

20 November 2025
EMA/57555/2025
European Medicines Agency

European Medicines Agency's Data Protection Notice

For PMS User Acceptance Stakeholder Involvement

All personal data will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.

This data protection notice provides details on how the European Medicines Agency (hereinafter 'the Agency' or 'EMA'), in its capacity as data controller, will process the information collected and processes during the activities explained below.

For the collection of data via EUSurvey form, EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see:
<https://ec.europa.eu/eusurvey/home/privacystatement>.

1. Who is responsible for processing your data?

The EMA is responsible for the PMS User Acceptance Stakeholder Involvement activities mentioned in this notice, as well for as the parametrisation and content of EUSurvey and for the processing of personal data collected via the registration form. Internally, the Head of Information Management 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.infomanagement@ema.europa.eu

The European Commission (EC DG-DIGIT) is the processor for the web-based interface of the survey and the hosting of survey data and any submitted responses.

The EC-DIGIT is responsible for the processing of personal data collected and processed for traffic statistics and analytics via Europa Analytics, the corporate service that monitors and evaluates the effectiveness and efficiency of the EC's websites on Europa. The allocation of respective roles, responsibilities, and practical arrangements between controller and processor can be found in the [Data Processing Agreement](#).

The EMA may engage with additional third parties (data processor) to process data on behalf of the Agency:

The PMS Change Management team (responsible for organising webinars, send invitations and communications) is outsourced to

PRICEWATERHOUSECOOPERS PWC EU SERVICES EESV

Woluwedal 18, 1932 Sint-Stevens-Woluwe (Belgium)

be.privacy@pwc.com

and

Intellera Consulting S.P.A.

Via Gaetano de Castillia 23, 20124, Milan, Italy

privacy@intelleraconsulting.com

During user acceptance testing, to streamline the interactions between testers and the Agency, the Azure DevOps (ADO) platform or other means will be used. This means are used to gather more information following bug-reporting from the testers and supports the prompt identification, triaging and planning of the necessary fixes. To support these interactions, specific PMS-related teams such as FHIR adapter and/or PMS team members may interact with testers and therefore access their name, contact information.

FHIR adapter team is outsourced to the following companies:

Company 1:

NTT Data Belgique SRL

Rue de Spa, 8, 1000 Bruxelles, Belgium

Data Protection Office: data.protection.office@emeal.nttdata.com

Company 2:

Network Research Belgium SA

Parc Industriel des Hauts-Sarts,

2e Avenue, 65, 4040 Herstal, Belgium

Data Protection Office: dpo@nrb.be

PMS team is outsourced to the following company:

Accenture B.V.

Gustav Mahlerplein 90, 1082 MA Amsterdam, Netherlands

Data Protection Office: DataPrivacyOfficer@accenture.com

Further information can be obtained from the organiser of the particular webinar or testing event(s).

2. Purpose of this data processing

Nomination of user acceptance testers

The purpose of the present data processing activity is to collect the interest and/or availability of stakeholders and/or concerned individuals in relation to their participation in a particular EMA activity, particularly participation to the PMS API UAT. In addition, the e-mail address provided in this registration form may be used by the EMA to send out meeting links, pre-meeting documents and post-meeting documents.

Furthermore, the EMA may use the e-mail address provided in this registration form to send a satisfaction survey (via EUSurvey) after the particular meeting. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

Organisation of PMS API UAT-related webinar

The purpose of the present data processing activity is to organise PMS API UAT related webinars with the testers nominated by the Industry Trade Organisation in relation to their participation in a particular EMA activity, particularly meetings (e.g. kick-off and follow-up meetings, workshops). In addition, the e-mail address provided in this registration form may be used by EMA to send out meeting links, pre-meeting documents and post-meeting documents.

Furthermore, EMA may use the e-mail address provided in this registration form to send a satisfaction survey (via EUSurvey) after the particular meeting. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

The registrations to such webinars may be collected via EUSurvey.

User acceptance testing

The purpose of the present data processing activity is to collect feedback and any bug identified in the context of the PMS API UAT activities from the testers nominated by the Industry Trade Organisation. For this purpose and in order to streamline the interactions between testers and the Agency, testers will be granted access to the ADO platform. This platform is used to gather more information following bug-reporting from the testers and supports the prompt identification, triaging and planning of the necessary fixes.

In addition, the e-mail address provided in this registration form may be used by EMA to send out meeting links, pre-meeting documents and post-meeting documents.

Furthermore, the EMA may use the e-mail address provided in this registration form to send a satisfaction survey (via EUSurvey) after the particular meeting. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

2.1. Personal data concerned

Nomination of user acceptance testers

The Agency may collect the following personal data via email, namely:

- Full name
- Job title and place of employment
- Contact details
- EMA Account Management portal details (ie. email address; username)
- Whether the nominated tester belongs to:
 - Software Development Company Associated with a Marketing Authorisation Holder (MAH): provide name of MAH associated
 - Marketing Authorisation Holders (MAHs) with In-House Software Development
 - Independent Software Development Companies

Organisation of PMS API UAT-related webinar

In the context of the organisation of PMS API UAT-related webinars, the personal data collected in the nominations (as explained above) is processed together with the information provided by the representatives during the nomination activities.

User acceptance testing

In the context of the user acceptance testing, the personal data collected in the nominations (as explained above) are processed together with the feedback provided by the representatives during the testing activities.

2.2. Legal basis of the processing

The activities explained in this data protection notice are necessary for the operational functioning and management of the Agency, as mandated by EMA's Founding Regulation (EC) No 726/2004 and other Union pharmaceutical legislation. In particular, the objective of PMS data and documentation is to fulfil the legal requirements of Article 57 of Regulation 726/2004. In the course of this work, online meetings and communication with external stakeholders are necessary for the performance of the Agency tasks carried out in the public interest. Therefore, the processing is lawful under Article 5.1 (a) of Regulation (EU) No 2018/1725.

Please note that you have the **right to object** as mentioned in Section 5 below.

3. How long do we keep your data?

Nomination of user acceptance testers

If you provide your nomination via email, your personal data will be securely stored in the Agency's record management system.

Your personal data will be kept for a period of 2 years.

Organisation of PMS API UAT-related webinar

When you complete and send a webinar registration form via EUSurvey, your personal data will be kept in EUSurvey until the end of the response period. After this, the replies to the survey will be securely stored in the Agency's record management system. Your personal data will be kept for 5 years in relation to the meetings and events.

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

Personal data collected in the nominations and during the user acceptance testing is processed by authorised staff within the EMA Information management Division, authorised staff of the PMS Change Management team and (potentially) by authorised FHIR adapter team members.

Access to the replies to EMA surveys is secured in EUSurvey and in the EMA records management system and accessed only by authorised EMA staff.

The replies are recorded in a secured and protected database hosted by the Data Centre of the EC, the operations of which abide by the EC's security decisions and provisions established by the Directorate of Security for this kind of servers and services. The database is not accessible from outside the EC.

Lists of meeting participants (names and organisation represented) may be disclosed to national Competent Authorities and EU institutions

Meeting documents (such as lists of participants, agendas, presentations, minutes or meeting reports) may be disclosed to national Competent Authorities, EU institutions as well as regulatory authorities of third countries and international organisations based on EMA's mutual cooperation agreements or confidentiality arrangements. They may also be published on the EMA's corporate website.

The Agency may share your personal data when the Court of Justice of the EU or the European Ombudsman would require such transfer in the framework of their duties. This is without prejudice to Regulation (EC) 1049/2001 regarding public access to documents.

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 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

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** by contacting the meeting organiser 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