pre-CTA and SAWP-CTCG pilots

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Objectives of the pilots

Launched in June 2024 to **facilitate dialogue** between regulators and sponsors prior to submission of their applications.

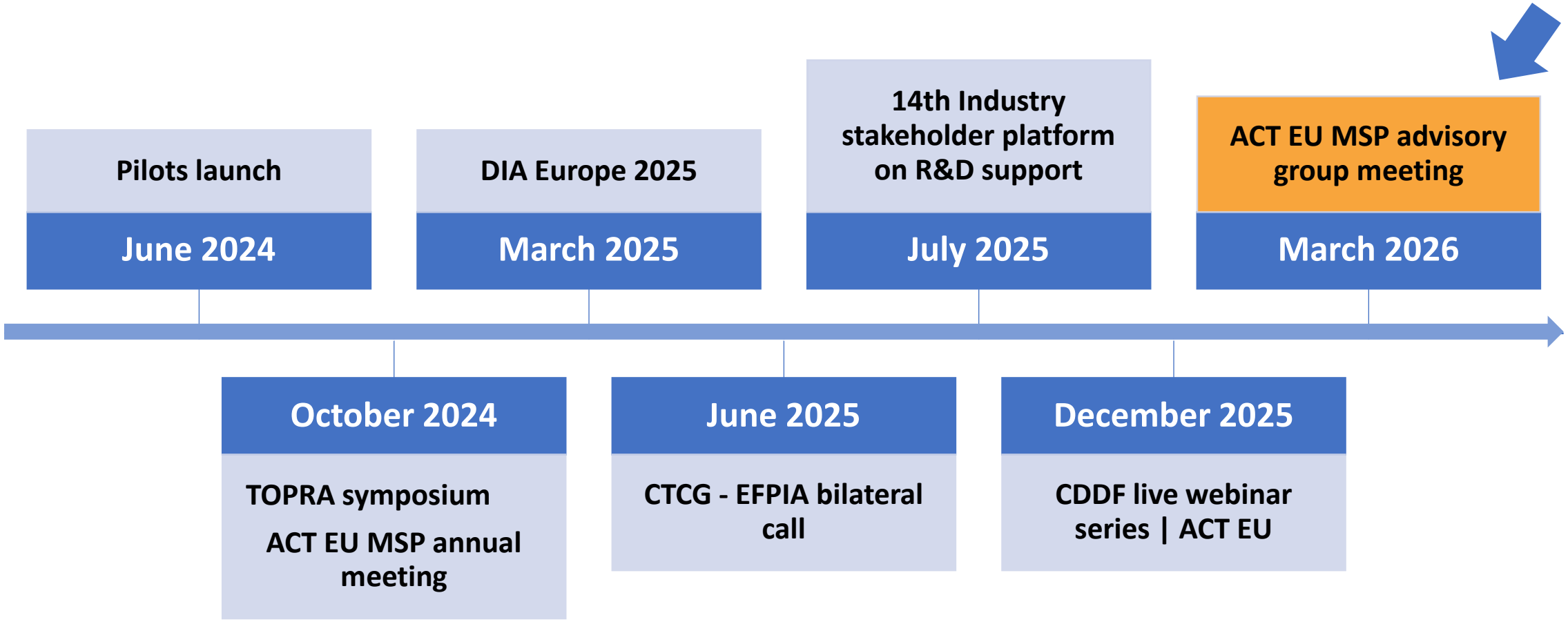
- **SAWP-CTCG pilot** aims to reinforce scientific advice coordination between clinical trial approval and clinical trial design.
- **pre-CTA pilot** offers advice on regulatory aspects prior to submission of the application in CTIS.

General feedback provided by the industry:

The pilots meet the established objectives and provide added value to the existing regulatory tools.

CTA: clinical trial application, CTIS: clinical trials information system

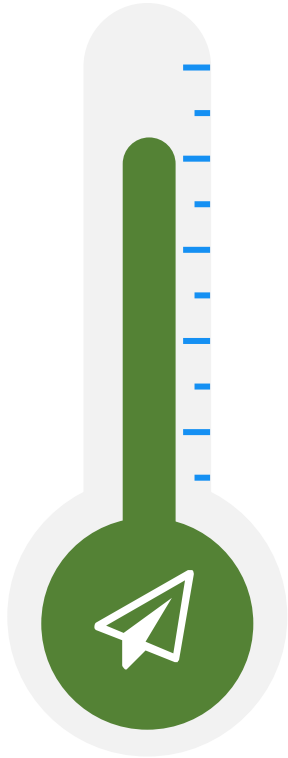
Continuous communication and experience sharing



CDDF: Cancer Drug Development Forum, MSP: multistakeholder platform

Experience recap for both pilots

Pre-CTA	SAWP-CTCG
Well-defined scope and eligibility criteria and possibility to include multiple NCAs.	Same process as CHMP/SAWP advice with no delays in timetables.
Effective validation procedure and clear and predictable timelines.	Effective validation process and overall smooth procedure.
Options for communication and clarification valued.	Clarity needed around the position of the CTCG representative with respect to the feedback provided by SAWP.
Some hiccups experienced in the past.	Doubts if the advice letter will be shared with all CTCG members prior to CTA review.
No major issues from recent experience shared. Overall positive feedback.	Will this collaboration have actual positive impact on subsequent steps, i.e. CTA/MAA review?
Involvement of the RMS not always ensured.	



READY TO GO

STILL TESTING THE CONCEPT FOR SAWP-CTCG BUT BASED ON EXPERIENCE GATHERED SO FAR INDUSTRY CONSIDERS THAT BOTH PILOTS COULD GO PERMANENT

Opportunities for improvement

Pre-CTA Advice

Expansion of the scope of the pilot to include additional topics / new approaches, allow more than 5 questions and provide transparent information on applicable fees.

Options to arrange **discussion meetings** in case of complex questions / requests for clarification.

For **alternative or innovative approaches** possibility to expand beyond the initial advice and consider the topic broadly by CTCG, e.g. specific guidance development.

Could we link the pre-CTA advice with the selection of RMS?

SAWP-CTCG

Provide details **who is representing CTCG and SAWP** to help better understanding the comments / concerns and improve the responses/engagement.

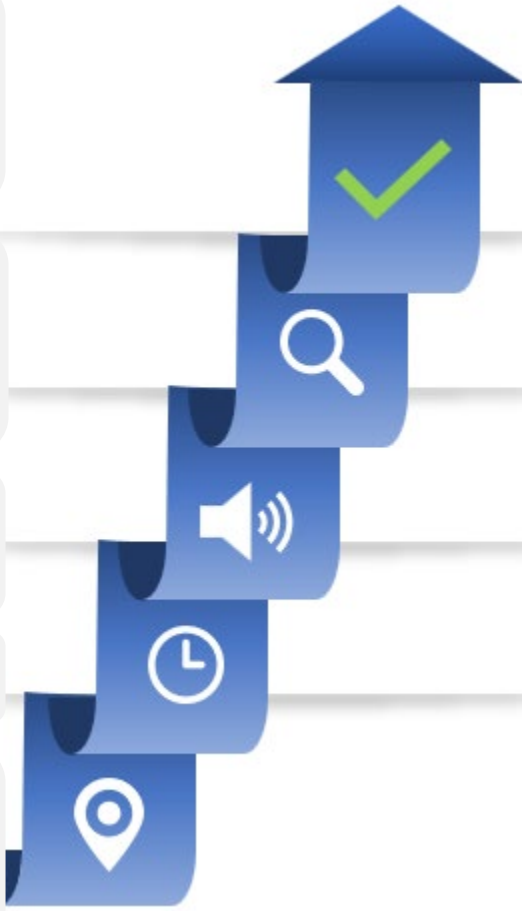
Should aim to **consolidate the views** of SAWP (responsible for advice on MAAs) and the MSs represented at CTCG (that oversee CTAs) to minimise avoidable divergences.

Collect and analyse feedback regarding impact on subsequent CTA review / outcome.

Resources identified as a potential challenge.

Ensure involvement of **additional stakeholders** to improve the value of the pilots:

- requests that include questions pertaining to part II of the upcoming CTA – ethics committees
- combined studies/combination products – ethics committees, notified bodies
- applications related to paediatric developments (with an agreed PIP) – PDCO



Towards permanent implementation

Increased participation

Collaborative effort

✓continue to apply

✓ involve more countries

Involvement of the proposed RMS

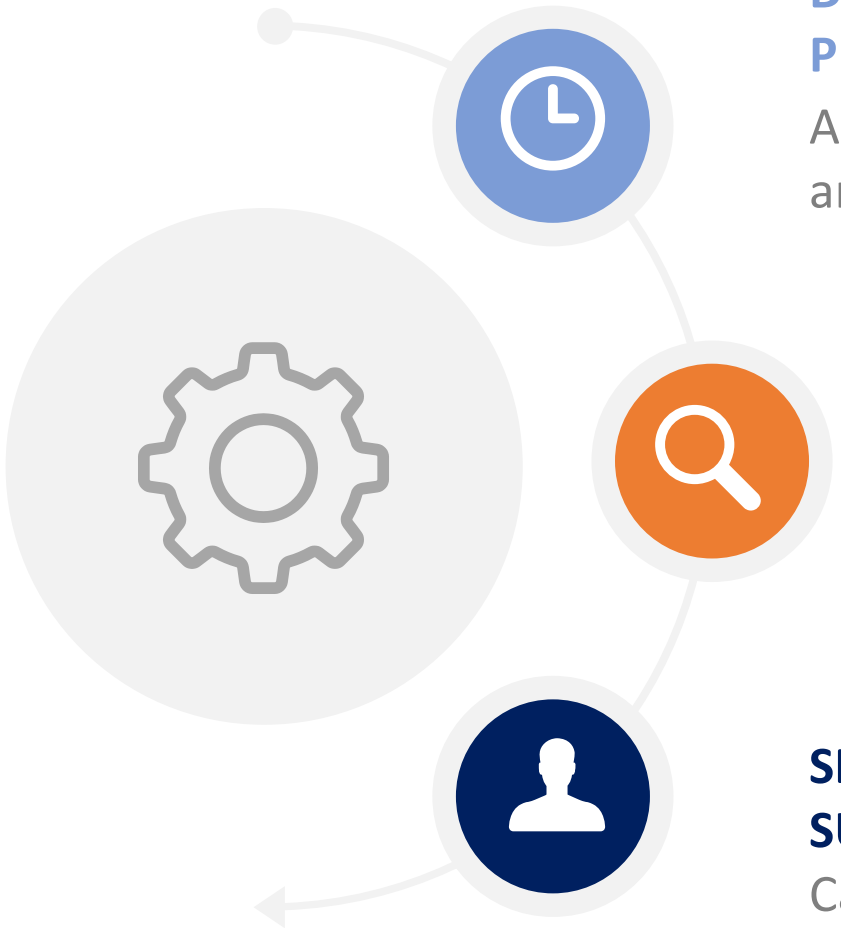
Systematic assignment of the proposed RMS as lead-MS in the pre-CTA advice while ensuring timelines are kept.

Broad uptake of the final advice

The outcome should represent the collective viewpoint of the network / CTCG, to avoid challenging disconnections.

The final advice is to be included in the CTA and flagged to all MSs.

Key takeaways



DRIVING CONSISTENCY AND PREDICTABILITY THROUGH PERMANENT PILOT IMPLEMENTATION

Are there plans to move towards full implementation and what are the timelines?

ENSURING NETWORK-WIDE TRANSPARENCY AND STAKEHOLDER ALIGNMENT

Are there any efforts ongoing to ensure alignment and reliance on the provided advice?

SECURING SUSTAINABLE RESOURCES TO ENABLE LONG-TERM SUCCESS

Can stakeholders that are part of ACT EU provide support to raise awareness?

Thank you