Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

CHAPTER XIV

IT INFRASTRUCTURE

Article 81

EU database

1 The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a EU database at Union level. The Agency shall be considered to be the controller of the EU database and shall be responsible for avoiding unnecessary duplication between the EU database and the EudraCT and Eudravigilance databases.

The EU database shall contain the data and information submitted in accordance with this Regulation.

The EU database shall identify each clinical trial by a unique EU trial number. The sponsor shall refer to this EU trial number in any subsequent submission relating or referring to that clinical trial.

2 The EU database shall be established to enable cooperation between the competent authorities of the Member States concerned to the extent that it is necessary for the application of this Regulation and to search for specific clinical trials. It shall also facilitate the communication between sponsors and Member States concerned and enable sponsors to refer to previous submissions of an application for authorisation of a clinical trial or a substantial modification. It shall also enable citizens of the Union to have access to clinical information about medicinal products. To this end all data held in the EU database shall be in an easily searchable format, all related data shall be grouped together by way of the EU trial number, and hyperlinks shall be provided to link together related data and documents held on the EU database and other databases managed by the Agency.

3 The EU database shall support the recording and submission to the Medicinal Product Dictionary, contained in the Eudravigilance database, of all the data on medicinal products without a marketing authorisation in the Union and substances not authorised as part of a medicinal product in the Union, that are necessary for the maintenance of that dictionary. To this effect and also with the purpose of enabling the sponsor to cross-refer to prior applications, an EU medicinal product number shall be issued for every medicinal product without a marketing authorisation and an EU active substances code shall be issued for each new active substance not previously authorised as part of a medicinal product in the Union. This shall be done before or during the application for authorisation of the first clinical trial with that product or active substance submitted in accordance with this Regulation. Those numbers shall be mentioned in all subsequent applications for clinical trials and for substantial modifications.

The data submitted, in accordance with the first subparagraph, describing medicinal products and substances shall comply with Union and international standards for the identification of medicinal products and active substances. When an investigational medicinal product which already has a marketing authorisation in the Union and/or an

active substance which is part of a medicinal product with a marketing authorisation in the Union, is to be used in a clinical trial, the relevant product and active substance numbers shall be referred to in the application for that clinical trial.

4 The EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the following grounds:

a protecting personal data in accordance with Regulation (EC) No 45/2001;

b protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure;

c protecting confidential communication between Member States in relation to the preparation of the assessment report;

d ensuring effective supervision of the conduct of a clinical trial by Member States.

5 Without prejudice to paragraph 4, unless there is an overriding public interest in disclosure, data contained in the application dossier shall not be publicly accessible before the decision on the clinical trial has been made.

6 The EU database shall contain personal data only insofar as this is necessary for the purposes of paragraph 2.

7 No personal data of subjects shall be publicly accessible.

8 The user interface of the EU database shall be available in all official languages of the Union.

9 The sponsor shall permanently update in the EU database information on any changes to the clinical trials which are not substantial modifications but are relevant for the supervision of the clinical trial by the Member States concerned.

10 The Agency, the Commission and Member States shall ensure that the data subject may effectively exercise his or her rights to information, to access, to rectify and to object in accordance with Regulation (EC) No 45/2001 and national data protection legislation implementing Directive 95/46/EC, respectively. They shall ensure that the data subject may effectively exercise the right of access to data relating to him or her, and the right to have inaccurate or incomplete data corrected or erased. Within their respective responsibilities, the Agency, the Commission and Member States shall ensure that inaccurate and unlawfully processed data are deleted, in accordance with the applicable law. Corrections and deletions shall be carried out as soon as possible, but no later than 60 days of a request being made by a data subject.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Article 81.