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Guidance for applicants: Pre-CTA advice pilot

ACT EU priority action on consolidated advice

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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 Good Laboratory Practice (GLP) guideline.
- Regulatory request on Auxiliary Medicinal Product (AxMP) guideline.
- 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 do I apply for Pre-CTA advice pilot procedure? - *updated*

- 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.
- 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 MSCs for the application.

Finally, it is considered useful to submit a cover letter containing as much information as possible about the advice request sent.

- 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. The validation phase takes a maximum 7 calendar days, and it is aimed at assessing whether the

questions do fall within the scope of the Pre-CTA and to select the Lead-MS. Applicants will be informed of the receipt of the request by the SNSA coordination unit, which indicates the start of the validation phase.

- Sponsors/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. The assessment phase takes a maximum 30 calendar days.
- A Pre-CTA application may be declined if the request is not related to technical/regulatory matters and therefore does not fall within the scope of the pilot or if the proposed RMS and/or none of the MSCs apply for the Lead-MS role.

For any further information please write an email to the following address:
prectaadvice@ema.europa.eu.

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

For the Pre-CTA pilot, only the Lead-MS might require a fee according to national requirements and following national procedures. Different approaches might exist for commercial and non-commercial sponsor/applicants depending on the national requirements. There is no published list of national fees for Pre-CTA advice, it is therefore necessary to communicate with single MS for detailed information.

6. How many pilot procedures are foreseen?

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

7. What is the process?

For high level details of the process flow see annex 1.

8. 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.

9. 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.

10. Pilot – Deliverables and measure of success - *updated*

The aim of a Pre-CTA is to provide a single consolidated opinion, thus promoting harmonisation of regulatory expectations between different MSC, with the possibility of achieving greater consistency in the interpretation and application of technical and regulatory requirements.

The sponsors/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. Interim analyses will be provided to monitor progress of projects and identify potential issues during the course. Long-term feedback on the outcome of the CTA will be also requested.

List of annexes

Annex 1 Process flow for Pre-CTA pilot.

Annex 1

