13 February 2025
EMA/704295/2022

Records of data processing activity (public) regarding the processing of personal data in the Clinical Trials Information System (CTIS)

1.	Last update of this record, version number:	Version 2.0: 10/02/2025, superseding version 1.0: 23/08/2022.
2.	Reference number:	EMA-TDA-006
3.	Name and contact details of controller:	European Medicines Agency Internally: datacontroller.clinicaltrials@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controllers	The organisation name and contact details of the joint controllers are as follows: ▪ European Medicines Agency ▪ European Commission ▪ Member States in the European Economic Area (EEA) Please refer to the contact points as list in Annex I of the Joint Controllership Arrangement (JCA)[1]. ▪ Commercial, non-commercial organisations and academia acting as sponsors of clinical trial (hereafter referred to as 'Sponsor') and marketing authorisation applicants/holders (hereafter referred to as 'MAA/MAH'). A dedicated contact point for data subjects is available from the website of these organisations.

[1] Available at: https://www.ema.europa.eu/en/documents/other/joint-controllership-arrangement-regard-clinical-trials-information-system-ctis_en.pdf

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6.	Name and contact details of processor	Contact details of the EMA processors (and, if necessary, of other joint controllers' processors) can be made available to the data subject upon request.
7.	Purpose of the processing	The purpose of the CTIS data processing activities is based on the requirements set out in the Clinical Trials Regulation (Regulation (EU) No 536/2014) and can be summarised as follow: **Area of clinical trials** The submission of the data and documents for a clinical trial through the EU Portal to the EU Database is summarised as follows: ▪ A sponsor of a clinical trial can submit through the EU Portal to the EU Database, a Clinical Trial Application (CTA) and subsequent modifications, responses to requests for information raised as part of the evaluation process, notifications, summary of results, opinions to corrective measures and a response to an ad hoc assessment. ▪ Member States concerned, responsible for the supervision of the clinical trials in their territory including inspections carry out an assessment of the CTAs. ▪ Marketing authorisation applicants/holders can submit clinical study reports with appendices, except those listing individual patient data. **Area of Annual Safety Reports (ASR)** ▪ For investigational medicinal products other than placebo, a sponsor of a clinical trial is required to submit annually to EMA a report (ASR) on the safety of each investigational medicinal product used in a clinical trial for which they are the sponsor. Member States cooperate in assessing the information reported. **Registration of organisations/CTIS users and management of access permissions** Personal data are processed for the purpose of the following: ▪ Creation of records of new organisations /new locations in EMA's Organisation Management System (OMS) for the purpose of registering users in CTIS; ▪ User registration in CTIS and user access management via EMA's Identity Access Management (IAM) system to generate user credentials required to access the CTIS secure domain;

		▪ Allowing registered users to upload, view, change in CTIS contents/documents in accordance with their access permissions; ▪ Supporting communication between the registered CTIS users and the joint review of CTIS content; ▪ Receiving technical support and secure interaction with the CTIS; ▪ Enabling sponsors, including sponsor's staff and sponsor's third-party representatives, investigators and principle investigators to comply with the obligations set out in the Clinical Trials Regulation when using CTIS.
8.	Description of categories of persons whose data EMA processes and list of data categories	**Personal data of CTIS registered organisations and users having access to the CTIS sponsor's and authority's secure domain** ▪ Personal data of users creating records of new organisations /new locations in EMA's Organisation Management System (OMS) for the purpose of registering users in CTIS; ▪ Personal data such as name, surname, e-mail address captured at the time of the creation of user accounts via Identity Access Management, to obtain credentials required to access CTIS. **Personal data provided by the sponsors, including sponsor's staff** ▪ Contact point in the Union (i.e., first name, last name, telephone number and e-mail address); ▪ Legal representative (i.e., first name, last name, telephone number and e-mail address); ▪ Scientific and public contact point (i.e., functional contact point name, telephone number, e-mail); ▪ Third parties contact point (i.e., telephone number and e-mail address) of the third-party organisation to whom tasks have been delegated; ▪ Sponsor's contact details for ASR submission (full name, organisation details, telephone number and e-mail address). **Personal data in documents provided by the joint controllers in CTIS** The joint controllers provide in the CTIS secure domain several documents, which may contain personal data such as: ▪ Sponsor documents: protocol, investigator brochure, Good Manufacturing Practice certification, cover letter which may

		contain personal data of sponsor staff, qualified person for GMP, summary of results, others; ▪ Member States national Competent Authority users, including Member States' experts: assessment reports and inspection reports; ▪ Marketing authorisation applicants/holders: clinical study report (CSR) with appendices, except those listing individual patient data. Should any of these documents contain personal data, as applicable and as required in accordance with Article 81(2) of Regulation (EU) No 536/2014, these may be provided in the version of the documents 'not for publication'. The version of the documents 'for publication' on the CTIS public portal should not contain personal data. **Personal data of principal investigators' conducting the trial at the site and the person issuing suitability statement of the facilities:** ▪ Principal investigator details captured in the CTIS secure domain including name, surname, professional telephone number, professional e-mail address; ▪ Curriculum Vitae (including training on the principles of good clinical practice or other relevant experience related to professional information only which is relevant to the conduct of clinical trials); ▪ Any circumstances, such as economic interests and institutional affiliations, that might influence the impartiality of the investigators; ▪ The name of the person (i.e., head of the clinic/institution or some responsible person) issuing the written statement testifying to the suitability of the facilities and human resources available for the trial.
9.	Time limit for keeping the data	Initial period of 25 years upon which the retention of the data will be subject to review. The initial retention period starts from 31 January 2022.
10.	Recipients of the data	The provisions of access to the CTIS secure domains for authorities (EMA, European Commission, National Competent Authorities and Ethics Committees on behalf of Member States) and Sponsors, marketing authorisation applicants/holders, where data and documents are stored, are set in the 'Functional specifications for the EU portal and EU database to be audited', which defines a role

		based access and the assignment of roles and permissions to CTIS users. **CTIS users** have access to the clinical trials information based on their profile, which implies that not all users in CTIS will have access to the same level of information or documentation that may contain personal data. **The general public** have access via the CTIS Public Portal. Personal data is not expected to be published on the public module of the CTIS, unless otherwise specified, in accordance with data protection requirements.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Where personal data is made publicly available via the CTIS Public Portal and data are accessed from outside the EU/EEA, this is based on Article 50(1)(g) of Regulation (EU) 2018/1725, or Article 49(1)(g) of Regulation (EU) 2016/679, i.e. the transfer is made from a register which, according to Union law, is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down in Union law for consultation are fulfilled in the particular case. If EMA authorises a user to access the secure domain of CTIS from outside the EU/EEA, EMA must ensure that an appropriate data transfer mechanism is established prior to any access by that user, and that such international data transfer comply with the rules of Chapter V of Regulation (EU) 2018/1725 or Regulation (EU) 2016/679, respectively.
12.	General description of security measures, where possible.	The joint controllers, including EMA, are responsible for implementing appropriate technical measures in CTIS to allow for the secure processing of personal data pursuant to Article 33 of Regulation (EU) 2018/1725 and Article 32 of Regulation (EU) 2016/679, respectively. Access to personal data stored in the secure domain of CTIS undergoing joint processing is granted to authorised staff/personnel/ users of the joint controllers, for the purposes of administering, operating and using the IT system, which facilitates the processing operations. This access is subject to ID and password requirements based on a defined registration process. The joint controllers handle security incidents, including personal data breaches, in accordance with their internal procedures and applicable legislation.
13.	For more information, including how to	Details concerning the processing of your personal data are available on the Agency's website at:

	exercise your rights to access, rectification, object and data portability (where applicable), see the data protection notice:	https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement Relevant data protection document regarding this specific data processing operation: • Joint Controllership Arrangement: https://www.ema.europa.eu/en/documents/other/joint-controllership-arrangement-regard-clinical-trials-information-system-ctis_en.pdf • Data Protection Notice: https://www.ema.europa.eu/en/documents/other/data-protection-notice-regarding-personal-data-processing-clinical-trials-information-system-ctis_en.pdf • Questions and Answers on the Joint Controllership Arrangement and data protection matters related to the use of the Clinical Trials Information System: https://www.ema.europa.eu/en/documents/other/questions-answers-joint-controllership-arrangement-data-protection-matters-related-use-clinical_en.pdf