Consolidated advice pilots
ACT EU Priority Action on consolidated advice

Industry platform Meeting

Presented by Marianne Lunzer and Massimiliano Sarra

Consolidated advice pilots

The Accelerating Clinical Trials in the EU (ACT EU) launched **two advice pilots** aimed at **improving the quality of applications** for clinical trials, **the foundation for the development** of safe and effective medicines in Europe:

I Pilot: SAWP-CTCG

II Pilot: Pre-CTA Advice

Pilots started officially on **June 10th**

The pilots enhance the coordination within the EMRN to offer applicants **harmonised advice** on how to improve the quality of their applications for clinical trial application and marketing authorisation.

ACT EU initiative has **mapped information on current voluntary procedures** available from EU regulators on Medicines for human use and collated this information in the form of questions and answers.

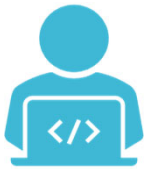
Advice on medicines for Human use in the EMRN (europa.eu)

Scientific advice - European Union (europa.eu)

Consolidated advice pilots:
Scientific advice from SAWP-CTCG

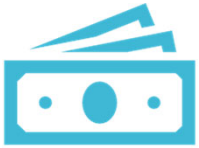
Scientific advice on suitability of clinical trial design to support marketing authorisation and/or clinical trial applications

Harmonised advice through increased coordination of Scientific Advice Working Party (SAWP) and Clinical Trials Coordination Group (CTCG) on topics of common interest

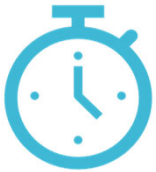


Applications via established SAWP procedure

With justification



Normal fee structure ensuring payments are directed to those doing the work



10 cases (1 per month x 10 months)

What's new in the SAWP-CTCG advice?

What is the SAWP-CTCG advice 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).** The pilot enhances coordination of advice activities on clinical trial and development program design within the EMRN, to facilitate the development of safe and effective medicines for human use.

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 should seek advice according to the legal remit of the topic, as explained in the mapped information on voluntary procedures available within the EMRN. **The SAWP-CTCG pilot allows consolidated scientific advice on both clinical trial application requirements (NCA remit) and marketing authorisation evidence requirements (centralised scientific advice remit).**

Benefits of SAWP-CTCG pilot

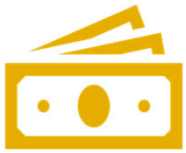
- **Targeted surveys** to Applicant, Assessors (SAWP Coordinators + assessor, NCAs) to get feedback
- **Applicant perspective: to assess (should be carried out after completion of case)**
  - Increased efficiency of procedure binary (yes vs no)
  - Perceived downstream benefit
  - Harmonized opinion on applications for marketing authorisation and clinical trial application.
- **Assessors' perspective:**
  - Efficiency of procedure SA – binary (yes vs no)
  - Perceived benefit downstream from NCAs' assessor perspective
  - Additional time consumed vs more holistic assessment

Consolidated advice pilots:
Pre-CTA advice from CTCG

Technical, regulatory advice before the submission of a clinical trial application (CTA)

Short timeline: 30-day procedure

Applications via Simultaneous National Scientific Advice (SNSA inbox)



Reporting Member State raises a single fee based on the reduced scope of the advice

Interim evaluation of the pilot every 5 advice

Pre-CTA pilot: a new opportunity of advice for the applicants

What is the pre-CTA pilot?

This pilot provides consolidated **technical, regulatory advice to applicants before the submission of a clinical trial application (CTA)** in the Clinical Trials Information System (CTIS). The pilot is coordinated by the Clinical Trials Coordination Group (CTCG) with the involvement of assessors from NCAs.

What is the novelty?

Before this pilot, applicants could only receive technical and regulatory support at national level from the Member State evaluating the application. **The pre-CTA advice pilot will provide consolidated views of the Member States concerned on pre-submission topics.** The scope of this pilot covers a number of areas such as advice on regulatory aspects of low interventional clinical trial status and submission of trials with decentralised elements or complex design.

Benefits of pre-CTA pilot

- **Applicant perspective**
  - A support prior to the clinical trial application
  - Harmonized opinion on specific technical and regulatory aspects related to a clinical trial application
  - Short timelines: 30-day procedure
- **Assessors and NCAs perspective:**
  - Coordinated assessment of complex regulatory issues
  - Align position before CTA
  - Trigger for guidance development.

Consolidated advice pilots: Webinar for applicants

Participants are encouraged to use Slido to submit questions in advance of the webinar. The most popular ones will be answered by speakers during the Q & A session. Please provide your questions between 24 June 2024 and 12:00 on 10 July 2024.

Date: July 17th 15:00 (CEST) - 17:00 (CEST)

European Medicines Agency, Amsterdam, the Netherlands

Live broadcast and video recording available after

The webinar aims at:

- providing information on the newly launched consolidated advice pilots (SAWP-CTCG and pre-CTA advice).
- Informing on the background of the pilots and why they were launched.
- Highlighting the benefits of the pilots,
- Outlining the scope of the SAWP-CTCG and pre-CTA advice
- Answering questions and collecting feedback from stakeholders.

Any questions?

Marianne Lunzer - CTCG co-chair - marianne.lunzer@ages.at
Massimiliano Sarra - ACT EU pilots coordinator - massimiliano.sarra@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

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