



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

MSP AG meeting

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# Pilots on scientific and regulatory advice

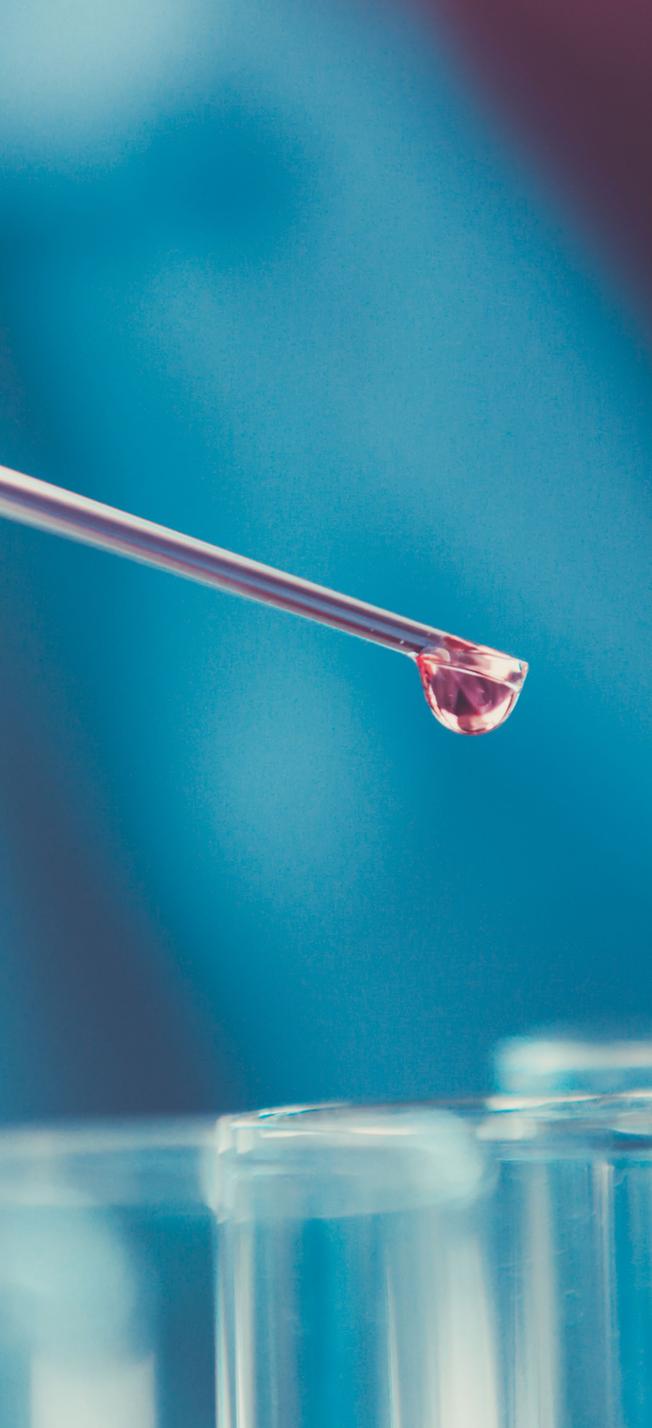
- The Accelerating Clinical Trials in the EU (ACT EU) initiative launched two pilots on consolidated advice in June 2024.
- The pilots aim to deliver **better, more impactful clinical trials**, benefitting patients and healthcare in Europe.
- Initially foreseen to end after 1 year or after 10 procedures for each pilot, the initiative has now been extended to gather more experience and additional feedback from applicants.
- 35 Applications received: 21 Pre-CTA and 14 SAWP/CTCG



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



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

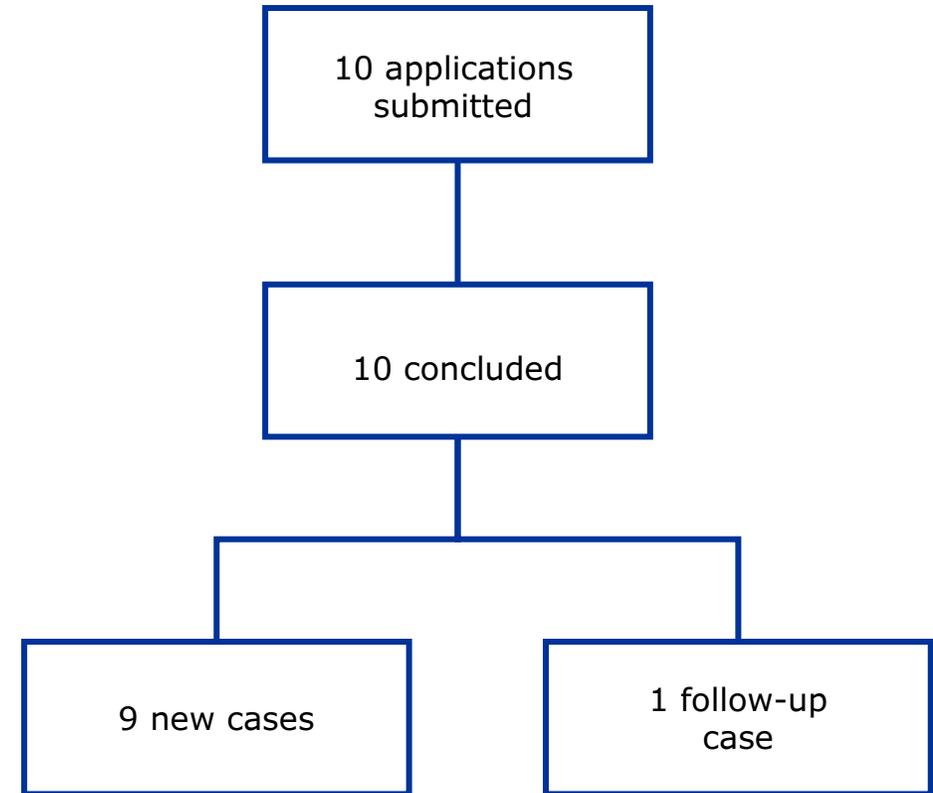


# SAWP/CTCG: Consolidated scientific advice on clinical trials

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*

# Feedback from SAWP/CTCG applicants

*based on 11 responses from 10 different applicants*

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

# 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**

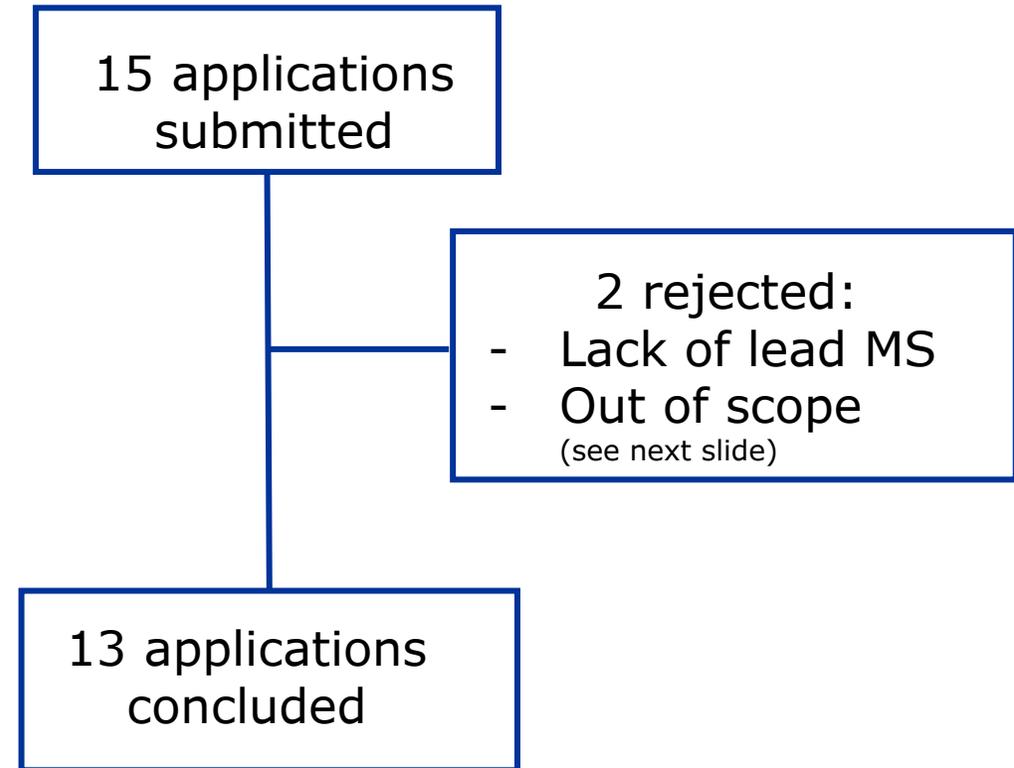


# Pre-CTA: Consolidated advice on technical regulatory issues

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*

# Feedback from Pre-CTA applicants

*based on 12 responses from 12 different applicants*

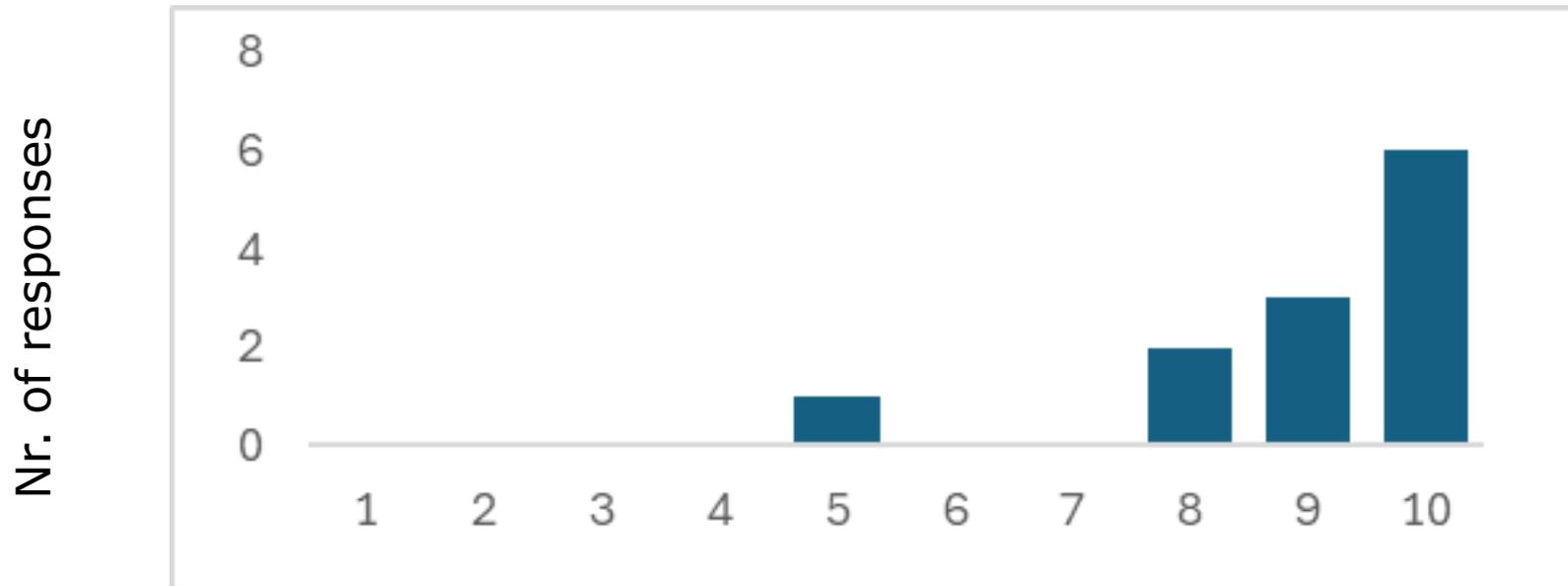
<b>Advice impact on the CTA</b>	<b>Added value of the pilot</b>	<b>Participant recommendations</b>
<ul style="list-style-type: none"><li>• MSC alignment</li><li>• Provides relevant guidance for sponsors</li><li>• Clarifies national requirements</li><li>• Helps improve and simplify CTA submission</li>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

**Feedback shows strong willingness to reapply for Pre-CTA advice**

# 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**

# Take away message

- 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
- **Action points for Sponsors**
  - The pilots are still accepting applications in 2026 to gain more experience
  - We encourage all developers of medicines to apply - including those who have already benefited from the pilots in earlier rounds (with some flexibility with the proposed RMS to increase diversification of experience)



# Thank you

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