



ACT EU Pilots on consolidated advice in clinical trials

CTIS Information Day Webinar
2026

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ACT EU Pilots on Scientific and Regulatory advice in Clinical Trials

- ACT EU launched **two pilots on consolidated advice on 10 June 2024**



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



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

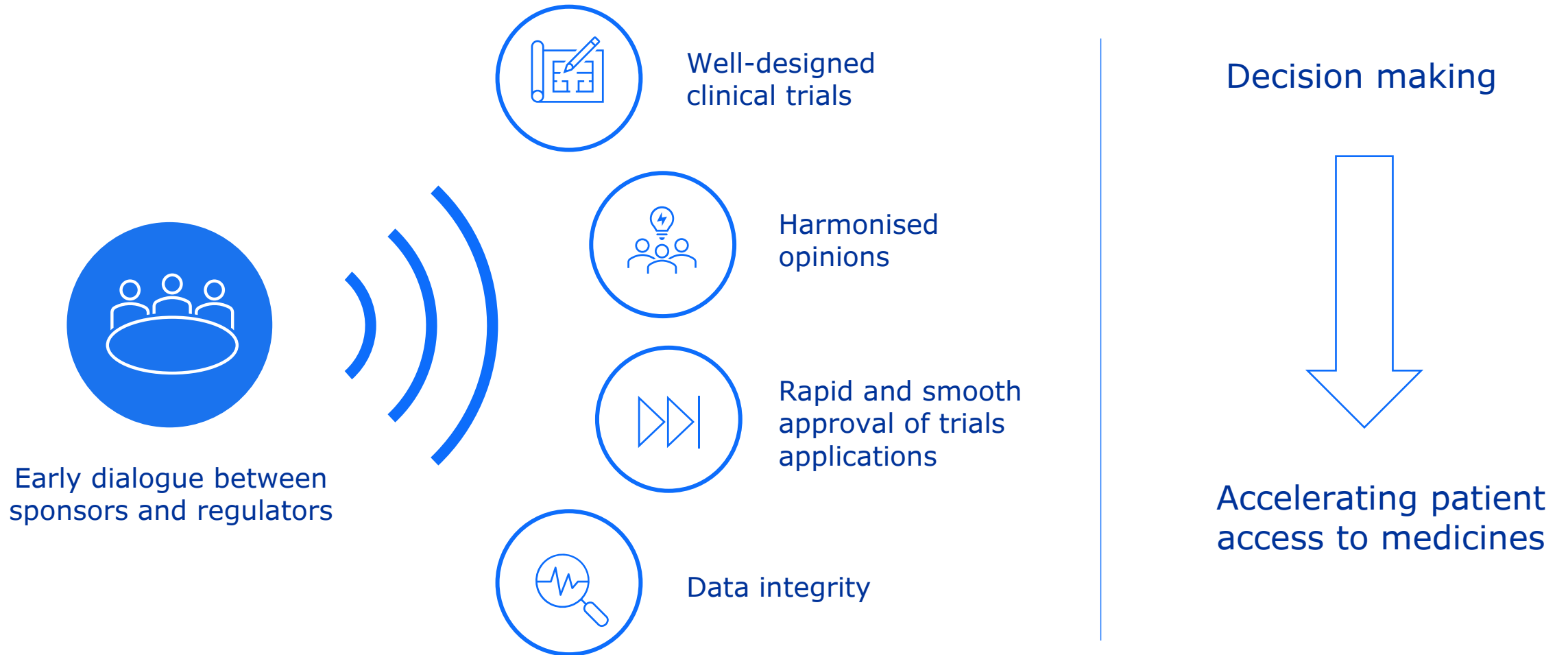
Webinars for [applicants \(recorded\)](#) and for assessors

Published [guidance documents](#) on ACT EU website

Up-to-date [mapped information](#) on current voluntary advice procedures available from EU regulators

Lists: [Member States participating in ACT EU pilots on consolidated advice](#)

How do the pilots contribute to optimised CTs in the EU?



Scientific advice from SAWP-CTCG

For developers of medicines



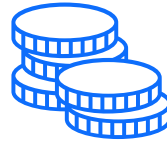
What advice is offered?

Scientific advice on suitability of clinical trial design to support marketing authorisation application (MAA) and/or clinical trial applications (CTA)



Who is providing the advice?

Scientific Advice Working Party ([SAWP](#)) and the Clinical Trials Coordination Group ([CTCG](#))



How much does it cost?

[Standard fees](#) for scientific advice by SAWP apply



How long does it take?

[Standard timelines](#) for scientific advice by SAWP apply



How to apply?

Via the [IRIS platform](#), justifying why joint advice from SAWP-CTCG is requested

Pre-CTA advice from CTCG

Technical, regulatory advice on clinical trials



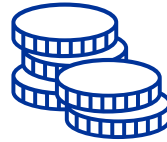
What advice is offered?

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



Who is providing the advice?

The Clinical Trials Coordination Group ([CTCG](#)) of clinical trial experts from all EU Member States



How much does it cost?

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



How long does it take?

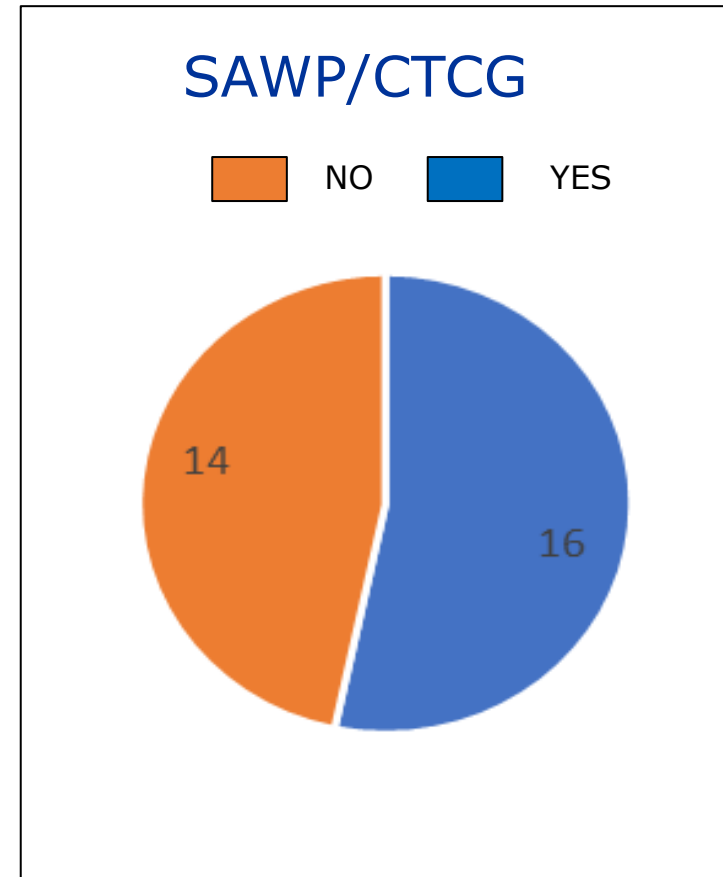
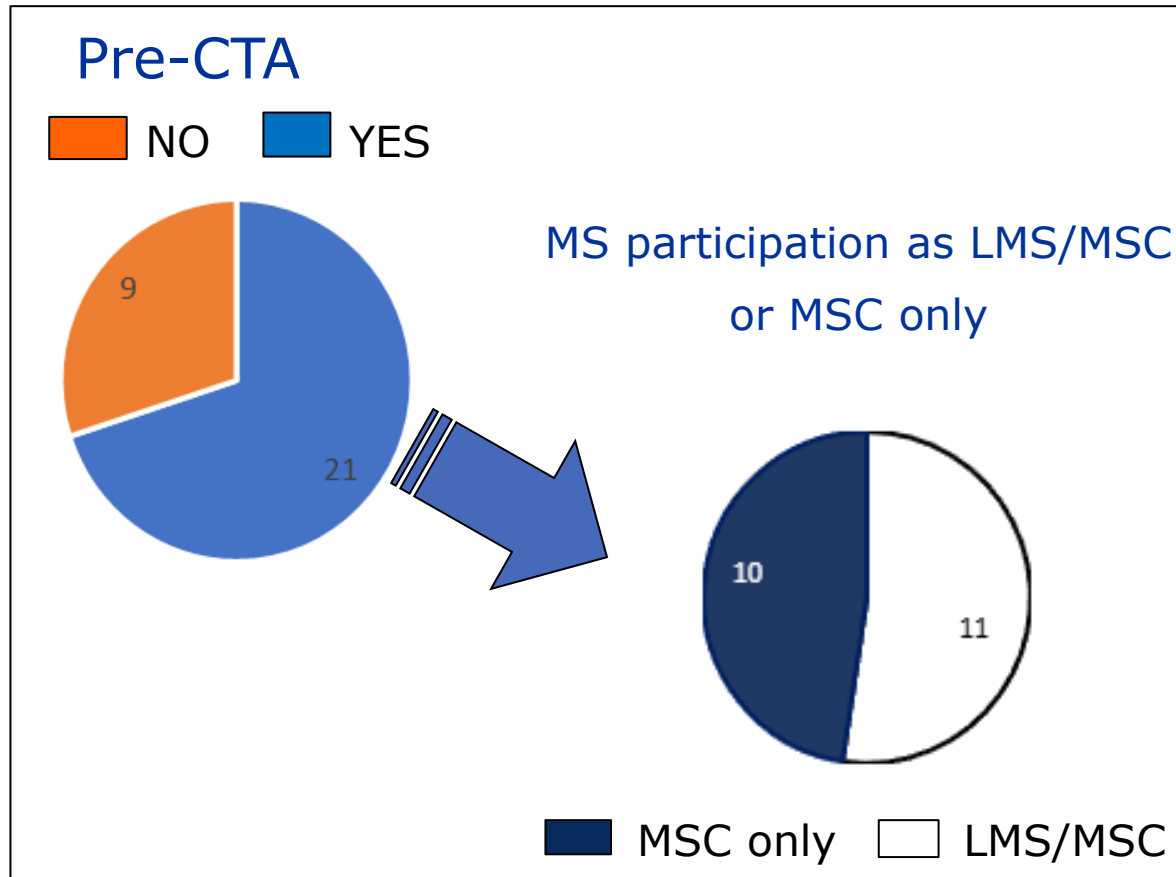
Short timeline, advice provided within 30 days



How to apply?

Fill out the [application form](#) and submit via email to snsa@fagg-afmps.be

MS participation in the pilots



Link: [List of MS participating in the pilots](#)

Applications and Topics

- Total Application submitted 46 - 28 Pre-CTA and 18 SAWP/CTCG
- 36 Successfully concluded

Pre-CTA

- Operational aspects of the submission of the CTA in CTIS / CT with complex design
- Regulatory and technical aspects of the CTA
- Combination products / combined CTs (MDR/IVDR)
- Regulatory request on AxMP GL
- Operational aspects of the submission of the CTA in CTIS / Transition to the CTR
- Verify if the CT is within scope of the Clinical Trial Regulation

SAWP/CTCG

- Study design
- Population enrolled in the CT
- Endpoints
- Statistical analysis plan
- Master Protocol Approach
- Adequacy of non-clinical study to start Phase I trials



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

Interim report covering the first year
(June 2024 – June 2025)

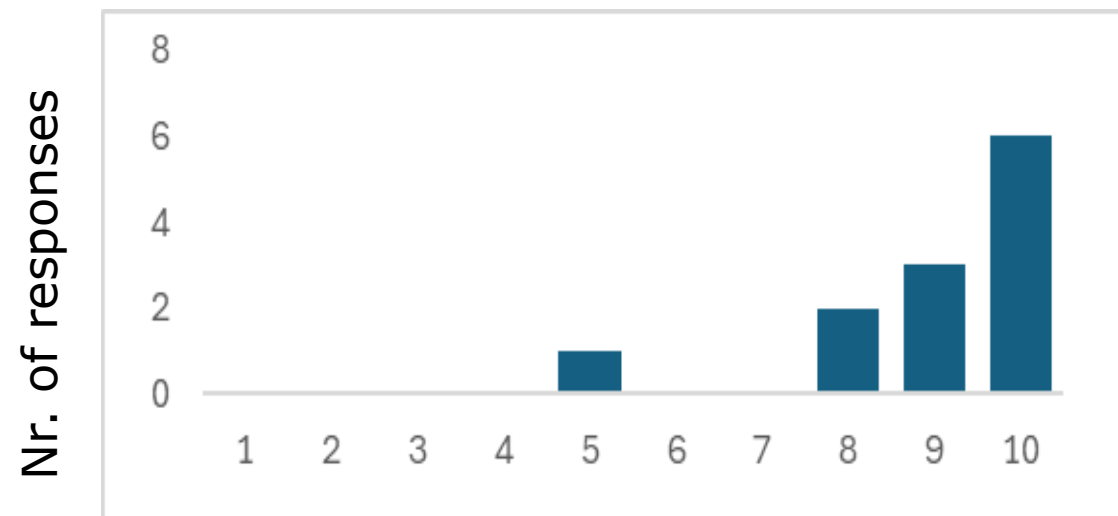
Available on the ACT EU [Website](#)

Feedback from Pre-CTA and SAWP/CTCG Applicants collected through dedicated survey

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 • Pre-CTA: Quick and simple procedure • 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 Pre-CTA and SAWP/CTCG 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 or Pre-CTA advice?



Feedback shows strong willingness to reapply for SAWP/CTCG or Pre-CTA advice

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

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