EMA/76223/2026
30 March 2026

European Medicines Agency's Data Protection Notice

Modelling and Simulation Pilot – Use of Clinical Study Data for Scientific Advice

This Data Protection Notice describes the most essential elements of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "the Agency") in the context of the analysis of clinical study data submitted to EMA as part of initial Marketing Authorisation Applications (iMAAs) and post-authorisation applications. More specifically, the processing concerns the use of clinical study data for modelling and simulation activities carried out, on a pilot basis, in support of the provision of scientific advice.

1. Who is responsible for processing your data?

1.1. Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Human Division is appointed as the Internal Controller to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:

datacontroller.humanmedicines@ema.europa.eu

1.2. Who is the data processor?

Where necessary, EMA may engage external third parties to process personal data on behalf of the Agency. The contact details of the data processor for the data storage and access control are as follows:

- **Microsoft Ireland Operations Limited**, South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland

2. Purpose of this data processing

EMA provides scientific advice to support the timely and sound development of high-quality, effective and safe medicines, for the benefit of patients. It is important that due account is taken of previous drug development programmes submitted to the EMA to support consistency and quality of the scientific advice.

The purpose of this processing operation is to enable the Agency to make use of data relating to the safety and efficacy of medicines and to strengthen its modelling and simulation capabilities, informed by relevant regulatory precedents, to provide the best possible scientific advice on the evaluation of the safety and efficacy of medicinal products for human use.

The following personal data processing activities are carried out and focusing on data extraction and analysis:

- Extraction of clinical study data from the electronic Common Technical Document (eCTD);
- Aggregation of pseudonymised clinical study participants' data;
- Creation and storage of datasets across therapeutic indications and/or clinical study participant subgroups (e.g. paediatric or elderly populations);
- Analysis including the development of pharmacometric meta-analytic models based on aggregated data;
- Dissemination of modelling and simulation results, limited to anonymised personal data, in support of regulatory decision making.

2.1. Personal data concerned

In the context of this processing operation, EMA processes personal data that are submitted by applicants or marketing authorisation holders (MAHs) in pseudonymised form as part of the medicines regulatory applications (iMAAs or post-authorisation). The pseudonymisation applied ensures that the data cannot be attributed to an identified or identifiable natural person without the use of additional information, which is not held or processed by EMA.

Personal data in scope may include the following:

- Clinical study participant identifier which is replaced with a randomly generated number
- Region
- Country
- Patient characteristics (e.g. age, race, sex, height, weight, co-morbidities, etc.)
- Trial Treatment group (Experimental / Placebo)
- Information on follow-up and treatment compliance (incl. drug exposure)
- Information on concomitant medication
- Health related variables collected at baseline and all subsequent study visits
- Treatment-effect related variables collected at baseline and all subsequent study visits (incl. primary and secondary efficacy outcomes)

2.2. Legal basis of the processing

This processing operation is carried out to enable the EMA to comply with its statutory obligation to provide scientific advice to applicants, as set out in Article 57(1) of Regulation (EC) No 726/2004 and further reinforced by Recital (25) thereof. In accordance with its mandate, the Agency is required to provide the best possible scientific advice on questions relating to the quality, safety and efficacy of medicinal products. This includes supporting EMA's scientific committees[1] in providing scientific advice to companies researching and developing new medicines.

In this regard the extracting and anonymisation of clinical study data is necessary for the performance of a task carried out in the public interest and in the exercise of official authority vested in the Union institution or body as set out in Article 5(1)(a) of the EUDPR. Furthermore, since the processing relates to data concerning health, this is based on Article 10(2)(i) of the EUDPR i.e. the processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices, on the basis of Union law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.

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

3. How long do we keep your data?

The data set used in support of the Modelling and Simulation Pilot will be kept for a period of five years from the date of publication of the pilot results.

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

The pseudonymised personal data are being accessed internally by staff within the EMA Human Medicines Division and more particularly, the Scientific Advice Office.

Results from the analysis of the anonymised data may be published on the EMA corporate website and scientific literature.

5. Your data protection rights

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

- **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

[1] How the committees work | European Medicines Agency (EMA)

certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency 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 EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.
- **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 Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

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.humanmedicines@ema.europa.eu

EMA Data Protection Officer at dataprotection@ema.europa.eu.

Address	Postal Address	EMA Switch Board
European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands	European Medicines Agency PO Box 71010 1008 BA Amsterdam The Netherlands	+31 (0)88 781 6000

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