# Implementation of the EU Clinical Trials Regulation
# Update for the Federal Office of Public Health
# - June 2017 -

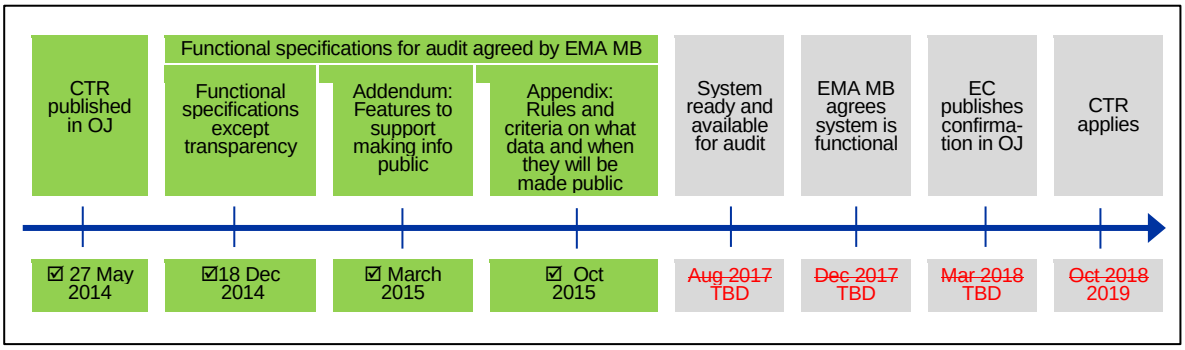
## 1. EU PORTAL AND EU DATABASE

### 1.1. EMA process and milestones

At its meeting in June 2017, the Management Board of the European Medicines Agency (EMA) announced that the entry into application of the Clinical Trials Regulation (CTR) will be postponed from October 2018 to a still undefined timepoint in 2019. This delay is due to technical difficulties in the implementation of IT systems of the EU portal and the EU database. As a result, the EU portal will not be able to go live in October 2018 as previously scheduled.

EMA's Management Board will in October 2017 discuss a new delivery timeframe provided that progress in the implementation of the IT systems has been confirmed. The new timeframe will replace the one from December 2015.

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




*Source: EMA 2017 (CTR: Clinical Trials Regulation; OJ: Official Journal of the EU; EC: European Commission; MB: Management Board) red: updated timelines*

### 1.2. User acceptance testing

At the workshop of the European network of paediatric research on 16 May 2017, the EMA provided more insights on the results of the fifth round of user acceptance testing (UAT 5). Participants in UAT 5 that took place between February and March 2017 came from the European Commission, 24 EU Member States and 14 sponsor organizations. Among other things, the total of 77 testers found 30 bugs and suggested 28 improvements. All scenarios and freeform testing received an average rating between 5.9 and 7.3 out of 10.

### 1.3. Implementation in Belgium

On 22 May 2017, a new law on clinical trials was published in the Belgian Official Journal with the aim of, inter alia, ensuring the practical implementation of the CTR in Belgium. It will enter into force on the same date as the CTR, which will be sometime in 2019 due to the delay mentioned in

section 1.1. above. This new law defines the Belgian Federal Agency for Medicines and Health Products (FAMHP) as competent authority in relation to the CTR. The FAMHP is designated as the national point of contact and put in charge of all communications that are to take place through the EU portal of the CTR.

The new Belgian law brings the evaluation process and timelines for applications for clinical trials into line with the CTR. It creates an independent assembly (college) within the Belgian Federal Service for Public Health that will be responsible for designating the competent ethics committee and for coordinating the assessment process between the FAMHP and the respective ethics committee.

Separate from the publication by the Belgian authorities of the new law on clinical trials, the FAMHP published in May 2017 an update on its pilot project to develop and test procedures for the review of applications for clinical trials (see also Report February 2017). The pilot project, which started in January 2017, is run in collaboration with the new college, the current ethics committees and sponsors of clinical trials.

In relation to the pilot project, the FAMHP has published guidance on the procedure and the dossier structure to be submitted.

### 1.4. Relocation of the EMA

On 22 June 2017, the EU heads of state (European Council) announced that the decision on the relocation of the EMA would take place in November 2017 at the meeting of the General Affairs Council on Article 50 of the Lisbon Treaty.

The European Council also published a list of six criteria that will be taken into account in the decision regarding the city where the EMA will be relocated to. The criteria are the following:

- The assurance that the agency can be set up on site and take up its functions at the date of the United Kingdom's withdrawal from the Union
- The accessibility of the location
- The existence of adequate education facilities for the children of agency staff
- Appropriate access to the labour market, social security and medical care for both children and spouses
- Business continuity
- Geographical spread

Applicants have until 31 July 2017 to send the candidacy for their city to host the EMA.

## 2. CLINICAL TRIAL SAFETY REPORTING

No update available.

## 3. ADOPTION OF IMPLEMENTING ACTS, DELEGATED ACTS AND GUIDELINES

On 23 May 2017, the EMA launched a public consultation on a draft guideline for the notification of serious breaches of the CTR or of the clinical trial protocol. Article 52 of the CTR requires the sponsor to notify the EU Member States concerned of any serious breach of the CTR or of the trial protocol. A serious breach means a breach that is likely to affect to a significant degree the safety and rights of a clinical trial participant or the reliability or robustness of the data generated by the clinical trial.
This guidance document offers advice (1) on the practical arrangements for notification of serious breaches (2) on what should and what should not be classified as a serious breach and what must be reported and (3) on possible actions that may be taken by the EU Member States concerned in response to notifications of serious breaches.

The guidance's appendix lists some examples of serious breaches. The deadline for submitting comments is set for 22 August 2017.

## 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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- SFL intelligence.