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EU-Innovation Network guidance on available scientific and regulatory support tools at national and European level for human medicinal products/technologies/methodologies

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

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1. Introduction

Iterative interaction with medicines regulators provides an opportunity to optimize the development of new or existing medicinal products, orientating developers towards the most suitable guidance to comply with regulatory requirements, with the aim of ultimately leading to a marketing authorisation and access to safe, effective and high-quality medicines for patients.

Interaction is foreseen and encouraged at both national and European level. The European Medicines Regulatory Network (EMRN) is working to raise awareness and encourage use of its supports for medicine development, with National Competent Authorities (NCAs) promoting access to supports for researchers and developers at national level, as well as providing information on and encouraging use of supports offered at European level via the European Medicines Agency (EMA).

To this purpose, this guidance aims to help the researchers and developers to identify the most appropriate support tools to use during the medicinal product's development. The guidance contains info boxes that provide manageable, concise and easily understandable descriptions of the regulatory support tools, including their scope, optimal timing in relation to the product development maturity and output.

This guidance should be considered along with the glossary of regulatory terms embedded in the document and/or already available information at EMA and/or NCA websites.

The regulatory and support tools described in this guidance are complementary to each other. In order to gain the best support from regulators and to optimise time and resources, it is recommended to consider the nature of the product, its development phase and the scope / intended use of the advice or guidance needed to choose the most appropriate tool on each occasion. For example, for questions related to the suitability of the design of a clinical trial to generate data to support a centralised marketing authorisation, EMA scientific advice would be recommended, while in very early development stages of innovative products/methodologies/technologies an innovation meeting (either at national or EMA level) may be a more suitable option.

Developers should be aware that depending on the stage of their product's development and/or data maturity, they may be advised to engage with regulators through a different tool than the one identified through this guidance. In cases of doubt, developers are advised to submit a direct enquiry to an NCA's Innovation Office or the identified EMA Office to discuss and identify the most optimal strategy to follow.

Developers can apply for more than one support offering over time, depending on their development phase and the specific support they need.

This guidance is intended solely as an orientation tool providing an overview of support options, including some pilot projects currently ongoing within the European Regulatory Medicines Network and highly related to the tools described in this guidance. The info boxes concerning national regulatory and support tools (e.g., national scientific advice and innovation meetings) provide general descriptions. However, specific features of these tools may vary slightly depending on the policies and scope of individual NCAs—for example, in terms of eligible Applicants, expected outcomes, or required documentation. Developers are therefore strongly encouraged to consult the official websites of the relevant NCAs for complete, up-to-date information and access to supporting materials. Likewise, developers should refer to the EMA website for further details and additional resources related to tools available at EU level. Further complementary information could be also retrieved in the mapping document on current voluntary procedures available from EU regulators on Medicines for Human use, published in the context of the Accelerating Clinical Trials in EU (ACT-EU) initiative.

The current scope of this guidance is limited to selected European and national regulatory tools relevant to the development of human medicinal products.

EU-IN does acknowledge the collaboration with the colleagues in EMA Academia Office, EMA SME Office, EMA Emergency Task Force, EMA Scientific Advice Working Party, EMA Quality Innovation Group, and ACT EU for the preparation of this guidance.

2. National Innovation Office support

National Innovation Office support	
Scope	National Innovation Office is the **initial and informal national entry point** to start a dialogue with regulators at an **early stage of development** of **innovative/emerging medicinal products, technologies, methodologies** to get input on regulatory and scientific requirements, as well as on available support tools, to be considered in future plans. Innovation Office could offer different forms of support (e.g. Innovation Meetings, short calls and email exchanges), therefore it is recommended to refer to each NCA for any details. **Questions** could be: • Regarding a **general understanding on the future development** in compliance with regulatory requirements, especially when guidelines are lacking or clarification is needed. • Specific to the project. • Related to **regulatory, technical and scientific concerns**. • Related to **quality, non-clinical, clinical and methodology aspects**. Please refer to the NCAs for any exception in the scope, the remit and competence of product/technology/methodology (i.e. medicinal products – human/veterinary; medical devices; Substances of human origin - SOHO, etc).
Who can apply	Any Applicant, with a particular emphasis on academic and not-for-profit researchers. Please refer to the NCAs policy for any restrictions on Applicant's type.
When to apply	Preferably, at the earliest stages of development, typically **well in advance of seeking formal scientific advice**. Please refer to NCA for time schedule for submission.
What to expect	Regulators could: • Provide a general guidance on regulatory or scientific issues to be considered during development. • Provide high level feed-back on the overall product development. • Confirm/suggest any appropriate and available guidance (EMA/ICH) to refer to during product development.

National Innovation Office support	
	• Give an overview of the regulatory applicable framework and suggest other regulatory tools, national or European, to be followed during the development. • Scale to the European network the case with the Applicant's agreement. The Innovation Meeting and the other formats of support available do not constitute a pre-assessment of the documentation of the product that may be subject to a Clinical Trial Application (CTA), Scientific Advice (SA) or Marketing Authorisation Application (MAA). Meeting format (meeting/online/in writing) depends on each NCA policy. Please refer to NCA for any deviation.
What to submit	A Briefing document should be provided including an **overview** of the product/technology/methodology, a short explanation of the **scientific rationale** and **background**, and describe any **preliminary data** that support the Applicant's future plan of the development. Questions raised to regulators should be concrete to allow regulators to give useful indication and support. All documents are treated with **confidentially**. Please refer to NCA for the application procedure and the required documents.
Output of the procedure	**Written responses or meetings.** **Meeting minutes** could be requested to the Applicant and then revised by the NCA. The answers provided should not be interpreted as regulatory guidance or review recommendations for an application, but as a preliminary set of scientific considerations on the information presented. Unlike SA procedures, although advisable, it is **not mandatory** for the Applicant to mention any Innovation Meeting received in any future formal submissions at EMA or national level (e.g. CTA, SA; MAA). Please refer to NCA for further details and possible exceptions (e.g. meeting minutes as final document).
How to submit	Please refer to NCA
Fees	Please refer to NCA

3. EMA Innovation Task Force (ITF) Briefing Meeting

EMA Innovation Task Force (ITF) Briefing Meeting	
Scope	**Initial and informal entry point** to start a dialogue with European regulators at an **early stage of development** of **innovative/emerging medicinal products, technologies, methodologies** to get inputs on regulatory and scientific requirements, as well as on other EMA procedures and support tools, to be considered in future plans. **Questions** could be: • Regarding a **general understanding on the future development** in compliance with regulatory requirements, especially when guidelines are lacking or clarification is needed. • Related to **regulatory, technical and scientific concerns**. • Related to **quality, non-clinical, clinical and methodology aspects**.
Who can apply	Any type of Applicant, with a particular emphasis on academic researchers and small and medium-sized enterprises (SMEs).
When to apply	Early stages of development, typically **well in advance of seeking formal scientific advice**. There are no fixed deadlines for the submission of applications and subsequent documents. Please refer to EMA for the application procedure and the required documents.
What to expect	Regulators could: • Provide a general guidance on regulatory or scientific issues to be considered during development. • Provide high level feedback on the overall product development. • Confirm/suggest any appropriate and available guidance (EMA/ICH), concept papers or relevant documents to refer to during product development. • Give an overview of the regulatory applicable framework and suggest other regulatory tools and procedures to be followed during the development. The views expressed in this meeting are the personal opinions of the participating experts. ITF briefing meetings do not substitute any other regulatory procedure (e.g., Scientific Advice, Qualification of Novel Methodology, ATMP classification). Meetings are held virtually (1.5 hour).

EMA Innovation Task Force (ITF) Briefing Meeting	
What to submit	Applicants should complete the ITF briefing meeting request form and send it to ITFsecretrariat@ema.europa.eu Upon requests, EMA may ask Applicants to complete a Briefing Document which should contain: • Background information on the innovative medicine or technology/methodology • Any preliminary data available • Proposed questions/topics for discussion • The Applicant position/vision/plan/strategy on those topics All documents are treated **confidentially**. Please refer to EMA for the application procedure and the required documents.
Output of the procedure	**Meeting minutes** are drafted by the Applicant and revised by EMA experts. The answers provided should be interpreted as a preliminary set of scientific considerations on the information presented.
How to apply	Submit ITF request form to ITFsecretariat@ema.europa.eu. Please refer to EMA for further details.
Fees	Meetings are offered free-of-charge

4. National Scientific/Regulatory Advice

National Scientific/Regulatory Advice	
Scope	National Scientific Advice (SA) provides prospective guidance and direction on the development of **new and existing human medicinal products** to be compliant to the EU scientific and regulatory requirements, in view of a planned future Clinical Trial Application (CTA), Marketing Authorisation Application (MAA) or variation to an existing marketing authorisation (*). For questions related to the **early clinical development stages with a view to support a CTA**, or questions related to the **suitability of the proposed clinical development to support** a national MAA (i.e. **mutual recognition, decentralised**), national SA is the recommended regulatory support tool. **Questions** could be **related to**: regulatory, quality, non-clinical, clinical aspects, and pharmacovigilance. Please refer to NCA for the remit and competence of product/technology/methodology (i.e. medicinal products – human/veterinary; medical devices; Substances of human origin - SOHO, etc)

National Scientific/Regulatory Advice	
	(*) For questions related to the suitability of the proposed clinical development to support a centralised MAA application or a variation to an existing centralised marketing authorisation, EMA SA is the recommended regulatory support tool.
Who can apply	Any Applicant (from pharmaceutical industry to academic researchers and small and medium-sized enterprises (SMEs)).
When to apply	At any stage of development **before the submission of an initial MAA** or later on, during the post-authorisation phase (e.g. at the planning stage of the clinical development **to support the extension of indication**). In particular: • To obtain a competent authority's perspective on specific scientific or regulatory questions related to a medicinal product • When there appears to be **no or insufficient** relevant **detail in EU guidelines or guidance** documents, or in **Pharmacopoeia monographs**, including draft documents or monographs released for consultation when developers propose **to deviate from scientific guidelines** in their development plan • When developers have **limited knowledge** about medicine regulation
What to expect	Regulators provide scientific/regulatory advice by **responding to specific questions** posed by the developer. For each question **a clear position will be provided**, expressing agreement or recommending alternative approaches, based on well justified arguments. A **meeting might be envisaged** to discuss all or part of the submitted questions, to allow regulators to get additional information and/or clarifications regarding the Applicant's position, before providing the final advice. Scientific/regulatory advice can also be provided by writing. In some instances, a follow-up advice might be suggested, if additional data to be generated by the Applicant are deemed necessary to provide a well-informed advice, and/or if changes to the initially proposed development are envisaged. The scientific/regulatory advice procedure **does not constitute a pre-assessment** of the documentation of the medicinal product that may be subject to an application of a clinical trial or a marketing authorisation. Meeting format (meeting/online/in writing) and timelines depend on NCA policy.
What to submit	A Briefing document should be provided including **an overview of the product/technology**, illustrate the **scientific rationale and background**, present and **describe the data** that support the Applicant's development plan. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support. Applicants must **provide clear justification** on their position for each of the questions.

National Scientific/Regulatory Advice	
	All documents are treated **confidentially**. Please refer to NCA for the application procedure and the required documents.
Output of the procedure	Applicant will receive final ***Scientific/regulatory advice report*** (confidential and not published on NCA website) which will include the NCA position to each of the questions submitted within the Briefing document. The SA **is not legally binding** on either NCA/EMA or on the medicine developer regarding any future CTA and MAA for the medicine concerned. However, it would be expected that **any subsequent deviation from the advice provided is justified** in future applications (e.g. CTA, MAA). National SA makes no determination **on whether the benefits of the medicine outweigh the risks**. Applicants are **required to mention any national SA received** in any subsequent regulatory submissions related to the same product in the same therapeutic indication (e.g. SA, CTA, MAA).
How to submit	Please refer to NCA
Fees	Please refer to NCA Reductions may be applicable for certain types of medicines and Applicants.

5. Simultaneous National Scientific Advice (SNSA)

Simultaneous National Scientific Advice (SNSA)	
Scope	Similar to the National Scientific/Regulatory Advice (SA), SNSA provides guidance from **two or three NCAs simultaneously** (one Lead NCA and one/two Participating NCA(s)) for: • Products in early stages of development (*). • Multi-country clinical trials. • Planned marketing authorisation applications to be submitted by MRP/DCP. • Planned worksharing procedures which involve complex variations. *(*) For questions related to the suitability of the proposed clinical development to support a centralised marketing authorisation application (MAA), EMA scientific advice SAWP is the recommended regulatory support tool.* *(*) NCAs participate on an opting-in basis for individual SNSA procedures. Please refer to HMA for the list of participating NCAs.*
Who can apply	Any Applicant (particularly academic researchers and small and medium-sized enterprises (SMEs)).

Simultaneous National Scientific Advice (SNSA)	
When to apply	At any stage of development **before the submission of an initial MAA** or later on, during the post-authorisation phase (e.g. at the planning stage of the clinical development **to support the extension of indication**). It proves most useful when: • There appears to be **no or insufficient** relevant **detail in EU guidelines or guidance** documents, or in **Pharmacopoeia monographs**, including draft documents or monographs released for consultation. • Developers choose **to deviate from scientific guidelines** in their development plan. • Developers have **limited knowledge** about medicine regulation.
What to expect	Regulators from the NCAs selected by the Applicant provide regulatory or scientific advice by **responding to the same set of specific questions** posed by the Applicant. For each question **a clear position will be provided by each NCA**, expressing agreement or recommending alternative approaches, based on well justified arguments. SA could be provided **by writing or meeting,** between the participating NCAs and the Applicant, before providing the final advice. The SA **does not constitute a pre-assessment** of the documentation of the medicinal product that may be subject to CTA or a MAA.
What to submit	An Application Form and a Briefing document. The Briefing document should be provided including **an overview of the product/technology**, illustrating the **scientific rationale and background**, **describing the data** that support the Applicant's development plan. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support. Applicants must **provide clear justification** on their position for each of the questions. All documents are treated **confidentially**. Please refer to HMA for the application procedure and the required documents.
Output of the procedure	The Applicant will receive final ***Scientific/regulatory advice report*** (**confidential and never** published on NCA website) which will include the NCAs position to each of the questions submitted within the Briefing document. The SA **is not legally binding** on either NCAs/EMA or on the medicine developer regarding any future CTA and MAA for the medicine concerned.
How to submit	By email to Lead and participating NCAs copying Coordination Unit at: snsa@fagg-afmps.be.
Fees	Fees are charged by each participating NCA as appropriate.

Simultaneous National Scientific Advice (SNSA)	
	Reductions may be applicable for certain types of medicines and applicants according to each NCA policy. Please refer to NCA

6. EMA Scientific Advice/Protocol Assistance

EMA Scientific Advice/Protocol Assistance - SAWP	
Scope	EMA Scientific advice (SA) provides prospective guidance and direction on the development of **new and existing human medicinal products** to be compliant to the scientific and regulatory requirements for a Marketing Authorisation (MA) in Europe. Protocol assistance (PA) is a scientific advice for medicines that have received an **orphan designation** (that are for the treatment of rare diseases). For questions related to the suitability of the proposed **clinical development to support a centralised Marketing Authorisation Application (MAA) or a variation to an existing centralised MA**, EMA SA/PA is the recommended regulatory support tool. Regulators provide SA by **responding to specific questions** posed by the developer on the development of a particular medicine. **Questions** could be **related to**: quality, non-clinical, clinical and methodological aspects. Please refer to EMA for examples of questions in or out of scope. *(*) For questions related to the early clinical development with a view to support a CTA, or questions related to the suitability of the proposed clinical development to support a national MAA (i.e. mutual recognition, decentralised), national SA is the recommended regulatory support tool.*
Who can apply	Any Applicant (from pharmaceutical industry to academic researchers and small and medium-sized enterprises (SMEs)).
When to apply	At any stage of development, **before the submission of an initial MAA** or later on, during the post-authorisation phase (e.g. at the planning stage of the clinical development **to support the extension of indication**). It proves most useful when: • There appears to be **no or insufficient** relevant **detail in EU guidelines or guidance documents**, or in **Pharmacopoeia monographs**, including draft documents or monographs released for consultation. • Developers choose **to deviate from scientific guidelines** in their development plan. • Developers have **limited knowledge** about medicine regulation.

EMA Scientific Advice/Protocol Assistance - SAWP	
What to expect	EMA delivers SA by **responding to the specific questions** posed by the Applicant. For each question **a clear position will be provided**, expressing agreement or recommending alternative approaches, based on well justified arguments. A **meeting might be envisaged** to discuss all or part of the submitted questions, to allow regulators to get additional information and/or clarifications regarding the Applicant's position, before providing the final advice. In some instances, a follow-up advice might be suggested, if additional data are needed to be generated by the Applicant, and/or are deemed necessary to provide a well-informed advice, and/or if changes the initially proposed development are envisaged. The SA procedure **does not constitute a pre-assessment** of the documentation of the medicinal product that may be subject to CTA or a MAA. A **Pre-submission meeting** can be held, upon request by the Applicant, to better define the application form. The **Final Advice Letter** prepared by the EMA SAWP is adopted by the EMA Committee for Medicinal Products for Human Use (CHMP).
What to submit	A Briefing document should be provided including **an overview of the product/technology**, illustrating the **scientific rationale and background**, **describing the data** that support the Applicant's development plan. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support. Applicants must **provide clear justification** on their position for each of the questions. All documents are treated **confidentially**. Please refer to EMA for the application procedure and the required documents.
Output of the procedure	The Applicant will receive a ***Scientific Advice Letter*** (**confidential and never published** on EMA website) which will include the CHMP position on the recommendation of the SAWP on each of the questions submitted within the Briefing Document. The SA provided **is not legally binding** on EMA or on the medicine developer regarding any future Marketing Authorisation Applications for the medicine concerned. However, it would be expected that **any deviation from the given advice is justified** in any subsequent clinical trial application and marketing authorisation application. EMA SA **in no way concludes on whether the benefits of the medicine outweigh the risks**.

EMA Scientific Advice/Protocol Assistance - SAWP	
	Applicants are **required to mention any SA received** (at both national and European level) in any of the future formal requests related to the same product in the same therapeutic indication (e.g. SA, CTA, MAA).
How to submit	Please refer to EMA for the application procedure and the required documents.
Fees	Fees are required by the EU legislation. Fee reductions and waivers apply for certain types of medicines and Applicants. Please refer to EMA for fee details.

7. EMA Qualification of novel methodologies for medicine development

EMA Qualification of Novel Methodologies for medicine development	
Scope	The EMA Qualification of Novel Methodologies provides a voluntary, scientific pathway to support development, evaluation and regulatory endorsement of innovative methodologies in specific contexts of use to generate evidence for regulatory assessment and decision making related to medicinal products. Qualification advice is based on the assessment on the **rationale and preliminary data** and provides recommendations on the **proposed development** to establish the use of a **defined novel methodology** for a specific purpose in drug development. Qualification opinion is released based on the assessment of data produced and submitted to CHMP on the **acceptability of the use of a defined novel methodology** for a specific purpose in drug development. Examples of innovative drug development methods and tools include e.g. novel biomarkers and novel endpoints, including digital technology- based and Artificial Intelligence-based methods, disease or patients registry to be used as a data source and infrastructure for registry-based studies aimed to provide evidence to support regulatory decision-making, etc. Please refer to EMA for further details. This support option also applies to medicines under the ETF remit with no differences in rules and procedures.
Who can apply	Any Applicant (from pharmaceutical industry to consortia, networks, public/private partnerships, learned societies and pharmaceutical industry, academic researchers and small and medium-sized enterprises).
When to apply	**At any stage of development** of a new methodology to be applied to drug development. In particular, when at least a **scientific rationale and preliminary data** to establish the use of a defined novel methodology for a specific purpose in drug development are available. Please refer to EMA for the application procedure and the required documents.

EMA Qualification of Novel Methodologies for medicine development	
What to submit	The application should be accompanied by a dossier that ideally includes **protocols, study reports and supportive data** to establish the use of a defined novel methodology for a specific purpose in drug development. In this case the procedure may more **likely lead to a Qualification opinion**. In earlier development stages, the dossier may include only **draft protocols and development plans for future studies** to establish the use of a defined novel methodology for a specific purpose and **any data available** so far to support these plans. In this case, the procedure will more **likely lead to a Qualification advice**. Reports of initial informal discussion at EMA or international level shall be submitted as supportive appendices. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support. Applicants must **provide clear justification** on their position for each of the questions. All documents submitted in Qualification advice are treated with the **confidentially**. Please refer to EMA for the required documents.
What to expect	Regulators will provide a **clear guidance for each of the questions** submitted by the Applicant. A **discussion** with the Applicant will take place in a closing door meeting in the framework of the SAWP plenary meeting.
Output of the procedure	At the end of the review procedure, the SAWP will recommend whether the procedure will be eligible for a qualification opinion or a qualification advice and will forward the outcome to the CHMP. The **CHMP** will discuss and **adopt the qualification advice for future studies or discuss the qualification opinion as appropriate**. In case of Qualification opinion, the draft document will be released for **6 weeks of public consultation** on the EMA website in order to ensure that the views of the wider scientific community are duly reflected in the final Qualification opinion. When the data package is deemed immature for a Qualification opinion, a CHMP Qualification advice is released on future protocols and studies to be further performed for qualification purposes (confidential document). Based on the Qualification advice a **letter of support** may be proposed by EMA as an option, when the novel methodology under evaluation cannot yet be qualified but is shown to be promising based on preliminary data. This letter includes a high-level summary of the novel methodology, context of use, available data and on-going/future investigations. Letters of support will be made publicly available on the EMA website subject to the Applicant's agreement. The objective of the Letter of support is to encourage the efforts for data sharing and facilitate studies towards qualification for the novel methodology under evaluation.

EMA Qualification of Novel Methodologies for medicine development	
How to submit	Please refer to EMA for the application procedure and the required documents.
Fees	Fees are required by the EU legislation. Reductions apply for certain types of medicines and Applicants. Please refer to EMA for fee details.

8. EMA Emergency Task Force (ETF) Scientific Advice

EMA Emergency Task Force Scientific Advice	
Scope	EMA ETF Scientific advice (SA)provides prospective guidance and direction on the development of **new and existing human medicines**, including vaccines, targeting selected pathogens and threats with the potential to cause a public health emergencies (e.g. COVID-19) or public health threats (e.g. Antimicrobial Resistance - AMR) to be compliant to the scientific and regulatory requirements for a Marketing Authorisation in Europe. (*) EMA ETF SA-CTA is special type of SA given by the ETF, which provides advice on scientific aspects of clinical trials aiming to clarify both clinical trial and marketing authorisation requirements via the increased collaboration between the ETF, EU clinical trials units, Clinical Trial Coordination Group (CTCG) and experts of the Public Health Emergency Ethics Advisory Group (PHE EAG). Please refer to EMA website for further details. Regulators provide SA by **responding to specific questions** posed by the developer on the development of a particular medicine. **Questions** could be **related to**: quality, non-clinical, clinical and methodological aspects, clinical trials applications. ETF does also engage in early dialogue, also referred to as preliminary discussions, providing developers feedback on medicine development under ETF remit. Please refer to EMA website for further details. Please refer to EMA ETF workplan (Annex 1) for a full list of human medicines under ETF remit. *(*) Human medicines not under ETF remit: for questions related to the suitability of the proposed clinical development to support a centralised marketing authorisation application or a variation to an existing centralised marketing authorisation, EMA scientific advice/protocol assistance – SAWP- is the recommended regulatory support tool.*
Who can apply	Any Applicant (from pharmaceutical industry to academic researchers and small and medium-sized enterprises). Applicants who are planning to conduct CTs in any specific EU Member States are additionally eligible to apply to the ETF SA-CTA.

EMA Emergency Task Force Scientific Advice	
When to apply	At any stage of development, **before the submission of an initial Marketing Authorisation Application** or later on, during the post-authorisation phase (e.g. at the planning stage of the clinical development **to support the extension of indication**). It proves most useful when: • There appears to be **no or insufficient** relevant **detail in EU guidelines or guidance documents**, or in **Pharmacopoeia monographs**, including draft documents or monographs released for consultation. • Developers choose **to deviate from scientific guidelines** in their development plan. • Developers have **limited knowledge** about medicine regulation.
What to expect	EMA delivers SA by **responding to the specific questions** posed by the Applicant. For each question **a clear position will be provided**, expressing agreement or recommending alternative approaches, based on well justified arguments. A **meeting might be envisaged** to discuss all or part of the submitted questions, to allow regulators to get additional information and/or clarifications regarding the Applicant's position, before providing the final advice. In some instances, further advice might be suggested, if additional data are needed to be generated by the Applicant, and/or are deemed necessary to provide a well-informed advice, and/or if changes the initially proposed development are envisaged. The SA advice procedure **does not constitute a pre-assessment** of the documentation of the medicinal product that may be subject to an application of a clinical trial or a marketing authorisation. A **Pre-submission meeting** can be held, upon request by the Applicant, to better define the application form. The **Final Advice Letter** prepared by the EMA ETF is adopted by the **CHMP**.
What to submit	A Briefing document should be provided including **an overview of the product/technology**, illustrating the **scientific rationale and background**, **describing the data** that support the Applicant's development plan. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support. Applicants must **provide clear justification** on their position for each of the questions. To trigger the start of the ETF's SA-CTA procedure, relevant information is requested to be provided in the IRIS application form and in the submission notes section of the application form. All documents are treated **confidentially**.

EMA Emergency Task Force Scientific Advice	
	SA applications in the remit and assessed specifically by the ETF follows the same process and timelines as for SAWP. Please refer to ETF SA webpage (Scientific advice for public health emergencies and threats | European Medicines Agency (EMA) and to the Guidance for Applicants for further details specifically on the ETF SA-CTA.
Output of the procedure	The Applicant will receive a ***Scientific Advice Letter*** (**confidential and never published** on EMA website) which will include the CHMP position on the recommendation of the ETF on each of the questions submitted within the Briefing Document. The views expressed by the Ethics experts who are part of the PHE EAG are solely those of the experts and do not represent the views of the Ethics Committees they are affiliated with. The SA provided **is not legally binding** on EMA or on the medicine developer regarding any future MAA for the medicine concerned. However, it would be expected that **any deviation from the given advice is justified** in any subsequent CTA and MAA. EMA SA **in no way concludes on whether the benefits of the medicine outweigh the risks**. Applicants are **required to mention any SA received** (at both national and European level) in any of the future formal requests related to the same product in the same therapeutic indication (e.g. SA, CTA,MAA).
How to submit	Please refer to general EMA guidance on how to submit SA applications (Scientific advice and protocol assistance | European Medicines Agency (EMA)) for the application procedure and the required documents. Additionally, refer to the Guidance for Applicant for additional requirements for the ETF SA. For technical information on how to prepare your dossier for a SA please contact scientificadvice@ema.europa.eu. To discuss the regulatory support route for your medicine under the ETF remit, please contact PHEearlyinteractions@ema.europa.eu
Fees	Fees are required by the EU legislation. Fee reductions and waivers apply for certain types of medicines and Applicants. Please refer to EMA for fee details.

9. ACT EU pilots on consolidated advice on clinical trials

ACT EU pilot SAWP/CTCG	
Scope	The SAWP/CTCG pilot provides advice on scientific aspects of clinical trials aiming to clarify both clinical trial (CTA) and marketing authorisation (MAA) application (or extension of indication application) requirements via the increased collaboration between the EMA SAWP, NCAs via the Clinical Trials Coordination Group (CTCG).

ACT EU pilot SAWP/CTCG	
	SAWP and NCA Clinical Trial Units involved in a CTA provide scientific advice by **responding to specific questions** posed by the Applicant on the development of a particular medicine. Please refer to the ACT EU the guidance for Applicants for further details.
Who can apply	Any Applicant (from pharmaceutical industry to academic researchers and small and medium-sized enterprises).
When to apply	At any stage of development, **before the submission of a CTA or a Substantial Modification Application and before an initial MAA** or later on, during the post-authorisation phase (e.g. at the planning stage of the clinical development **to support the extension of indication**). Submission of a mature protocol is preferred. It proves most useful when: • There appears to be **no or insufficient** relevant **detail about the product under development in EU guidelines or guidance documents**, or in **Pharmacopoeia monographs**, including draft documents or monographs released for consultation. • Developers choose **to deviate from scientific guidelines** in their development plan. • Developers have **limited knowledge** about medicine regulation.
What to expect	The SA is provided following evaluation conducted by **the SAWP and CTCG** by **responding to the specific questions** posed by the Applicant. The response includes the position of the clinical trials units in the NCAs on the aspects related to the clinical trial design. For each question **a clear position will be provided**, expressing agreement or recommending alternative approaches, based on justified grounds. A **meeting might be envisaged** to discuss all or part of the submitted questions, to allow regulators to get additional information and/or clarifications regarding the Applicant's position, before providing the final advice. In some instances, a follow-up advice might be suggested, if additional data are needed to be generated by the Applicant, and/or are deemed necessary to provide a well-informed advice, and/or if changes to the initially proposed development are envisaged. The SA procedure **does not constitute a pre-assessment** of the documentation of the medicinal product that may be subject to a CTA or MAA. A **Pre-submission meeting** can be held, upon request by the Applicant, to better define the application form. The **Final Advice Letter** prepared by the EMA SAWP is adopted by the EMA Committee for Medicinal Products for Human Use (**CHMP**).

ACT EU pilot SAWP/CTCG	
What to submit	A Briefing document should be provided including **an overview of the product/technology**, illustrating the **scientific rationale and background**, **describing the data** that support the Applicant's development plan. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support. Applicants must **provide clear justification** on their position for each of the questions. Annex to the Briefing document should include: • An advanced mature CT protocol, if available for the clinical trial in question, or • A draft synopsis of the protocol in the case of more high-level questions concerning the clinical trial. All documents are treated **confidentially**. Procedures and timelines follows the EMA Scientific advice –SAWP. Please refer to EMA for the application procedure and the required documents.
Output of the procedure	The Applicant will receive a **Scientific Advice Letter** (**confidential and never published** on EMA website) which will include the CHMP position on the recommendation of the SAWP and CTCG on each of the questions submitted within the Briefing Document. Any NCA specific comments may also be included. The SA provided **is not legally binding** on EMA or on the medicine developer regarding any future MAA for the medicine concerned. However, it would be expected that **any deviation from the given advice is justified** in any subsequent CTA and MAA. EMA SA **in no way concludes on whether the benefits of the medicine outweigh the risks**. Applicants are **required to mention any SA received** (at both national and European level) in any of the future formal requests related to the same product in the same therapeutic indication (e.g. SA, CTA, MAA).
How to submit	To request participation in the SAWP/CTCG pilot, relevant information should be provided to the submission notes section in the IRIS application. There is no need to list different sets of questions in the briefing document. Please refer to EMA for the application procedure and the required documents. Please refer to Requesting scientific advice or protocol assistance from EMA | European Medicines Agency (europa.eu).
Fees	No additional costs will be charged to the Applicant for requesting a SAWP/CTCG scientific advice other than what is required by the EU legislation for EMA SA. Fee reductions and waivers apply for certain types of medicines and Applicants. Please refer to EMA for fee details.

ACT EU pilot_Pre-CTA	
Scope	The Pre-CTA advice pilot addresses **regulatory and technical questions** providing consolidated technical and regulatory advice related to the submission of a **Clinical Trial Application** (CTA) to the Clinical Trial Information System (CTIS) under European Regulation (EU) No 536/2014. The aim is to **improve the quality of the CTA** and **reduce the risk of divergent views** among the Member States concerned due to differing national approaches. Regulators involved in the pilot are NCA assessors. The pilot project is **coordinated by CTCG.** The Pre-CTA pilot does not replace the existing procedures provided by EU regulators for Medicines for Human Use. Please refer to the guidance for Applicants for further details.
Who can apply	Any Applicant, with a particular emphasis on academic researchers and small and medium-sized enterprises (SMEs).
When to apply	At any stage of development **before the submission of a CTA.** These criteria will need to be satisfied in order to be considered as a possible pilot case: • Only (up to 5) regulatory and technical questions are allowed for each Pre-CTA advice request. • The Applicant should already have an almost mature protocol. • The Applicant should know the proposed Reporting MS for the future CT application in CTIS.
What to expect	Regulators from the NCAs CT units selected by the Applicant provide regulatory advice by **responding to the same set of specific questions** posed by the Applicant. For each question **a clear consolidate position will be provided by all the NCAs of the MSC identified by the Applicant**, expressing agreement or recommending alternative approaches, based on well justified arguments. The regulatory/technical advice will be provided solely **by writing**. The Pre-CTA advice **does not constitute a pre-assessment** of the documentation of the medicinal product that may be subject to CTA or a MAA.
What to submit	Please use the application form available on HMA and ACT EU websites, ticking the box indicating that the request refers to a Pre-CTA advice. Please add the following information: • Request to be admitted to the Pre-CTA advice pilot. • The proposed Reporting Member State (RMS) for the application. Where applicable provide the Trial reference number.

ACT EU pilot_Pre-CTA	
	• The proposed MSCs for the application. A **cover letter** including as much information as possible about the advice request is recommended. Questions and the Applicant's position should be clearly indicated in a dedicated document that includes all relevant information. Please also submit any additional documents you consider relevant for the advice. Sponsors/Applicants are recommended to review the list of MS participating and their roles. Please ensure that the proposed RMS can take the role of Lead-MS in the Pre-CTA advice.
Output of the procedure	The Applicant will receive a **Pre-CTA advice letter** which will include the **opinion of the RMS and the MSCs** on the questions raised by the Applicant. The Pre-CTA advice **is not legally binding** on EMA or on the medicine developer regarding any future MAA for the medicine concerned. However, it would be expected that **any deviation from the given advice is justified** in any subsequent clinical trial application and marketing authorisation application.
How to submit	For the Pre-CTA advice pilot, you can apply through the Specific National Scientific Advice (SNSA) entry point via a dedicated email address SNSA@fagg-afmps.be
Fees	Fees are required only for the Lead-MS according to national requirements and procedures. Fee reductions and waivers might apply for certain types of Applicant depending on the national requirements. Please refer to NCA.

10. EMA Academia Briefing Meeting

EMA Academia Briefing Meeting	
Scope	**Earliest entry point** for researchers and developers from the **academic sector.** The meetings provide a mutual exchange to discuss **challenges** encountered by researchers in the research or development activities, to advance understanding on regulatory aspects and R&D, with a view to inform regulatory strategy and to engage on regulatory science research needs. **Exchange and discussion** could aim: • At familiarising researchers with the different regulatory pathways and incentives available for their developments. • At acquainting EMA staff with latest research activities and challenges. • At exchanging information and views on topics mutually relevant. ** EMA's potential involvement in externally funded research projects take place under the form of Collaboration Management Meetings*.
Who can apply	Researchers and developers from the academic and Non-For-Profit sector (consortia, public-private partnerships, and public-public partnerships).

EMA Academia Briefing Meeting	
When to apply	At any moment of the medicines or tools for medicines development.
What to expect	Regulators could offer: • Insights into related issues experiences. • Exploration of researchers' needs and suggestions for researchers to consider e.g., in terms of regulatory strategy. • Discussion on high-level aspects of the research project, involved disciplines, scientific plan, quality, non-clinical, clinical studies or other regulatory science research aspects. • Discussion and suggestion on regulatory pathways to consider, support offerings available for academic researchers, and fee reductions and other incentives. • Support in preparing and using Scientific Advice, Qualification Advice, Orphan Designation and other regulatory services. • Discussion of potential collaboration opportunities. Meetings are held virtually (1 hour) with EMA experts.
What to submit	A brief presentation about development or research project including questions. Questions raised to regulators should **be concrete** in order to allow regulators to give useful indication and support during discussion. No Briefing document is requested.
Output of the procedure	**Meeting report** are drafted by the Applicant and revised by EMA experts. The answers provided should be interpreted as a preliminary set of scientific considerations on the information presented.
How to apply	By email to academia@ema.europa.eu Please refer to EMA for further details.
Fees	Meetings are offered free of charge.

11. EMA PRIME (Priority Medicines) Scheme

EMA PRIME (Priority Medicines) Scheme	
Scope	Voluntary scheme by EMA to support and optimise the development of medicines not yet authorised in the EU and targeting an unmet medical need (i.e., for which no treatment option exists, or where they can offer a major therapeutic advantage over existing treatments). The scheme is based on the existing regulatory framework and tools, enhances interaction and early dialogue with developers, and foresees an accelerated assessment at the time of application for a marketing authorisation. The access to PRIME scheme is granted upon evaluation of a PRIME eligibility request. Please refer to EMA for further details
Who can apply	Any Applicant (from pharmaceutical industry to academic researchers and small and medium-sized enterprises (SMEs)).
When to apply	At **exploratory clinical trial phase** of development, based on the availability of **preliminary clinical evidence** to demonstrate the promising activity of the medicine and its potential to address to a significant extent an unmet medical need**, or proof of concept.** Applicants from academia and SMEs may submit an eligibility request for **Early Entry PRIME status** if: • Compelling non-clinical data in a relevant model provide early evidence of promising activity, or **proof of principle.** • First-in-human studies indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability.
What to submit	In the PRIME eligibility request, Applicant must provide any available data showing a **meaningful improvement of clinical outcomes**, such as: • Impacting the prevention, onset and duration of a given condition. • Improving the morbidity or mortality of a disease.
What to expect	All developers of products granted PRIME eligibility benefit from the following: • Early appointment of a Rapporteur from the appropriate EMA committee (CHMP or CAT). • Dedicated EMA contact point (PRIME scientific coordinator). • Dedicated meeting with the Rapporteur and a multidisciplinary group of experts from EMA/ERMN experts to provide guidance on the development plan and regulatory strategy ('kick off meeting'). • Iterative scientific advice on overall development plans involving other stakeholders such as HTA bodies, patients and FDA.

EMA PRIME (Priority Medicines) Scheme	
	• Submission readiness meeting approximately one year before the Marketing Authorisation Application submission date to discuss development status and maturity of the dossier, post-marketing evidence-generation and potential regulatory challenges. • Confirmation of the potential for accelerated assessment at the time of an application for marketing authorisation. • A dedicated toolbox to support the quality data package development. • Fee exemption for scientific advice to Applicants from academia and SMEs.
Output of the procedure	At the end of the review procedure, the SAWP will recommend whether the procedure will be eligible for the PRIME scheme. The CHMP will discuss and adopt the eligibility request. Applicant will receive the **evaluation outcomes**, via letter, following their adoption by CHMP. The information is also published in the annexes of the monthly CHMP highlights. Only for products deemed eligible to PRIME, CHMP makes public the name of the active substance/international non-proprietary name (INN), substance type, therapeutic area, therapeutic indication, type of data supporting request, type of Applicant.
How to submit	Through EMA online **IRIS platform**, once completed the registration step. Please refer to EMA for the application procedure and the required documents. Please refer to the relevant Guidance on EMA website
Fees	No fee for the request submission.

12. EMA SME Briefing Meeting

EMA SME Briefing Meeting	
Scope	An informal platform for early dialogue between small and medium-sized enterprises (SMEs) and a multidisciplinary team from the EMA. The meeting aims to discuss the regulatory strategy for the development and authorisation of a medicinal product and to provide information on relevant procedures, support tools, guidance and incentives.
Who can apply	SME registered with EMA. Please refer to guidance on EMA SME registration.
When to apply	Usually at the early stages of a product development, but may also take place in later stages. For medicinal products to be submitted via the centralised procedure to EMA.
What to submit	A briefing document and/or Power Point presentation which includes: • Product details • An overview of the planned development programme.

EMA SME Briefing Meeting	
	• Specific questions or discussion topics, each accompanied by relevant background information and the Applicant's proposed position.
What to expect	EMA representatives: • Offer **general and specific guidance on requirements** for a development programme intended to support a marketing authorisation application. • Highlight **available tools** (e.g. PRIME, Scientific Advice) and relevant **guidance** to support a product development and authorisation. • Discuss regulatory considerations such as eligibility and legal basis for a MAA, data exclusivity and marketing protection including those related to orphan and paediatric authorisations.
Output of the procedure	**Meeting minutes**, drafted by the Applicant and reviewed by EMA. The views expressed during the meeting represent the opinions of participating EMA attendees and may not necessarily reflect those of EMA's scientific committees or working parties.
How to submit	By email to: SME@ema.europa.eu
Fees	Meetings are free-of-charge.

13. EMA Quality Innovation Group (QIG)

EMA Quality Innovation Group 1-to-1 meetings	
Scope	**An informal entry point** to **discuss and identify solutions on potential regulatory, technical, and/or scientific challenges** regarding the implementation of innovative pharmaceutical manufacturing approaches to the design, manufacture and quality control of medicinal products. Developers can also discuss to request a scientific advice on topics under the QIG remit. Please refer to EMA for further details.
Who can apply	Any Applicant (from pharmaceutical industry to consortia, academic researchers, public/private partnerships, learned societies, equipment manufacturers and small and medium-sized enterprises).
When to apply	At any stage of development before the submission of an initial Marketing Authorisation Application, typically **well in advance of seeking formal scientific advice,** and during the post-authorisation phase.
What to submit	A request should be submitted by email, including the following information: • Short summary of the advanced manufacturing technology in development. • Scientific and regulatory challenges they are facing. • Proposed solutions to these challenges for discussion with the group.

EMA Quality Innovation Group 1-to-1 meetings	
	Once the request is accepted by the QIG, a Briefing document and any supporting materials must be submitted. All documents are treated **confidentially.** There are no fixed deadlines for the submission of the request. Please refer to EMA for the required documents.
What to expect	The QIG members (quality assessors of chemical or biological medicines, or good manufacturing practice (GMP) inspectors) could: • Clarify the regulatory requirements for manufacturing and control. • Provide a general guidance on regulatory or scientific issues to be considered during development. • Provide high level feedback on the overall product development. • Contribute to the assessment of procedures that include these new technologies. • Identify new technologies expected to impact regulatory decision making in the medium to long term. • Confirm/suggest any appropriate and available guidance (EMA/ICH), concept papers or relevant documents to refer to during product development. • Provide an overview of the regulatory applicable framework and suggest other regulatory tools and procedures to be followed during the development. On an exceptional basis, **individual meetings may occasionally include site visits** (virtually or on-site) when these are relevant for reviewing the technology. Meetings are held virtually (1.5 – 2 hour).
Output of the procedure	**Meeting minutes** are drafted by the Applicant and revised by QIG members and any additional experts participating at the meeting. The views expressed in this meeting are the personal opinions of the participating experts. QIG 1:1 meeting do not substitute any other regulatory procedure (e.g., Scientific Advice, Qualification of Novel Methodology, ATMP classification).
How to submit	Submit requests to qig@ema.europa.eu
Fees	Meetings are offered free-of-charge.

14. Links

EMA Glossary

https://www.ema.europa.eu/en/about-us/glossaries/glossary-regulatory-terms

NCA Innovation Offices contacts

https://www.ema.europa.eu/en/documents/other/national-innovation-offices-contacts_en.pdf

NCA list of contacts for national scientific advice

National Scientific Advice Contacts

NCA websites

https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

EMA ITF briefing meeting

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/innovation-task-force-briefing-meetings

EMA Research & development webpage

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

EMA SME Office

Support to SMEs | European Medicines Agency (EMA)

EMA Academia webpage

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

EMA Scientific Guidelines

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

EMA's brochure 'From laboratory to patient'

https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorised-medicine_en.pdf

EMA SAWP

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

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance/requesting-scientific-advice-or-protocol-assistance-ema

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-advice-protocol-assistance#types-of-questions-addressed-11152

EMA Fees webpage

https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency

ACT-EU

https://accelerating-clinical-trials.europa.eu/document/download/d0b4538a-3936-49a2-a43e-e7bcf09f9aea_en?filename=science-advice-medicines-human-use-eu-medicines-regulatory-network_en.pdf

QIG

https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp-working-parties-other-groups/quality-innovation-group

15. List of acronyms

ACT-EU: Accelerating Clinical Trials in the European Union

ATMP: Advanced Therapy Medicinal Products

CAT: Committee for Advanced Therapies

CHMP: Committee for Medicinal Products for Human Use

CT: Clinical Trial

CTA: Clinical Trial Application

CTCG: Clinical Trial Coordination Group

EMA: European Medicines Agency

EMRN: European Medicines Regulatory Network

ETF: Emergency Task Force

ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

IM: Innovation Meeting

ITF: Innovation Task Force

MAA: Marketing Authorisation Application

MSC: Member State Committee

NCA: National Competent Authority

PA: Protocol Assistance

PHE EAG: Public Health Emergency Ethics Advisory Group

QA: Qualification Advice

QIG: Quality Innovation Group

QO: Qualification Opinion

QoNM: Qualification of Novel Methodologies

RMS: Reporting Member State

R&D: research and development

SA: Scientific Advice

SAWP: Scientific Advice Working Party

SMEs: Small and Medium-Sized Enterprises

SNSA: Simultaneous National Scientific Advice

SOHO: Substances of Human Origin