13 February 2024
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European Medicines Agency

Record of data processing activity regarding the HMA-EMA Catalogue of real-world data studies

1.	Last update of this record, version number:	Not applicable, this is version 1.
2.	Reference number:	EMA-TDA-009-RoPA
3.	Name and contact details of controller:	European Medicines Agency Head of Data Analytics and Methods Task Force contact: datacontroller.analytics@ema.europa.eu
4.	Name and contact details of Data Protection Officer (DPO):	Contact: dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	Not applicable
6.	Name and contact details of processor (where applicable)	The Agency may engage third parties to support the: • development and maintenance of functionalities of the HMA-EMA Catalogue of real-world data studies; • collection, management and validation of the information that the HMA-EMA Catalogue of real-world data studies contains; • provision of system and data support to the users of the HMA-EMA Catalogue of real-world data studies. Contact details of the EMA processors can be made available to the data subjects upon request.

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7.	Purpose of the processing	The HMA-EMA Catalogue of real-world data studies is enhancing and replacing the European Union electronic register of post-authorisation studies (EU PAS Register®). The purpose of these data processing activities is to: • ensure compliance with legal requirements set out in Union pharmacovigilance legislation, in particular Articles 107n-q of Directive 2001/83/EC, and GVP Module VIII.B.2 • increase transparency, • reduce publication bias, • promote the exchange of information and facilitate collaboration among stakeholders including academia, regulatory bodies, and pharmaceutical companies.
8.	Description of categories of persons whose data EMA processes and list of data categories	The HMA-EMA Catalogue of real-world data studies contains information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available. **Personal data connected to the study**, which may include the following: • Names and contact details of primary lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study. • Documents uploaded to the database which may contain contact details and names of authors and investigators. In principle, these documents hold only aggregated results and do not contain personal data related to study participants/ patients (e.g., study protocols and reports), in accordance with the Good Practice Guide. • Documents uploaded to the database, in particular relating to 'ENCePP Seal' studies, which may contain names and contact details of researchers and other individuals involved in the performance of the study (e.g. declaration of interest, checklists, declaration on compliance with the ENCePP Code of Conduct, composition of steering group/observers). **Personal data of registered users of the HMA-EMA Catalogue of real-world data studies**, also referred to as

		editors, authors and co-authors in the context of the catalogue (hereafter referred to as "users"). Users are registered using the EU-Login[1] authentication service of the European Commission. Personal data may include the following: • Names and contact details of editors, authors and co-authors, who are inserting and managing study records, in the catalogues.
9.	Time limit for keeping the data	Information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available as well as general contact details of lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study is maintained for the duration of the operation of the HMA-EMA Catalogue of real-world data studies. This is to provide for an important public resource for scientific research with a large and coherent data pool covering a wide range of medicinal products and studies.
10.	Recipients of the data	Personal data connected to the study (as defined in previous point 8): the data is available to the general public. Personal data of registered users of the HMA-EMA Catalogue of real-world data studies (as defined in previous point 8): the data is available to EMA staff managing the HMA-EMA Catalogues and Data processor
11.	Are there any transfers of personal data to third countries or international organisations?	Register intended for consultation by the public
12.	General description of security measures, where possible.	The HMA-EMA Catalogue of real-world data studies is kept in a secure electronic environment designed and maintained to prevent accidental or unlawful destruction, loss, alteration or transfer of the data stored. Data may only be changed or deleted by authorised persons using a username and password. Authorisation is given at senior management level and based on business needs.

[1] IAM Privacy Statement (europa.eu)

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 where you may find the EMA General Privacy Statement as well as the privacy statements on specific data processing operations.