07 December 2021
EMA/194707/2021

Data protection notice regarding personal data processing in the Clinical Trials Information System (CTIS)

This Data protection notice explains the most essential details of the processing of personal data in the context of the operation of the Clinical Trial Information System (CTIS), including the EU Portal and the EU Database established in accordance with the requirements of Article 80 and 81, respectively, of the Regulation (EU) No 536/2014[1], hereinafter the Clinical Trials Regulation.

The European Medicines Agency (hereafter referred to as 'the Agency'), in collaboration with Union Member States and the European Commission, has set up the CTIS database and it is responsible for its maintenance. CTIS enables the submission of clinical trials related information, from submission of clinical trials applications up to supervision during the clinical trial life cycle.

This Data protection notice explains the most essential details of the processing of personal data in CTIS, which includes:

the area of clinical trials applications and supervision during the trial lifecycle. This information is submitted through the EU Portal and stored in the EU Database;

the area of submission and evaluation of annual safety reports (ASRs).

The joint controllers ensure that processing of personal data in the context of the operation of the CTIS complies with all applicable requirements of Regulation (EU) 2018/1725 (EUDPR) and Regulation (EU) 2016/679 (GDPR), respectively, and other applicable national rules on data protection.

1. Who is responsible for processing your data?

1.1. Who are the joint controllers?

The joint controllers under the Joint Controllership Arrangement (JCA) are: European Commission, European Medicines Agency, Member States, commercial, non-commercial organisations and academia acting as sponsors of clinical trials and marketing authorisation applicants/holders.

The Parties of the Joint Controllership Arrangement act as joint controllers for the purpose of processing operations of personal data provided, in structure data and documents, in CTIS. The contact points of joint controllers are the following:

European Medicines Agency: datacontroller.clinicaltrials@ema.europa.eu

European Commission: SANTE-DATA-PROTECTION-COORDINATOR@ec.europa.eu

1 REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Member States: Annex I of the JCA

For sponsors or marketing authorisation applicants/holders contact points are identified at the time of their registration in CTIS.

The respective roles and relationship vis-à-vis Data Subjects are explained in the JCA. In accordance with the applicable rules of EUDPR and GDPR, Data Subjects may exercise their rights under the Regulations in respect of, and against each of, the joint controllers. In order to ensure that any request can be handled as swiftly as possible, it is recommended that data subject contacts the joint controller who, in line with the activities allocated in the JCA, collected and mainly processes the personal data concerned.

1.2. Who is the data processor?

The Agency engages third parties to provide support for the:

development of CTIS functionalities;

maintenance of CTIS functionalities;

assurance of data quality in CTIS.

Contact details of the EMA processors (and, if necessary of other Parties' processors), can be made available to the data subjects upon request.

2. Purpose of this data processing

The purpose of the CTIS data processing activities can be summarised as follow:

Area of clinical trials: data and documents for a clinical trial submitted through the EU Portal to the EU Database in the context of:

The sponsor can submit through the EU Portal to the EU Database, Clinical Trials Applications (CTA) and subsequent modifications, responses to the request for information raised as part of the evaluation process, notifications, summary of results, opinions to corrective measures and response to an *ad hoc* assessment.

Following these submissions by the sponsors, there will be a corresponding evaluation carried out by the Member States concerned, responsible for the supervision of the clinical trials in their territory including inspections.

Marketing authorisation applicants/holders can submit clinical study reports with appendices, except those listing individual patient data.

Area of Annual Safety Reports (ASR):

Regarding investigational medicinal products other than placebo, the sponsor shall submit annually to the Agency a report on the safety of each investigational medicinal product used in a clinical trial for which it is the sponsor. This will be done via the submission of ASR to CTIS. Member States shall cooperate in assessing the information reported.

Personal data might be provided to enable compliance with the following:

For CTIS registered users:

To enable registration in CTIS and ensure user access management, via Identity Access Management (IAM) system, used to generate users' credentials to access CTIS secure domain;

To enable registered users uploading, viewing, changing the CTIS contents/documents in accordance with their access permissions;

To enable communication between the registered CTIS users and joint review of the CTIS contents;

To enable receiving technical support and secure interaction with the CTIS.

For sponsors, including sponsor's staff and sponsor's third party representatives:

e.g., to enable compliance with the obligation of CTR.

For investigators, principle investigators.

e.g., to enable compliance with the obligation of CTR.

2.1. Categories of Data Subject and personal data concerned

In the context of the use of CTIS, the submission of clinical trials applications, submission of ASR and during the clinical trials life cycle, examples of personal data that can be processed by Member States (also through National Competent Authorities and Ethics Committees), the Agency, the European Commission, the marketing authorisation applicants/holders and sponsors of clinical trials are presented below[2]:

Personal data of CTIS registered users having access to the CTIS sponsor's and authority's secure domain:

- Personal data such as name, surname, e-mail address, are captured at the time of creation of the accounts via Identity Access Management, to obtain credentials to access CTIS;
- These details are visible in the CTIS secure domain to the Administrator(s) within the user's organisation for the purpose of administering users' profiles;
- Name, surname and role of the user in CTIS are visible via the 'user' tab for each clinical trial;
- Users contact details will be visible only in the CTIS secure domain, and not disclosed in the public domain.

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: will be captured only in CTIS secure domains and will not be disclosed in the public domain);
- Legal Representative (i.e. first name, last name, telephone number and e-mail address: will be captured in CTIS secure domain and will be made public;
- Scientific and public contact point (i.e. Functional contact point name, telephone number, e-mail will be captured in CTIS secure domain and will be made public. These are expected to be functional contact points;
- Third parties contact point (i.e. telephone number and e-mail address) of the third-party organisation to whom tasks have been delegated will be in CTIS secure domain and will be made public. These are expected to be functional contact points;
- Sponsor's contact details for ASR submission (Full name, organisation details, telephone number and e-mail address) are captured in the ASR module of CTIS in relation to the submission of the

[2] See also section 4.2. of the Appendix, on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014

Annual Safety Report. These details will be captured only in CTIS secure domains and will not be disclosed in the public domain;

Personal data in documents provided by the joint controllers in CTIS:

The joint controllers will be required to provide in the CTIS secure domain several documents possibly containing personal data for example:

- Sponsor documents: protocol, investigator brochure, GMP certification, cover letter which may contain personal data of sponsor staff, qualified person for GMP, summary of results, others; [3]
- Authorities users, including Member States' experts: assessment reports and inspection reports; [4]
- Marketing authorisation applicants/holders: clinical study report (CSR) with appendices, except those listing individual patient data. It is important to note that the names (not signatures) of the sponsor and coordinating investigator signatories of the clinical study report and the identities of the investigator(s) who conducted the trial should remain visible in the clinical study report loaded into the database and will be made public.

Should any of these documents contain personal data, as applicable and as required in light of Article 81(2) of Regulation (EU) No 536/2014, this can be provided in the version of the documents 'not for publication'. The version of the documents 'for publication' 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 include name, surname, telephone number, e-mail address. These may be provided as functional contact points, but if they are provided as contact details of natural persons these will be made public.

- The following information will be made public from the database:
- The list of principal investigators' names, contact details and the names and addresses of the clinical trial sites;
- Investigator CV, including training on the principles of good clinical practice or other relevant experience, but in any case, containing only professional information relevant to the conduct of clinical trials;
- Any conditions, such as economic interests and institutional affiliations, that might influence the impartiality of the investigators;
- The written statement issued by the head of the clinic/institution or some responsible person testifying to the suitability of the facilities and human resources available for the trial is part of the application dossier, will include the name of the person issuing that statement.

Personal data of users creating records of new organisations / new locations in Organisation Management System (OMS)[5] for the purpose of use in CTIS:

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[3] With regard to ASR, in order to comply with Art 43.3 of the CTR and protect patients' rights, SARs in the line listing should be identified by case ID and study ID without including subject ID in the document. Similarly, the case ID and study ID when reporting the list of deceased and trial participants who dropped out in association with an AE, should not allow the identification of natural persons, see also https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf

[4] There is no specific requirement in the Clinical Trials Regulation for the names of Member State experts to be included in the database.

[5] The OMS provides a single source of validated organisation data that can be used as a reference to support EU regulatory activities and business processes. It stores master data comprising organisation name and location address for organisations such as sponsors, regulatory authorities and manufacturers.

- When creating a new organisation in OMS, or a new location for an existing organisation, the user is prompted to provide certain details. Requestors details provided at the time of registration via OMS will not be captured in the CTIS secure domain and therefore not be made public.

However, organisation details, like telephone number and e-mail address provided for the organisation/location registered in OMS, will be captured in CTIS secure domain and will be made public.

2.2. Legal basis of the processing

The processing of the personal data in CTIS, including collection, publication and archiving of clinical trial information in documents and structured data, is necessary for the management and functioning of the Agency and the performance of its tasks carried out in the public interest mandated by Union law, as controller of the CTIS, which includes the EU Portal and Database, for the effective materialisation of the objectives of the Clinical Trials Regulation. Therefore, this data processing by the Agency is lawful under Article 5(1)(a) of the EUDPR and justified on the grounds of public interest.

In addition, the Member States, the European Commission, the commercial, non-commercial organisation and academia acting as sponsors of clinical trials and marketing authorisation applicants/holders, are also joint controllers in the CTIS. They are legally obliged to collect and upload relevant documents in the CTIS. Therefore, the data processing by the Member States and the European Commission also relies on the lawful ground of public interest under Article 6(1)(e) of the GDPR and Article 5(1)(a) of the EUDPR, respectively. In the case of sponsors and marketing authorisation applicants/holders their activities in CTIS and the related personal data processing is necessary for compliance with their legal obligations under the Clinical Trials Regulation in accordance with Article 6(1)(c) of the GDPR.

Since personal data processing by the Agency and the European Commission in the CTIS is based on the legal ground that this is necessary for the performance of a task carried out in the public interest, Data Subjects (i.e. those individuals whose data is processed in CTIS) **have the right to object against such processing**. See section 5 below.

2.3. Transfer of personal data outside of EU/EEA

The data centres used for CTIS are stored in the following EU countries: Netherlands, Ireland and Germany.

Where personal data is made available to the public in the public domain of CTIS and is 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 a Party authorises a user to access the secure domain of CTIS from outside the EU/EEA, that Party shall ensure that an appropriate data transfer mechanism is established prior to any access by that user, and that such international data transfers comply with the rules of Chapter V of Regulation (EU) 2018/1725 or Regulation (EU) 2016/679, respectively.

3. How long do we keep personal data in CTIS?

Clinical Trials data and documents and Annual Safety Reports provided in CTIS are going to be retained in CTIS for an initial period of 25 years[6] upon which the retention of the data will be subject to review.

The initial retention period starts from the date of the launch of CTIS, on 31 January 2022.

4. Who has access to your information and to whom is it disclosed?

The provisions of access to the CTIS secure domains for authorities (the Agency, 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 foresees the implementation of a role based access and the assignment of roles and permissions to CTIS users.

CTIS users will have access to the clinical trials information based on their profile, therefore, not all the users in CTIS will have access to the same level of information or documentation that may contain personal data.

A public module of CTIS will ensure increased transparency and access to clinical trials data. Article 81(4) of Regulation (EU) No 536/2014 states that the EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on the grounds: of protecting personal data. Accordingly, personal data is not expected to be published on the public module of the CTIS, unless otherwise specified, in accordance with data protection requirements.

5. Data subjects' data protection rights

Data subjects (i.e. the individual whose personal data is processed) have a number of rights:

- **Right to be informed** – This Data protection notice provides information on how the joint controllers, via CTIS, collect and use personal data. Requests for other information regarding the processing may also be directed to datacontroller.clinicaltrials@ema.europa.eu
- **Right to access** – Data subjects have the right to access their personal data. Data subjects have the right to request and obtain a copy of the personal data processed regarding them.
- **Right to rectification** – Data subjects have the right to obtain - without undue delay - the rectification or completion of their personal data if it is incorrect or incomplete.
- **Right to erasure** – Data subjects have the right to require the Agency to delete or stop processing their personal data, for example where the data is no longer necessary for the purposes of processing. In certain cases, the data may be kept to the extent it is necessary, for example, to comply with a legal obligation or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, Data subjects have the right to obtain the restriction of the processing, meaning that their 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

[6] Retention period of data and documents in CTIS has been set for an initial period of time of 25 years by analogy with the timing foreseen for the maintenance of a trial master file as defined in Article 58 of the CTR. The obligations for sponsors and investigators under Article 58 of Regulation (EU) No 536/2014 remain intact.

the EMA General Data protection notice, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.

- **Right to object – Data subjects have the right to object at any time to this processing on grounds related to their particular situation**. In case of such objection against the processing, it must be stopped unless it is shown that the personal data is processed for compelling legitimate reasons which override the interest or rights raised by the data subject, or if it is needed for the establishment, **exercise** or defence of legal claims.

The rights of the data subjects can be exercised in accordance with the provisions of Regulation (EU) 2018/1725 and Regulation (EU) 2016/679, as may be the case.

6. Recourse

In case data subjects have any questions regarding the processing of their personal data, or they think that the processing is unlawful or it is not in compliance with this Data protection notice or the general EMA Data protection notice, the **joint controllers can be contacted** via the contact points listed in Section 1.1.

Data subjects also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** via edps@edps.europa.eu or with a competent Data Protection Authority whose contact details you may find here: https://edpb.europa.eu/about-edpb/board/members_en