12 November 2025
EMA/47386/2025

# Guidance for applicants: the ETF scientific advice that facilitates clinical trial authorisations (SA-CTA)

## Table of Contents




**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

# 1. What is SA-CTA scientific advice?

It is a type of scientific advice (SA) offered in the context of the European Medicine Agency's (EMA) Emergency Task Force (ETF) mandate as set out in article 16 of Regulation (EU) 2022/123. The aim is to foster harmonisation of scientific advice provided by EU regulatory authorities responsible for either medicines authorisation or clinical trial authorisation (CTA). This type of SA is called SA-CTA throughout this document.

The SA-CTA includes **advice on scientific aspects of clinical trials** and aims to clarify requirements for both clinical trial and marketing authorization applications (or extension of indication applications) via increased collaboration between the ETF, the Clinical Trial Coordination Group (CTCG), Member States (MSs) and National Competent Authorities (NCAs) as well as a newly created group of ethics experts (Public Health Emergency Ethics Advisory Group, PHE EAG). The PHE EAG was set-up under the ACT EU initiative on clinical trials in public health emergencies with the help of MedEthicsEU. One of the main roles of the PHE EAG is to contribute to ETF activities related to clinical trials, including involvement in ETF SA-CTA assessment.

The ETF is responsible for assessing SA applications for medicines addressing declared public health emergencies. During interpandemic periods, the remit of the ETF is confined to assessing SA applications pertaining to specific pathogens and health threats with pandemic potential, which are listed in Annex 1 of the ETF workplan. Any other SA application is assessed by the Scientific Advice Working Party (SAWP). Both ETF and SAWP are empowered to conduct such assessments on behalf of the CHMP, which is responsible for issuing the final advice letter to applicants on the basis of the groups' recommendations in their own remit.

# 2. How many avenues are there for seeking scientific advice?

There are multiple avenues for seeking scientific advice in the EU Medicines Regulatory Network (EMRN). It is suggested that applicants consult the **mapped information** on voluntary procedures available within the EMRN (Advice on medicines for Human use in the EU medicines regulatory network) depending on the topic and the legal remit of advice bodies. Two of these procedures are offered by the EMA's SAWP and ETF.

The SAWP/CTCG SA was initially set up as a pilot under the ACT EU programme which, depending on the outcome, may evolve into a formal procedure. It has been designed to enable consolidated advice on the scientific aspects of clinical trials through enhanced collaboration between the EMA's SAWP/ Committee for Medicinal Products for Human Use (CHMP) and the HMA's CTCG.

The ETF's SA-CTA is a formal scientific advice procedure building on previous experience with interactions with the CTCG, and it is expected to undergo rounds of improvements as experience is gathered. The SAWP/CTCG SA pilot and the ETF's SA-CTA are broadly aligned in scope and principles.

# 3. What are the main features of SA-CTA procedure? How will collaborations be enhanced within the EMRN to consolidate advice?

To apply for an ETF SA-CTA, the sponsor/applicant should follow the usual EMA SA route of submission. The validation phase too remains the same as in standard SA procedures. The SA application form in IRIS has been updated to include information on whether advice on clinical trial(s) applications is sought and, if yes, in which EU MS(s) said trial(s) is/are planned to be conducted. This

is a critical step that will trigger the SA-CTA and the involvement of the specific experts from the start of the procedure. For the time being, the SA-CTA procedures shall only apply to clinical trials planned to be conducted in the EU/EEA. Moreover, in the submission notes section of the application form, the sponsor/applicant must indicate the Member States Concerned (MSCs) that will be part of the Clinical Trial Application (CTA), and the proposed Reporting Member State (RMS) according to the Clinical Trial Regulation (CTR). See question n.5 for more details.

The ETF coordinators will be appointed preferentially among the members corresponding to the RMS and/or one of the identified MSCs and will be responsible for assessing the marketing authorisation-related questions. An assessor representative of the RMS, and/or one of the MSCs, will lead the assessment of clinical trial related questions and will directly interact with the ETF coordinators. The views of the PHE EAG will also be captured and included in the assessment report(s) as applicable. The assessment of clinical trial aspects from the RMS/MSCs and the PHE EAG experts will firstly be shared with the rest of the MSCs and the ETF coordinators via the so-called Assessors' Roundtable (see below).

Afterwards, the two first reports will be discussed with the full ETF and subsequently integrated into the final report submitted to the CHMP. Exchanges within the ETF plenary meeting, including Clinical Trial Assessors and CTCG members as well as the PHE EAG contribute to the consolidation of the final advice.

See Annex 1 for a Process flow of the SA-CTA procedure.

In the context of the SA-CTA, the Assessors' Roundtable meeting (ART) serves as a forum for exchange and communication between clinical trial unit assessors from the MSCs and the coordinators of the ETF, similar to the SAWP/CTCG SA. Established by the CTCG, ART facilitates discussions among assessors from different NCAs on clinical trial-related topics.

The representatives of the RMS/MSCs responsible for the assessment of SA-CTA's questions on clinical trials are clinical trials experts identified at national level within the CTCG. The ethics experts that will be involved in the SA-CTA are part of the PHE EAG described under question 1 above.

## 4. What are the criteria to apply for the SA-CTA scientific advice procedure?

The only criterion that needs to be met to apply for the ETF's SA-CTA is that the clinical trial is conducted in the EU/EEA and its scope falls within the ETF remit.

Moreover, it is important for the advice to be meaningful that the proposed RMS and MSCs are identified by the Applicant in the cover letter. Ideally, a mature protocol of the clinical trial should be available.

### *Out of scope of SA-CTA*

- Cases falling under the SAWP/CTCG pilot;
- Regulatory or technical questions in preparation for a CTA, which are better suited for the pre-CTA CTCG pilot;
- Pre-assessment of data to support a Marketing Authorisation Application (MAA) or a clinical trial application.

### *Who should I contact for further information on ETF SA-CTA*

For technical or content questions on the preparation of the dossier, please write to scientificadvice@ema.europa.eu

For general questions on the role of the ETF or to discuss a broader strategy ahead of a SA application with the EMA Department of Public Health Threats, please contact PHEearlyinteractions@ema.europa.eu

## 5. How do I apply for the SA-CTA procedure?

Applications should be submitted through the IRIS portal as a single point of contact for applicants; see Requesting scientific advice or protocol assistance from EMA | European Medicines Agency (europa.eu). SA applications intended for either SAWP or ETF are submitted through the same route and follow the same principles.

To direct a SA application to ETF and 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. There is no need to list different sets of questions in the briefing document to the RMS/MSCs or EAG experts. The questions will be looked at in a joint manner as needed and appropriate.

Please add the following information to the **submission notes section** in the IRIS application:

- The proposed RMS of <Trial reference number > is < >;
- The proposed MSCs of <Trial reference number > are < ..> etc.;

Please also complete all the relevant information in the IRIS **procedural information section** relating to clinical trial section (EUDRACT/CTIS number, planned countries).

Please also ensure the following documents are uploaded in the Scientific advice briefing document dossier as an **annex:**

- **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.

The **usual CHMP scientific advice procedure briefing document template** and **submission deadlines** apply. Applicants can also consult the general guidance for scientific advice.

## 6. Which MSs are participating in the SA-CTA?

The assessment of the CTA related questions will be led by one of the MSC (RMS, where known, or Lead-MS) but all the other MSCs will be contributing to it. The MS proposed by the sponsor as the RMS of the future CTA is the best candidate to take the role of Lead-MS. However, depending on the availability of the various teams of assessors, the role of Lead-MS may be taken by another MSC or by one of the CTCG representatives within the ETF. The ART meeting will be held systematically to ensure alignment of views across MSCs and ETF coordinators.

The assessment of all the other questions related to the marketing authorisation aspects will be coordinated by the ETF members who volunteer to be assigned to the assessment as per standard practice.

The views of the ethics experts will be conveyed as a group's view, following the lead assessment of one of the PHE EAG members who will be appointed from the MCSs, where possible. Ethics experts can join the PHE EAG on a voluntary basis and started with 13 experts from 11 MSs. The exact composition may change overtime.

## 7. What is the duration of the SA-CTA procedure?

The SA-CTA follows the standard ETF and SAWP procedures, including the timelines. Please see the

information on the EMA website (Scientific advice and protocol assistance | European Medicines Agency (EMA) (europa.eu)). No timeline extension is needed for the SA-CTA procedure. The timeline is depicted in Figure 1. Even if ETF does not follow monthly meetings occurrence, differently to SAWP, its SA procedures follow the SAWP meetings timeline as stated in figure 1, for convenience of both Applicants and assessors.

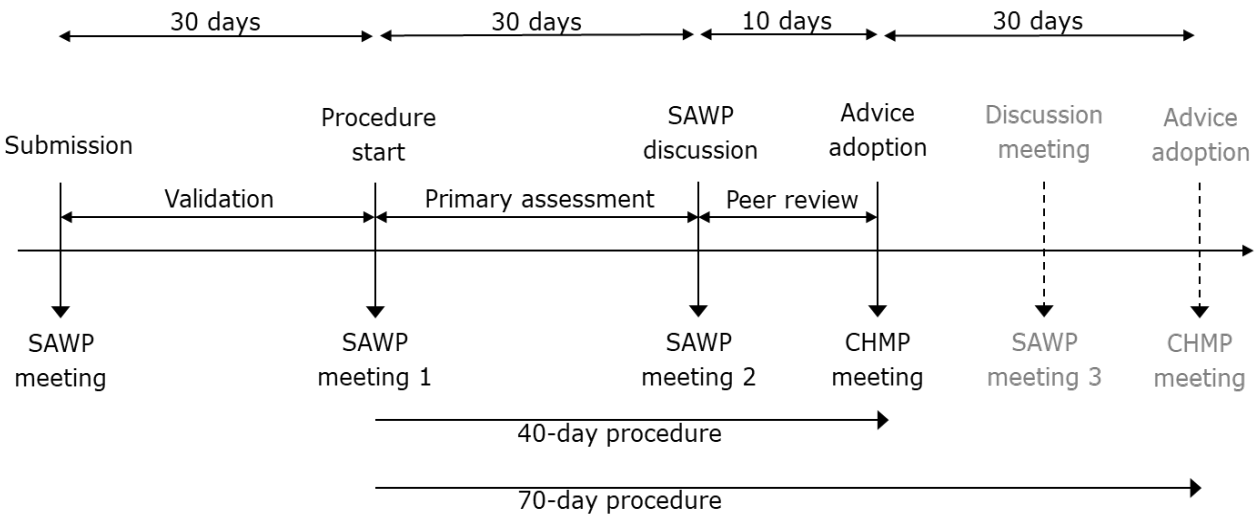


**Figure 1. Description of the normal SAWP/ETF scientific advice procedure and timeline.**

For high level details of process flow of the components of the SA-CTA procedure, see Annex 1.

## 8. Which committees will be involved, and which other interactions will take place for a SA-CTA procedure?

Relevant EU regulatory groups are represented in the core ETF composition, including representatives from HCPs and patients' groups. Therefore, no specific additional interactions are foreseen by default. For instance, for questions on paediatric clinical trials, the Paediatric Committee (PDCO) has representatives in the ETF, who will be engaged in the SA-CTA discussions. However, ad hoc consultations with specific groups such as the Non-Clinical Working Party (NcWP) or the Methodological Working Party (MWP) will be considered where necessary.

## 9. What is the outcome of a SA-CTA procedure?

At the end of the procedure, sponsors/applicants receive a SA letter with the consolidated scientific content. The responses or comments from CT experts and PHE EAG experts will be included under each relevant questions in addition to the responses related to MAA. The 'Other Comments' section of the letter may include any additional MS comments.

As for any CHMP scientific advice, this Scientific Advice is not legally binding. Applicants should, however, justify any divergence from the advice received in case of subsequent submission of a formal CTA and MAA.

The Scientific Advice does not constitute a pre-assessment of the data for clinical trial application or marketing authorisation application in the EU.

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.

## 10. How many procedures are foreseen?

The ETF endeavours to accept and assess all the applications which will be submitted under its remit. Depending on the number of applications and the available capacity, further information may be provided to applicants.

## 11. What fees will I have to pay?

The scientific advice fees and fee incentives already established for the standard SA procedures apply to the SA-CTA procedures as well. No additional costs will be charged to the Applicant for requesting a SA-CTA scientific advice.

## 12. How can I be assured that the information is kept confidential?

As for standard CHMP scientific advice, normal principles of confidentiality and handling of competing interests apply.

## 13. What are the deliverables and what is the measure of success of the SA-CTA?

The outcome of an ETF's SA-CTA procedure will be a final advice letter. The aim of the procedure is to provide a single consolidated opinion, thus promoting harmonisation of scientific expectations between different MSs, with the possibility of achieving greater consistency in the interpretation and application of scientific requirements for the CTA and for the MAA.

The applicants who will apply to the ETF SA-CTA during the first year since implementation will receive a questionnaire upon completion of the SA procedure regarding the more immediate benefits of the procedure and of the perceived downstream benefits. This feedback will help the evaluation of the new process and the need for any improvement. Long term feedback on the outcome of the CTA and the MAA will be also requested.

# 14. Annex 1

Process flow for ETF SA-CTA procedure.