Public consultation on the transparency rules for the operation of the Clinical Trials Regulation (CTR) and its Clinical Trials Information System (CTIS)

Fields marked with * are mandatory.

Background information

The public consultation from EMA in collaboration with the European Commission and the Member States, is open from **3 May to 28 June 2023**.

The Clinical Trials Regulation (EU) No 536/2014, hereinafter CTR, requires an unprecedented level of transparency and accessibility to clinical trials information, provided by the public interface of the Clinical Trials Information System (CTIS), which includes the EU database established by the Agency in line with the requirements of Article 81 of the CTR.

The transparency rules of the EU database are described in the Appendix on disclosure rules, to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014", endorsed by the EMA Management Board in 2015.

The Appendix on disclosure rules defines the high level principles for system behaviour for disclosure of public information, as well as deferral functionalities implemented to delay the publication of certain trial structured data and documents.

Please see below an example of deferrals applicable to CTIS sponsor users.

Actor	Grouping	Category 1 FIH, PK/PD, BE/BA, Bio similarity	Category 2 Phase II and III	Category 3 Phase IV
Sponsor	• Main Characteristics	Publication of final **summary of results**		
Sponsor	• Notifications	Publication of final **summary of results**		
Sponsor	• Subject information sheet	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	
Sponsor	• Protocol & Scientific Advice	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	Publication of final **summary of results**
Sponsor	• IMPD S&E sections and Investigator Brochure	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	Publication of final **summary of results**
Sponsor	• RFI and Responses to RFI	Up to **7 years** after the end of the trial in EU/EEA	Up to **5 years** after the end of the trial in EU/EEA	Publication of final **summary of results**
Sponsor	• Clinical trial results summary for an intermediate data analysis	1. 12 months after interim analysis date 2. up to **30 months** after the end of the trial in the EU/EEA		
Sponsor	• Clinical trial results summary and lay person summary	1. 12 months after the end of trial date in the EU/EEA 2. Up to **30 months** after the end of trial in the EEA		

Access to clinical trials information is important to enable enrollment of patients in clinical trials, to build public trust, and to share knowledge on trial design, conduct and results which should invigorate clinical research in the European Union and facilitate access to medicines to patients.
At the same time as delivering high levels of transparency, the disclosure rules must ensure that personal data are protected (in line with the terms of the CTIS joint controllership arrangement) and sponsors' legitimate economic interests are protected by avoiding disclosure of information considered commercially confidential (CCI).
At the December 2022 EMA Management Board meeting it was agreed to seek the views of CTIS users and clinical trial stakeholders on the CTIS transparency rules. This should build on the experience acquired with the launch of CTIS which occurred on 31 January 2022 and the subsequent application of the CTR.
The consultation of CTIS transparency rules intends to collect views from system users and stakeholders and stimulate discussions on the best possible approaches to balance transparency of clinical trials information in CTIS with confidentiality requirements, while also simplifying the modalities of use of the new system.
Any changes agreed to the transparency rules may result in modification of CTIS functionalities, and will maintain the high level of transparency provided by the CTR, without excessive administrative burden for the public authorities and for the sponsors. Simplification of the rules and CTIS functionalities shall not entail a reduced protection of personal data and CCI.

The completion of this survey is expected to take 20 minutes and will be available until the 28 of June 2023 (midnight CET).

In case of queries please contact: ctreg@ema.europa.eu

We take this opportunity to thank you in advance for your contribution!

Data protection statement for 'Public consultation on the transparency rules for the operation of the Clinical Trials Regulation (CTR) and its Clinical Trials Information System (CTIS)'.

By participating in this survey, your submission will be assessed by EMA. However, EMA does not collect, process or store your personal data. Therefore, please make sure that you do not reveal your identity or include other personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format.

Survey

* **1.** Affiliation

- ○ Academics as non-commercial sponsors
- ○ Academics as users of clinical trial data
- ○ Clinical Research organisations (CRO) and other clinical trial service, including consultants
- ○ Clinical trial investigators
- ○ Ethicists and ethics committee members
- ○ Healthcare professionals (HCP) and HCP organisations
- ○ Health technology assessment (HTA) bodies
- ○ Inspectors
- ○ Patients and patient organisations
- ○ Payers
- ○ Policy makers
- ○ Regulators: National Competent Authorities and medical device bodies
- ○ Research funders
- ○ Commercial sponsors, incorporating pharmaceutical companies and small-medium enterprises
- ◉ Other

1.1 If "Other" was selected, please specify:

150 character(s) maximum

International Society of independent drug bulletins - ISDB (International network)

* **2.** UN member states

FR - France

3. Publication of clinical trials structured data (i.e. data fields) and related documents is paramount to enable recruitment of patients at the site, facilitate exchanges of clinical trials information and ultimately foster innovation of clinical research in the EU.
Based on your experience using CTIS, or your perspective as a clinical trial stakeholder, please express your views on the following points:

3.1 Of the structured data and documents provided in CTIS for publication, which ones would you consider critically important for publication at the time of decision of a trial application and during the trial life cycle, as applicable?
Please, mark (Y/N) for clinical trial information, namely structured data and documents, that you consider critically important for publication:

Structured data

	Yes	No
Clinical trial design information, including trial title, trial population, inclusion/exclusion criteria, endpoints	◉	○
Details of the medicinal products used, including details of the active substance, strength, pharmaceutical form, and posology	◉	○
Details of the trial sponsor, including sponsor contact point and third parties involved	○	◉
Request for information (RFI) and RFI responses, raised as intermediate steps in the evaluation of a clinical trial application	○	◉
Principal investigator's contact details	○	◉
Trial status (start, restart, end of trial)	◉	○
Recruitment status (start, restart, end of recruitment)	◉	○
Temporary halt, including safety related	◉	○
Serious Breaches	◉	○
Urgent safety measures	◉	○
Unexpected events	◉	○
Assessments carried out by regulatory authorities on notifications, when this is applicable	◉	○
Third countries inspection reports	◉	○

Other structured data not listed above, please enter here

150 character(s) maximum

No legal & ethical grounds to deny access to anonymized individual-patient data (IPD). If the EHDS is to be done, trials IPD should also be published.

Documents

	Yes	No
Cover letter	○	◉
Sponsor statement of GDPR compliance	○	◉
Protocol	◉	○
Scientific advice	◉	○
Investigator's Brochure	◉	○
IMPD safety and efficacy	◉	○
Recruitment arrangements	○	◉
Subject information and informed consent form	◉	○
Investigator CV and suitability of investigator	○	◉

Suitability of the facilities	○	◉
Proof of insurance cover and indemnification	○	◉
Compliance with national requirements on data protection	○	◉
Compliance with the use of biological samples	○	◉
Final assessment reports part I and part II	◉	○
Inspection reports	◉	○
Intermediate data analysis results	◉	○
Summary of results	◉	○
Clinical study reports	◉	○
Supporting documentation, including for trial design, RFI/ RFI responses, notifications, notifications evaluation carried out by regulatory authorities when this is applicable	◉	○

Other documents not listed above, please enter here

150 character(s) maximum

EMA should require Case Report Forms (eCRFs) by default from the companies for all trials & make them publicly available
Updates on protocol changes

3.2 Deferrals have been introduced in CTIS as a functionality enabling the delay of publication of structured data and documents during the clinical trial life cycle to protect CCI. The deferral mechanisms are provided in the Appendix on disclosure rules, to the Functional specifications for the EU portal and EU database to be audited.

Do you consider that there are compelling reasons to keep the deferral functionalities in the CTIS?

- ○ YES
- ◉ NO

Please provide additional feedback for choosing the selected option:

500 character(s) maximum

Making protocols public before starting to recruit and carry out a trial is a key mechanism to enhance research integrity and accountability. Requirements for publication of all trial results within one year of trial completion is an important mechanism to prevent selective and biased publication of trial results, or delays if results are less favourable. These are well-documented problems that can only be addressed through consistent transparency standards.

Do you consider that CCI can be protected by means of redaction of documents without use of the deferral mechanism?

- ◉ YES
- ○ NO

Please provide additional feedback for choosing the selected option:

500 character(s) maximum

CCI can be protected by means of redaction without the use of the deferral mechanism. However, as laid down in EU case law, redactions of whole parts of documents is not acceptable.
To be considered as CCI, taking into account EU case-law, EMA shall call on the clinical trial sponsor or marketing authorisation applicant/holder to provide solid justification clearly demonstrating that disclosure may undermine its commercial interest. Redacted documents need to remain meaningful to the public.

3.3 Please provide any further comments/suggestions you might have to achieve simplification of CTIS publication rules.

1000 character(s) maximum

We call on the EMA to clearly state in the guidance document that clinical data is scientific data of an overriding public interest and cannot be considered as CCI. They shall be made publicly available, as they represent an overriding public interest and should not be subject to deferrals or redactions. In line with recital 67 of the CTR, we consider that the clinical trial protocols shall not be deferred and shall be made public at the time of trial authorisation decision.

The deferral mechanism should be duly justified and only be applied on an exceptional basis after an in-depth assessment by a NCA.
Whatever the category of trial, above mentioned documents and data should be made publicly available in the CTIS at the latest 12 months after the end of the trial (as not all trials - especially those with negative outcomes - will be included in marketing authorisation applications).

Transparency is key for public trust, healthcare, research and innovation.

Data protection statement for 'Public consultation on the transparency rules for the operation of the Clinical Trials Regulation (CTR) and its Clinical Trials Information System (CTIS)'.

Any personal data that might be provided within this questionnaire will be processed in accordance with Regulation (EU) 2018/1725 on the protection of individuals regarding the processing of personal data by the Union institutions and bodies on the free movement of such data.

This data protection statement provides details on how the Agency, in its capacity as data controller, will process the information that you have given in your questionnaire.

Internally, the Head of Stakeholders and Communication Division is appointed as ‘Internal Controller’ to ensure the lawful conduct of this processing operation. The contact details of the Internal Controller are the following: S-Datacontroller@ema.europa.eu.

Collection of data
EMA does not directly intend to collect personal data but to use the aggregated data for the purpose of this survey. EMA does not intend to connect your ID with your answers given in the survey. Please do not reveal any personal data in the free text fields.

For the collection of data in this Survey, EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home/privacystatement.

The EU Survey external system uses:
Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated. Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.
The local storage contains the IDs of the questions and the draft answers.
IP of every connection is saved for security reasons for every server request. Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage.

Your consent to the processing of your data
When you submit this questionnaire, you consent that EMA will process your personal data provided in the questionnaire as explained in this data protection statement. You may also withdraw your consent later at any time. However, this will not affect the lawfulness of any data processing carried out before your consent is withdrawn.

Start of data processing
EMA will start processing your personal data as soon as this questionnaire is received.

Purpose of data processing
The purpose of the present data processing activity is to collect the views of stakeholders and/or concerned individuals in relation to the particular subject-matter of the survey.

Location of data storage
All data is stored within a secure data centre at the EMA premises which is password protected and only available to EMA staff members.

Publication of data
Data collected in this questionnaire will not be published, but aggregated survey results may be shared with third parties.

Retention period
If you complete and send this questionnaire, your personal data will be kept until the results have been completely analysed and utilised.

Your rights
You have the right to access and receive a copy of your personal data processed, as well as to request rectification or completion of these data. You may also request erasure of the data or restriction of the processing in accordance with the provisions of Regulation (EU) 2018/1725. You can exercise your rights by sending an e-mail to S-Datacontroller@ema.europa.eu.

Complaints
If you have any complaints or concerns about the processing of your personal data, you can contact

EMA’s Data Protection Officer at dataprotection@ema.europa.eu.

You may also lodge a complaint with the European Data Protection Supervisor: edps@edps.europa.eu.

For more details on how EMA processes personal data, please see the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

☑ Please confirm that you have read and understood the data protection statement above and you consent to the processing of your personal data.

Contact

Contact Form