Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)

CHAPTER VI

CLINICAL EVIDENCE, PERFORMANCE EVALUATION AND PERFORMANCE STUDIES

Article 69

Electronic system on performance studies

1 The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system:

a to create the single identification numbers for performance studies referred to in Article 66(1);

b to be used as an entry point for the submission of all applications or notifications for performance studies referred to in Articles 66, 70, 71 and 74 and for all other submission of data, or processing of data in this context;

c for the exchange of information relating to performance studies in accordance with this Regulation between the Member States and between them and the Commission including the exchange of information referred to in to Articles 72 and 74;

d for information to be provided by the sponsor in accordance with Article 73, including the performance study report and its summary as required in paragraph 5 of that Article;

e for reporting on serious adverse events and device deficiencies, and related updates referred to in Article 76.

2 When setting up the electronic system referred to in paragraph 1 of this Article, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council[(1)] as concerns performance studies of companion diagnostics.

3 The information referred to in point (c) of paragraph 1 shall only be accessible to the Member States and the Commission. The information referred to in the other points of that paragraph shall be accessible to the public, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds:

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

b protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of the conformity assessment for the device, unless there is an overriding public interest in disclosure;

c effective supervision of the conduct of the performance study by the Member State(s) concerned.

4 No personal data of subjects shall be publicly available.

5 The user interface of the electronic system referred to in paragraph 1 shall be available in all official languages of the Union.

(**1**) 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 (OJ L 158, 27.5.2014, p. 1).