*

**Question {X}**

**Does the CHMP agree that/with...?**

**Applicant's position**

{}

**Draft CHMP answer to Question {X}**

*Scientific discussion*

*Conclusion*

*3.5. <Questions on Clinical development>*

**Question {X}**

**Does the CHMP agree that/with...?**

**Applicant's position**

{}



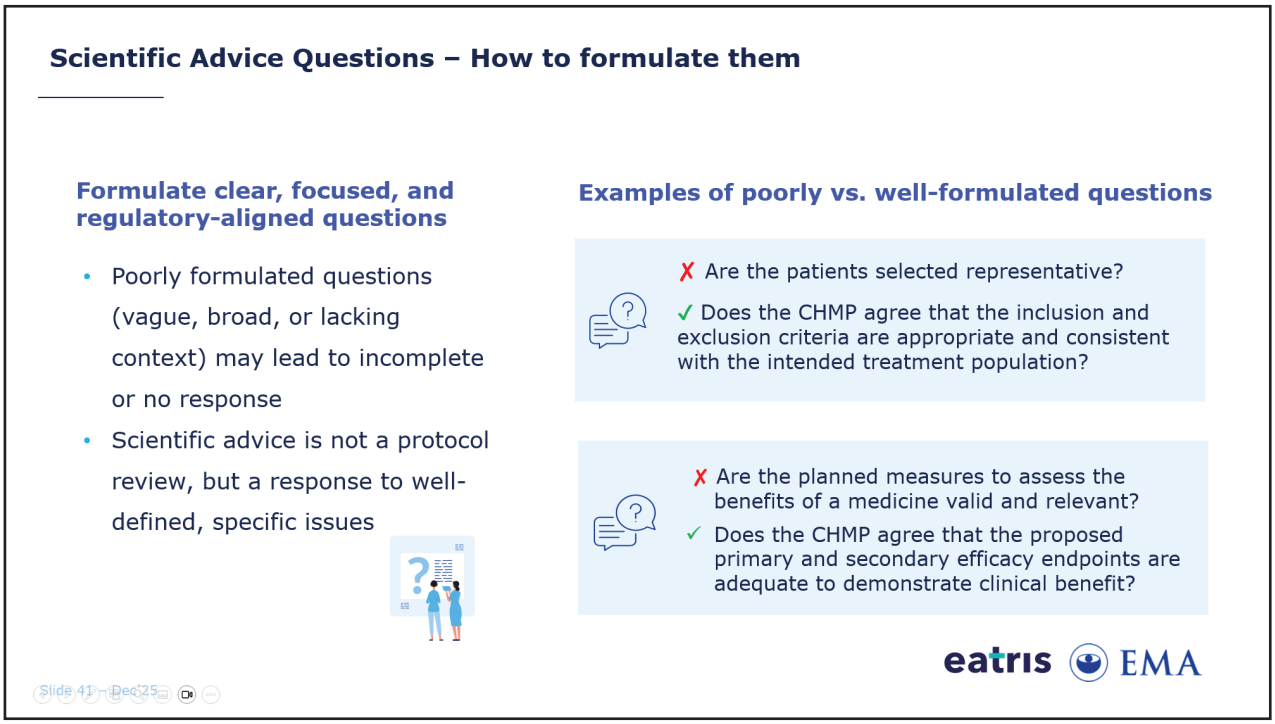
**Completed by regulators**

Draft answer will include a discussion on your position and conclusion indicating:

- Fully supported
- Partially supported with caveats
- Not supported (with suggested alternatives)



After each question and applicant's position, there is a section called 'draft CHMP Answer to questions'. This section will be filled by regulators. The coordinators' draft answer will include a discussion of the applicant's proposal and a conclusion indicating whether the proposal is supported, partially supported with caveats, or not supported, with alternatives if relevant.




To make your Scientific advice request as effective as possible, it's essential to formulate your questions clearly, precisely and in line with regulatory expectations. Questions that are too broad, ambiguous, or lacking scientific context often result in unhelpful, incomplete, or even no response at all. Scientific advice is not a review of a study protocol; it's a targeted response to specific, well-framed issues that need regulatory input. Here are some examples of commonly encountered **poorly formulated questions**, along with explanations of why they miss the mark and how they can be improved:

*Are the patients selected representative?*

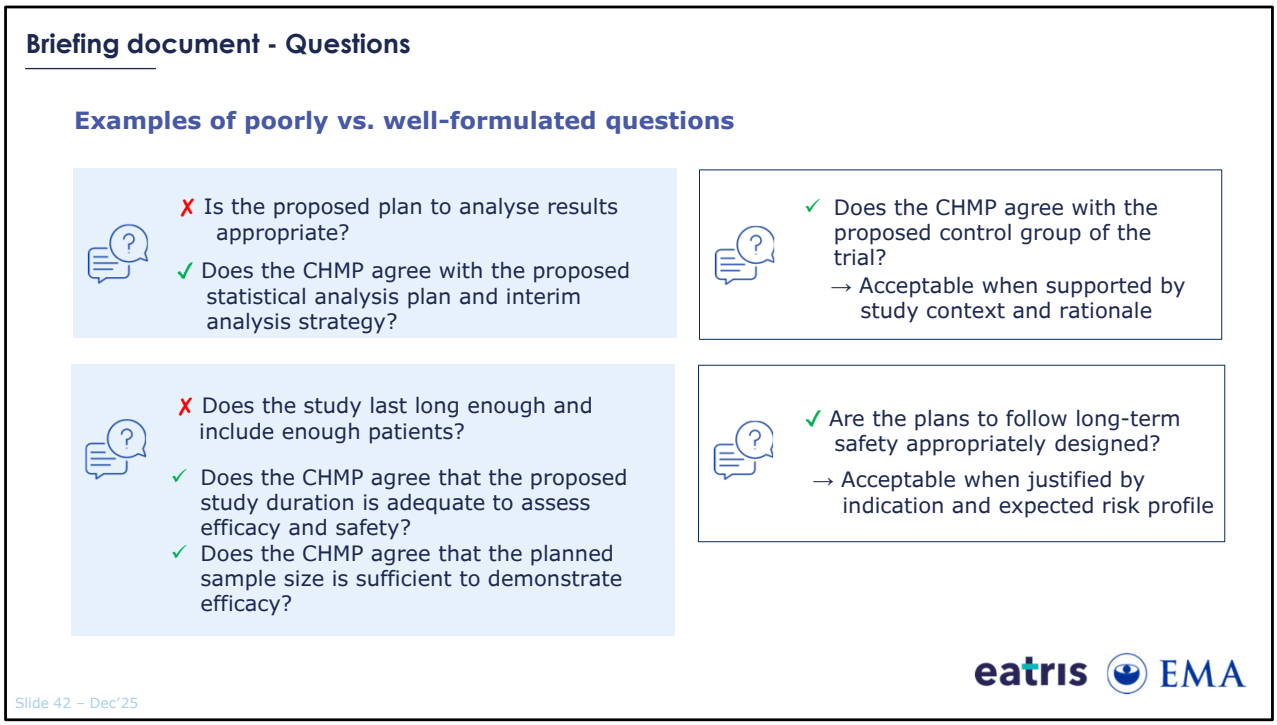
✗ Too unclear—lacks context and does not specify which criteria or population.

✓ **Better:** Does the CHMP agree that *the inclusion and exclusion criteria are appropriate and consistent with the intended treatment population?*

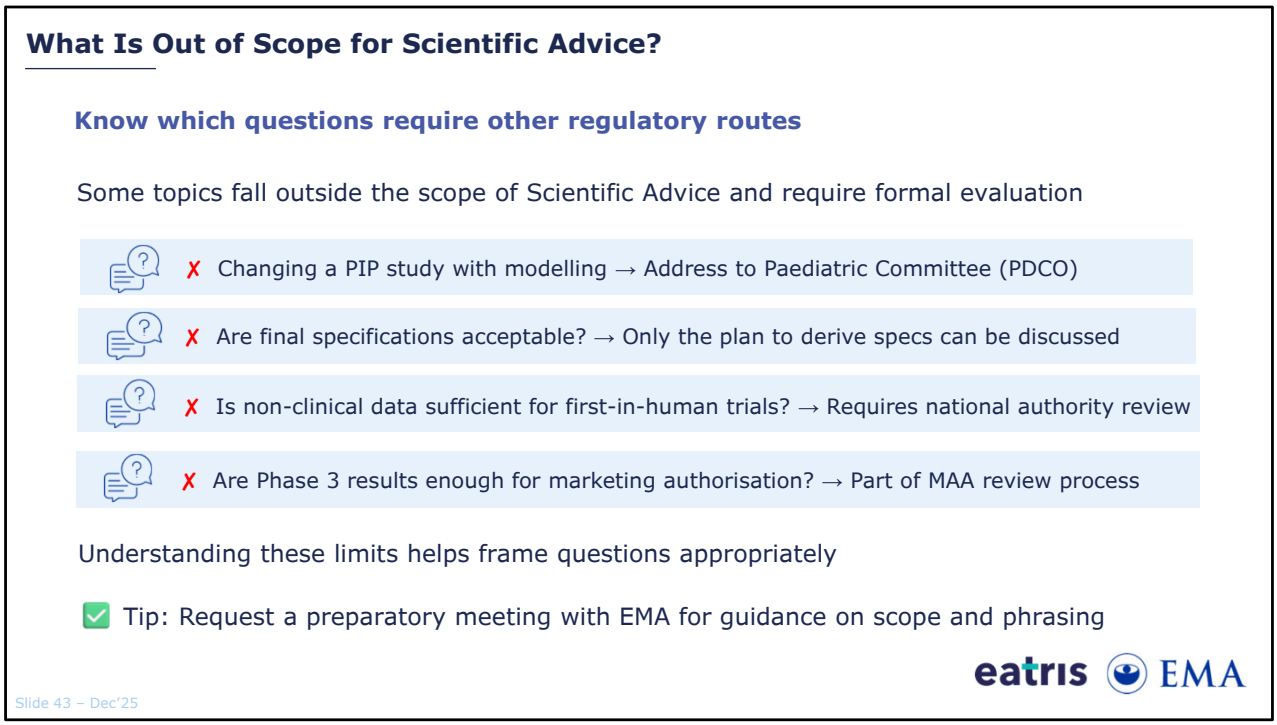
Are the planned measures to assess the benefits of a medicine valid and relevant?

✗ Uses ambiguous terms like "valid" and "benefits," which are hard to assess without specifics.

✓**Better:** Does the CHMP agree that *the proposed primary and secondary efficacy endpoints are adequate to demonstrate clinical benefit in the intended patient population?*




Is the proposed plan to analyse results appropriate?
✗ Overly general—regulators cannot respond meaningfully without knowing what aspect of the design and analysis plan is being referred to.
✓ **Better:** *Does the CHMP agree with the proposed statistical analysis plan and methodology, including an interim analysis to stop the study early in case of positive results?*
Does the study last long enough and include enough patients to provide the necessary data for the benefit-risk assessment?
✗ This question combines multiple variables (duration, size, outcomes) and uses a general term—"benefit-risk assessment"—that lacks precision at the planning stage.
✓ **Better to rephrase into the following distinct questions:** Does the CHMP agree that *the proposed study duration is adequate to assess the efficacy and safety endpoints? / to assess clinical benefit and inform the benefit/risk assessment in the intended patient population?*
✓ *Does the CHMP agree that the planned sample size is sufficient to demonstrate the efficacy of the product?*
Other questions:
*Does the CHMP agree with the proposed control group of the trial?* ✓ This question is acceptable when supported by the study context and rationale.
A*re the studies to follow the long-term safety of the product appropriately designed?*
✓ This question is generally acceptable when justified by the indication and expected risk profile.




In addition to avoiding poorly formulated questions, it's important to understand which topics are outside the scope of EMA's Scientific advice. For example, questions that would require results assessment or that fall under the responsibility of other regulatory pathways or bodies. For example:

Proposal to change an agreed paediatric investigation plan (PIP): Questions such as *"Could the proposed modelling study replace study X in the agreed Paediatric Investigation Plan?"* are outside the scope of scientific advice and must be addressed to the Paediatric Committee (PDCO).

Acceptability of final specifications: Asking whether the proposed active substance or finished product specifications are *acceptable* implies a conclusive review. Instead, Scientific Advice can only address whether the plan is appropriate *to derive* those specifications.

Adequacy of non-clinical data for first-in-human trials: Scientific Advice is not the right forum to determine this as it requires a full review of the non-clinical package. This question may be addressed to national competent authorities in EU Member states who review the non-clinical data in the context of an application for clinical trial authorisation.

Phase 3 results and marketing authorisation: Questions in how far existing results of a Phase 3 trial are sufficient to support a marketing authorisation are outside the scope of Scientific advice and belong to the marketing authorisation application process.

Understanding these limitations ensures that your questions are well-targeted and appropriately framed for regulatory consideration in the Scientific Advice procedure.

As mentioned earlier, a preparatory meeting with EMA scientific staff can be requested to receive input and guidance on scope and phrasing of questions and positions for further refinement

## Briefing document

### References & annexes

- List all cited references in footnotes or as a bibliography
- Include annexes with supporting documents, such as:

Investigator's brochure

Study protocols and reports

Statistical analysis plans

Previous regulatory correspondence

- Well-organized annexes enhance clarity and credibility
- Help assessors fully understand your development strategy and evidence base

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**References & annexes**

In this final section of your briefing document, ensure that all cited references are clearly listed—either as footnotes throughout the document or compiled in a dedicated bibliography.

You should also include annexes with key supporting materials that complement and substantiate the scientific and regulatory positions presented. These may include the Investigator's Brochure, relevant study protocols and reports, statistical analysis plans, and any previous regulatory correspondence that provides important context.

Providing complete, well-organised annexes enhances the clarity and credibility of your submission

## Useful resources and links

Scientific guidelines


https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines

Medicine Finder and EPARs


https://www.ema.europa.eu/en/medicines

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When developing medicines, it is essential to consult and use **EMA scientific guidelines** to ensure your approach aligns with the current regulatory and scientific expectations in the EU. These guidelines provide harmonised advice on how best to meet legal requirements for quality, safety, and efficacy. In parallel, the European Pharmacopoeia sets binding standards for pharmaceutical quality—especially for the dossier's quality part—while scientific guidelines help applicants navigate evolving topics like clinical trial design or advanced manufacturing. Together, these tools ensure consistency, scientific rigour, and regulatory readiness throughout the development process.
Link: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines

EMA's Medicine Finder helps you locate information on authorised medicines by searching for the product name or active substance. However, It only includes centrally authorised medicines, that is, those evaluated by EMA. To refine your search further, the Advanced Search tool allows you to filter by procedure type, status (e.g. refused or withdrawn), and other criteria.
A key output of these searches are the **European Public Assessment Reports (EPARs)**, one webpage for each medicine, with each page providing detailed regulatory evaluations of medicines. EPARs cover the full development spectrum—including quality, non-clinical and clinical data—and offer insights into how similar products were assessed, helping you align your development strategy with regulatory expectations.
Link: https://www.ema.europa.eu/en/medicines

# Submitting your application through IRIS

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## Submitting your application through IRIS

Once you've completed your briefing document, submit your application through IRIS

**Training recording:**

How to submit initial and follow-up scientific advice applications (human) using IRIS

- Registration steps required to access IRIS,
- How to navigate the platform
- Where to find user guidance and support


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Once you've completed your briefing document and you're ready to submit your application to the EMA, the next step is to use the IRIS platform.
To support applicants, EMA has created a detailed, step-by-step tutorial. This guide walks you through the entire scientific advice submission process—from registering for access to IRIS, to navigating the platform, creating your application, and finally, submitting it.
Link: https://www.youtube.com/watch?v=d6q2o4K7R6I&feature=youtu.be&ab_channel=emainfo

You'll also find guidance on where to access user support and helpful documentation, ensuring you have everything you need to complete your submission smoothly

1. What is scientific advice
2. Online submission portal IRIS
3. How to write your briefing document
4. Scientific advice questions
5. **What happens after submitting your scientific advice request**
6. Other EMA interaction pathways

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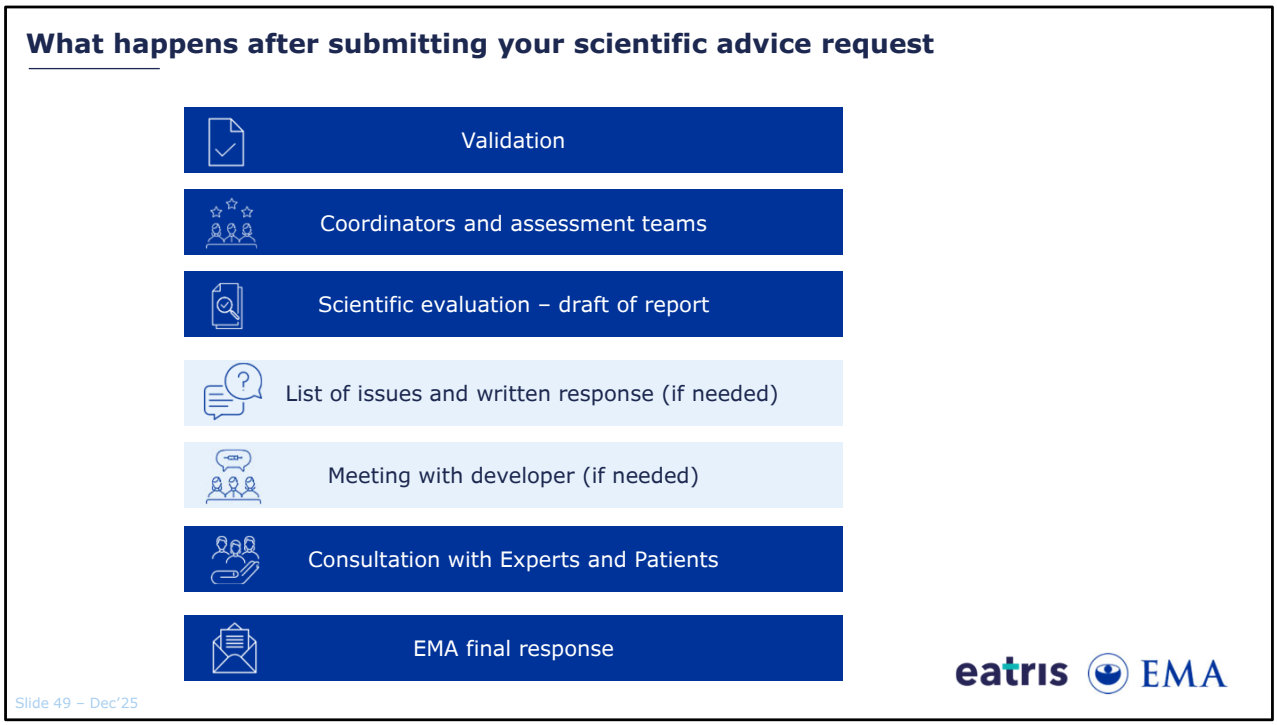


During the validation phase of the submission, the EMA scientific officer will review the briefing documentation and may identify the need for submission of additional documents, and/or provide comments for improving the structure, questions or applicant's positions in the briefing document.
After the Scientific Advice request is validated, two expert members of the SAWP are appointed as coordinators.
The two SAWP coordinators have expertise relevant to the advice request and are supported by experts from their national agencies or from other EU agencies. Each coordinator prepares a draft report, and in particular areas of disagreement are discussed during the SAWP meeting.
In most cases the draft reports are combined into a single report which then forms the basis of the advice letter adopted by the CHMP after the SAWP meeting. Sometimes, however, the SAWP may need additional clarification or justifications. In that case, SAWP sends the developer a list of issues around Day 40 of the procedure. Receiving a List of Issues means the developer will also be invited to a discussion meeting at the next SAWP meeting, and they may need to provide written responses to some of the issues beforehand.
A discussion meeting is not an indication of the likely outcome, but simply reflects the need to discuss specific points in more detail. During the discussion meeting, SAWP seeks to clarify potential disagreements with the developer and alternative development strategies.
Throughout the scientific advice process, input is gathered from other EMA committees such as CAT, PDCO or COMP, and external experts who can include patients—either through written comments or by attending meetings.
The advice process concludes with the adoption of the final advice letter by the CHMP, which is then shared with the developer.

## What happens after you receive Scientific Advice

- Scientific Advice is not a verdict or peer review
- It is a regulatory dialogue based on your submitted data
- Designed to inform and support development—not to judge or limit
- Use it to refine, adapt, or reshape your research strategy

**Ways to continue interaction with EMA:**

- Written Clarification
  - For unclear advice or help with implementation
  - Supports integration into ongoing development plans
- Follow-Up Scientific Advice
  - When new data become available
  - Enables EMA to reassess and provide updated guidance

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Scientific Advice is not a verdict or peer review, but a regulatory dialogue offering expert guidance based on the data provided. It's meant to inform and support your development—not to judge or limit it—so you can use it to refine, adapt, or reshape your research strategy.
Depending on how your development progresses, there are several ways to continue the dialogue with EMA after receiving Scientific Advice:

**Written Clarification**

If parts of the advice seem unclear or if you need help interpreting a recommendation, you may request a written clarification. This is especially useful when trying to implement the advice into ongoing development plans.

**Follow-Up Scientific Advice**

If new data become available or your approach has evolved since the original advice, it may be appropriate to request a formal follow up Scientific Advice. This allows EMA to reassess your development strategy in light of new evidence and offer updated guidance.

# Scientific Advice for Veterinary Products

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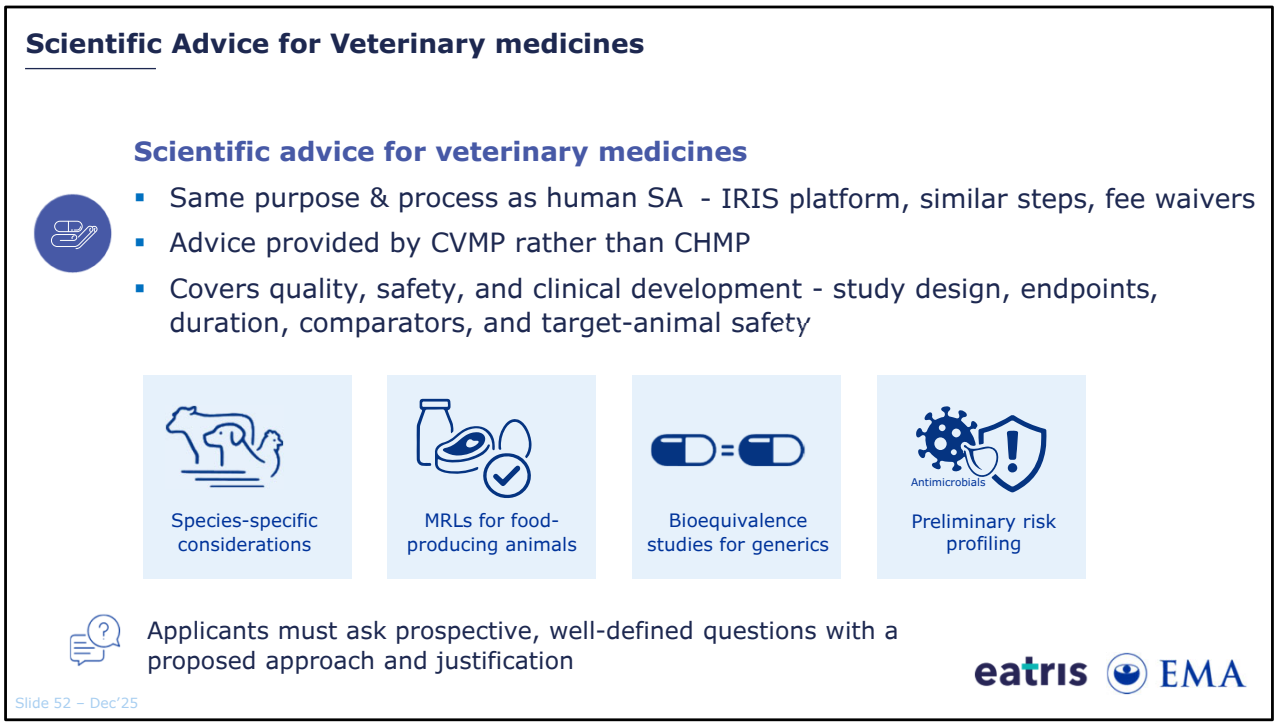
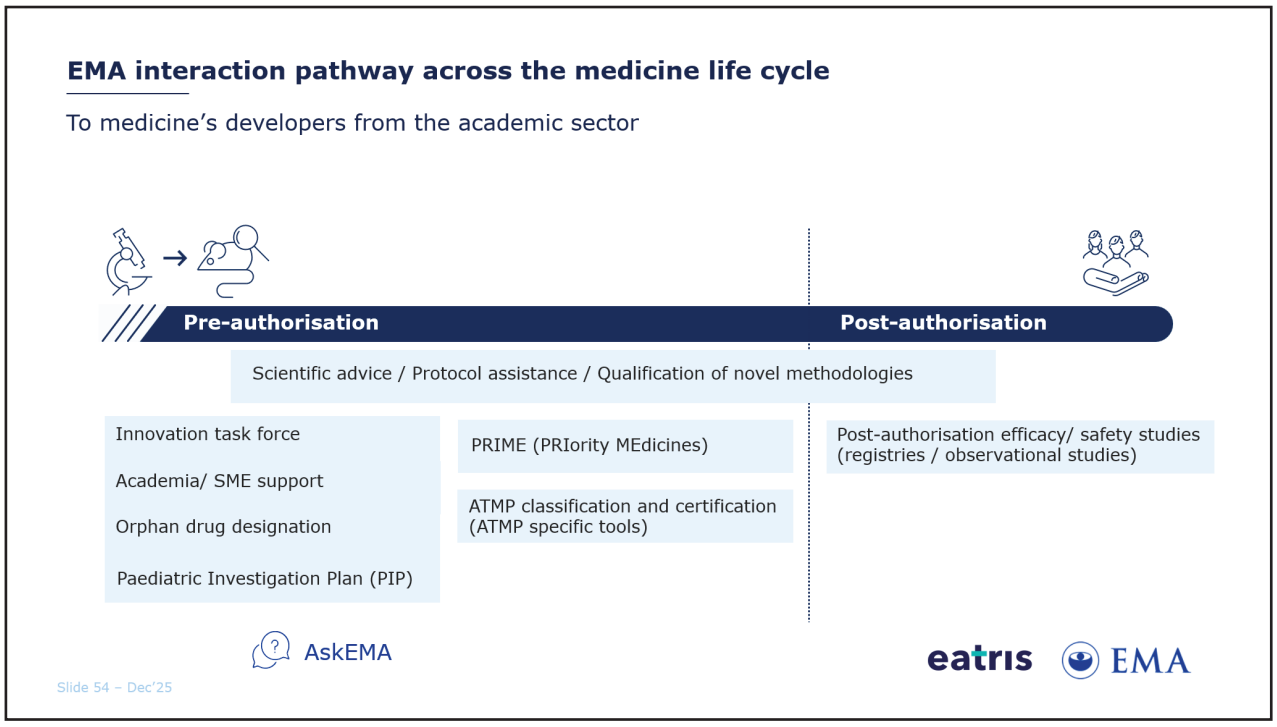



Veterinary Scientific Advice follows the same overall purpose as human Scientific Advice: to guide developers in generating robust, regulatory-relevant evidence for their product. It is handled through the same IRIS platform, follows similar procedural steps, and benefits from the same fee waiver provisions. However, there are important differences. Advice for veterinary medicines is provided by the **Committee for Medicinal Products for Veterinary Use (CVMP)**, and the scope reflects the unique considerations of veterinary product development. In addition to quality, safety, and clinical development questions—such as study design, endpoints, duration, comparators, and target-animal safety—veterinary advice also covers **species-specific aspects**, including how a product behaves in different target animal populations. A key area unique to veterinary medicines is guidance on **Maximum Residue Levels (MRLs)** for food-producing animals, ensuring consumer protection. For generic products, developers may also request advice on **bioequivalence studies**, while developers of new antimicrobial or antiparasitic medicines can obtain **preliminary risk profiling**, which assesses antimicrobial resistance hazards, environmental release, human exposure, and potential public-health consequences. As with human Scientific Advice, applicants submit focused scientific questions, provide their proposed approach and justification, and include relevant supporting documents in annexes. Across both systems, the principles are the same: ask prospective, well-defined questions that show how you intend to design your studies—rather than requesting general instruction on study design—and provide enough context for assessors to offer meaningful guidance.

1. What is scientific advice
2. Online submission portal IRIS
3. How to write your briefing document
4. Scientific advice questions
5. What happens after submitting your scientific advice request
6. **Other EMA interaction pathways**




Academic developers and SMEs who develop therapies may have limited regulatory expertise to navigate through the various complementary procedures in place at EMA that would support them during the development of the product.
Several of these tools are especially relevant for academic developers and will be described in more detail shortly, but here we first provide an overview of the main options available.
For instance, the **Innovation** Task Force offers a platform for early dialogue on innovative products and methodologies, while the SME and Academia Office provide support for small enterprises and academic research groups and organisations for all products and developments.
If you're developing a treatment for a rare disease, applying for orphan drug designation can ensure access to important incentives—such as market exclusivity against similar products and reduced fees for scientific advice, also known as protocol assistance.
The inclusion in the PRIME scheme provides further valuable support for promising treatments that address unmet medical needs. Developers granted PRIME status benefit from early and enhanced interaction with EMA, along with potential fee reductions or waivers for scientific advice, depending on their profile.
For specific aspects of Advanced Therapy Medicinal Products (ATMPs), EMA offers two tools: ATMP classification and ATMP certification.
The classification procedure confirms whether a product qualifies as an ATMP—especially useful for medicinal products in borderline areas.
The certification procedure allows SMEs to submit quality and non-clinical data for scientific evaluation. This helps identify issues early in development and provides reassurance that the development is on the right track.
You can also contact EMA anytime via AskEMA by submitting a question through the online form on the corporate website. It's a flexible way to request information or guidance, complementing other support tools like the Scientific Advice, an ITF briefing meeting, and the Academia Office support.
We will now highlight a few of these in more details.

# Protocol assistance

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## Protocol Assistance for Orphan Medicines

**Protocol assistance = scientific advice for designated orphan medicines**

Protocol assistance

- Available for developers of designated orphan medicines
- Can be requested at any stage after orphan designation
- Covers quality, non-clinical, and clinical development—same as for non-orphan medicines
- May include questions on significant benefit over existing authorised products
- No limit on the number of requests a sponsor can submit

Limited markets

**For any questions**

Please contact scientificadvice@ema.europa.eu

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Protocol assistance is a special form of scientific advice available for developers of designated orphan medicines for rare diseases. It is only available for human medicinal products; for veterinary products, the counterpart is known as 'limited markets'.
Sponsors can request protocol assistance from EMA at any stage of development, after receiving the designation.
The process is the same as for scientific advice; during protocol assistance, sponsors can raise the same type of questions regarding the quality, non-clinical and clinical development of orphan medicines, as for non-orphan medicines.
Protocol assistance can however include additional questions on the demonstration of significant benefit at the time of marketing authorisation, if authorised products exist.

There is no restriction on the number of times a sponsor can request protocol assistance or scientific advice.
Further information can be found:
https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance#protocol-assistance-section
Scientific advice and protocol assistance | European Medicines Agency (europa.eu)
For any questions, please contact scientificadvice@ema.europa.eu.

# Qualification of Novel Methodologies

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## Qualification of Novel Methodologies

### Scientific Advice on the acceptability of novel methodologies

- Not to specific medicinal products, but applies to methods and tools
- Aims to speed up or improve development

**Examples:**

- Methods to predict toxicity
- Methods to enrich a patient population for a clinical trial
- Surrogate clinical endpoints: new sensitive scales to measure efficacy of a new drug instead of hard clinical endpoints
- Patient and caregiver reported outcomes
- Disease registries to support safety and efficacy of medicines


EMA's Quality Innovation Group (QIG)

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As part of EMA's support tools for developers, the Qualification Procedure offers a formal pathway to seek scientific advice on the acceptability of novel methodologies—such as new clinical endpoints or disease registries—that can support evidence generation.
Qualification procedures are broad and do not refer to a medicinal product. The qualification concerns methods and tools that can speed up or otherwise improve medicine development. Some examples of what could be appropriate for qualification include:

- novel methods to predict toxicity
- methods to enrich a patient population for a clinical trial
- "surrogate" clinical endpoints, meaning new sensitive scales to measure efficacy of a new medicine instead of currently used endpoints
- patient reported outcomes which need to be validated or
- Disease registries to support assessing the safety and efficacy of medicines

A dedicated video on how to apply and benefit from the Qualification procedure can be viewed through this link: https://youtu.be/TCufzPsTnr0
Those academic developers who are working on innovative approaches in the area of pharmaceutical quality are encouraged to also engage with EMA's Quality Innovation Group (QIG). This group provides a platform to explore novel manufacturing, control, and quality assessment technologies. One key initiative is the Listen-and-Learn Focus Group meetings, which offer an informal setting for researchers to present ideas and challenges and receive non-binding regulatory feedback. These sessions are particularly valuable in early development stages. Interested academics can find more information and contact details to express their interest in participating on the Quality Innovation Group webpage:
https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp-working-parties-other-groups/quality-innovation-group

# EMA Emergency Task Force (ETF)

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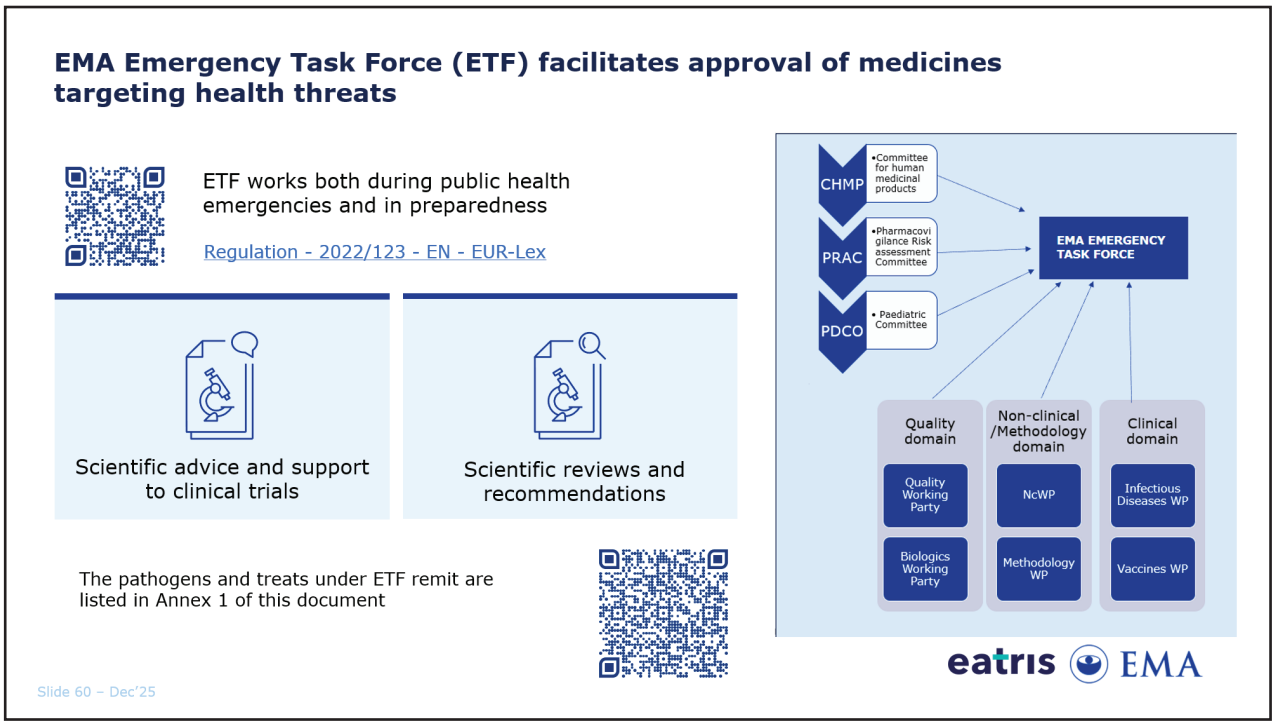


The Emergency Task Force (ETF) is an advisory and support body that handles regulatory activities in preparation for and during a public-health emergency, such as a pandemic. The European Medicines Agency (EMA) established the ETF in accordance with the Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123) . The ETF was already working during pandemics and major outbreaks since 2009 but the new Regulation made the group permanent and entrusted it with an important role in crisis preparedness.
The key activities of the ETF include providing scientific advice to developers for medicines that target a declared or a future potential pandemic. It includes advice on **clinical trials** and related **ethical** aspects. The ETF also performs reviews of evidence on medicines under investigation or authorized to respectively facilitate authorization during crises or provide recommendations to EMA committees, MSs or the EC.

In preparedness the ETF works on specific viral pathogens in line with the WHO R&D blueprint for viral families with pandemic or epidemic potential.
It also works on all bacterial vaccines and treatments against Antimicrobial resistant (AMR pathogens). Finally is responsible for preparedness against CBRN (chemical, biological, radiological and nuclear materials) threats. The remit is defined in Annex 1 of the ETF workplan (link: https://www.ema.europa.eu/en/documents/work-programme/consolidated-3-year-work-plan-emergency-task-force-etf_en.pdf).
The ETF is composed of experts on infectious diseases who are part of other committees and groups within EMA, as depicted in the right hand part of the slide.

## ETF provides scientific advice to developers


Scientific advice | Scientific reviews | Scientific recommendations

**Scientific advice application by developer** → Add questions on Clinical Trial Applications

Standard | on MAA

Emergency Task Force (ETF) ← Clinical trial & ethics experts from National Authorities

**CHMP adoption**

Applicant

**KEY BENEFITS**

Harmonisation of advices across EU authorities to facilitate clinical trials authorisations and vaccine licensure

- ETF scientific advice follows standard 40-70 days timetable in interpandemic periods
- ETF scientific advice is accelerated to 20 days and free of charge during declared emergencies

Scientific advice for public health emergencies and threats | European Medicines Agency (EMA)

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The ETF performs scientific advice assessments for developers of medicines under its remit.
ETF scientific advice follows the standard 40–70 day timetable in interpandemic periods, in line with the regular scientific advice procedure.
During declared emergencies, ETF scientific advice is accelerated to 20 days and provided free of charge.
Recently, the ETF updated its scientific advice process to allow for questions related to clinical trial authorisations (CTAs).
For this purpose, the ETF will involve clinical trial and ethics experts from national authorities at no additional cost.
The aim is to facilitate clinical trial authorisation and harmonisation of requirements across EU authorities, both for product authorisation and the authorisation of clinical trials during development.
This initiative is similar to the SAWP–CTCG pilot and is supported by broader activities under ACT-EU, which aim to speed up clinical trials in the EU, particularly in emergency contexts. These initiatives will be discussed in more detail in the next section.

## ETF engages in iterative dialogue with vaccines developers


- **Informal TCs and workshops** with industry, academia and learned societies (myocarditis after vaccination, long COVID, vaccine effectiveness)
- **Early interactions on infectious pathogens, threats (CBRN), AMR**

### Support for treatment and vaccine developers

EMA is committed to establishing close contact with developers of treatments or vaccines for emerging health threats.

Developers of **treatments** and **vaccines** targeting infectious diseases and threats that could cause a public health emergency should contact EMA's ETF at PHEearlyinteractions@ema.europa.eu.

Developers should include a description of the candidate product, its development plan and a summary of available evidence.

- These activities plus scientific advices build the necessary knowledge for drafting guidelines for developers

*ETF set to become a point of reference to support product development / life cycle end to end*

*ETF includes specialist experts on infectious diseases and CBRN from the regulatory network, but also non-regulatory (clinicians and researchers)*

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ETF plays an important role in maintaining continuous, iterative dialogue with vaccine developers. This includes informal teleconferences and dedicated workshops with industry, academia and learned societies—for example on myocarditis following vaccination, long COVID, or vaccine effectiveness.
ETF also supports early interactions on infectious pathogens, Chemical, biological and radio-nuclear threats and antimicrobial resistance.
EMA is committed to maintaining close contact with developers working on treatments or vaccines for emerging health threats, and encourages them to reach out early. Developers targeting infectious diseases or other potential public health emergencies can contact EMA directly via the dedicated mailbox.
These ongoing exchanges, together with formal scientific advice procedures, help build the evidence base needed to draft high-quality guidance for developers.
Over time, ETF is set to become a key reference point supporting product development across the entire lifecycle.
Its membership includes specialist experts in infectious diseases and Chemical, biological and radio-nuclear agents from both the regulatory network and the wider scientific community, ensuring robust and multidisciplinary input

# Scientific Advice in clinical trials

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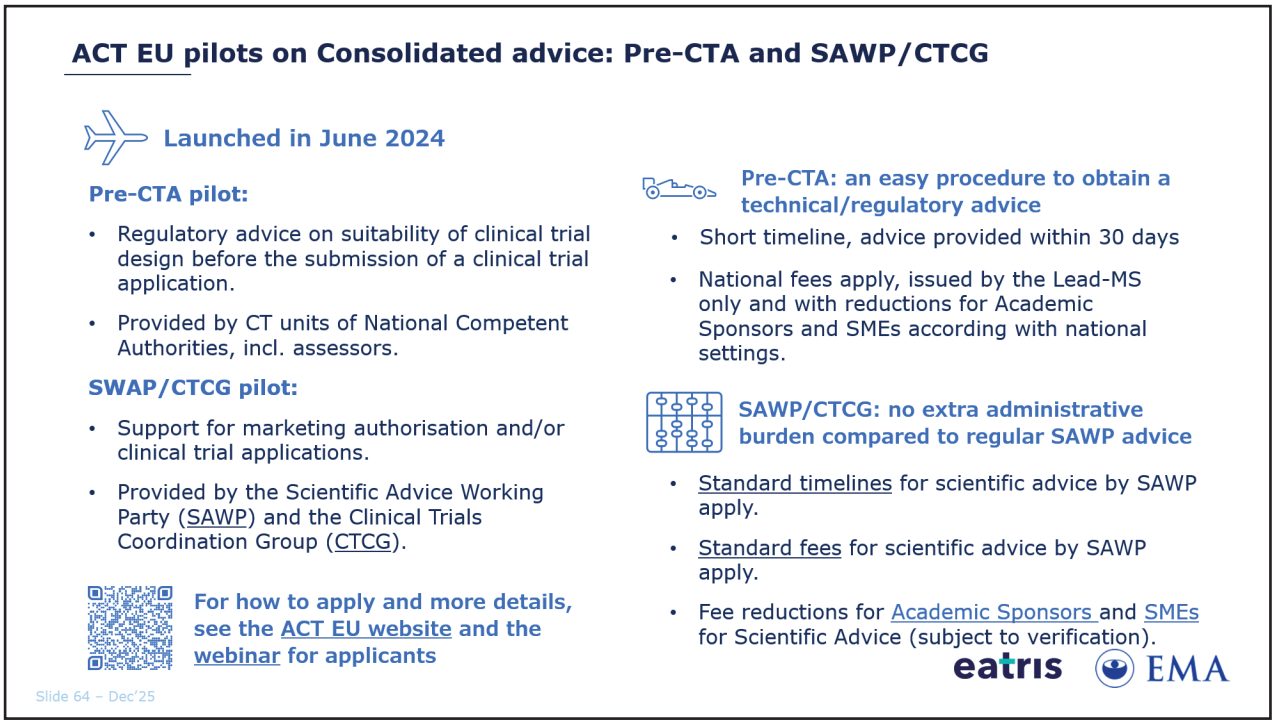


The Accelerating Clinical Trials in the EU (ACT EU) initiative was launched to modernize and streamline clinical trial processes across Europe. A key priority under this initiative is the implementation of two pilots on consolidated advice in clinical trials, the Pre-CTA and SAWP CTCG, launched in June 2024. These pilots aim to foster early dialogue between sponsors or applicants and regulators, particularly clinical trial assessors. This collaborative approach promotes harmonization, minimizes duplication, and ultimately accelerates the development of innovative medicines.

The Pre-CTA pilot offers technical and regulatory guidance prior to the submission of a clinical trial application, provided by the clinical trial units of National Competent Authorities. The SAWP/CTCG pilot delivers integrated scientific advice on clinical trial design, helping sponsors align development plans with both marketing authorization and clinical trial requirements. This advice is jointly provided by the Scientific Advice Working Party (SAWP) and the Clinical Trials Coordination Group (CTCG). Importantly, clinical trial assessors from National Competent Authorities actively participate in both pilots, ensuring that trial design considerations are fully addressed.

All guidance documents, recorded webinars, and the list of participating Member States are available on the ACT EU website.

One of the defining features of these pilots is their simplicity; Pre-CTA follows a quick and straightforward process. SAWP/CTCG involves no additional administrative burden compared to standard SAWP advice, maintaining usual timelines and fees. Moreover, the pilots offer significant financial incentives for Academic sponsors and SME, in terms of reduction of fees. These measures make the pilots particularly accessible to academic and non-commercial organizations, enabling them to benefit from high-quality regulatory input without prohibitive costs.

# SA-HTA

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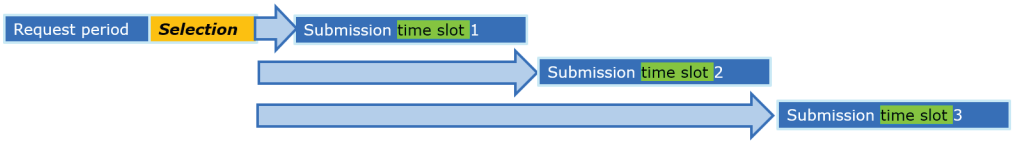
## HTA/EMA JSC – Joint Scientific Consultations

- Joint Scientific Consultations in force since Jan 2025, either simple JSC (only HTAs) or parallel JSC (EMA + HTAs)
- Applicants receive outcome documents from both sides (consolidated JSC document + Final Advice Letter from SAWP)
- Application per fixed **request periods** with subsequent selection by HTACG
- **Good HTA participation expected**, (e.g. HAS, G-BA, IE, NO, BE, HU, but also PT, PL, ES; NL?)

| **Previous** JSC in collaboration with EUnetHTA24 | **JSC under the HTA Regulation (HTAR)** |
|---|---|
| Hands-On-Group with active HTAs and observers | Assessor and co-assessor selected from JSC-SG |
| Applications upon call for interest (1x per year) | Applications during **request periods (3 per year)** |
| One HTA (G-BA) acting as HTA Coordination Contact | EC in charge of HTA secretariat |
| Identical selection criteria; **Selection by HTACG**; EMA not involved | |
| **Timeslot** for parallel JSC being allocated after selection | |

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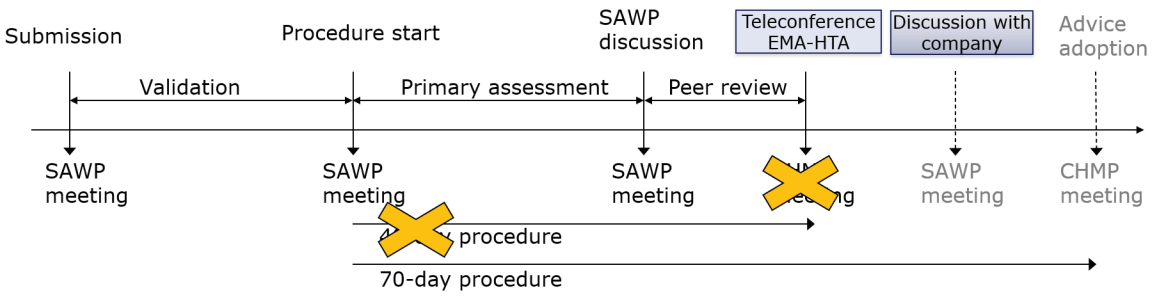
- https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-scientific-consultations_en
- https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/parallel-scientific-advice-special-development-aspects-or-product-types#parallel-joint-scientific-consultations-with-the-member-state-coordination-group-on-hta-htacg-72648

## The parallel EMA/HTA Joint Scientific Consultations




Adjustments made to for the parallel JSC

- Early recruitment of SAWP coordinators, simultaneous submission to EMA and JSC-secretariat
- **Liaison between** EMA and HTA ahead of the Discussion Meeting (TC), exchanges of Lists of Issues (LoI)
- **Always 70-day procedure** with a discussion meeting
- Longer duration of the Discussion Meeting (3.5 hrs)
- 2 co-chairs (EMA, HTA) for the Discussion Meeting
- Applicant receives responses from HTAs and EMA (FAL) separately (validated by JSC SG adopted by HTACG)

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- https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-scientific-consultations_en
- https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/parallel-scientific-advice-special-development-aspects-or-product-types#parallel-joint-scientific-consultations-with-the-member-state-coordination-group-on-hta-htacg-72648

# National Scientific Advice

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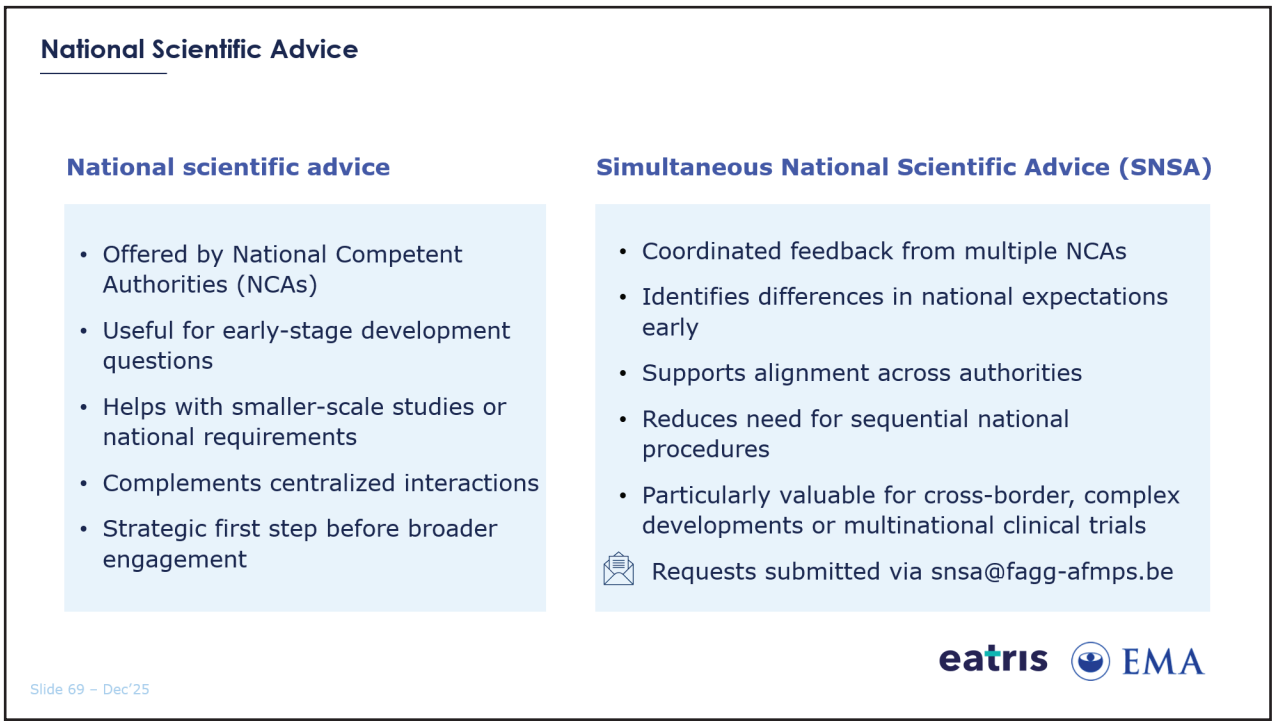


In addition to seeking scientific advice at the European level through EMA, academic researchers are also encouraged to explore national scientific advice offered by their respective national competent authorities.
This form of advice can be particularly valuable for early-stage development questions, smaller-scale studies, or when navigating specific national requirements.
Each country may have slightly different procedures, but national advice often complements EMA advice —helping you prepare better for centralised interactions or clarify context-specific regulatory expectations.
If you're unsure whether to approach your national agency or EMA, consider the type of feedback you need and the scope of your development. In many cases, starting at national level can be a strategic first step.
In addition to single-agency national advice, researchers can also benefit from the Simultaneous National Scientific Advice (SNSA) procedure. This pathway enables applicants to obtain coordinated feedback from more than one National Competent Authority at the same time. By engaging several agencies in parallel, SNSA helps to highlight potential differences in national expectations early on, supports greater alignment across authorities, and reduces the need for multiple sequential procedures. This makes SNSA particularly valuable for projects with cross-border relevance, complex development questions, or multinational clinical trials, where early clarity on regulatory expectations is essential. Applicants can submit new SNSA requests via snsa@fagg-afmps.be.

# Other early interaction pathways

to medicine's developers from the academic sector

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## Assistance from SME Office

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### Regulatory assistance

- SME definition and incentives
- Early development advice (scientific advice, ITF, PRIME)
- Regulatory topics (legal basis, data protection)
- Criteria for orphan designation, market exclusivity
- Paediatric requirements
- Clinical trials, CTIS

### SME briefing meetings

Raise strategic questions such as:

- When should I apply for Scientific Advice?
- Which guidelines are most relevant for my development?
- Is my product eligible for the centralised procedure?
- What legal basis should I choose for my application?

### Training events & material

- SME user guide
- Subscribe to the SME newsletter

### Financial incentives

- 90% fee reduction for Scientific Advice (100% for orphan products)
- MAA conditional fee exemption (SA taken into account and MAA not successful)

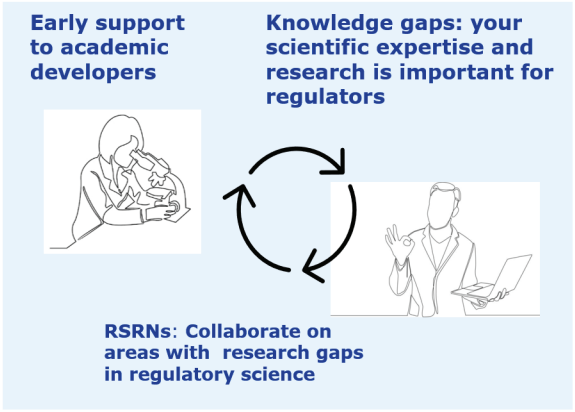
sme@ema.europa.eu
EMA support for SMEs
+31 (0)88 781 8787

EMA

## Academia briefing meeting – scope

Welcoming researchers and developers from academic sector, NFPs, societies:

- EMA listens to researchers' challenges
- Bidirectional exchange through engaging researchers on EMA's scientific challenges
- Opportunity to discuss regulatory aspects
- Support on how to advance R&D
- No fee, no briefing book
- Possibility of iteration and follow-up




academia@ema.europa.eu
https://www.ema.europa.eu/en/partners-networks/academia

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To better support academic researchers, not-for-profit developers, and scientific societies and provide orientation in the regulatory landscape, EMA offers *Academia briefing meetings*—dedicated sessions designed to foster open dialogue, early guidance, where academic developers can openly share the hurdles they face during the development of innovative products, from regulatory uncertainties to scientific bottlenecks.
These meetings cover both human and veterinary medicine development, ensuring that academic projects in either domain can benefit from early regulatory orientation.
These meetings are not just about offering advice—they're also about dialogue. EMA actively engages with scientists to understand how academic research can contribute to solving current regulatory challenges.
Developers can raise questions on a wide range of regulatory topics—from product classification and trial design to pathways for rare disease treatments—getting early insights to shape their strategy.
The meetings offer guidance on how to structure research in a way that aligns with future regulatory requirements, helping academic teams move their projects forward with clarity.
Academia Briefing Meetings are free of charge and do not require any formal package, making them accessible and low-burden for academic teams.
Developers are encouraged to reconnect with EMA as their projects evolve, fostering a continuous and supportive engagement throughout the R&D lifecycle.
These meetings not only offer early support to academic developers but also enable meaningful exchange with regulators—allowing academic insights to inform regulatory science, bridge knowledge gaps, and shape guidance in emerging areas of innovation.

## Dedicated Academia Webpage


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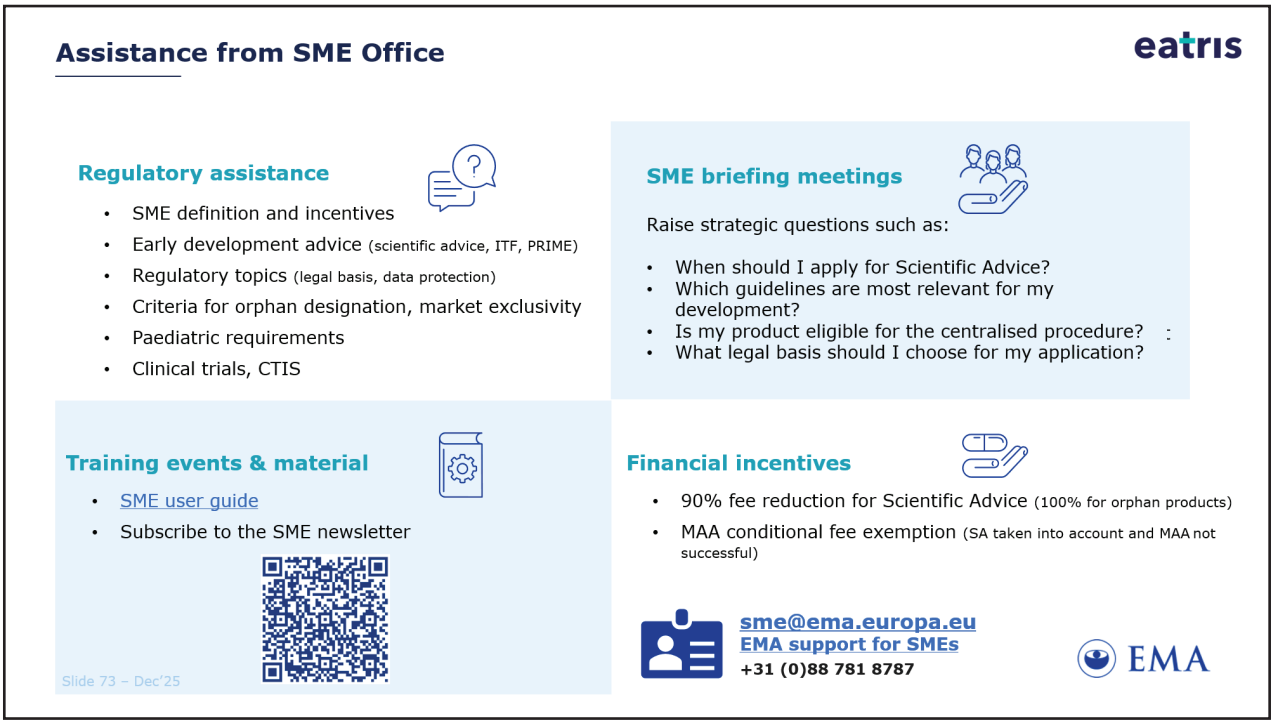
For an overview of the support available for academia, please visit the newly updated EMA Academia webpage. It offers a clear overview of tailored support opportunities for academic and not-for-profit researchers and illustrates how EMA. collaborates with academia to advance medicine development, regulatory assessment, and deliver regulatory science solutions.
Link: https://www.ema.europa.eu/en/partners-networks/academia




For small and medium-sized enterprises developing medicines, the EMA SME Office provides tailored assistance.. It acts as a dedicated communication channel, helping SMEs navigate regulatory requirements and product development, with targeted guidance on incentives, orphan designation, paediatric obligations, data protection, and clinical trial requirements. Support through the SME Office applies to both human and veterinary medicinal products.

For SMEs, a key tool is the SME Briefing Meeting—a structured 90-minute session, free of charge, with an interdisciplinary EMA team. These meetings focus on shaping regulatory strategy and result in written minutes that capture advice and outcomes.

SMEs are encouraged to raise strategic questions such as:

when should I apply for Scientific Advice?

Which guidelines are most relevant for my development?

Is my product eligible for the centralised procedure?

What legal basis should I choose for my application?

Training and educational materials are available to SMEs, like the SME user guide which provides a comprehensive overview of the centralised procedure and helps SMEs navigate the EU regulatory framework for medicines. To ensure receiving the latest scientific and regulatory news, developers can subscribe to the EMA SME newsletter.

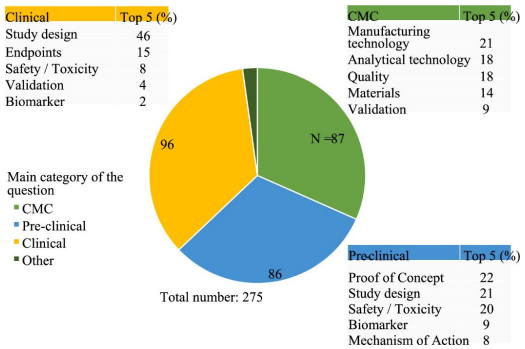
SMEs with a valid EMA SME status have access to financial incentives, including a 90% fee reduction for scientific advice, and 100% fee reduction for SMEs with a product holding an orphan drug designation.

The EMA offers a conditional fee exemption for SMEs, allowing them to avoid paying marketing authorisation application fees if the application fails despite having followed EMA scientific advice. To qualify, the SME must demonstrate that the recommendations from the scientific advice were properly considered and implemented in the application.

To access this support and further resources, SMEs can visit the EMA SME Office webpage

## Innovation Task Force (ITF) - briefing meeting

Multidisciplinary platform
for preparatory dialogue and orientation on
**innovative methods, technologies and medicines**




- Support **innovative** drug development
- **Early informal** dialogue with opinion leaders
- 1,5-hour discussion – *Free of charge*
- Brainstorming "style" on innovation in areas without existing guidance
- First step to engage is submit completed 3-page template

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Innovation Task Force (ITF) Briefing meetings focus on support to highly innovative developments by offering early engagement between developers and various European regulatory experts. These meetings serve as a first opportunity for dialogue with regulators, often long before formal scientific advice is requested. ITF support explicitly covers both human and veterinary innovation, ensuring early regulatory dialogue for novel technologies and products across both sectors.

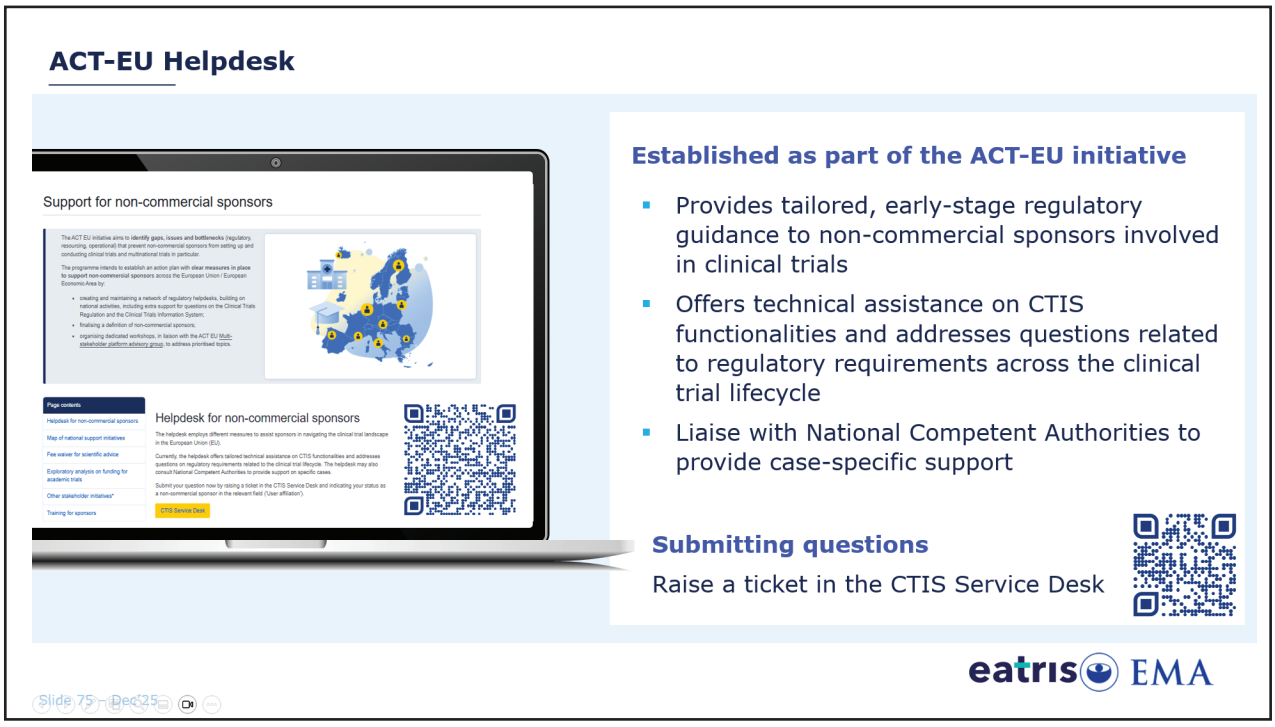
The service is not limited to innovative medicines such as cell & gene therapies but also includes innovative technologies such as artificial intelligence, in manufacturing, in medicine delivery (e.g., nano-formulations) and novel approaches to replace, reduce and refine animal use (3Rs) in medicine development as well as biomarkers.

Each 90-minute meeting is free of charge and conducted in a brainstorming format, where developers can present their ideas, technologies, or methodologies—particularly those in areas with little or no existing regulatory guidance. The emphasis is on open, exploratory discussion/orientation rather than formal positions, making it ideal for early-stage innovation.

To apply for a meeting, developers must submit a concise 3-page ITF meeting request form, available on the EMA website. Once accepted, they meet with a multidisciplinary panel of EU experts who provide insight into scientific, technical, and regulatory aspects.

Topics discussed vary widely—from cutting-edge manufacturing methods and 3D bioprinting to AI-enabled trial endpoints, and New Approach Methodologies (NAMs) supporting the 3Rs (refine, reduce, replace animal use), including in vitro assays, organoids, and organ-on-chip technologies.

Importantly, an analysis of recent ITF interactions revealed that 85% of meetings result in actionable guidance, helping applicants navigate the regulatory landscape These early interactions support a smoother transition from early-stage medicine development to marketing authorisation by preparing applicants for subsequent regulatory procedures - such as scientific advice, qualification of novel methodologies, and formal submissions. At the same time – while also helping the EU regulatory system anticipate and adapt to emerging innovations.

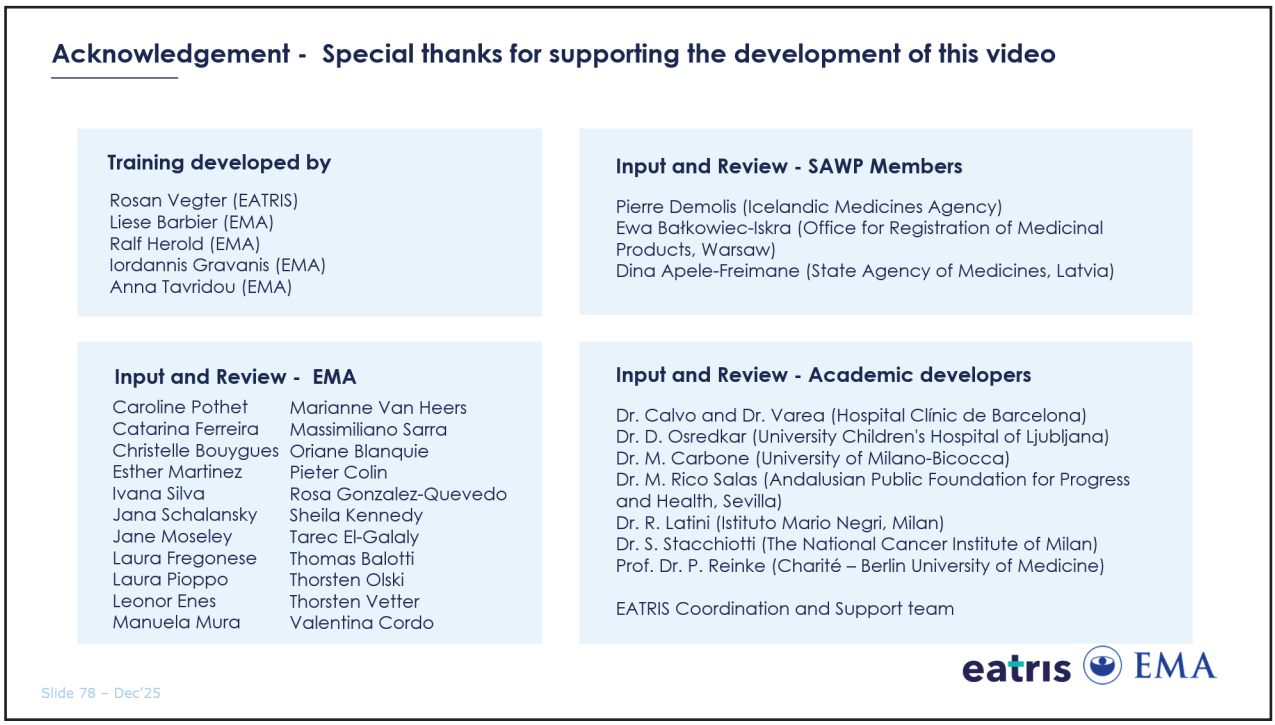



To further support academic and not-for-profit developers, EMA has established the ACT-EU Helpdesk—part of the Accelerating Clinical Trials in the EU (ACT-EU) initiative. Link: https://accelerating-clinical-trials.europa.eu/our-work/support-non-commercial-sponsors_en

The Helpdesk provides tailored, early-stage regulatory guidance to non-commercial sponsors of clinical trials. It offers technical assistance on CTIS functionalities and addresses questions related to regulatory requirements across the clinical trial lifecycle. Where appropriate, the Helpdesk may also liaise with National Competent Authorities to provide case-specific support.
You can submit your question by raising a ticket about CTIS in the EMA Service Desk and indicating your status as a non-commercial sponsor in the relevant field ('User affiliation').


To wrap up this tutorial, here are the key messages to keep in mind:
Scientific Advice helps align your development with regulatory expectations, reducing uncertainty, strengthening your research, valorising your asset and clearing a way towards approval.
IRIS is the central portal for submissions—ensure your account, documentation, and briefing book are complete and compliant.
Early engagement and clear questions with well-justified applicant positions lead to more effective feedback and can prevent costly delays.
Academic developers are strongly encouraged to apply, with dedicated support tools like fee waivers, preparatory meetings, and protocol assistance.


This concludes our tutorial on the EMA Scientific Advice process. We hope it has equipped you with the insights and practical steps needed to plan, prepare, and submit a successful request.
By engaging proactively and using the tools and resources available, you can help accelerate your medicine's development and improve its chances of regulatory success.
For an overview of the support available for academic researchers, please visit the newly updated EMA Academia webpage. You can also contact EMA directly via Academia@ema.europa.eu for further guidance. Thank you for watching—and we wish you the very best in your development journey.



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EATRIS Coordination and Support team

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We express our sincere gratitude to everyone who contributed to the development of this video, including colleagues from EMA, SAWP members, EATRIS C&S and the academic developers whose expertise and support made this work possible.

# How to apply and benefit from Scientific advice

ERDERA
European Rare Diseases Research Alliance

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