12 August 2025
EMA/269302/2025

# Records of data processing activity (public)
## For Microsoft (MS) Copilot 365 - EMA pilot phase

| | | |
|---|---|---|
| 1. | Last update of this record, version number: | 12 August 2025 |
| 2. | Reference number: | EMA/269302/2025 |
| 3. | Name and contact details of controller: | European Medicines Agency<br>Internally: Head of Information Management Division<br>Contact: Datacontroller.infomanagement@ema.europa.eu |
| 4. | Name and contact details of DPO: | dataprotection@ema.europa.eu |
| 5. | Name and contact details of joint controller (where applicable) | N/A |
| 6. | Name and contact details of processor (where applicable) | Microsoft Ireland Operations Limited<br>One Microsoft Place, South County Business Park,<br>Leopardstown, Dublin 18 D18 P521, Ireland<br>Telephone: +353 (1) 706-3117<br>Microsoft Data Protection Officer: https://www.microsoft.com/en-gb/privacy/privacy-support-requests |
| 7. | Purpose of the processing | The purpose of the data processing activities using Copilot aim to enhance the Agency's digital capabilities and improve its processes taking into account technological advancements in accordance with the Agency's Network Strategy 2028. More specifically, the aim is to leveraging data, digitalisation and artificial intelligence (AI) improving decision-making, optimising processes and increasing efficiency. This is with a view to strengthen EMA's capacities in managing its tasks and obligations and supporting its mission set out in the pharmaceutical legislation and other applicable Union legislation.<br>EMA interacts with many stakeholders and works closely with its scientific committees, working parties and experts. This |

| | | |
|---|---|---|
| | | involves the management of large volumes of data which may include personal data and special categories of personal data. The processing of such data and information is essential for EMA to fulfil its mission of fostering scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health in the European Union (EU) and to fulfil EMA's missions and tasks as set out in Union legislation. The Agency also supports research and innovation in the pharmaceutical sector and promotes the development of new medicines by European micro-, small-, and medium-sized enterprises. Additionally, the EMA has responsibilities for monitoring and mitigating potential, or actual shortages of critical medicines caused by major events and in crisis situations.<br><br>**Use of Copilot in support of EMA's business processes**<br>The Copilot 365 tool, developed by Microsoft, is intended to provide personalised assistance and recommendations in applications like Word, Outlook, Teams, Excel, OneNote, and PowerPoint. It utilises Large Language Models (LLMs) and business data through Microsoft Graph to offer capabilities such as content design, creation, generation, summarisation, semantic search, natural language to code translation, accelerated automation, language translation, predictive analytics, forecasting, creative writing. The scope of the second pilot focuses on Copilot's capabilities focusing on specific capabilities.<br><br>For each Copilot capability, EMA enforces a risk-based approach to determine whether the use case is allowed or prohibited. A Copilot user must score the risk of their use case regarding the data in scope for processing, the target audience of the AI-generated output and the business process for which Copilot is being used. Depending on the outcome of the risk score, a user may use Copilot, if the overall risk is within the acceptable boundary; otherwise, they must refrain from doing so. All Copilot users receive explicit training.<br><br>**Automated decision making**<br><br>Copilot provides suggestions but does not make binding decisions affecting individuals without human review. No automated decisions with legal or similar significant effect are taken. Detailed guidance, covering permitted and prohibited Copilot scenarios and safeguards to ensure that no decision with legal or similarly significant effects is taken automatically, is available to all Copilot users.<br><br>All outputs generated by Copilot must undergo thorough review for accuracy and correctness by EMA users. Human oversight is essential to ensure that the information provided is reliable, relevant, and free from errors. This process helps maintain the integrity and trustworthiness of AI-generated content, safeguarding against potential inaccuracies and ensuring compliance with ethical standards. |
| 8. | Description of categories of persons whose data EMA processes and list of data categories | The categories of data subjects are directly linked to the main processing activities supported by Copilot in the context of the performance of the tasks and responsibilities of EMA. This relates to data subject categories such as:<br><br>• EMA staff members, staff members previously working at EMA and prospective staff members including their family members and dependents. |

• Scientific committee and working party members and appointed experts or representatives of national Competent Authorities in the EU/EEA and EU enlargement countries, the European Commission, non-EU/EEA regulatory authorities/bodies and international organisations (like the WHO and the Council of Europe).

• Stakeholders, partners or individuals who actively collaborate, communicate, or otherwise interact with employees of the EMA.

• Professionals with professional privilege (doctors, lawyers, notaries, private citizens, stakeholders) who actively or passively interact with EMA mentioned in documents or correspondence from or to the EMA.

• Patients and consumers, professionals working in healthcare, representatives of academia, pharmaceutical industry, Health Technology Assessment bodies participating in EMA's framework of interactions.

• Representatives of sponsors of clinical trials, investigators and representatives of Ethics Committees.

• Study participants in clinical trials and non-interventional studies, patients, consumers and healthcare professionals whose data is submitted to the EMA in accordance with the pharmaceutical legislation.

• External end-users (e.g., from other EU institutions, EU bodies, national Competent Authorities, sponsors, MAHs, Patients organisations) who use communication tools provided by the EMA.

• EMA's contractors.

A summary of the main processing areas and personal data in scope of the Agency's second pilot phase is provided as follows as follows:

| **Processing area** | **Personal data in scope** |
|---|---|
| Processing of information related to data subject categories for stakeholder management | Name, (email) address, (professional) contact details, job role, function, organisation/entity |
| Information Security | Personal data related to user registration, authentication, permissions and access rights, logs, connecting information |
| Systems operation | System generated and telemetry data such as IP addresses, cookies, tenant & user IDs, diagnostics logs, time stamps and features used, (see also EMA DPN for the use of Microsoft applications) |
| Medicines regulatory procedures (Human and Veterinary) including pre-and post-authorisation | Personal data processed as part of EMA's medicines regulatory procedures |

| | | | | |
|---|---|---|---|---|
| | | | studies in accordance with EMA's mission and roles and responsibilities set out in Union legislation and internal rules | |
| | | | Human Resource management in accordance with Union legislation and internal rules | Personnel number, personal data relating to the employment of the data subject, including employment and career history, recruitment and termination details, attendance records, health and safety records, performance appraisals, training records, and security records |
| | | | Processing of information related to family life, lifestyle and social circumstances | Information relating to the family or lifestyle of data subjects such as marriage and partnership status, marital history, details of family and other household members, housing, travel details and leisure activities and interests |
| | | | Finances and budget management in accordance with Union legislation and internal rules | Information related to financial affairs of data subjects including income, salary, assets and investments, payments, loans, benefits, grants, insurance details, pension information, invoices, fees |
| | | | Contracts and services | Personal data related to goods or services supplied or to be supplied, licences issued, and contracts |
| | | | Stakeholder engagement and interactions | Personal data in the context of methods of communication and interaction with EMA's stakeholders |
| | | | Multimedia | Personal data in the context of sound/video recordings, phone calls and recording transcripts |
| | | | Education and training | Personal data which relates to the education and any professional training of the data subject, including academic records, qualifications, professional and language skills, training records, professional expertise, and student records |
| | | | Validation of identification issued by a public authority (where applicable) | Passport details, national insurance numbers, identity card numbers, driving license details, diplomatic identification cards (excluding special categories of personal data) |
| 9. | Time limit for keeping the data | Microsoft retains Copilot prompts and responses for a period of 6 months, after which the prompts and responses are permanently deleted within a maximum of 30 days following expiration. The same applies to audit logs containing customer data. | | |

| | | |
|---|---|---|
| | | Copilot prompts and responses can also be deleted under the following circumstances:<br>• A user explicitly deletes the associated chat in Microsoft 365 Copilot.<br>• A user deletes his/her Copilot activity history (in accordance with the guidance provided by Microsoft)<br>In such instances, the prompts and responses will be scheduled for deletion within a maximum of 30 days from the moment the deletion takes place or the request is submitted. The outputs generated by Copilot, for example a summary of a document or a PowerPoint presentation, are maintained according to the applicable retention policies. |
| 10. | Recipients of the data | Personal data related to user registration, authentication, permissions and access rights, logs, connecting information is accessible to appointed EMA security personnel (AF-INS).<br>Authorised EMA network administrators of the Agency's Information Management Division (I-Division) and Information Security Service (DED-INS) can temporarily access all exchanges made with Copilot in all platforms if there is a legitimate reason to do so, e.g., for the purpose of providing technical support and compliance with applicable terms of use and EMA's code of conduct (see https://www.ema.europa.eu/en/documents/other/european-medicines-agency-code-conduct_en.pdf).<br>This might include information like exchanges in chats or email threads that the administrator is not a member of, if they have been incorporated in the response provided by Copilot.<br>Microsoft and their sub-processors may access customer and personal data as necessary for the purposes of providing the service. In accordance with EMA's security measures, Microsoft does not have access to prompts and does not use prompts to train the models.<br>Personal data is accessible to authorised EMA users in accordance with the Agency's access policies/rules including Copilot prompt outputs. EMA staff abide by statutory confidentiality agreements and compliance with Union data protection rules.<br>This is without prejudice to a possible transfer to bodies in charge of a monitoring, auditing or inspection function (e.g. Court of Auditors, EU Court of Justice, European Data Protection Supervisor) in accordance with Union legislation.<br>Data may also be accessed in relation to administrative inquiries and disciplinary proceedings. Please refer to the EMA Data Protection Notice covering this processing.<br>Where EMA receives a request for access to data from a data subject, the EMA data protection officer |

| | | |
|---|---|---|
| | | may access data within the Microsoft applications for the purpose of fulfilling the request. |
| 11. | Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards? | If applicable, any transfer of personal data to a third country or an international organisation by the Agency's processor shall be done only on the basis of documented instructions from the Agency or in order to fulfil a specific requirement under Union or Member State law to which the processor is subject and shall take place in compliance with Chapter V of Regulation (EU) 2016/679 or the EUDPR. Microsoft commits that it will never use any data involved in processing, as well as the prompts submitted by a user, to train Copilot's underlying models and affirms its compliance with EUDPR, the EU Data Boundary initiative, and the ISO/IEC 27018 cloud-privacy standard. |
| 12. | General description of security measures, where possible. | The EMA IT network is protected by multi-factor authentication (MFA). Data is encrypted at rest and in transit.<br><br>In order to protect users personal data, the agency has put in place several strong contractual safeguards complemented by technical and organisational measures.<br><br>Copilot is restricted from accessing data that users do not have permission to view in the first place, adhering to EMA's access policies and security measures.<br><br>Microsoft and their sub-processors also ensure technical and organisational measures are in place to protect the confidentiality, integrity and availability of data. For more information see: Data, Privacy, and Security for Microsoft 365 Copilot \| Microsoft Learn<br><br>Prompts and responses from Copilot are protected by Enterprise Data Protection (EDP) measures. Data is secured with encryption at rest and in transit, rigorous physical security and data isolation between tenants. Microsoft provided safeguard against AI-focused risks such as harmful content and prompt injections. For more information see: Enterprise data protection in Microsoft 365 Copilot and Microsoft 365 Copilot Chat |
| 13. | For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement: | Details concerning the processing of your personal data are available on the Agency's website at:<br><br>https://www.ema.europa.eu/en/about-us/data-protection-privacy-ema<br><br>Here you may find the data protection notice regarding this specific data processing operation as well.<br><br>EMA-I-015-DPN-Copilot<br>https://onedctm.emad.opentext.cloud/D2-Smartview/ui/?docbase=EDMS#d2/nodes/090142b28bb3d65d |