



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 July 2024
EMA/79066/2024

Records of data processing activity (public)

Regulatory Science and Innovation Task Force (TRS) activities

1.	Last update of this record, version number:	New
2.	Reference number:	EMA/79066/2024
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Regulatory Science and Innovation Task Force datacontroller.horizonscanning@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	Not applicable.
6.	Name and contact details of processors (where applicable)	Not applicable.



7.	Purpose of the processing	The purpose of this data processing activity is to handle personal data exchanged with TRS in the context of its horizon scanning and forecast activities, identification of regulatory science needs, and relevant interactions with companies, public bodies, consortia, research centres, academia, and natural persons. These interactions aim at collecting relevant information for the Agency to prepare horizon scanning reports, forecast future submissions via the centralised procedure, plan workload and expertise needed within the regulatory network, and identify regulatory science needs. This Data Protection Notice applies to the below-mentioned processing activities: • Business pipeline e-update • Early Point of Contact (EPOC) tracking table • Tracking table for academia interactionsTracking table for European projects • Portfolio and Technology meeting (PTM) • Innovation task force (ITF) meeting These activities are further highlighted in the Agency website under the <i>Innovation in medicines</i> section (link).
8.	Description of categories of persons whose data EMA processes and list of data categories	Personal data refer to any information relating to an identified or identifiable natural person ("data subject"). An identifiable natural person is one who can be identified, directly or indirectly, in particular by an identifier such as name, an identification number or others¹. When submitting an application as part of one of the regulatory procedures described above, personal data of any person creating, editing, submitting an application to interact with EMA may be included. Please see the tabular overview of the data processing activities in section 2.3 for a detailed overview of personal data categories concerned in each activity. These personal data will be kept in the application form of the different interactions (link), internal records, and internal databases.

¹ Definition in accordance with Article 3(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC)

		<u>Processing activity</u>	<u>Personal data concerned</u>	<u>Data subject concerned</u>
		<u>Business pipeline e-update</u>	<u>Email address; EudraLink credentials</u>	<u>Point of contact within the pharmaceutical company</u>
		<u>Early point of contact (EPOC) tracking table</u>	<u>Name; email address; business telephone number</u>	<u>Point of contact within the entity requesting the interaction</u>
		<u>Tracking table for academia interactions</u>	<u>Email address</u>	<u>Point of contact in entity requesting interaction</u>
		<u>Tracking table for European projects</u>	<u>Name</u>	<u>EMA contact person</u>
		<u>Portfolio and Technology Meeting (PTM)</u>	<u>Email address; name; function; business telephone number</u>	<u>Participants to the meeting</u>
		<u>Innovation Task Force (ITF) briefing meeting</u>	<u>Email address; name; function; business telephone number</u>	<u>Participants to the meeting</u>
9.	Time limit for keeping the data	The retention period of the data is 25 years. This retention period is necessary to allow for the review of previous information regarding relevant interactions with the applicants and their potential marketing authorisation applications in line with the mission of the Agency.		
10.	Recipients of the data	The data collected will be processed internally by authorised EMA staff within TRS and the Agency staff have a read access on a need-to-know basis.		
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	No.		

12.	General description of security measures, where possible.	The Agency has put in place appropriate technical and organisational measures (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to your personal data. The Agency takes all the necessary measures to ensure the security of personal data held. The data provided are held in a secured IT system and protected database hosted by EMA, the operations of which abide by EMA's security policy. The database is not accessible from outside EMA. Within EMA, the database is managed/administered using a user ID and password.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	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. • 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 data if it is incorrect or incomplete. • Right to restrict processing – In a few, codified cases, you have the right to obtain the restriction of the processing of your personal data, 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 Data Protection and Privacy, hosted at https://www.ema.europa.eu/en/about-us/data-protection-privacy. • 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. • Right to withdraw consent – When consent is the legal basis for personal data processing, you have the right to withdraw your consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. 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
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