EMA/119622/2024
4 March 2024

Records of data processing activity (public)

Name and reference number of processing operation: Scientific Explorer

1.	Last update of this record, version number:	1.0
2.	Reference number:	EMA-H-011-RoPA
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Human Medicines Division Contact: Datacontroller.HumanMedicines@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 One Microsoft Place South County Business Park Leopardstown Dublin, 18 Ireland EU Data Protection Officer's contact: DPOffice@Microsoft.com Telephone: +353 1 7063117 CapGemini Nederland B.V. Reykjavikplein 1, 3543 AK Utrecht, the Netherlands Data Protection Officer contact:

		ema.nl@capgemini.com
7.	Purpose of the processing	The purpose of data processing in Scientific Explorer is to support and improve the retrieval of relevant information concerning applicable regulatory precedents. The scientific advice related documentation and associated structured data are required to support medicines regulators in the EMRN to perform their tasks. More specifically, the processing of personal data enables authorised users of the Scientific Explorer to identify or search for staff of EMA or medicines regulators associated with a particular procedure in procedural (structured) data coming only from IRIS. There are no AI extractions relating to personal data. In the context of the scientific advice procedures, and enabling the development of new medicines, this is essential to: • discuss the corresponding scientific advice precedents with the applicable coordinators (if they are current members of the Scientific Advice Working Party (SAWP)), or with assessors or experts of the EMRN where there are related scientific advices (e.g. same product or class, indication, qualification methods), • deepen understanding regarding these previous procedures and • involve the current SAWP members, or the respective EMRN medicines regulators in ongoing or upcoming advice procedures.

8.	Description of categories of persons whose data EMA processes and list of data categories	In this processing operation, we process personal data from IRIS and regulatory procedure documents. Such data may include the following data subject roles and personal data categories:
		
		• Personal data from IRIS (structured data):
		  ○ First and last name of EMA Assistant, Scientific Officer, Scientific Coordinators.
		
		• Personal data in scientific documents produced in the context of EMA scientific advice procedures (unstructured data):
		  ○ Final advice, protocol assistance and qualification letters: first and last name of EMA Scientific Officer and two to four Scientific Coordinators.
		  ○ Clarification letters: first name and last name of applicant contact person; first name, last name and signature of Head of Scientific Advice Office.
		
		There are no personal data expected to be included in scientific documents submitted by applicants in the context of EMA's scientific advice procedures, e.g. briefing documents (unstructured data). In exceptional cases, the briefing document may contain personal data from the applicant (e.g. first name, last name, work email address, work phone number).

9.	Time limit for keeping the data	In line with EMA records retention list (EMA/750675/2013), personal data are 'kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Outputs of scientific advice procedures (the documents and data referred to above) contain scientific and regulatory precedents material to potential future scientific advice and marketing authorisation procedures in same or related indication or products. Personal data will be kept for as long as the activities described in the section "Purpose of this data processing" remain relevant.
10.	Recipients of the data	Scientific Explorer is confidential for the European Medicines Regulatory Network. The product, and therefore the personal data referred to above, is only accessible by authorised and authenticated users at EMA, including the maintenance and support teams, and NCA staff who are specifically authorised to have access to the product.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	To implement Scientific Explorer EMA uses Microsoft Cloud services used by IRIS, as well as Microsoft Azure services, including OpenAI. All services store and manage data within EU. For further information please refer to the following DPNs and RoPas: • EMA-TDT-003-DPN-IRIS-Public-2022 (europa.eu) • EMA-TDT-003-RoPA-IRIS-Public-Update-May-2023 (europa.eu) • European Medicines Agency's Data Protection Notice for the use of Microsoft Applications: OneDrive, Outlook 365, Teams and SharePoint (europa.eu) • EMA I-008 RoPA -MS Suite (europa.eu)
12.	General description of security measures, where possible.	The access control lists for approved users is the same as for IRIS, and access is managed via IAM (access to IRIS = access to SE).
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: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement Here you may find the data protection notice regarding this specific data processing operation as well.