Consolidated advice on clinical trials

Presented by

ACT EU programme overview at the MSP meeting 22 October 2024

Overview

Launch of pilots, aims, guidance

SAWP CTCG pilot

- Principle features, scope, process, progress

Pre-CTA pilot (CTCG)

- Principle features, scope, process, progress, feedback

Summary of pilots, benefits to be evaluated and next steps

Consolidated advice on clinical trials

Consolidated pilots on scientific and regulatory advice

The Accelerating Clinical Trials in the EU (ACT EU) launched **two advice pilots**

The pilots
- enhance the **coordination within the EMRN**
- to offer applicants **harmonised advice** on
- how to improve the quality of their applications for **clinical trial application** and **marketing authorisation**.

I Pilot: SAWP-CTCG

II Pilot: Pre-CTA Advice

Pilots started officially on **June 10th**

Context:
Up to date **mapped information on current voluntary advice procedures** available from EU regulators on Medicines for human use

Supported by training Webinars
for Applicants (recorded)
for Assessors
Published Guidance documents on ACT EU website

List of MS participating in the pilot projects:
Member States participating in ACT EU pilots on consolidated advice (europa.eu)

Consolidated advice pilots:
Scientific advice from SAWP-CTCG

I Pilot: SAWP-CTCG

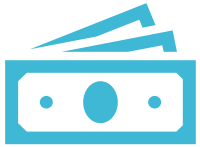
II Pilot: Pre-CTA Advice

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

Scientific Advice Working Party (**SAWP**) and Member States Clinical Trials Coordination Group (**CTCG**) provide a harmonized view on clinical trial design applicable to the CTA and MAA

Applications via **established SAWP** procedure

With justification



Normal fee structure

10 cases (1 per month x 10 months)

Scope for the SAWP CTCG pilot

Essential criteria

- Pilot cases should involve **multi-national clinical trials** across 2 or more EU MS;
- The **proposed Reporting Member State** should be known;
- The applicant should provide a **justification** for inclusion and prioritization in the SAWP-CTCG pilot,
  - ✓ What is the scientific/methodological clinical trial topic that requires both SAWP/CHMP and CTCG feedback?
  - ✓ What is the issue for the clinical trial design in the context of the MAA dossier?
  - ✓ What is the medical need for the proposed medicinal product?
  - ✓ Why is the development program of public health benefit?

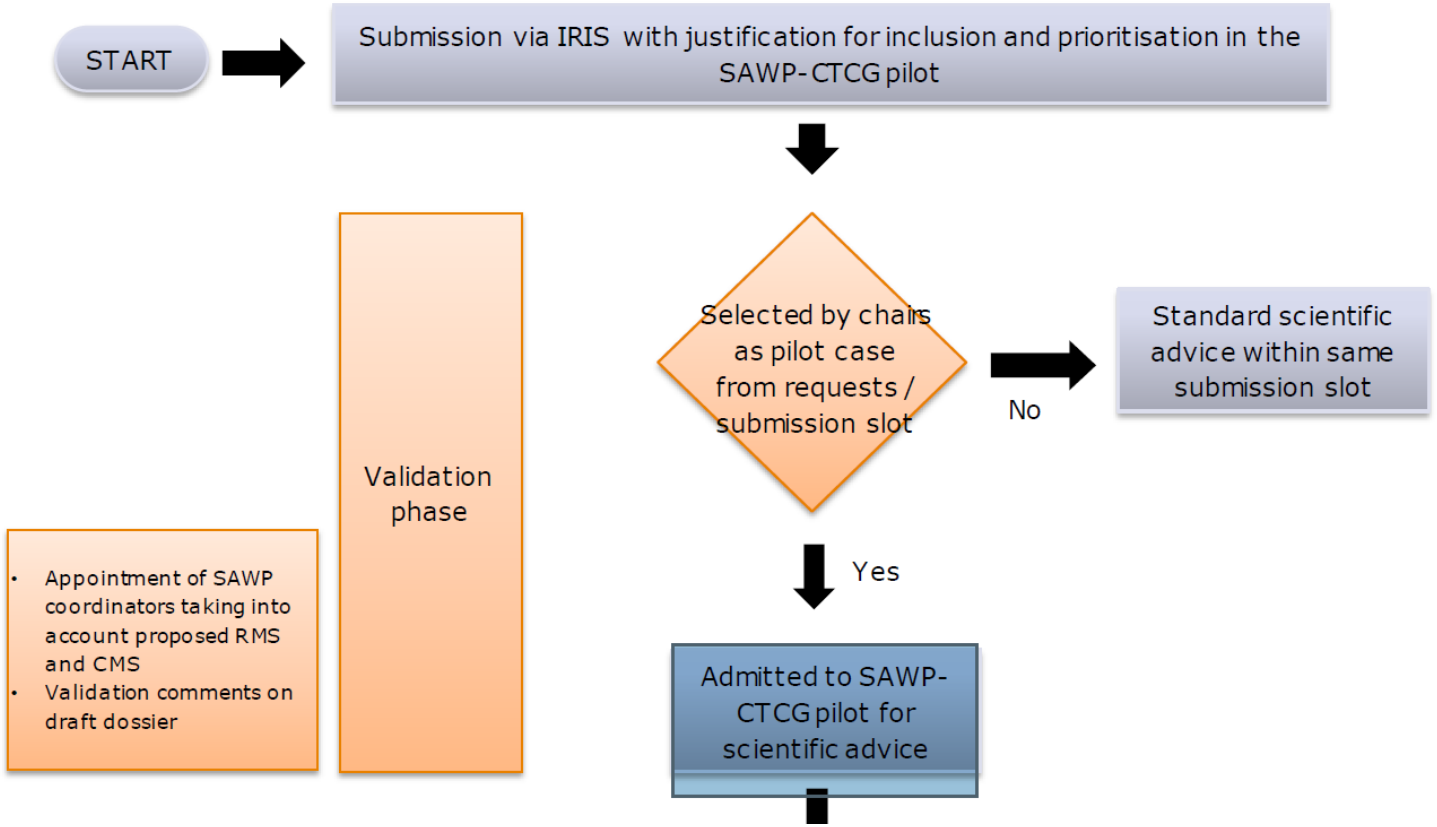
Scope for the SAWP CTCG pilot

Desirable criteria

- An advanced mature protocol of the clinical trial is preferred;
- Proposed Member States Concerned are known;
- Trial features, indication or program will be taken into account in the prioritisation and selection of pilot cases (i.e. ATMP, rare disease, PRIME, complex trials with/without paediatric issues, highly decentralised trials, academic sponsors, rejected CTA with multiple scientific /methodological issues requiring trial re-design.

Note COMP, CAT, PDCO, PRAC and other groups will be **engaged as relevant** to scope as per normal SAWP interactions

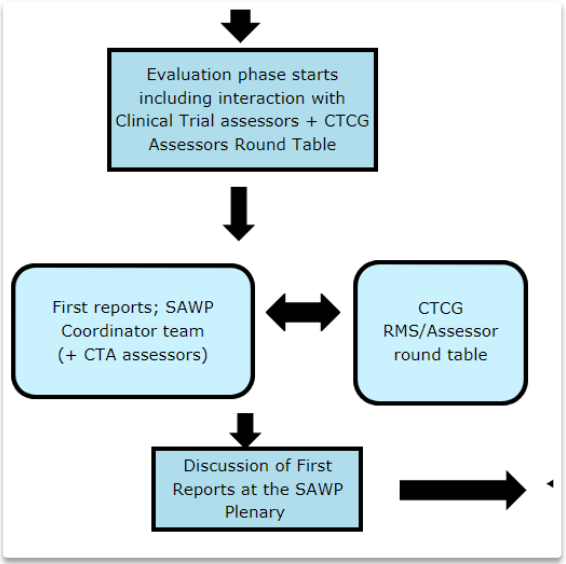
Validation – 30 days SAWP CTCG process (high level)



SAWP/CTCG

2 Procedures; 1 ongoing / 1 under validation

- 1 Selected on July and 1 selected in October
- area of advice including clinical, non-clinical and quality
- First procedure started on September 2nd
- Proposed RMS: DE
- The Forum for exchange are ART (CTCG) and SAWP (CHMP)
- Second procedure to start 28th October
- Timetable respected and positive interactions



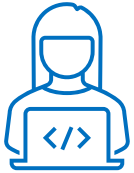
Consolidated advice pilots:
Pre-CTA advice from CTCG

I Pilot: SAWP-CTCG

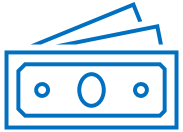
II Pilot: Pre-CTA Advice

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

Short timeline: 30-day written procedure



Applications via entry point SNSA procedure (snsa@fagg-afmps.be)

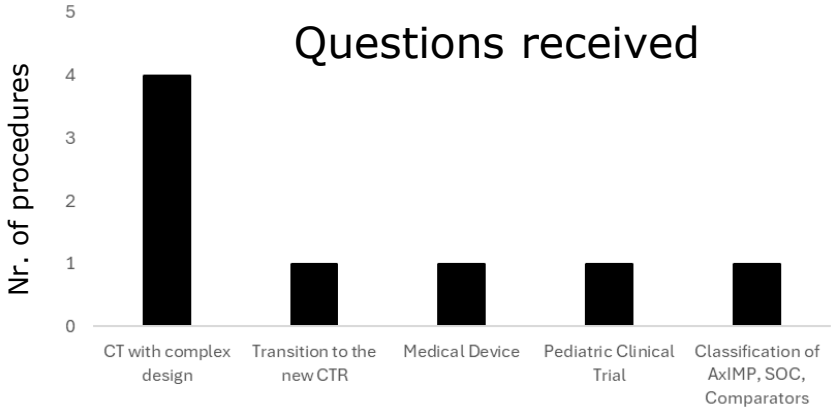


Lead Member State raises a single fee based on the reduced scope of the advice

Interim evaluation of the pilot every 5 applications

Scope of the pre-CTA advice and topics so far

- CTR scope (CT Y/N)
- Low intervention CT
- Combination products/Combined trials (MDR, IVDR select MSs according to landscape)
- Operational aspects of the submission of the CTA in CTIS (CCT, transition)
- Regulatory advice on GLP GL
- Regulatory advice on AxMP GL
- Decentralized elements in CTs
- 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



Timelines (max) pre-CTA advice

Pre-validation phase (2 working days)

Application via SNSA
SNSA@fagg-afmps.be

Request forwarded to the Pre-CTA coordinator including view on scope by SNSA coordinator

Validation phase (7 calendar days)

Time stops

Pre-CTA coordinator receives the Application

Request for further information (optional)

The request fall within the scope Lead-MS confirmed

Assessment phase (30 calendar days)

Time stops

12 days (≥ 3 days before ART)

Lead-MS circulate the draft advice

Discussion at ART slot

Request for further information (optional)

5 days for MSC

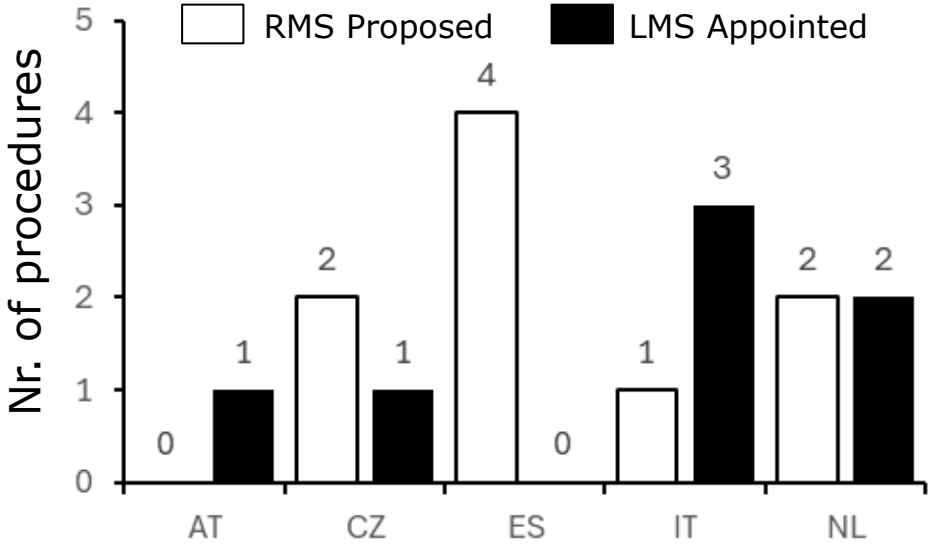
Consolidated advice for blocking comments to MSC

Final advice letter

Pre-CTA

- 9 procedures received so far:
  - ✓ 6 completed
  - ✓ 1 rejected due to the lack of LMS
  - ✓ 2 ongoing

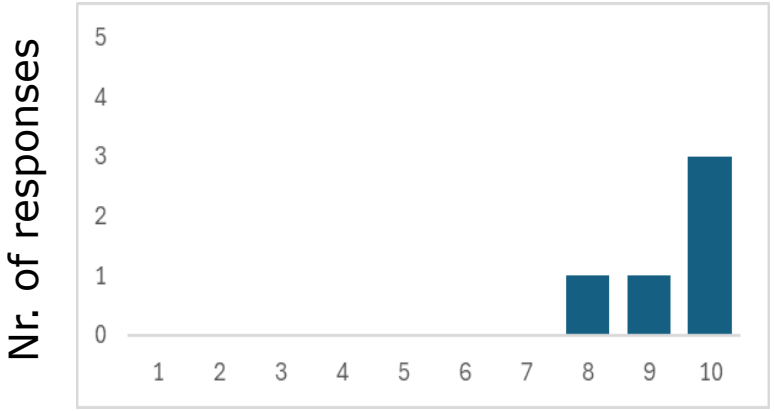
- 30-day timeline were respected
- A first interim analysis on the conclusion of the procedure Nr.5 is available
- List of MS participating in the pilots published on ACT-EU website
- Open to new applications



Applicants feedback on Pre-CTA added value

- The focus on regulatory and technical questions related to submission (outside of SAWP advice)
- Opportunity to identify potential issues earlier, ahead of CTA submission
- Harmonisation of regulatory expectations across different MS, potentially leading to greater consistency in the, therefore streamlining the process for multinational trials
- Quick and simple procedure (less than 1 month: simplified dossier, written advice, large scope of advice,, smooth communication with the pre-CTA team)

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



Wrap-up summary of pilots

	Pre-CTA technical/regulatory advice	SAWP/CTCG Scientific Advice
Scope	Regulatory and technical questions	Scientific aspects of clinical trials
Objective	Facilitate CTA review via CTIS	Clarify both CT and MAA requirements
Stakeholders	**RMS / MSC**	**SAWP, CTCG, RMS / MSC**
Protocol maturity	Almost mature (mandatory)	Advanced mature (advised)
MD/IVD in scope	**Can include MD/CDx**	**Out of scope (initially)**
Number of questions	Limited to 5 questions	No limit
Discussion meeting	**Yes (only in exceptional cases)**	**Yes**
Flexibility	**Flexible process**	**Fixed process**
Timelines	**Quickly addressed 30d**	**SA timetable, 40 or 70d**
Fees	As per national requirements (leading MS)	Usual SAWP SA fee
Pilot	"Iterations" of 5 SA procedures	1 pilot case per month for 10 months

Evaluation of Benefits and Next steps

Benefits

Evaluation of perceived benefits and efficiency for applicants and assessors

After procedure

After CTA

Next steps

Evaluate pilot against objectives when data available

Further consider optimisation, deliverables and workplan objectives for coming year in consultation with ACT-EU matrix

Any questions?

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Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Telephone +31 (0)88 781 6000
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Feedback from the webinar to Applicants on PreCTA and SAWP CTCG pilots

- 188 participants (Broadcasted event and summer period) and 45 questions received
- Hot topics: Added value of the new advice procedures; difference with the other procedures available (i.e. SNSA, traditional SAWP); involvement of third parties (i.e. ethics committees, PDCO, patients associations); list of the MS participating.
- QnA document to reply to the questions (currently in draft)

Consolidated advice pilots on clinical trials

Objectives	Current assessment
Consolidated advice for applicants from EU regulatory Network on clinical trials	Consolidated advice activity and content delivered in *pilot* cases;
Improved EU environment for clinical trials	A step forward with launch of *pilot activity;* to be further evaluated with more cases and impact on CTAs, more communication needed
Increased network coordination & efficiency	Increased Network coordination and interaction! further evaluation pending on efficiency gains, and issues to be addressed next slide

Next steps

Deliverables/issues to tackle	Proposed Actions
MS resource and pilot participation – especially for Lead MS in preCTA Defragmentation – further consolidation of advice between MS Ethics consultation -	Enhance support to MS via administrative secretariat and preparation Active communication case by case, Develop strategy in collaboration with CTCG and HMA Build interaction with Collaborate and PA7, and PA11
Collect feedback on procedures, analysis, reporting Process optimisation, and further communication	Undertake deliverables