



ACT EU consolidated advice pilots: Pre-CTA and SAWP/CTCG

Interim report

March 2026

Pilots on scientific and regulatory advice

- The Accelerating Clinical Trials in the EU (ACT EU) initiative launched two pilots on consolidated advice in June 2024.
- The pilots aim to deliver **better, more impactful clinical trials**, benefitting patients and healthcare in Europe.
- Initially foreseen to end after 1 year or after 10 procedures for each pilot, the initiative has now been extended to gather more experience and additional feedback from applicants.

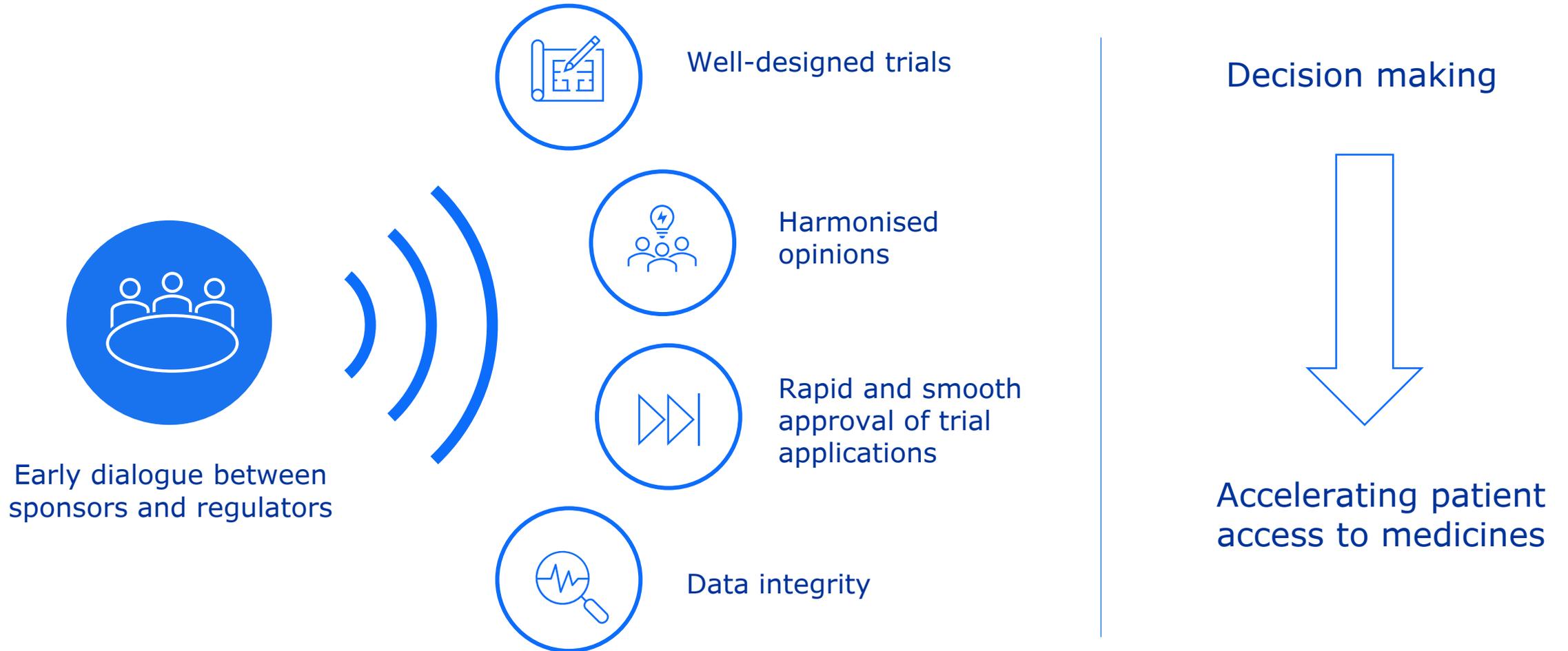


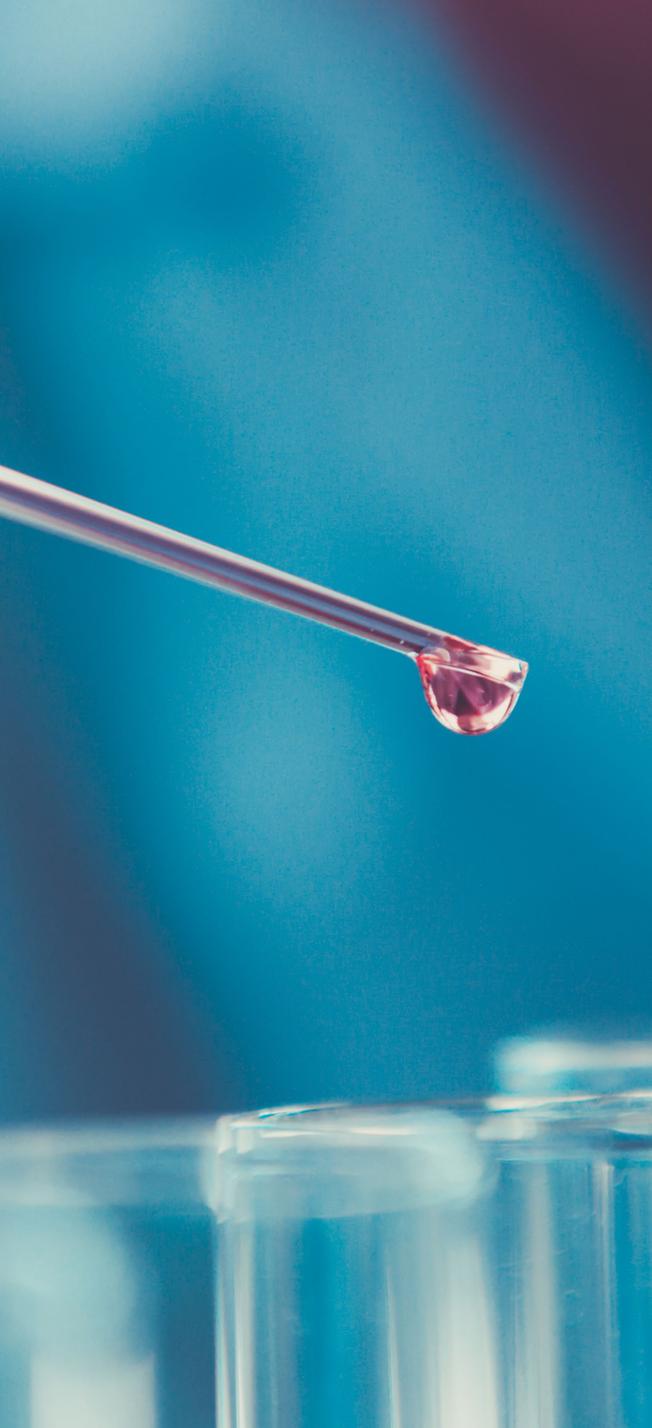
Pilot I: Scientific Advice Working Party (SAWP)-Clinical Trials Coordination Group (CTCG)



Pilot II: Pre-CTA (clinical trial application) advice

How do the pilots contribute to optimised clinical trials in the EU?



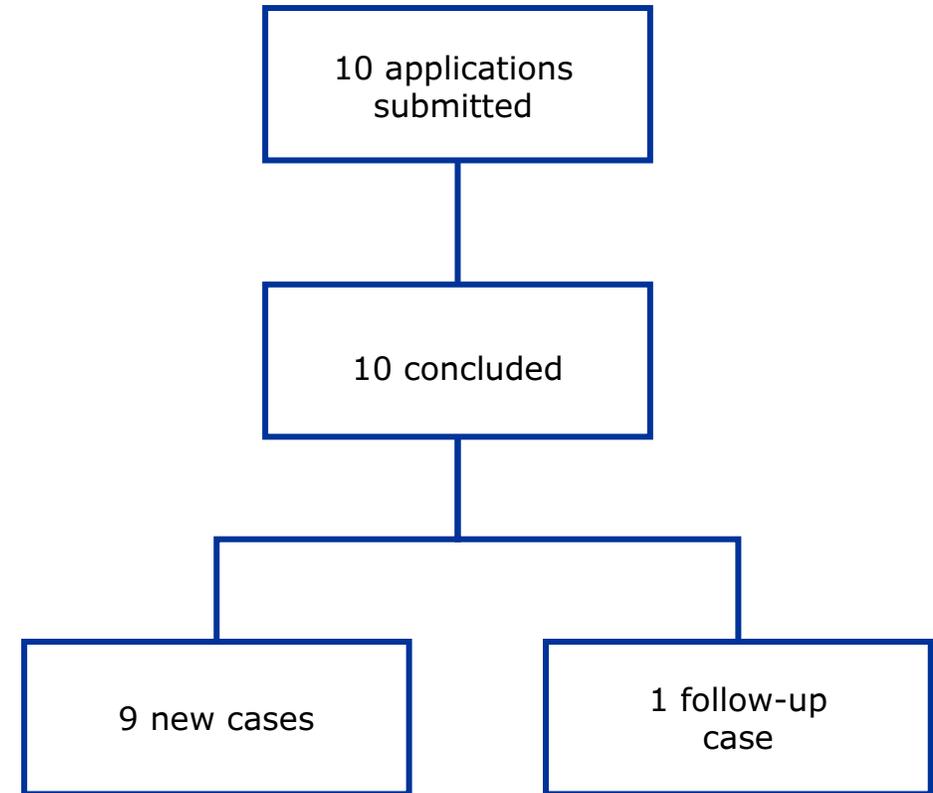


SAWP/CTCG: Consolidated scientific advice on clinical trials

Conclusions from 10 procedures

Methodology

- The analysis is based on the evaluation of 10 procedures
- Analysis of applicant feedback is based on 11 responses from 10 different applicants*, collected via survey at the end of the advice procedures



**Including 2 responses on the same application*

Proposed RMS and SAWP Coordinators

- The SAWP coordinator was from the proposed Reporting Member State (RMS) in 8 out of 10 cases
- MS participation is voluntary and the list of participating MS is publicly available: [Member States participating in ACT EU pilots on consolidated advice](#)

List of MS participating 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



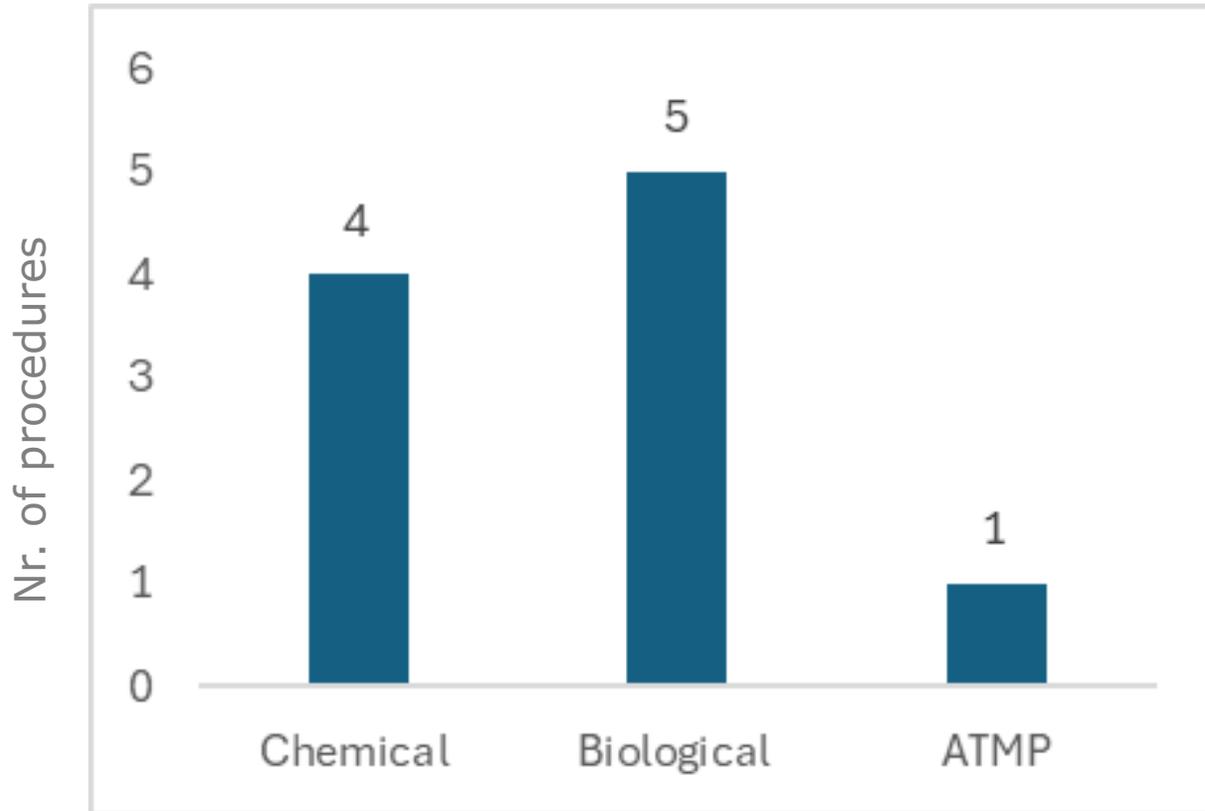
Scope of the SAWP/CTCG pilot

- Pilot cases should involve multi-national clinical trials across 2 or more EU Member States
- The proposed Reporting Member State should be known at the time of the pilot application
- 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? Questions could be at strategic/conceptual or detailed level.
 - What is the medical need for the proposed medicinal product? / Why is the development program of **public health benefit**?

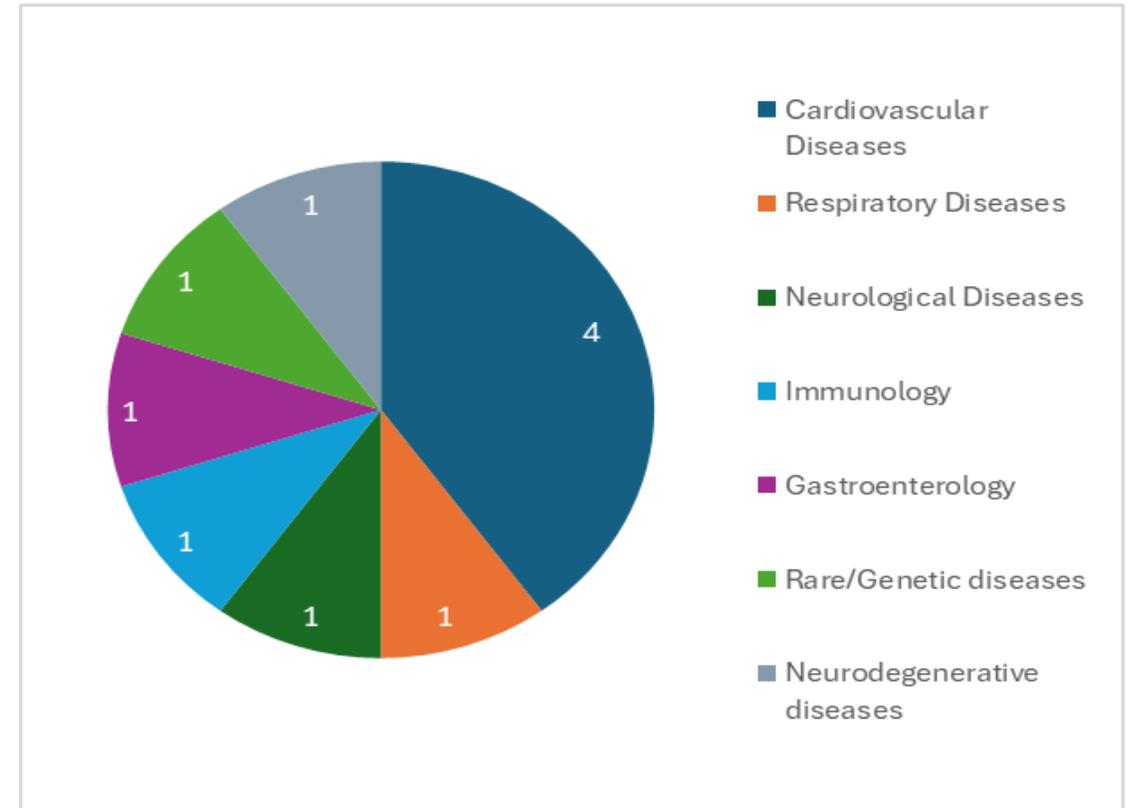


Type of products and therapeutic areas

Type of product



Therapeutic areas of the applications



*Advanced Therapy Medicinal Product

Questions by SAWP/CTCG applicants in the pilot

- Focused on non-clinical and clinical questions
- No questions on quality issues
- Examples:
 - Adequacy of the design/scope of non-clinical package to support the initiation of a clinical trial application (CTA) and marketing authorisation application (MAA)
 - Adequacy of the clinical study design to support the initiation of a CTA and MAA
 - Adequacy of the clinical study design and statistical analysis plan for complex clinical trials



Feedback from SAWP/CTCG applicants

based on 11 responses from 10 different applicants

Advice impact on the CT application	Added value of the pilot	Participant recommendations
<ul style="list-style-type: none">• Ensures consistency across Member States Concerned• Improves the quality of the study design• Helps applicants understand NCAs requirements• Reduces the number of issues raised during the evaluation of a Clinical Trial Application• Reduces the number of consultations needed at national level	<ul style="list-style-type: none">• Provides common advice on CTA and MAAs• Valuable opportunity to engage with clinical trial assessors earlier in the process• Helps address potential issues up front to reduce work during the start up period• Alignment in perspective and reduces potential discrepancies in addressing regulatory requirements• Extremely valuable for trials acceleration in EU, thus increasing EU attractiveness	<ul style="list-style-type: none">• Should be offered as standard scientific advice• It is encouraged that the proposed RMS for the CTA coincides with the MS leading the assessment in the pilot procedure• Applicants should know upfront which Member States take part in the discussions• Ethics committees should be involved in the process

Feedback from SAWP/CTCG applicants

based on 11 responses from 10 different applicants

On a scale from 1 to 10 where 1 means 'not at all likely' and 10 means 'extremely likely,' how likely are you to apply again for another SAWP/CTCG advice?



Feedback shows strong willingness to reapply for SAWP/CTCG advice

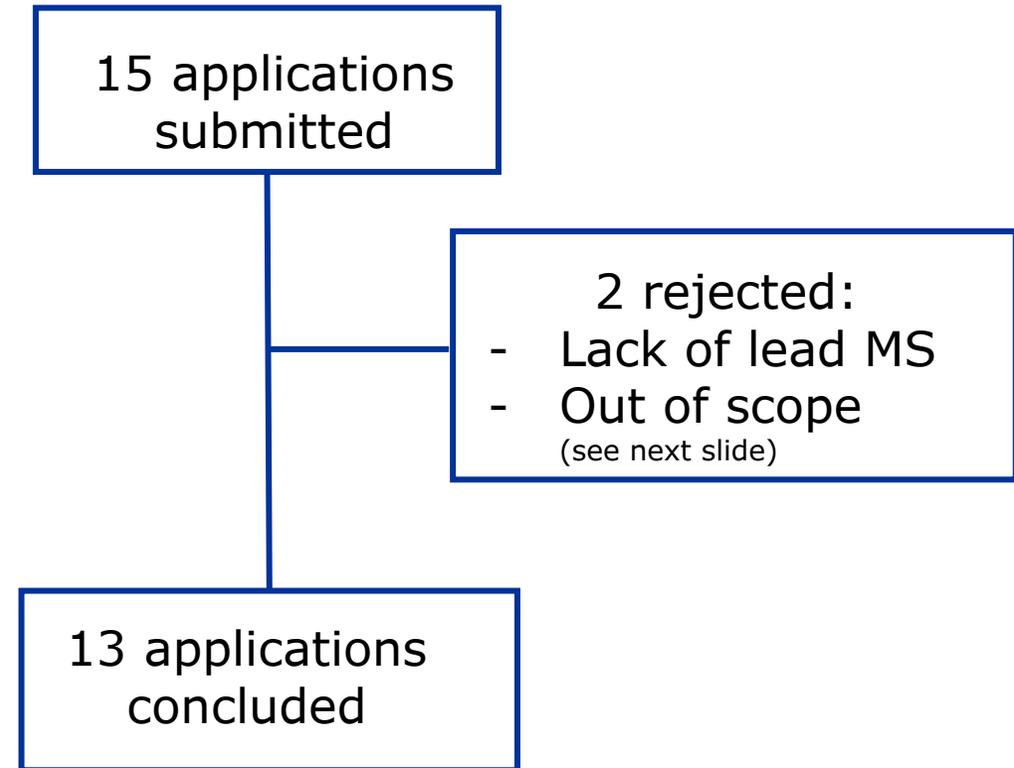


Pre-CTA: Consolidated advice on technical regulatory issues

Conclusions from 15 procedures

Methodology

- The analysis is based on the evaluation of 13 completed procedures in the first year of the pilot
- Analysis of applicants' feedback is based on 12 responses from 12 different applicants*, collected via survey at the end of the advice procedures



**1 applicant did not respond to the survey*

Proposed RMS and Appointment of the Lead-MS

- The proposed RMS is usually appointed as Lead MS (LMS) of the Pre-CTA
- The Member State Concerned (MSC) can act as LMS if the proposed RMS is not available
- MS participation is voluntary and the list of participating MS is publicly available: [Member States participating in ACT EU pilots on consolidated advice](#)

List of MS participating in the Pre-CTA pilot

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)



Scope of the pre-CTA advice

Clinical Trials Regulation

Low intervention clinical trials

Combination products/combined trials (MDR, IVDR* select MSs according to landscape)

Operational aspects of the submission of clinical trial applications in CTIS (complex CTs, transition)

Regulatory advice on Good Laboratory Practice (GLP)

Regulatory advice on Auxiliary Medicinal Products (AxMP)

Decentralised elements in clinical trials

Risk based trial conduct (e.g. reduced safety reporting)

Discussion of open questions before re-submission of updated dossier

Other regulatory and technical aspects of CTAs

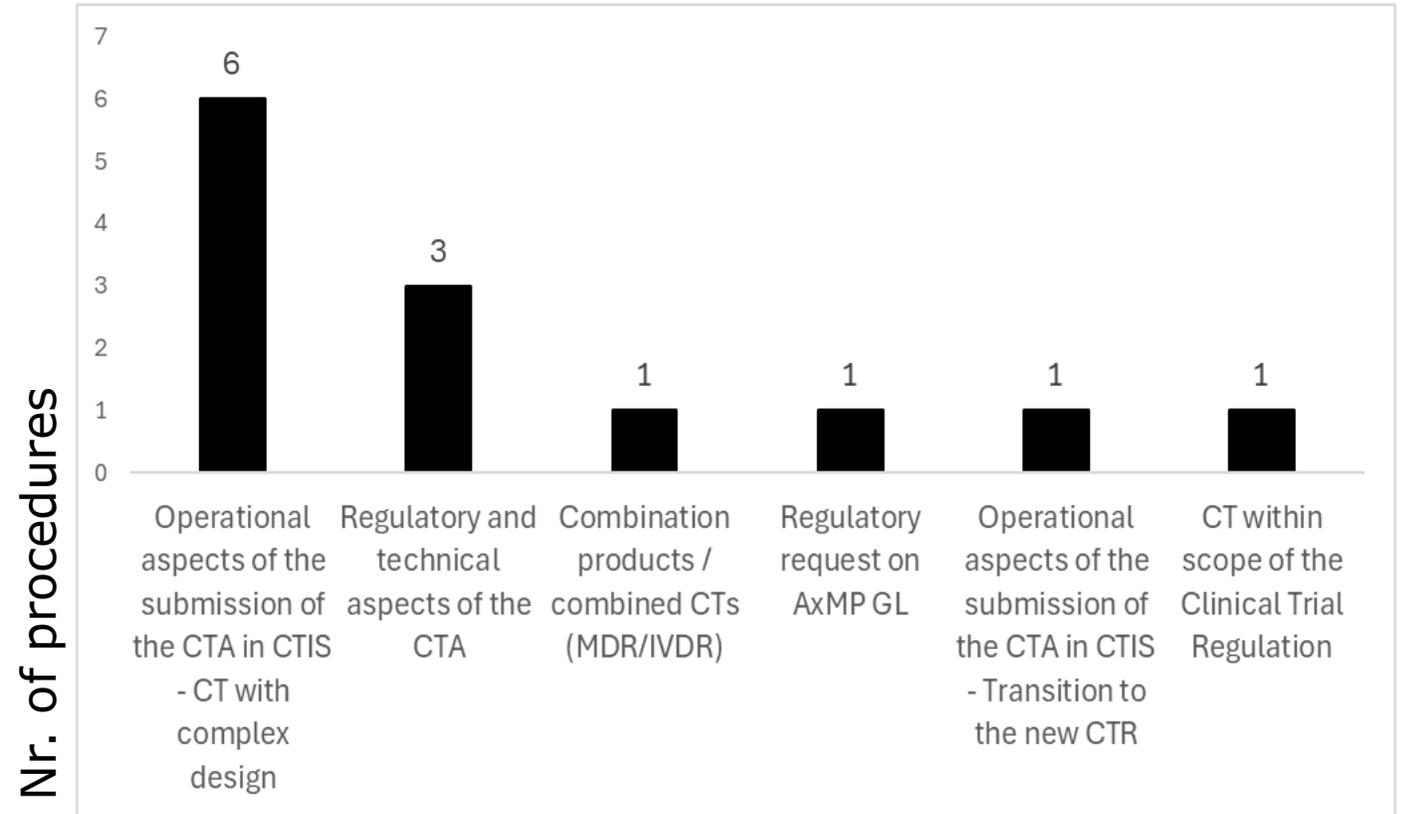
- This is a list of topics falling within scope of the pre-CTA advice pilot
- During the validation, a decision is made on whether the application is in scope

* MDR: Medical Device Regulation, IVDR: In vitro Diagnostic Regulation



Questions by Pre-CTA applicants

- Most frequent question topic (almost 50% of the applications) is on complex clinical trials (CCT)
- Main issues:
 - How to manage the submission of sub-study protocols as substantial modifications
 - Strategy of the CCT
 - Harmonisation of opinions among the Member States Concerned



Feedback from Pre-CTA applicants

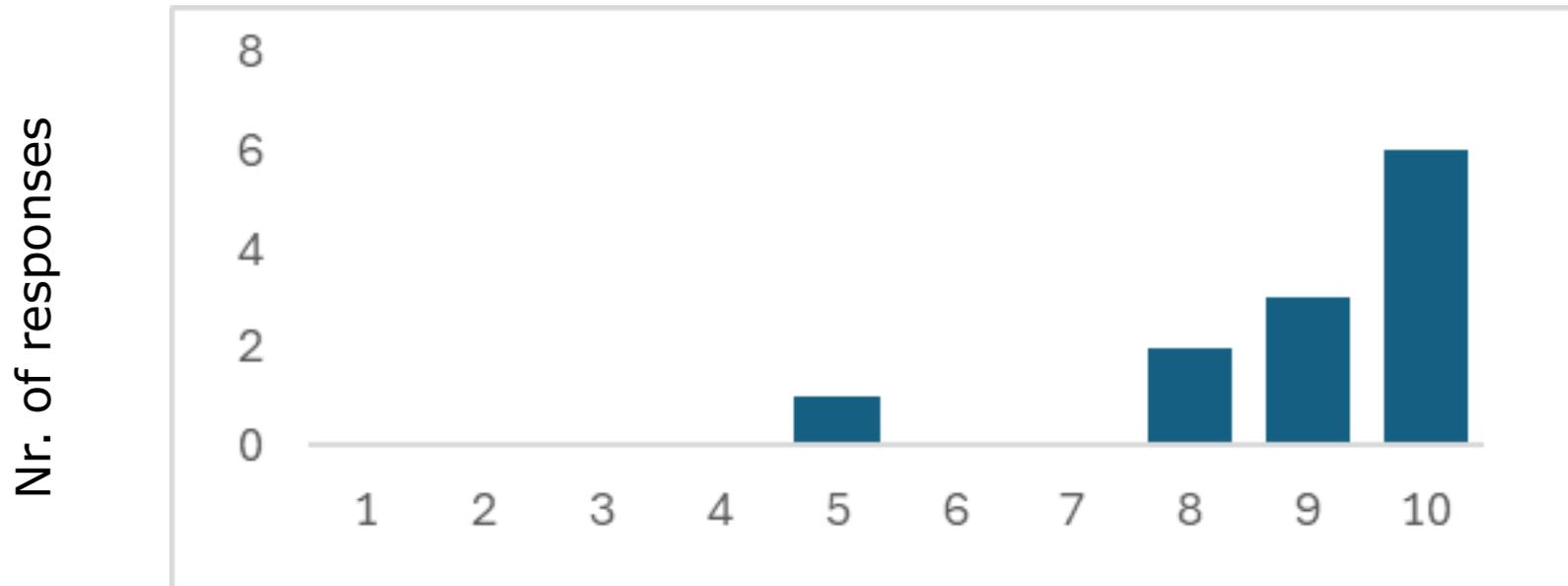
based on 12 responses from 12 different applicants

Advice impact on the CTA	Added value of the pilot	Participant recommendations
<ul style="list-style-type: none">• MSC alignment• Provides relevant guidance for sponsors• Clarifies national requirements• Helps improve and simplify CTA submission• Facilitates greater understanding of the role of ethics committees in Part I and II of CTA evaluation	<ul style="list-style-type: none">• Advice focussed on regulatory requirements• Harmonisation of regulatory expectations across different MS• Quick and simple procedure• Provides advice needed on behalf of multiple MSs in a single procedure• Possibility to ask specific questions	<ul style="list-style-type: none">• Highly recommended for trials with complex design• Ensure RMS participation in advice given• Possibility to obtain information on specific issues early before the CTA

Feedback from Pre-CTA applicants

based on 12 responses from 12 different applicants

On a scale from 1 to 10 where 1 means 'not at all likely' and 10 means 'extremely likely,' how likely are you to apply again for another pre-CTA advice?



Feedback shows strong willingness to reapply for Pre-CTA advice

Key conclusions from the two pilots

- Applicants confirm the added value of the pilots
- **Main benefits for applicants**
 - Opportunity for early dialogue
 - Aligned advice on both CTA and MAA
 - Potential to identify issues in advance and reduce requests for information during the evaluation of the CTA
- **Points for further consideration**
 - MS participation to align with the final advice and maintain consistency with the advice during the CTA assessment
 - Ethics committees' participation
 - Medical Device/In Vitro Device combined products



Get advice to improve your applications

- The pilots are **still accepting applications** in 2026
- **Positive feedback** from applicants indicates their added value
- We encourage all developers of medicines to apply - including those who have already benefited from the pilots in earlier rounds



For information on how to apply:



For queries on the Pre-CTA pilot:
prectaadvice@ema.europa.eu

Thank you

[ACT EU website](#)

