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Guidance for applicants: SAWP CTCG pilot on scientific advice

ACT EU priority action on consolidated advice

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1. What is the SAWP-CTCG pilot?

The SAWP-CTCG pilot is a scientific advice pilot offered as part of the ACT-EU priority action on consolidated advice. The pilot provides **advice on scientific aspects of clinical trials** aiming to clarify both clinical trial and marketing authorization application (or extension of indication application) requirements via the increased collaboration between the European Medicine Agency's (EMA) Scientific Advice Working Party (SAWP) and the Clinical Trial Coordination Group (CTCG), Member States (MS) and National Competent Authorities (NCA).

The pilot enhances coordination of advice activities on clinical trials and development program design within the European Medicines Regulatory Network (EMRN), to facilitate the development of safe and effective medicines for human use.

2. What are the main features of SAWP/CTCG procedure? How will collaborations be enhanced within the EMRN to consolidate advice? - *updated*

There are multiple avenues for seeking scientific advice in the 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 medicinesregulatory network (europa.eu)) depending on the topic and the legal remit of advice bodies.

The SAWP/CTCG pilot is a **scientific** advice pilot 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 Member States' CTCG.

To apply for participation in the SAWP/CTCG pilot project, the sponsor/applicant must follow the formal SAWP procedure by requesting the involvement of the CTCG in the assessment. Only one procedure per month will be selected for the pilot. The sponsor/applicant must indicate which are the Member States Concerned (MSCs) that will be part of the Clinical Trial Application (CTA), and which is the proposed Reporting Member State (RMS) according to the Clinical Trial Regulation (CTR).

The RMS, or one of the MSC, will lead the assessment of clinical trial design-related questions by directly interacting with the SAWP delegate from their MS. This delegate will be one of the two SAWP coordinators (these two are members of the SAWP, appointed as coordinators, who have sound expertise to address the scientific questions). The assessment of clinical trial aspects from the RMS firstly will be shared with the rest of the MSCs and the other SAWP Coordinator. Afterwards, it will be shared with the full SAWP and subsequently integrated into the final report submitted to the CHMP.

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 SAWP/CTCG. Established by the CTCG, ART facilitates discussions among assessors from different NCAs on clinical trial-related topics.

Additionally, further exchanges within the SAWP plenary meeting, including Clinical Trial Assessors, contribute to the consolidation of the final advice.

3. What are the criteria to apply for the SAWP-CTCG pilot scientific advice procedure?

3.1. Essential criteria

The below criteria needs to be satisfied to be considered SAWP-CTCG pilot:

- Pilot cases should involve multi-national clinical trials across 2 or more EU Member States;
- The proposed Reporting Member State should be identified by the Applicant;
- The applicant should provide a justification for inclusion and prioritisation in the SAWP-CTCG pilot, i.e.
  - What is the scientific/methodological clinical trial topic that requires both SAWP/CHMP and CTCG feedback? Note that questions to CHMP and CTCG concerning the trial could be at strategic/conceptual or detailed level.
  - What is the issue for the clinical trial design in the context of the Marketing Authorization Application (MAA) dossier that has a complex clinical trial application, regulation issue or other complex dimension?
  - What is the medical need for the proposed medicinal product? / Why is the development program of public health benefit?

3.2. Desirable criteria

- An available advanced mature protocol of the clinical trial;
- The proposed MSC are identified by the Applicant;
- The following features of the trial, indication or program will be taken into account in the prioritization and selection of pilot cases: rare disease, Advanced Therapy Medicinal Products, PRIME, complex clinical trials with/without paediatric issues, highly decentralized trials, entities not engaged in economic activities (e.g. academic sponsor[1]), rejected CTA with multiple scientific /methodological issues requiring trial re-design.

3.3. Out of scope of SAWP-CTCG pilot

- Cases falling under the EMA's Emergency Task Force for declared or potential public health emergencies;
- Consultation with ethics committees/ethics experts for clinical trials;
- 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 the MAA or the CTA;
- Combination product (medicinal product and medical device) developments due to additional assessment complexity will initially remain out of scope.

[1] For more information on the above-referred verification, please refer to the Academia Overview page (https://www.ema.europa.eu/en/partners-networks/academia).

3.4. Who should I contact for further information on SAWP-CTCG

For any further information on the SAWP/CTCG pilot please write an email to scientificadvice@ema.europa.eu and to CTCG@hma.eu.

4. Are (complex) trial modifications seen to be in the scope of SAWP-CHMP advice? - *new*

A proposed trial design modification that could impact on the evidence for MAA or be controversial for CTA could be submitted as a request for the SAWP CTCG pilot.

5. How do I apply for SAWP-CTCG pilot procedure? *updated*

Applications should be submitted through the SAWP procedure/IRIS portal as a single point of contact for applicants; see Requesting scientific advice or protocol assistance fromEMA | European Medicines Agency (europa.eu).

To request participation in the SAWP CTCG pilot, relevant information should be provided to the submission notes section in the IRIS application. The usual CHMP scientific advice procedure briefing document template and submission deadlines apply regardless of the pilot application. Sponsors/applicants can also consult the general guidance for scientific advice.

There is no need to list different sets of questions in the briefing document to the CTCG or MS. The questions will be looked at in joint manner as needed and appropriate.

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

- We request to be admitted to the SAWP-CTCG pilot program;
- The proposed reporting member state of <Trial reference number > is < >;
- The proposed concerned member state of <Trial reference number > are < ..> etc.;
- Our justification for inclusion and prioritisation in the SAWP CTCG pilot is as follows;
  - The scientific issues for <Trial reference number> requiring both SAWP and CTCG input are < >
  - The Public health impact of <Trial reference number> is < >
  - Other factors to consider *for prioritisation to the pilot are* < >

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 regardless of the pilot application. Applicants can also consult the general guidancefor scientific advice.

6. What are the reasons for rejecting a SAWP/CTCG application and what are the consequences? - *new*

The SAWP/CTCG aims to admit at least 1 pilot case per month for 10 months, with some flexibility on the expected cases per month, depending on available capacity. If a procedure is not accepted into the pilot, it can still be assessed as a normal SAWP procedure within the same time scale and within the same submission slot. A request may be rejected if it is deemed to be out of scope of the pilot. Where multiple and potentially acceptable requests for the pilot are received within the same submission slot, potential cases will be prioritised based on the applicant's submitted request justification. In this scenario, one to two selected requests will be admitted to the pilot per month and the remainder would be offered standard scientific advice if appropriate. Requests to postpone for the following submission slot could also be considered. In addition, a request for access to the SAWP/CTCG project may be refused if none of the MSCs is able to take the Lead-MS role. In this case, the request can be evaluated as a normal SAWP procedure.

7. Which MSs are participating in the pilot projects? - *new*

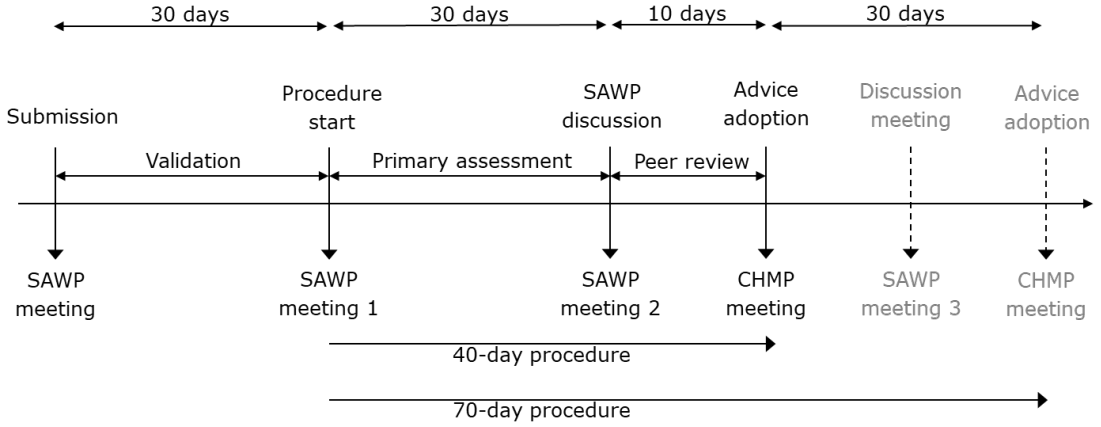
Participation in the SAWP/CTCG pilot is voluntary and is confirmed on a case-by-case basis depending on the MS indicated by the sponsor/applicant. For a procedure to begin, it is necessary that one of the MSC volunteers to lead the assessment (Lead-MS), which will then be shared with all the other MSC. The MS proposed by the sponsor as the RMS of the future CTA is the best candidate to take the role. However, it may occur that the proposed RMS might not be in the position to undertake the role of Lead-MS for the SAWP/CTCG procedure. In this case, another MSC may volunteer to take the lead of the procedure. If none of the MSC volunteers, the SAWP/CTCG application will be handled as a normal SAWP procedure without the involvement of the NCAs CT unit in the final scientific advice.

The list of the Member States who are actively participating in the pilots is available on the ACT-EU webpage (Member States participating in the ACT EU pilots on consolidated advice).

8. What is the duration of a SAWP/CTCG pilot procedure?- *new*

The SAWP/CTCG pilot follows the standard SAWP procedure, thus 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 SAWP/CTCG procedure. The timeline is depicted in Figure 1, while for high level details of process flow of the components of the interaction, see Annex 1.

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



9. When will I find out if my request to join the SAWP-CTCG pilot is successful?

Applicants will be informed before the end of the normal validation period for scientific advice whether or not the request has been admitted to the pilot.

10. What committee or other interactions will take place for a SAWP/CTCG procedure? *new*

EU regulatory groups relevant to the scientific topic will be consulted. For instance, with questions on paediatric clinical trials, the Paediatric Committee (PDCO) will be engaged.

11. What is the outcome of a pilot procedure?

At the end of the pilot procedure, sponsors/applicants receive a Scientific Advice letter with the consolidated scientific content. The 'Other Comments' section of the letter may include any MS specific comments.

As for standard CHMP scientific advice, the 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.

12. How many pilot procedures are foreseen? - *new*

SAWP-CTCG aims to admit at least 1 pilot case per month for 10 months, with some flexibility on cases per month foreseen, depending on the available capacity.

13. What fees will I have to pay if my procedure is accepted into the pilot?

The SAWP/CTCG pilot scientific advice fees and fee incentives already established for the standard SAWP procedures apply for procedures accepted into the pilot. No additional costs will be charged to the Applicant for requesting a SAWP/CTCG scientific advice.

14. 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.

15. What are the deliverables and what is the measure of success of the pilots? *new*

The outcome of a SAWP/CTCG pilot 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 MS, with the possibility of achieving greater consistency in the interpretation and application of scientific requirements for the CTA and for the MAA.

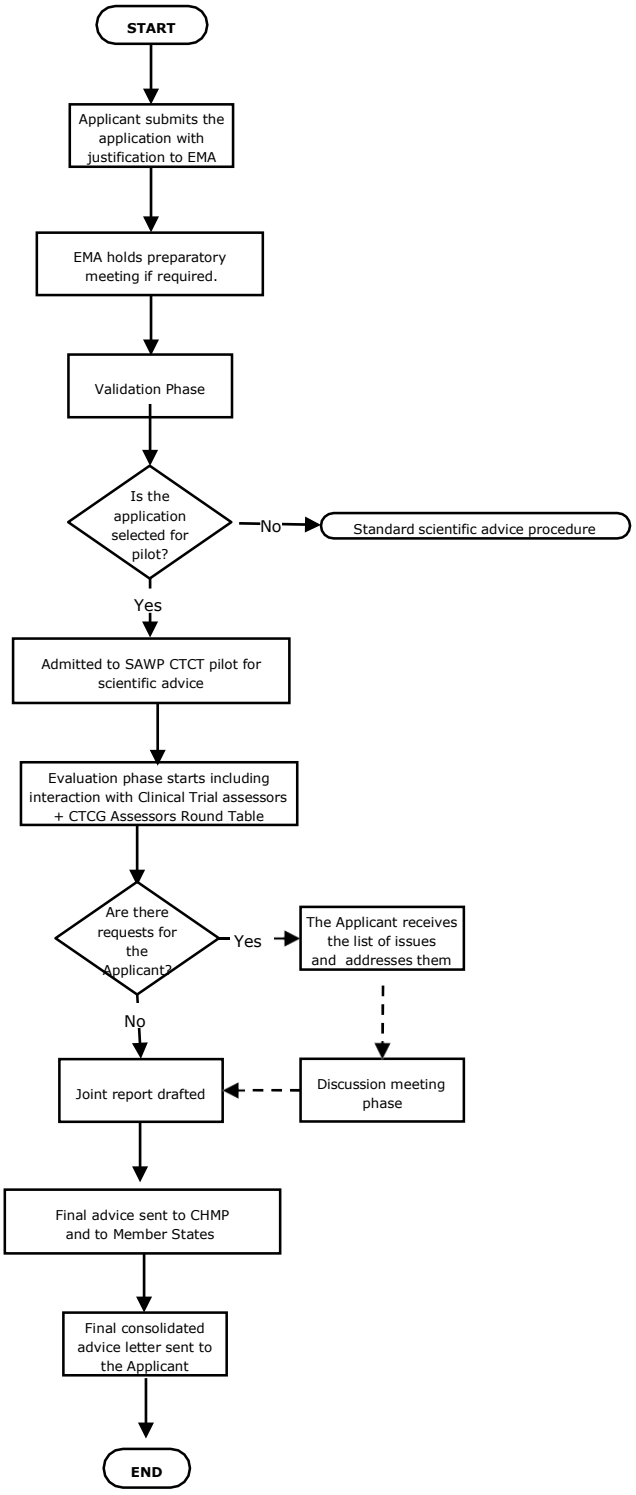
As for other standard European advice, the SAWP/CTCG advice will not be legally-binding, but sponsors/applicants should justify divergence with the advice received when submitting the formal CTA or MAA.

The applicants admitted to the SAWP/CTCG advice pilots will receive a questionnaire upon completion of the pilot procedure regarding the more immediate efficiency and benefits of the procedure, and of the perceived downstream benefits. This feedback will help the evaluation of the pilot. Interim analyses will be provided to monitor progress of projects and identify potential issues during their course. Long-term feedback on the outcome of the CTA and the MAA will be also requested.

16. List of annexes

Annex 1 Process flow for SAWP CTCG pilot scientific advice.

Annex 1


START
Applicant submits the application with justification to EMA
EMA holds preparatory meeting if required.
Validation Phase
Is the application selected for pilot?
No
Standard scientific advice procedure
Yes
Admitted to SAWP CTCT pilot for scientific advice
Evaluation phase starts including interaction with Clinical Trial assessors + CTCG Assessors Round Table
Are there requests for the Applicant?
Yes
The Applicant receives the list of issues and addresses them
No
Joint report drafted
Discussion meeting phase
Final advice sent to CHMP and to Member States
Final consolidated advice letter sent to the Applicant
END