Transitional Period for clinical trials

From the Directive to the Regulation

25 March 2024

CTR provisions

Article 98

Transitional provision

1. By way of derogation from Article 96(1) of this Regulation, where the request for authorisation of a clinical trial has been submitted before the date referred to in the second paragraph of Article 99 of this Regulation pursuant to Directive 2001/20/EC, that clinical trial shall continue to be governed by that Directive until three years from that date.

2. By way of derogation from Article 96(1) of this Regulation, where the request for authorisation of a clinical trial is submitted between six months after the date of publication of the notice referred to in Article 82(3) of this Regulation and 18 months after the date of publication of that notice, or, if the publication of that notice occurs earlier than 28 November 2015, where that request is submitted between 28 May 2016 and 28 May 2017, that clinical trial may be started in accordance with Articles 6, 7 and 9 of Directive 2001/20/EC. That clinical trial shall continue to be governed by that Directive until 42 months after the date of publication of the notice referred to in Article 82(3) of this Regulation, or, if that publication occurs earlier than 28 November 2015, until 28 May 2019.

(79) Directive 2001/20/EC should be repealed to ensure that only one set of rules applies to the conduct of clinical trials in the Union. In order to facilitate the transition to the rules set out in this Regulation, sponsors should be allowed to start and conduct a clinical trial in accordance with Directive 2001/20/EC during a transitional period.

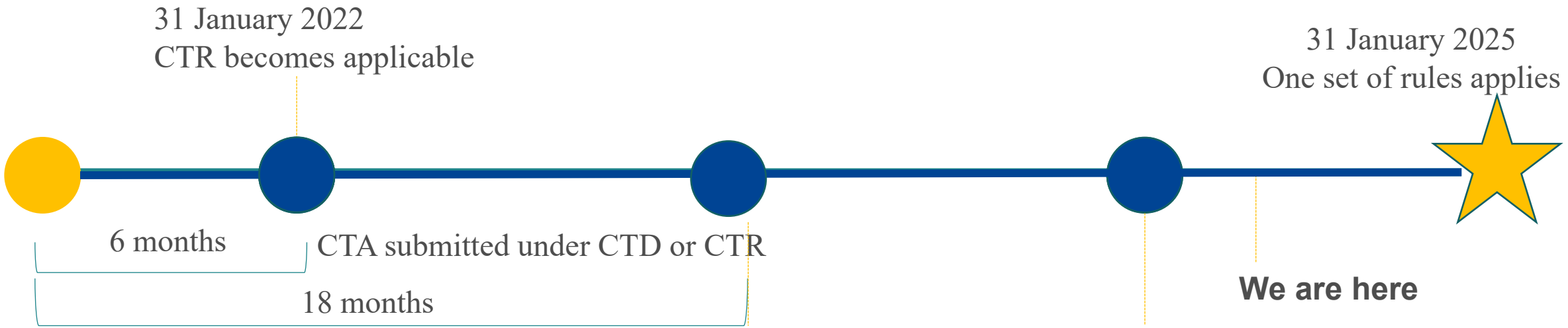
Transitional provision - Timelines

Article 99

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply as from six months after the publication of the notice referred to in Article 82(3), but in any event no earlier than 28 May 2016.



European Commission

Scope of the transitional phase – 2022/2025

This 3-year transitional phase allows to adapt to the new rules, record the information in CTIS, and be ready for a full CTR implementation.

Sponsors are urged to submit now to CTIS the "transitioning application(s)" avoiding last minute submissions.

CTD trials still ongoing on 31 Jan and after are to be considered as **non-compliant with the CTR** and **sponsors may be subject to corrective measures** by Member States pursuant to Article 77 of the CTR.

EudraCT remains open for the submission of trial result summaries even after 30/01/2025

Supporting COM documents: where to find them

Standalone document dedicated to transitional trials + updated quick guide for sponsors on Eudralex v. 10

1. **Guidance for the Transition of clinical trials from the Clinical Trials Directive to the Clinical Trials Regulation** → https://health.ec.europa.eu/document/download/10c83e6b-2587-420d-9204-d49c2f75f476_en?filename=transition_ct_dir-reg_guidance_en.pdf

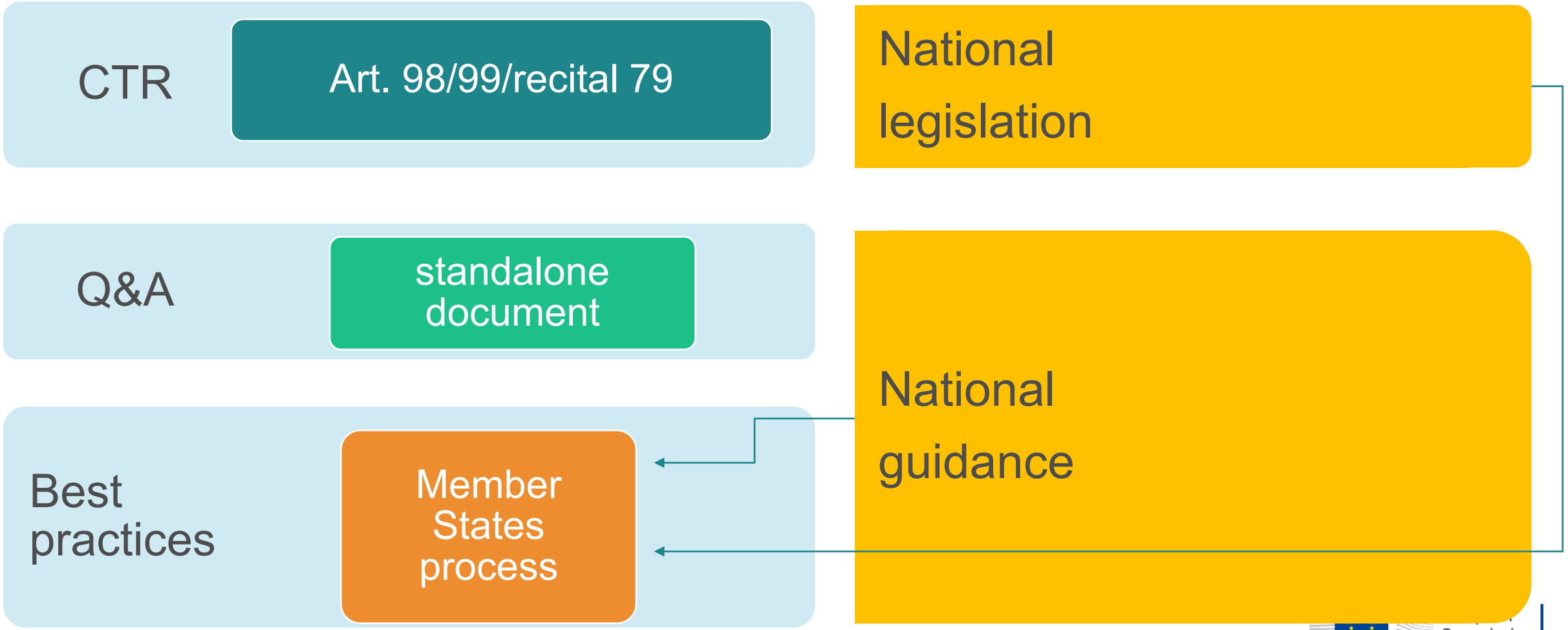
! NEW TABLE IN ANNEX for transparency and clarity on Part II: The table provides an overview of the documents that Member States request for Part II of the Transitioning Application. No additional part II documents should be submitted.

2. **Quick guide on the rules and procedures of the EU Clinical Trials Regulation** → https://health.ec.europa.eu/document/download/f5ad2a13-4a41-4ada-81a1-2854783c75c0_en?filename=mp_ctr-536-2014_guide_en.pdf

3. **Annex II and III of the Commission's Q&A document**

European Commission

Instructions for the transition



Thank you

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