



28 September 2021
EMA/577572/2021

Records of data processing activity (public)

Name and reference number of processing operation: Clinical data publication website

1.	Last update of this record, version number:	28 September 2021, Version 1
2.	Reference number:	577572
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Stakeholders and Communication Division Contact: S-DataController@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 processor (where applicable)	Oracle Belgium BVBA Medialaan 50, Vilvoorde B-1800 Belgium
7.	Purpose of the processing	The clinical data publication website was developed by EMA to implement Agency's policy on the publication of clinical data for medicinal products for human use, Policy 0070.
8.	Description of categories of persons whose data EMA processes and list of data categories	In this processing operation we process data directly collected from you when you accept the terms of use and request access to the published clinical data for academic and other non-commercial research purposes. Such data may include the following: <ul style="list-style-type: none">• An e-mail address;• A physical address in the European Union;



		<ul style="list-style-type: none"> • Elements concerning the identity of the user (i.e. name, date of birth, passport or ID card number, expiry date of the document; for legal persons, the affiliation and position within the organisation of the user should also be provided). <p>Other data collected regarding your user access and activity on the clinical data publication website include:</p> <ul style="list-style-type: none"> • Log in to access the clinical data published; • Terms of use acceptance on first time log in for access; • Terms of use confirmation to view and /or download each clinical data package or package together with a log of the documents selected for view or download; • Terms of use acceptance on upgrade from general information purposes to academic/non-commercial research purposes; • Saved searches for the duration that the specific search is saved;
9.	Time limit for keeping the data	<p>Personal data is retained for the duration that an individual holds an EMA account and /or access to the clinical data publication website.</p> <ul style="list-style-type: none"> • General information purposes access holder, who actively closes or does not use his/her EMA account (s) and /or clinical data publication website access: <ul style="list-style-type: none"> – the EMA account(s) is deemed inactive after 6 months; access to the clinical data publication website will be closed and – the access holder’s personal details/activity will be deleted after a further 6 months. • Academic/Non-commercial research purposes access holder who actively closes or does not use his/her EMA account and/or clinical data publication website access: <ul style="list-style-type: none"> – the EMA account is deemed inactive after 6 months, access to the clinical data publication website will be closed; and – personal details are deleted after a further 5 years.
10.	Recipients of the data	<p>Access to your data is provided to authorised EMA staff, according to the 'need to know' principle only. Such staff abide by statutory confidentiality obligations.</p> <p>EMA engages a third party (data processor) to host, manage and maintain the database necessary for the functioning of the clinical data publication website, the Oracle Internet Directory run by Oracle Corporation.</p>

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.	<p>EMA engages a third party, Oracle Belgium BVBA (data processor), who must ensure that personnel authorised to process personal data is under appropriate statutory obligation of confidentiality or has committed itself to confidentiality or in accordance with the contract signed with the data controller.</p> <p>The data processor has confirmed it has adopted appropriate technical and organisational security measures to prevent unauthorised access to personal data, in accordance with the data protection legislation.</p>
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	<p>Details concerning the processing of your personal data are available on the Agency's website at:</p> <p>https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement</p> <p>and particularly at:</p> <p>https://www.ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-clinical-data-publication-website_en.pdf</p>