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Guidance for applicants: SAWP CTCG pilot on scientific advice

ACT EU priority action on consolidated advice

Contents

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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** towards clarification of both clinical trial and marketing authorisation application requirements via the increased collaboration between the European Medicine Agency's Scientific Advice Working Party (SAWP) and the Clinical Trial Coordination Group (CTCG), Member States and National Competent Authorities.

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

2. How does this pilot fit within the landscape of all EU advice activities?

There are multiple avenues for seeking scientific advice in the EMRN. Applicants are advice to seek advice as explained in the **mapped information** on voluntary procedures available within the European medicines regulatory network (Advice on medicines for Human use in the EU medicines regulatory network (europa.eu)) the according to the legal remit of the topic. The SAWP CTCG pilot allows consolidated scientific advice on both clinical trial evidence requirements (NCA remit) and marketing authorisation evidence requirements (centralised scientific advice remit).

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

3.1 Essential criteria

The below criteria need to be satisfied for a case to be considered for inclusion in the 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 known;
- 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 MAA dossier that has a complex clinical trial application or 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 advanced mature protocol of the clinical trial is available;
- The proposed Concerned Member States are known;
- The following features of the trial, indication or program will be taken into account in the prioritisation and selection of pilot cases: rare disease, Advanced Therapy Medicinal Products, PRIME, complex clinical trials with/without paediatric issues, highly decentralised trials, academic sponsors, 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;
- CTA preparatory regulatory or technical questions which are better suited for the pre-CTA CTCG pilot;
- Pre-assessment of data to support the Marketing Authorisation Application (MAA) or the Clinical Trial Application (CTA);
- Combination product (medicinal product and medical device) developments, due to additional assessment complexity, will initially remain out of scope.

4. How many pilot procedures are foreseen?

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.

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

Normal scientific advice fees and fee incentives apply for procedures accepted into the pilot.

6. How do I apply for SAWP-CTCG pilot procedure?

For the SAWP-CTCG pilot, 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 from EMA | European Medicines Agency (europa.eu).

To request participation in the SAWP CTCG pilot, 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 guidance for scientific advice.

7. 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.

8. What is the process to be followed for the SAWP-CTCG pilot?

SAWP CTCG cases will follow standard SAWP scientific advice submission deadlines, process and timelines with the exception of the additional CTCG related interaction added to the standard process. For high level details of process flow of the components of the interaction, see Annex 1.

9. What is the outcome of a pilot procedure?

At the end of the pilot procedure, applicants receive a Scientific Advice letter with the consolidated scientific content. The 'Other Comments' section of the letter may include any Member State 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.

10. 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.

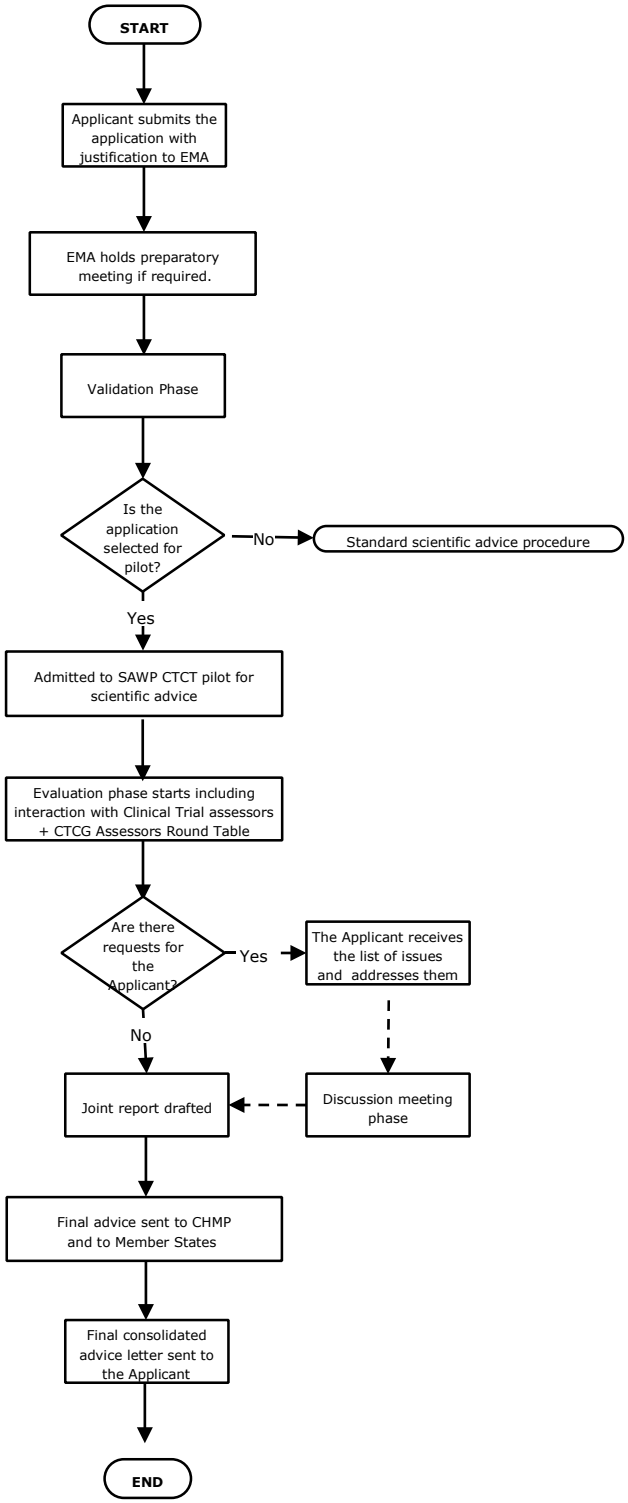
11. Will I be able to provide input from my experience with the pilot?

The applicants admitted to the SAWP-CTCG pilot will receive a feedback request upon completion of the pilot procedure regarding the more immediate efficiency and benefits of the procedure, and of the perceived downstream benefits. It is important to complete this feedback request for the evaluation of the pilot.

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