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**Subject: Consultation “controllership” in the context of the Clinical Trials Portal and Database**

Dear Mr [...],

We are writing to you concerning your consultation of 9 July 2018 relating to the interpretation of the term ‘controller’ in the context of the EU Clinical Trials Portal and Database.

Your consultation refers to the controllership of the European Medicine’s Agency (EMA), in this context, which would have a material impact on the responsibilities of EMA, the Commission, the Member States and the clinical trial sponsors with regard to the application of data protection legislation.

The term ‘controller’ is mentioned in several Articles of Regulation (EU) No 536/2014<sup>1</sup> on clinical trials for human use, and repealing Directive 2001/20/EC (hereinafter, the CT Regulation).

Article 81 (10) of the CT Regulation stipulates that *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.*

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<sup>1</sup> OJ L 158 of 27.5.2014, p. 1.

As you point out, similar provisions referring to common obligations on the processing of personal data imposed on the Agency, the Commission and the Member States are further described in Article 93 of the same Regulation. Article 93, entitled ‘Data protection’ stipulates that *Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.*

Furthermore, Article 82, providing for the establishment of functional specifications for the functioning of the Clinical Trial Portal and Database, refers to the responsibilities of the Agency, the Commission and the Member States. In particular, Article 82 (1) lays down that *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.*

Your questioning stems from the fact that Article 81 (1) uses the term controller in another context. In fact, Article 81 (1) states that *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* [emphasis added].

In your view, in the light of the other provisions cited above, you believe that the term ‘controller’ in Article 81 (1) cannot be construed to imply that EMA is the sole data controller for the purpose of the application of the relevant data protection legislation. According to you, on the basis of the context of this provision, you take the view that the term ‘controller’ must be interpreted in a mere technical manner as to signify that the Agency will act as technical hub for the transmission and storage of the data. You submit that with regard to the processing of personal data in the Portal and Database, however, EMA, the Commission, the Member States and clinical trial sponsors should be considered as ‘joint controllers’, i.e. each actor must be responsible for the correct processing of personal data for the actions falling within its direct responsibility and to follow the requirements of the Regulation 45/2001 (now replaced by Regulation (EU) No 2018/1725) and Directive 95/46/EC (now replaced by Regulation (EU) No 2016/679), respectively, as stipulated in Article 93 of the CT Regulation.

The EDPS agrees with this analysis. From a data protection point of view, EMA, the Commission, the Member States and clinical trial sponsors should be considered as ‘joint controllers’.

Article 3(8) of the Regulation (EU) 2018/1725<sup>2</sup> (‘the Regulation’) provides that ‘controller’ shall mean the Union institution or body or the directorate-general or any other organisational entity which, alone or jointly with others, determines the purposes and means of the processing of personal data. The concept was further developed by the Article 29 Working Party in its opinion 1/2010<sup>3</sup> (hereinafter: ‘WP 29 Opinion’) and by the case law of the Court of Justice of the European Union<sup>4</sup>.

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<sup>2</sup> OJ L 295, 21.11.2018, p. 39–98.

<sup>3</sup> Opinion 1/2010 on the concepts of ‘controller’ and ‘processor’, WP 169, available at: [http://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2010/wp169\\_en.pdf](http://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2010/wp169_en.pdf)

<sup>4</sup> See in particular the two following Judgments of the Court: judgment of 13 May 2014 in *Google Spain and Google* (case C-131/12) as well as judgment of 5 June 2018 in *Wirtschaftsakademie* (case C-210/16).

The WP 29 Opinion sets out that the concept of the controller is a functional concept based on a factual rather than a formal analysis<sup>5</sup>. In case of doubt other elements may be taken into account to determine the controller, such as the degree of actual control exercised by a party, the image given to data subjects and reasonable expectations of data subjects on the basis of visibility<sup>6</sup>. The WP 29 Opinion also specifies that parties have a certain degree of flexibility in distributing and allocating obligations and responsibilities among them as long as they ensure full compliance<sup>7</sup>.

Please note that the joint controllership is also explicitly codified in Regulation (EU) 2018/1725. Article 28 explains the obligations of ‘Joint controllers’: *Where two or more controllers or one or more controllers together with one or more controllers other than Union institutions and bodies jointly determine the purposes and means of processing, they shall be joint controllers. They shall in a transparent manner determine their respective responsibilities for compliance with their data protection obligations, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in Articles 15 and 16, by means of an arrangement between them unless, and in so far as, the respective responsibilities of the joint controllers are determined by Union or Member State law to which the joint controllers are subject. The arrangement may designate a contact point for data subjects.*

In the light of the CT Regulation’s provisions mentioned above, EMA, in collaboration with the Member States and the Commission, should draw up the functional specifications of the EU portal and database, which means that they determine jointly the means of processing of personal data. Also, the CT regulation further explicitly specifies the applicability of Member State data protection law and the Regulation applicable to EU institutions and bodies. Both frameworks further define the respective obligations which makes it clear that not only one party has to be considered as controller but that EMA and the Member states share responsibility. Therefore, the situation described can be qualified as joint controllership in the sense of Article 28 of the Regulation.

Concerning the practical aspects of the joint controllership, the EDPS has not yet issued guidance on the matter. Please note that the Regulation obliges the controllers to conclude an arrangement between them. Article 28 (2) stipulates that *The arrangement referred to in paragraph 1 shall duly reflect the respective roles and relationships of the joint controllers vis-à-vis the data subjects. The essence of the arrangement shall be made available to the data subject.* A summary of this arrangement could for instance be included in the data protection notice that needs to be made available to data subjects.

The EDPS is of course available to provide advice on a draft arrangement agreed between EMA, Commission, the Member States and clinical trial sponsors.

Yours sincerely,

Wojciech Rafał WIEWIÓROWSKI

(Signed)

Cc.: Mr [...], Acting Data Protection Officer, EMA

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<sup>5</sup> See page 11 of the WP 29 Opinion mentioned in footnote 3.

<sup>6</sup> See page 12 of the WP 29 Opinion mentioned in footnote 3.

<sup>7</sup> See page 26 of the WP 29 Opinion mentioned in footnote 3.