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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

COMBINE Project 1 'All-in-one' Coordinated Assessment Pilot

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CTIS Info Day Webinar

17th June 2026 - Online

Reminder - Project 1:

All in one coordination of assessment procedures under CTR/IVDR/MDR

The purpose of this project is to explore **coordinating** Member State assessments of applications for **combined studies** (including competent authorities and ethics committees) across the **CTR and IVDR** or MDR.

This particular project should initially focus on the **most common type** of combined study (CT of a medicinal product combined with PS of a companion diagnostic IVD).

The project should include an **analysis, a pilot and a review** of these with recommendations for next steps.

Pilot Key Features

- ✓ Pilot must remain within current legal frameworks
- ✓ PS requires a national application to officially start the assessment clock

Single submission in CTIS consisting of a parallel submission of:

CT documentation

PS documentation

EC documentation for the CT

EC documentation for the PS.

Coordinated RFI for CT and PS

Goal: To have questions raised together

Coordinated response from sponsor to the RFI

Goal: To have information/ changes to documentation occurring at the same time

Alignment of decisions

Goal: Decisions/ opinions provided together

Single procedure timeline

Phase 1 Applications

- **8** applications received from 6 sponsors
- **RMS:** Germany (5 applications) Netherlands (3 applications)
- **Participating MSs:** France, Spain, Belgium, Norway, Ireland
- **MSCs not participating:** Italy, Poland, Hungary
- **Planned submission timelines**: Nov (2), Dec (1), Jan (2), Mar (3)
- **Final submission timelines:** Nov (2), Feb (1), Mar (4), Unknown (1)

First application **authorised**: March 2026
7/8 Applications in progress or concluded

COMBINE Pilot Phase 2 - What is new?

2-Sponsors

ATMPs

SMs (not initially)

Combined medical device studies

Explore use of single documents

COMBINE Pilot - Phase 2

Participating MSs:

RMS	10
MSC	8
Awaiting Response	4

Member State	RMS/MSC
Austria	RMS/MSC
Belgium	MSC
Bulgaria	Not participating
Croatia	Awaiting response
Cyprus	MSC
Czech Republic	Not participating
Denmark	RMS/MSC
Estonia	Awaiting response
Finland	RMS/MSC
France	RMS/MSC
Germany	RMS/MSC
Greece	Awaiting response
Hungary	Not participating
Ireland	RMS/MSC
Italy	Not participating
Latvia	RMS/MSC
Lithuania	RMS/MSC
Luxembourg	Not participating
Malta	Awaiting response
Netherlands	RMS/MSC
Norway	MSC
Poland	Awaiting response
Portugal	MSC
Romania	MSC
Slovakia	Not participating
Slovenia	MSC
Spain	MSC
Sweden	RMS/MSC

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CTIS – General aspects

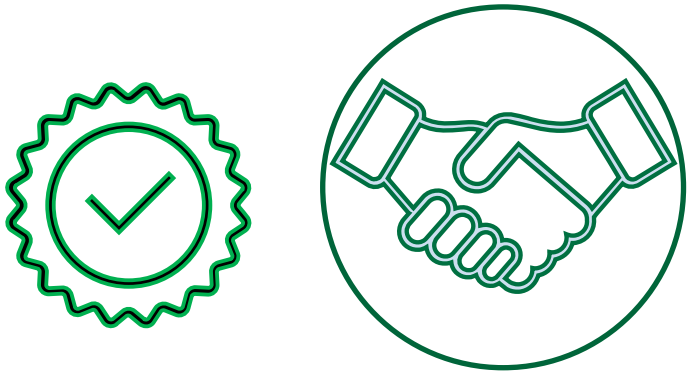
General principles for Phase 1 use of CTIS remain applicable

CTIS serves as a document repository and assessment tool

Leveraging existing CTIS functionalities

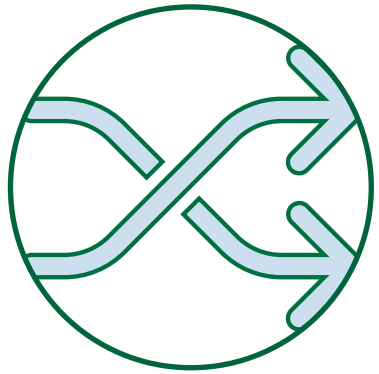
Prior experience with CTIS is highly recommended

Submission process – A two-way approach



Single application

- Essentially the **same approach** used in Phase 1
- Can be used for **same-sponsor** and **separate-sponsor** submissions (in which case the CT sponsor becomes the **coordinating sponsor**)
- CT and CI/PS **sponsors are responsible for setting up confidentiality agreements**



Parallel IMPD-Q application

- Applicable **only for separate-sponsor** submissions
- Limited for scenarios where **sponsors cannot reach confidentiality agreements** that would allow for a single application submission
- Ensures **parallel workflows** for the submission and assessment of MD/IVD-related confidential documents

CTIS training recommendations

- In addition to the COMBINE Sponsor Guide, CI/PS sponsors are advised to consult existing training and supporting materials on the use of CTIS, available on the EMA website (CTIS training and support)

- Detailed description of the current implementation of the IMPD-Q application process under the CTR is included in a dedicated section 2.15 of the CTR Q&A and also demoed in dedicated webinars (IMPD-Q only submission and Alternate IMPD-Q)

- If deemed necessary, CI/PS sponsors are advised to access industry training offerings that could help in clarifying the use of CTIS.

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Substantial modifications (SM) and single documentation

- **Substantial modifications**
  - Different scenarios
  - Template cover letter SM drafted to indicate type of SM (CT, PS, part I, part II, national requirements and any combination)

- **Single documentation** (e.g. protocol, recruitment, ICF, insurance)
  - Will start after procedure SM has been drafted
  - In the meantime: instructions for use single documents in sponsor guide

Formal Evaluation of Phase 1

Two structured surveys created to capture feedback

Survey to Sponsor

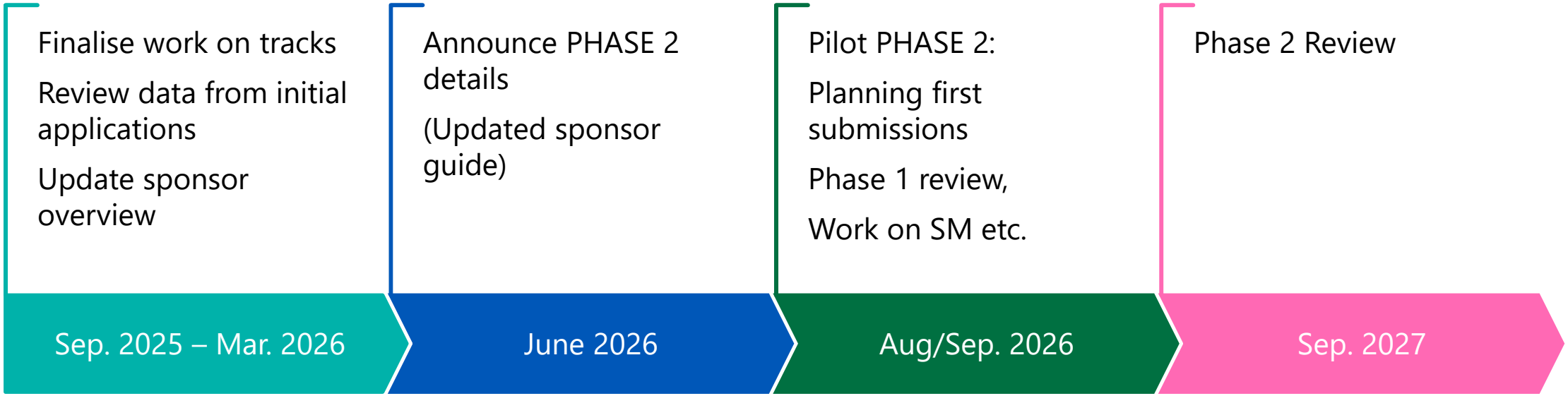
Survey to RMS/ MSC*

Surveys to be completed after the application has concluded.

For the purposes of Phase 2 feedback was integrated as received.

Formal Analysis of Phase 1 to be completed after all applications have concluded and survey responses received.

Timeline


Finalise work on tracks
Review data from initial applications
Update sponsor overview
Announce PHASE 2 details
(Updated sponsor guide)
Pilot PHASE 2:
Planning first submissions
Phase 1 review,
Work on SM etc.
Phase 2 Review
Sep. 2025 – Mar. 2026
June 2026
Aug/Sep. 2026
Sep. 2027

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Questions?