October 2022
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European Medicines Agency's Data Protection Notice

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter: "EMA") in the context of the **raw data Proof-of-Concept (PoC) pilot**[1]. This includes the submission and analysis of 'raw data' from clinical studies as part of selected initial Marketing Authorisation Applications (iMAAs) and post-authorisation applications submitted to EMA.

In the context of the PoC pilot the following data processing activities will be performed:

- submission and receipt of the (raw) data sets;
- storage of the (raw) data sets (including back-up);
- data exchange between EMA and National Competent Authorities (NCAs) in Union Member States;
- data analysis including data visualisation;
- reporting of raw data analysis results; and
- use of raw data analysis results for the regulatory assessment and decision-making.

1. Who is responsible for processing your data?

1.1. Who are the data controllers (joint controllers)?

The EMA and the NCAs act as joint controllers for the purposes of the PoC pilot processing activity. In particular, the EMA and the NCAs jointly determine the purpose and means of processing personal data for the PoC pilot. EMA and the NCAs have the responsibility to comply with your data protection rights and freedoms.

On behalf of EMA, the Head of the Data Analytics and Methods Task Force is appointed as 'Internal Controller' to ensure the lawful conduct of processing operations within EMA. You may contact the Internal Controller via the following email address: datacontroller.analytics@ema.europa.eu

Which NCAs will act as joint controllers will depend on the regulatory procedures included in the PoC pilot and is not yet known at the time of starting the pilot. A list of the NCAs participating in the pilot as well as their contact details will be provided upon request.

[1] EMA launches pilot project on analysis of raw data from clinical trials | European Medicines Agency (europa.eu)

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1.2. Who is the data processor?

The EMA will engage the following third parties for certain data processing activities:

- Data Analytics Centre at Lægemiddelstyrelsen (Danish Medicines Agency), Axel Heides Gade 1, 2300 Copenhagen S, Denmark, for the analysis of the raw data (contract awarded via procurement procedure under EMA/2020/46/TDA framework contract[2]);
- Microsoft Ireland Operations Limited, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland, for the storage, access, authorisation and versioning of the raw data (SharePoint); and
- Microsoft Ireland Operations Limited, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland, for the access and storage of the raw data (Microsoft Azure Virtual Desktop Infrastructure system).

2. Purpose of this data processing

The purpose of the data processing activities is to assess whether the analysis of 'raw data' from clinical trials by regulatory authorities improves the evaluation of iMAAs for new medicines as well as post-authorisation applications and to explore the practical aspects of the submission and analysis of such data in the context of performing EMA's tasks.

2.1. Personal data concerned

In this processing operation the EMA processes personal data submitted by applicants or marketing authorisation holders (MHAs). These personal data are collected by applicants and MAHs in the context of clinical trials.

Such personal data are pseudonymised (which means that they cannot be linked to a specific natural person without the use of additional information which is, however, not processed by EMA). Personal data processed may include the following (sensitive) data:

- Investigator name
- Data Subject ID
- Site
- Region
- Country
- Age of the data subject
- Sex of the data subject
- Height of the data subject
- Weight of the data subject
- Trial Treatment group (Experimental / Placebo)
- Race of the data subject
- Information on follow-up and treatment compliance
- Health related data variables collected at baseline and all subsequent study visits

[2] Services - 575628-2021 - TED Tenders Electronic Daily (europa.eu)

2.2. Legal basis of the processing

To be lawful, processing of personal data by the joint controllers must rely on one or more of the legal bases provided under Article 5 of Regulation (EU) 2018/1725 (EUDPR) or Article 6 of Regulation (EU) 2016/679 (GDPR). The lawfulness of the processing of personal data in the PoC pilot is justified on the basis that the processing is necessary for the performance of a task carried out in the public interest (i.e., public health) and in the exercise of the mandate of EMA and NCAs. To fulfil EMA's public health tasks, EMA must receive such personal data and process it with the view to examine applications for marketing authorisation or changes to the therapeutic indication, issue an opinion and grant or reject such applications.[3] The enhanced process will go one step further than the current assessment of iMAAs and post-authorisation applications by processing the raw data supporting the application. Such data are already submitted by applicants under current practice, nevertheless in different formats that do not allow the detailed analysis carried out in the PoC pilot.

EMA will ensure personal data are protected in full compliance with the provisions set out in Regulation (EU) 2018/1725 on the protection of personal data by the European Institutions and bodies. A data protection impact assessment was performed in Q2 to Q3 of 2022.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

2.3. Transfer of personal data outside of European Union

No personal data will be shared with international organisations or will be transferred to third countries outside the European Union.

3. How long do we keep your data?

The retention period for the raw data files will be the same as for the other 'core master files' from the underlying centralised procedure. In particular, the retention time for core master files is currently 30 years after withdrawal of the product from the market[4].

4. Who has access to your personal data and to whom is it disclosed?

The following parties will have access to your personal data from the raw data files received for a specific regulatory procedure:

- EMA staff involved in the receipt, storage, management and analysis of the raw data;
- NCA staff involved in the storage, management and analysis of the raw data; and
- EMA contractors (processors) involved in the processing of the raw data.

5. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

[3] In accordance with Article 7(c) of Regulation (EC) No 726/2004, the CHMP may request that the applicant supplements the particulars accompanying the application (e.g. raw data) within a specific time period in order to further qualify, as appropriate, the quality, safety and efficacy of a medicinal product. Article 16.3 of Regulation (EC) 1234/2008 provides a similar possibility for Type II variations applications. Under the terms of these Regulations, the applicant/MAH must answer such requests fully and promptly.
[4] SOP_EMA_1004.pdf (eudra.org)

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.
- **Right to rectification** – You have the right to obtain - without undue delay - the rectification or completion of your personal if it is incorrect or incomplete.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of EMA or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the general EMA Data Protection Privacy Statement, hosted at Data protection and privacy | European Medicines Agency (europa.eu).
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of the general EMA data Protection and Privacy Statement: Data protection and privacy | European Medicines Agency (europa.eu)

6. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at datacontroller.analytics@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en