Clinical Trial Regulation 536/2014

Arrangements for the transition period

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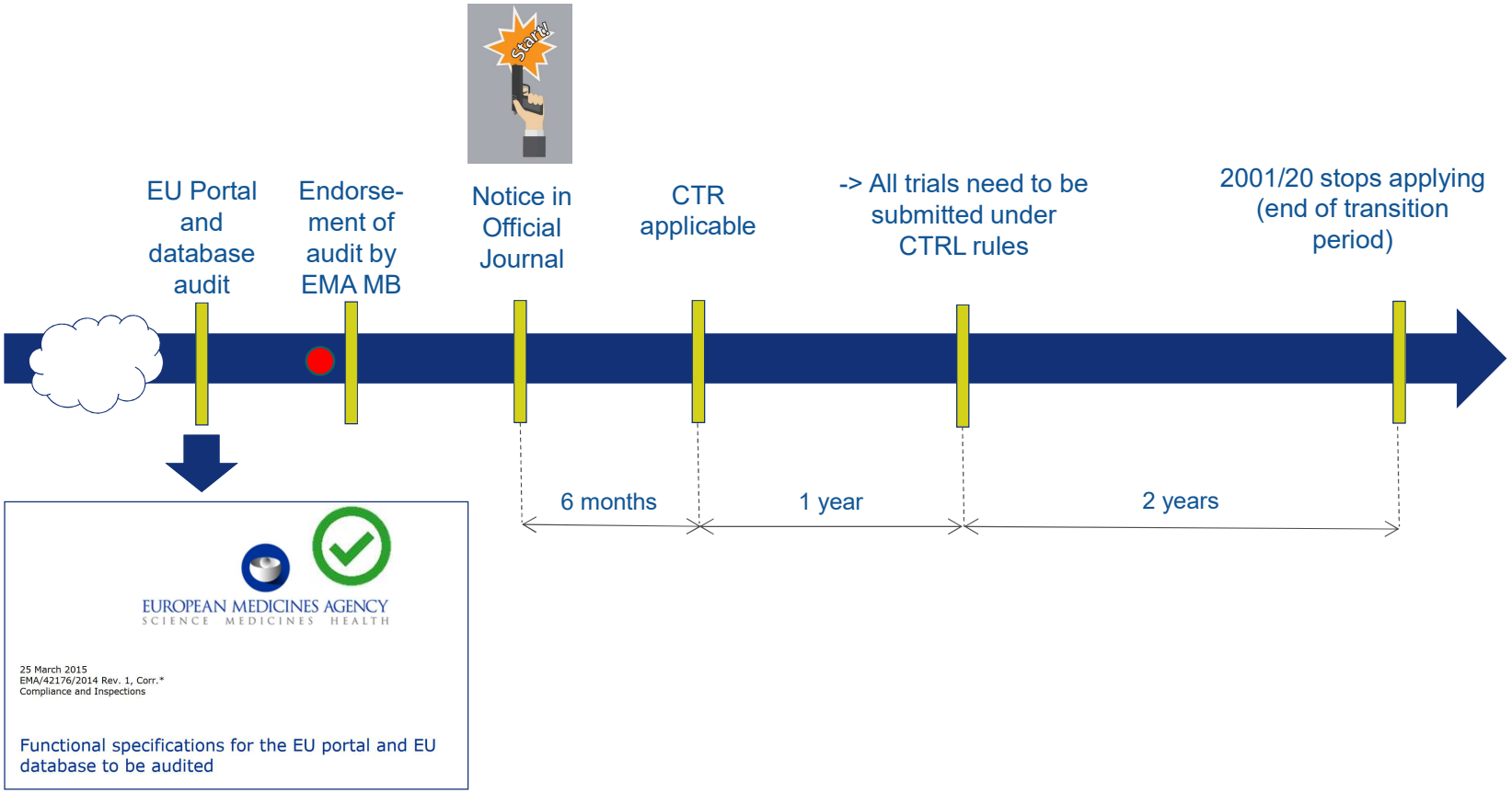
joint training - March 9-10, 2021

Clinical Trials Regulation (CTR)

- The Regulation was adopted in April 2014 by the **European Parliament** and published in May 2014.
- The Regulation is likely to become applicable **in January 2022.**
- All **new trials** will need to be submitted under the CTR **1 year** after the date of application.
- The **transition period** for the old and new procedures will be a maximum of **3 years** after the date of application of the Regulation.



- Endorsement of the full functionality is a condition for the publication of the notice in the official journal which is the start of the transition period of 6 months that precedes the applicability of the CTR

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Transition period 1

- to facilitate the transition it is allowed to start and conduct a clinical trial in accordance with Directive 2001/20/EC during a transitional period
- Trial applications can be submitted either under the CTD or the CTR for **1 year after application date** of the CTR
- clinical trials can continue under the CTD till the end of the **3-year transitional period**
- application to transition ongoing trials from CTD to CTR will need to be submitted in time for **a full assessment before the end of the transitional period**

Transition period 2

- trials that started **prior to the date of entry into application of Directive 2001/20/EC** and **not in line the CTD*** cannot continue after the entry into application of the Clinical Trials Regulation. A new initial application under the CTR will be needed.

*Trials in line with the CTD but started before the application date of the CTD can be transitioned

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Transition process

- Ongoing trials which are **compliant with CTR** and are **not subject to any ongoing assessmen**t in any EU/EEA country
- If necessary **substantial amendments** under CTD shall be used to make the trial compliant with CTR -> this needs to be completed in time for the assessment of the compliant CTA under CTR
- Sponsor’s responsibility to **ensure compliance**
- Member States can take **corrective measures** if the trial does not comply with CTR

Submission of an application for transition

- initial application (Art 5, CTR) to CTIS
- based on the latest authorized version of the dossier under CTD
- **New documents**: cover letter, CTR application form (Part I and II) in CTIS, harmonised or consolidated protocol* for multi-country trials (Annex I B-D)
- **Additional mandatory documents**: all part I and II documents need to be submitted in their latest approved version (not necessary to prepare new versions for CTIS submission).

* CTFG Best Practice Guide for sponsors of multinational clinical trials with different protocol versions approved in different Member States under Directive 2001/20/EC that will transition to Regulation (EU) No 536/201466).

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Transparency requirements

- **Transparency requirements and publication rules** will be applicable to all documents submitted in CTIS
- Documents under the CTD, **outside of CTIS**, will not fall retroactively under the transparency requirements (e.g. inspection reports, notifications)

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Thank you

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