



EMA/5888197/2023  
13/02/2024

## European Medicines Agency's Data Protection Notice For the exploration of the DEEP platform

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the DEEP-EFPIA-EMA pilot on Qualification of Novel Methodologies.

The process refers to creating and finalising the necessary documentation for the EMA pilot procedure by using the DEEP collaborative platform allowing co-creation, validation, and re-use of interactive catalogues of digital measurement components (the "DEEP platform"). Once the procedure and its accompanying documents are complete, they are converted into PDF format and submitted through the standard filing channels to officially conclude the EMA pilot.

The personal data processing includes the handling of user accounts for use of the online DEEP platform for the Qualification of Novel Methodologies pilot.

### 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 '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](mailto:datacontroller.HumanMedicines@ema.europa.eu)

#### 1.2. ***Who is the data processor?***

The Agency may engage third parties to process data on behalf of the Agency. For the purpose of access management of the DEEP platform used in the pilot, the contact details of the data processor is the following:

DEEP Measures Oy  
Hietalahdenkatu 4 A 6a

---

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## 2. **Purpose of this data processing**

The purpose of this data processing activity is the piloting of optimised pathways for the qualification of novel methodologies procedure in the context of the performance of the Agency's tasks, including:

- Organisation of Innovation Task Force (ITF) briefing meetings including receiving an ITF meeting request, conducting a coordinated review by Member States and providing a set of questions to the applicant, conducting the ITF briefing meeting and sharing of key regulatory (informal) feedback.

### 2.1. **Personal data concerned**

In this processing operation we process data directly collected from you when you register and submit your login information for the DEEP platform. Such data may include the following:

- Contact details (name, email address, organisation name) of the pilot participants (employees or contractors of EMA) who will get access to the DEEP platform.

### 2.2. **Legal basis of the processing**

When you provide your data, you consent to the processing of that data in accordance with this Data Protection Notice. The legal basis for the processing is Article 5(1)(d) of the [European Union Data Protection Regulation](#) (EU DPR).

You may opt-out from the processing in a response to the contact person mentioned in the training materials provided or by contacting the internal controller. In your response, please state what is the personal data that you want to exclude and what is the actual processing activity that you do not want EMA to carry out on your data. You also have the right to withdraw your consent later at any time. Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

### **Transfer of personal data outside of EU**

The processor uses data centres located within the EU/EEA.

The sub-processor may be established outside of the EU/EEA in which case the appropriate transfer mechanism and confidentiality and security obligations in accordance with the EU DPR will be adhered to.

## 3. **How long do we keep your data?**

Your personal data will be processed during the term of the pilot within the DEEP platform. The Instance used for the pilot within the Platform, along with all associated data and backups, will be permanently deleted and destroyed by the end of the pilot (31st of March, 2024).

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

The data collected will be processed internally by EMA staff within the Division responsible for the pilot, and employees and contractors of the processor who have the need to access your personal data to provide the access to the DEEP platform.

#### 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 withdraw consent** – You have the right to withdraw your consent to the processing of your personal data. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn.

Please note that if you withdraw your consent, the Agency may not be able to provide certain services to you. EMA will advise you if this is the case at the time you withdraw your consent.

- **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 the Agency or if it is necessary for reasons of public interest in the area of public health.

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](http://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](mailto:datacontroller.HumanMedicines@ema.europa.eu) or the **EMA Data Protection Officer** at [dataprotection@ema.europa.eu](mailto: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](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)