EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 December 2015
EMA/760345/2015 Endorsed

Delivery time frame for the EU portal and EU database

Draft time frame presented to European Medicines Agency Management Board	01 October 2015
Draft timeframe presented to IT Directors and Member States during the European Medicines Agency EU Portal and EU Database Workshop	21 October 2015
Consultation of the Member States	3 December 2015
Consultation of the European Commission	3 December 2015
Endorsement by the European Medicines Agency Management Board of the timeframe as revised during their meeting of 17 December 2015	17 December 2015
Sign off by the Executive Director	18 December 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Contents

1. Scope

The purpose of the document is to describe the planned time frame for the implementation of the EU portal and EU database.

2. Legal basis

In accordance with Article 82(1) of the new Clinical Trial Regulation (EU) No 536/2014, the Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the EU portal and the EU database, together with the time frame for their implementation.

The functional specifications (EMA/42176/2014 Rev. 1) were endorsed by the European Medicine Agency's Management Board on 19 March 2015.

This document describes the planned time frame for implementation of the EU portal and EU database.

3. Time frame for implementation of the EU portal and EU database

According to Article 82(2) of the Regulation, the Management Board of the Agency shall, on the basis of an independent audit report, inform the Commission when it has verified that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications.

In line with Article 82(3), the Commission shall publish a notice in the *Official Journal of the European Union* that the EU portal and the EU database is fully functional in accordance with its functional specifications.

The Regulation shall apply from six months after the publication of that notice.

A three year transition period is foreseen in Article 98 of the Regulation. These three years are counted from the date of its application. During the first year of that transition period clinical trial applications may be made either under the new Regulation using the EU portal and database, or under Directive 2001/20/EC. For the following two years clinical trials authorised under the Directive will continue to be governed by that Directive. Any trials authorised under the Directive and still ongoing 3 years after the Regulation comes into application will from then on be governed by the Regulation.

In terms of the development of the EU portal and the EU database, **Table 1** provides an overview of the planned time frame for the development of the version of the system which will be subject to the independent audit and the dates of the events mentioned above that will take place after that audit. In addition the table also reflects that, subsequent to the audit, the system development will continue and a further production release will go-live prior to the application of the Regulation. Further upgrades and enhancements of the system will be completed post-go live of the system. In establishing this timeframe the Agency has estimated a four month period for the planning, conduct and follow-up of the audit and its presentation to the Management Board, and three months from the date of agreement by the Management Board that the system is fully functional to the date of publication by the Commission of the notice in the Official Journal.

Table 1: Time frame for the implementation of EU portal and EU database

EU portal and EU database delivery time frame		
	Activity	**Date**
1.	Auditable Version released for audit, including implementation of auditable and non-auditable must requirements	July 2017
2.	Independent Audit commences	August 2017
3.	Development of remaining requirements commences	August 2017
4.	Independent Audit completed	November 2017
5.	Audit endorsed by EMA Management Board	December 2017
6.	European Commission notice published in *Official Journal of the European Union*	March 2018
7.	Production Version completed, including implementation of remaining should requirements	July 2018
8.	Production Version go-live	September 2018
9.	Regulation (EU) No 536/2014 becomes applicable	October 2018
10.	Further upgrade and enhancement of the system completed	Q3 2019
11.	Directive on Clinical Trials 2001/20/EC no longer applicable	October 2021

These are planned timelines. They have been set out to deliver the clear benefits, for researchers and for patients and the public, that derive from implementation of the Regulation in a timely manner whilst meeting the need for Member States to have available, in the EU Portal and Database, functionality to enable them to commence operation of the Regulation.

The auditable release will contain must requirements (auditable and non-auditable) drawn up in collaboration with the Member States and the Commission.

The specifications for the interface between the EU portal and database and workspace and Member States systems will be shared with Member States in mid-2016. The interface itself (Agency system side) will be delivered in Q2 2017.

The audit team will come from a company selected under the Commission Framework Contract No. BUDG-15-PO-03 for the Supply of Technical Assistance Services in the Field of Audits and Controls.

The delivery plan is based on an iterative approach with User Acceptance Testing (UAT) of each iteration. Users performing testing will include representative experts from Member States, sponsor organisations and associations representing users of public information – in particular patient and consumer and healthcare professional associations.

The plan and process for UAT will be shared with Member States and the Commission. Member States and the Commission will be involved in the prioritisation of changes to be made based on the results of the UAT, and in particular in the design of and follow-up to the UAT of the auditable release.

This is a maximum timeline and every effort will be made to bring the Regulation into application as soon as possible. The progress of implementation of the system will be closely monitored and timing of the audit adjusted (and hence application of the Regulation) to an earlier time as possible. Such adjustment will be agreed with the EMA Management Board and communicated by the Agency.