

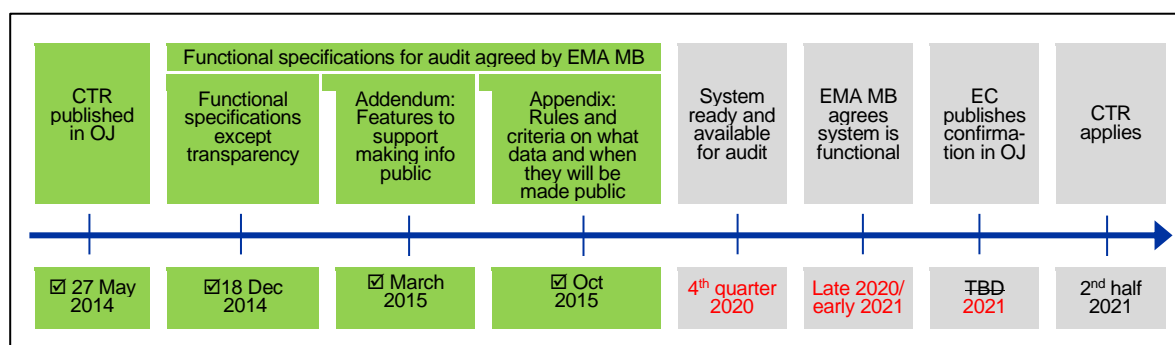
Implementation of the EU Clinical Trials Regulation Update for the Federal Office of Public Health - Addendum to December 2019 -

1. EU PORTAL AND EU DATABASE

1.1. EMA process and milestones

At its December 2019 meeting, the EMA Management Board confirmed that the current timelines foresee an audit of the Clinical Trials Information System (CTIS) (formerly referred to as the EU portal and database) in December 2020. These timelines are based on the conclusions of an "audit readiness assessment" of the CTIS, which was conducted by representatives of Member States' Authorities, the European Commission, sponsors, the EMA and the IT supplier. It aimed to identify critical business blockers to the delivery of the auditable version, i.e. issues that prevent a successful audit outcome and for which no appropriate workaround exists (see report from December 2019). Its conclusions, which were adopted by the EMA Management Board, were implemented in an updated plan outlining remaining critical items of the CTIS to be addressed. Such items will be under tight scrutiny in the first few months of 2020.

Figure 1: EMA key milestones and timelines for design and development of the EU portal and the EU database



Source: EMA 2020 (CTR: Clinical Trials Regulation; OJ: Official Journal of the EU; EC: European Commission; MB: Management Board), *updated timelines in red*

2. CLINICAL TRIAL SAFETY REPORTING

No update is available.

3. ADOPTION OF IMPLEMENTING ACTS, DELEGATED ACTS AND GUIDELINES

No update is available.

4. BACKGROUND

4.1. EU Clinical Trials Regulation

In the future, clinical trials in the EU will be uniformly regulated by the EU Regulation ([No 536/2014](#)) on clinical trials with medicinal products (CTR). Under the CTR, the authorization procedure will be harmonized in the EU. According to the current Clinical Trials Directive ([2001/20/EC](#)), sponsors of a multinational clinical trial must submit separate applications to the authorities and ethics committees of each participating EU Member State, in the local language and with different application forms.

In the future, one single application per multinational trial will be submitted by the sponsor via an online portal (EU portal) run by the EMA. The CTR entered into force on 16 June 2014 and will apply as soon as the EU portal is fully functional.

4.2. Implementation of the CTR

After the CTR's entry into force on 16 June 2014, the following implementation work is envisaged:

- **EU portal and EU database:** in collaboration with the EU Member States and the European Commission, the EMA will set up and maintain an EU portal and an EU database at Union level. Furthermore, it will draw up the functional specifications for the portal and database, together with the timeframe for their implementation (Articles 80 - 82 CTR).
- **EudraVigilance database:** the EMA will set up and maintain an electronic database for safety reporting (Article 40 CTR), which would be a module of the existing EudraVigilance database.
- **Secondary legislation:** the Commission has the power to adopt implementing acts, delegated acts (Chapter XVII of the CTR) and guidelines.

5. SOURCES

- EMA, EMA Management Board: highlights of December 2019 meeting, 20 December 2019, last updated on 10 January 2020; <https://www.ema.europa.eu/en/news/ema-management-board-highlights-december-2019-meeting>, last accessed on 21 January 2020.
- SFL Intelligence.