Member States support to the CTR implementation

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MS activities

- Collaboration with Ethics committees on single decision
- Definition of national requirements for submission
- Publication of transparent fee structure
- Responses to questions raised via national contact point
- Many additional activities varying between MSs
- …
- Assessment of applications

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CTCG change management activities

- Participation in all Act EU initiatives
- Coordination across MSs
- Monthly plenary meetings for creation of (internal) guidance documents
- Weekly assessors round tables for
  - training on existing guidance and
  - identification of gaps
  - discussion of and responses to procedural, regulatory and scientific questions
- Support of EMA organised trainings
- Initiation of several projects
  - for guidance development
  - on legal interplay MDR/IVDR/CTR
  - for closer collaboration with ethics committees across the EU/EEA
- Participation in CTIS prioritisation exercises
- Coordinated responses to questions raised to CTCG

Urgencies first: Transition of Clinical trials - status

Huge numbers of Clinical trials for transition

Currently only few transitions have taken place

CTCG created internal document for shortened administrative procedure

CTCG will publish updated external guidance document early July *

Additional clarifications still needed in the COM Q&A

-> Time for action now

*CTCG will publish updated guidance for sponsors on transition of multinational trials at the HMA website beginning of July (https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html), key documents

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Transition of Clinical Trials - a few details

- As of 31/01/2023, all new CTAs and additional MSC must be submitted under CTR using CTIS. They cannot be submitted under CTD in EudraCT.
- CTA authorised under the CTD can continue under the CTD till the end of the 3-year transition period (ending 30/1/2025).
- If trials are expected to continue after the end of the transition period, sponsors need to transition them to CTR before the end of the transition period **considering the time needed for finalization of the transition procedure,** and the two-week winter clock stop.
- Sponsors are recommended to use the CTCG expedited procedure to transition minimum dossiers restricted to documents already approved under the CTD.
- Only Member States with active sites (last-visit-last-subject did not yet occur) should be transitioned
- At the time of transition no substantial amendments can be ongoing in any Member State Concerned (MSC) under CTD

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Trials that should not be transitioned

- Trials that have already ended or will end before the end of the transition period (by 30/01/2025) in the EU/EEA.
- If an end of trial notification has been submitted in all EU/EEA member states, but the global end of the trial has not been notified, the trial should not need to be transitioned. Global end of the trial and trial summary results should be posted via EudraCT under the Directive.
- Trials that are old and started prior to the Directive 2001/20/EC coming into application. If they are interventional and need to continue to run after the end of the CTR transition period, then a new CTA under the CTR needs to be submitted.
- Paediatric trials that are being conducted entirely outside the EU/EEA but for which a EudraCT number has been created should also not be transitioned.

EudraCT remains active after end of transition

EudraCT remains active beyond the end of the transition for sponsors:

- to notify global end of the trial and submission of summary results of trials completed under the Directive.
- to keep registering paediatric trials that are being conducted outside the EU/EEA in EudraCT, until a relevant functionality is delivered in CTIS.
- to provide information on trials that have been transitioned and to be transparent about MSs where the trials has ended before the transition (making reference to the result reporting in CTIS)

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Transition package - general considerations

- Only “old” documents approved under the directive
- No retrospective documents: Only current latest approved versions should be included in the transition application.
- Blank documents for non existing mandatory documents (to be uploaded with a comment that the document does not apply)
- Cave transparency
- Multi-national clinical trials should be transitioned as a single multi-country CTA under the CTR -> harmonization/consolidation
- Consolidated protocols can be provided without prior CTD submission
- Please clarify all details in the cover letter -> Template will be provided

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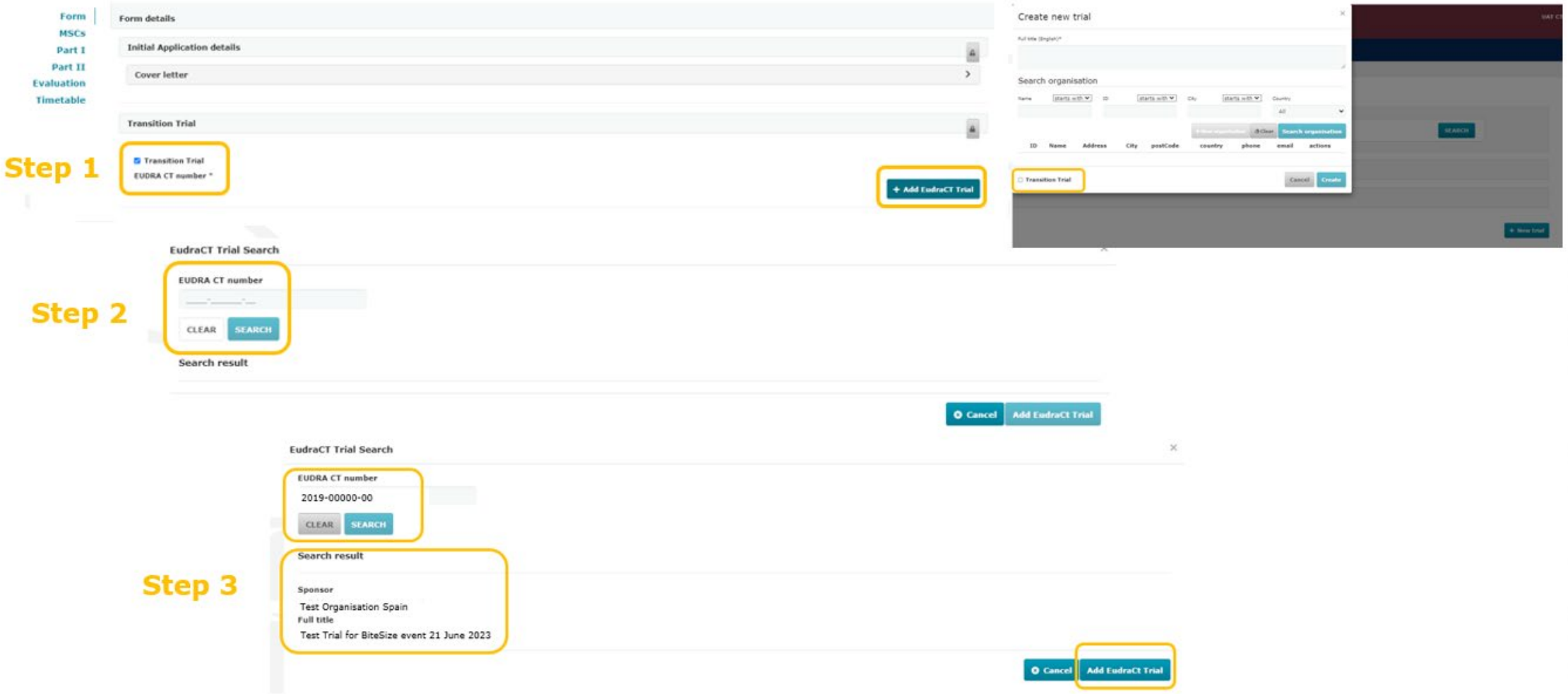

If trials are not expected to end in EU/EEA by 30/01/2025, transition them as soon as possible.

There will be no legal grounds for CTD trials (EU/EEA) to continue from 31/01/2025.

Thank you for listening.

Any questions?

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