10 June 2024
EMA/253080/2024

Guidance for applicants: pre-CTA advice pilot

ACT EU priority action on consolidated advice

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 the pre-CTA advice pilot?

The pre-CTA advice pilot is an advice to applicants who are planning to submit a clinical trial application (CTA) to the clinical trial information system (CTIS) under the Regulation (EU) No 536/2014.

For the pre-CTA advice there will be coordination between assessors from National Competent Authorities of the EU Member States on regulatory and technical aspects of clinical trials.

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

ACT EU priority action on consolidated advice has updated 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)]

3. What are the criteria to apply for the pre-CTA advice pilot?

Essential criteria

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.

Scope of the pre-CTA advice

The following topics fall within the scope of the pre-CTA advice. The list is not exhaustive.

- CT within scope of the Clinical Trial Regulation (Y/N).
- Low Intervention Clinical Trial.
- Combination products / combined CTs (MDR/IVDR).
- Operational aspects of the submission of the CTA in CTIS (Complex CT, transition of CT).
- Regulatory request on GLP GL.
- Regulatory request on AxMP GL.
- Decentralized elements in CTs.
- Risk based trial performance (e.g. reduced safety reporting).
- Open questions before re-submission of updated dossier.
- Other regulatory and technical aspects of the CTA.

Out of scope of pre-CTA advice pilot

- Requests on scientific aspects of clinical trials are out of scope and better suited for other advice procedures: Advice on medicines for Human use in the EU medicines regulatory network (europa.eu).
- Preassessment of CTA is out of scope.

4. How many pilot procedures are foreseen?

During the initial pilot phase iterations of **5 pre-CTA advice procedures** will be followed by an evaluation step leading to procedural optimisation. During this phase the pilot can continue. Some flexibility on cases is anticipated, based on the capacity.

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

During the pilot phase of the pre-CTA advice, the MS leading the advice procedure might require a fee according to national requirements and following national procedures.

6. How do I apply for pre-CTA advice pilot procedure?

- For the pre-CTA advice pilot, you can apply through the SNSA entry point via a dedicated email address SNSA@fagg-afmps.be.
- 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*.
  - The proposed concerned member state (MSCs) for the application.

  Please ensure that the documents relevant for the pre-CTA advice are made available together with the submission of the advice request.

7. When will I find out if my request to join the pre-CTA advice pilot is successful?

- Applicants will be informed of the receipt of the request by the SNSA coordination unit, which indicates the starting of the validation phase.
- Applicants will also receive a notification at the end of the validation phase indicating that the request will or will not continue with the assessment phase, the Lead MS and the timetable.

8. What is the process?

For high level details of draft process flow; see annex 1.

9. What is the outcome of a pilot procedure?

The outcome of a pilot procedure will be a pre-CTA advice letter.

As for other standard European advice, the pre-CTA advice will not be legally-binding, but applicants should justify divergence with the advice received when submitting the formal CTA.

The pre-CTA advice does not represent a pre-assessment of the data for CTA.

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

As for standard European advice procedures, normal principles of confidentiality and handling of conflicts of interest apply.

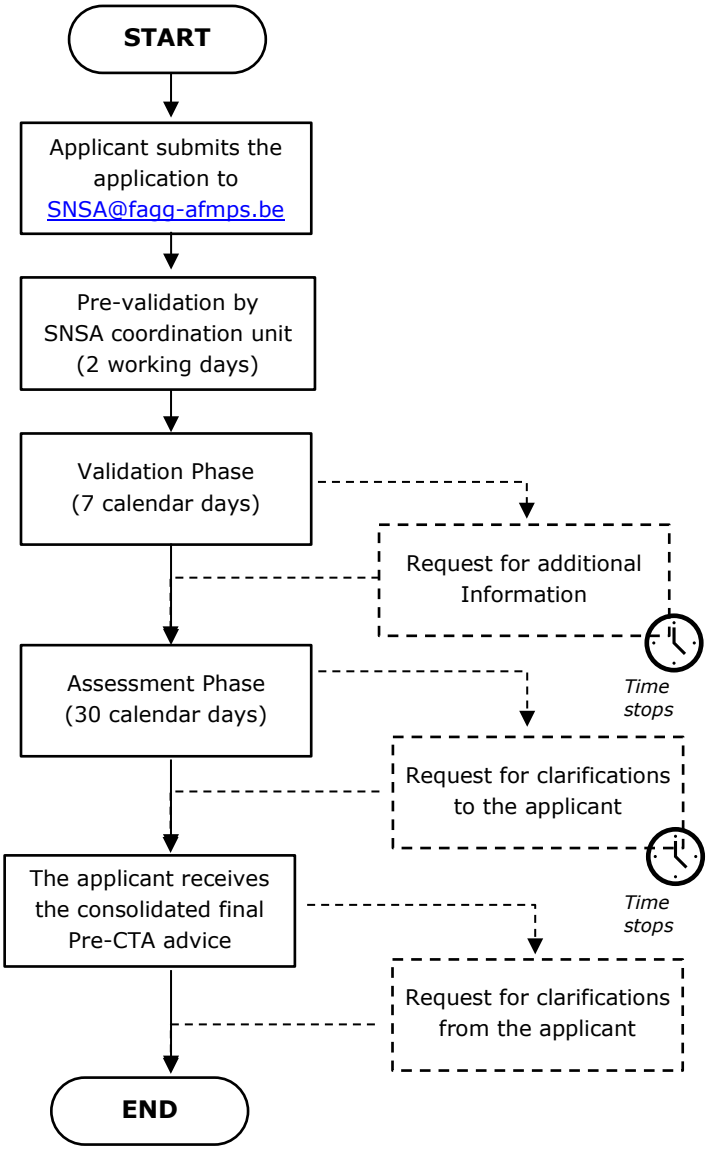
11. Pilot – Deliverables and measure of success

The applicants admitted to the pre-CTA advice pilot 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.

12. List of annexes

Annex 1 Process flow for Pre-CTA pilot.

Annex 1


START
Applicant submits the application to SNSA@fagg-afmps.be
Pre-validation by SNSA coordination unit (2 working days)
Validation Phase (7 calendar days)
Request for additional Information
Time stops
Assessment Phase (30 calendar days)
Request for clarifications to the applicant
Time stops
The applicant receives the consolidated final Pre-CTA advice
Request for clarifications from the applicant
END