



Member States participating in the ACT EU pilots on consolidated advice

The Accelerating Clinical Trials in the EU (ACT EU) initiative launched two advice pilots on 10 June 2024, aimed at enhancing the coordination within the European medicines regulatory network (EMRN). The pilots offer applicants harmonised advice on how to improve the quality of their applications for marketing and/or clinical trial authorisation(s). The initiative aims at establishing an early dialogue between sponsors/applicants and regulators, on scientific and regulatory matters, to facilitate the development of safe and effective medicines for human use in Europe.

The SAWP/CTCG pilot provides consolidated scientific advice to support applicants in the submission of marketing authorisation and/or clinical trial applications in the EU. The advice is offered via increased coordination between the Scientific Advice Working Party (SAWP) and the Clinical Trials Coordination Group (CTCG).

The Pre-CTA pilot provides consolidated technical, regulatory advice on the dossier of a clinical trial application (CTA) between Member States prior to its submission in the Clinical Trials Information System (CTIS). This pilot is coordinated by the CTCG.

The below tables provide an overview of the Member States (MSs) who will take part in each pilot (Table 1 and 2). MS participation in the pilots is voluntary and is confirmed on a case-by-case basis depending on the MS indicated by the applicant in the request of advice.

For the Pre-CTA pilot (Table 2), the table indicates if the MS is willing to take the lead of the procedure as Lead-MS (LMS) and/or as Member State Concerned (MSC). It may occur that the Member State proposed by the applicant as Reporting Member State (RMS) for the CTA might not be in the position to undertake the role of Lead-MS for the pre-CTA procedure. In this case, another MSC may volunteer to take the lead of the procedure. If no MSC volunteers, the application will be declined.

Please see the guidance documents for more details.

- SAWP/CTCG Pilot: [Guidance for applicants SAWP CTCG pilot on scientific advice](#)
- Pre-CTA Pilot: [Guidance for applicants Pre-CTA advice pilot](#)

Table 1. List of MS who participate in the SAWP/CTCG pilot

Member State
AT - Austria
CZ - Czech Republic
DE - Germany
DK - Denmark
EE - Estonia
FI - Finland
FR - France
IS - Iceland
IT - Italy
LT - Lithuania
LV - Latvia
NL - Netherlands
NO - Norway
PT - Portugal
SE - Sweden
SI - Slovenia

Table 2. List of MS who participate in the Pre-CTA pilot (LMS: Lead Member State; MSC: Member State Concerned)

Member State
AT - Austria (LMS and MSC)
BE - Belgium (LMS and MSC)
CY - Cyprus (MSC)
CZ - Czech Republic (MSC)
DE - Germany (LMS and MSC)
DK - Denmark (LMS and MSC)
EE - Estonia (MSC)
ES - Spain (MSC)
FI - Finland (LMS and MSC)
FR - France (MSC)
HU - Hungary (MSC)
IE - Ireland (MSC)
IT - Italy (LMS and MSC)
LT - Lithuania (MSC)
LV - Latvia (MSC)
NL - Netherlands (LMS and MSC)
NO - Norway (MSC)
PL - Poland (LMS and MSC)
PT - Portugal (LMS and MSC)
SE - Sweden (LMS and MSC)
SI - Slovenia (MSC)