



EMA/108052/2026
30 March 2026

Record of data processing activity for Modelling and Simulation Pilot – Use of Clinical Study Data for Scientific Advice (public)

1.	Last update of this record, version number:	1.0
2.	Reference number:	EMA-H-016
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 South County Business Park, One Microsoft Place, Carmanhall and Leopardstown, Dublin, D18 P521, Ireland
7.	Purpose of the processing	<p>The purpose of this processing operation is to enable the Agency to make use of data relating to the safety and efficacy of medicines and to strengthen its modelling and simulation capabilities, informed by relevant regulatory precedents, to provide the best possible scientific advice on the evaluation of the safety and efficacy of medicinal products for human use.</p> <p>The following personal data processing activities are carried out and focusing on data extraction and analysis:</p> <ul style="list-style-type: none">Extraction of clinical study data from the electronic Common Technical Document (eCTD);



		<ul style="list-style-type: none"> • Aggregation of pseudonymised clinical study participants' data; • Creation and storage of datasets across therapeutic indications and/or clinical study participant subgroups (e.g. paediatric or elderly populations); • Analysis including the development of pharmacometric meta-analytic models based on aggregated data; • Dissemination of modelling and simulation results, limited to anonymised personal data, in support of regulatory decision making.
8.	Description of categories of persons whose data EMA processes and list of data categories	<p>Personal data in scope may include the following:</p> <ul style="list-style-type: none"> • Clinical study participant identifier which is replaced with a randomly generated number • Region • Country • Patient characteristics (e.g. age, race, sex, height, weight, co-morbidities, etc.) • Trial Treatment group (Experimental / Placebo) • Information on follow-up and treatment compliance (incl. drug exposure) • Information on concomitant medication • Health related variables collected at baseline and all subsequent study visits • Treatment-effect related variables collected at baseline and all subsequent study visits (incl. primary and secondary efficacy outcomes)
9.	Time limit for keeping the data	The data set used in support of the Modelling and Simulation Pilot will be kept for a period of five years from the date of publication of the pilot results.
10.	Recipients of the data	<p>The pseudonymised personal data are being accessed internally by staff within the EMA Human Medicines Division and more particularly, the Scientific Advice Office.</p> <p>Results from the analysis of the anonymised data may be published on the EMA corporate website and scientific literature.</p>

11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	N/A
12.	General description of security measures, where possible.	<p>The Agency has appropriate technical and organisational measures in place, including organisational policies, to safeguard the security of personal data and ensure the confidentiality, integrity and availability of the relevant systems, services and the personal data processed within them.</p> <p>The pseudonymised personal data are being accessed internally by staff within the EMA Human Medicines Division and more particularly, the Scientific Advice Office.</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/data-protection-privacy-ema</p> <p>Here you may find the data protection notice regarding this specific data processing operation as well.</p>