Protection of personal data and commercially confidential information under the Clinical Trials Regulation (EU) No 536/2014

EMA "Revised CTIS Transparency Rules"

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Abstract

The Clinical Trials Regulation (EU) No 536/2014 (CTR) came in force on January 31, 2022, specifying requirements for performing clinical trials in the EU and the European Economic Area (EEA). The CTR and the Clinical Trials Information System (CTIS) harmonise the approval process of clinical trials across the EU/EEA, provide a transparent process, and increase public access to information from clinical trials. Such transparency efforts must assure protection of personal data and commercially confidential information. The CTIS transparency rules were revised and recently implemented. The revised CTIS transparency rules focus on easier and earlier access by the public to documents of primary focus for patients and researchers. This article highlights the protection of personal data and commercially confidential information in public clinical trial documents according to the revised rules and also the EMA Policy 0070, which have overlapping transparency requirements. Medical writers and other functions involved in the preparation of regulatory documents during the clinical drug development play an integral role in applying transparency principles.

Clinical trial disclosure

The efforts to increase transparency of clinical trial information in the EU and the European Economic Area (EEA) are again in focus. Implementation of the revised Clinical Trials Information System (CTIS) transparency rules (RTR)[1] was triggered by feedback from the stakeholders after the initial launch of CTIS.

The RTR were adopted by the European Medicines Agency (EMA) Management Board on October 5, 2023, and implemented on June 18, 2024, with the launch of a new version of the CTIS public portal.[2] The RTR changes the previous requirements by reducing the amount of information submitted to EMA for public disclosure, simplifying processes for sponsors, striking a balance for protecting personal data (PD) and commercially confidential information (CCI), and focusing on simpler and earlier disclosure of information to patients and researchers. Information included in the clinical trial application (CTA) and marketing authorisation application (MAA) is made public via the CTIS public database. Public documents must comply with legislations that protect the PD of clinical trial participants and personnel involved. Information that qualifies as CCI may also be protected.

This article focuses on the protection of PD and CCI in public clinical trial documents, according to the requirements of the RTR of the CTR and also according to the revised EMA Policy 0070 (Policy 0070),[3] because of interrelated disclosure requirements. The EU legal terms, the hierarchy of laws, rank in authority and scope are summarised in Table 1.

CTR and CTIS

The CTR[4] was adopted in 2014 and entered into application on January 31, 2022, with the launch of the CTIS.[5] CTIS is a single point entry (portal and database) for the online system of regulatory submission, authorisation, and supervision of interventional clinical trials in the EU/EEA. CTR repealed the Directive 2001/20/EC Clinical Trials Directive[6] from 2004 that used the EU Drug Regulating Authorities Clinical Trials Database (EudraCT).[7] The CTR harmonises processes for assessment and supervision of CTAs throughout the EU/EEA and contains a set of requirements for performing an interventional clinical trial in the EU/EEA. Public disclosure of clinical trial information is just one of the aspects addressed.

CTIS[5] has been mandatory for all new interventional CTAs with medicinal products for human use in EU/EEA since January 31, 2023. Any EU/EEA trial initiated under the CTD with a foreseen completion in EU/EEA after January 30, 2025, is required to transition to the CTR and use CTIS ahead of the January 30, 2025, cutoff date.[8]

CTIS is the tool through which the CTR requirements are implemented, including the clinical trial disclosure activities. CTIS supports the flow of information between clinical trial

Table 1. Summary of legal terms for the EU/EEA

Term	Definition
Regulation	In the EU legal hierarchy, a *regulation* is directly applicable under EC law and automatically becomes part of national law of the 27 EU member states (plus the 3 EEA states Iceland, Norway, Lichtenstein). A regulation is likely to achieve the intended purpose of the law in a fast and harmonised way among all the EU/EEA member states.
Directive	A *directive* is not directly applicable under the EC law; EU member states are required to implement directives, but they can choose the form and methods of how to do that at a national level. This can lead to a protracted process that is often imbalanced in interpretation and realisation of the law among the EU/EEA states.
Policy	A *policy* may or may not have a legal basis. It is a set of instructions and processes prepared by the organization/agency entrusted with fulfilling certain requirements. In the context of clinical trial disclosure and transparency legal requirements, EMA has created relevant policies.

Abbreviations: EC, European Commission; EEA, European Economic Area; EMA, European Medicines Agency; MS, member state

sponsors, member state (MS) authorities, and the European Commission (EC). As shown in Figure 1, CTIS consists of two main domains: secure and open access. Sponsors and authorities use two separate workspaces in the secure domain. The open access domain of the CTIS database content is accessible to the public.

The RTR define which part of the information and documents in CTIS are destined for public disclosure and also the timeline when these are publicly disclosed. Documents in scope for public access may still contain elements of PD/CCI that should be protected:

- PD, according to Regulation (EU) 2018/1725[9] and Regulation (EU) 2016/679.[10]
- CCI, by taking into account the status of the MA for the medicinal product, unless there is an overriding public interest in disclosure.[11]

Additional laws for clinical trial disclosure

In addition to the CTR,[4] two other laws (both regulations) are applicable for disclosure and public accessibility of clinical trial information in the EU/EEA. Moreover, Policy 0070[3] for MAAs also affects documents for public disclosure. The interaction of the requirements is summarised below and depicted in Figure 2.

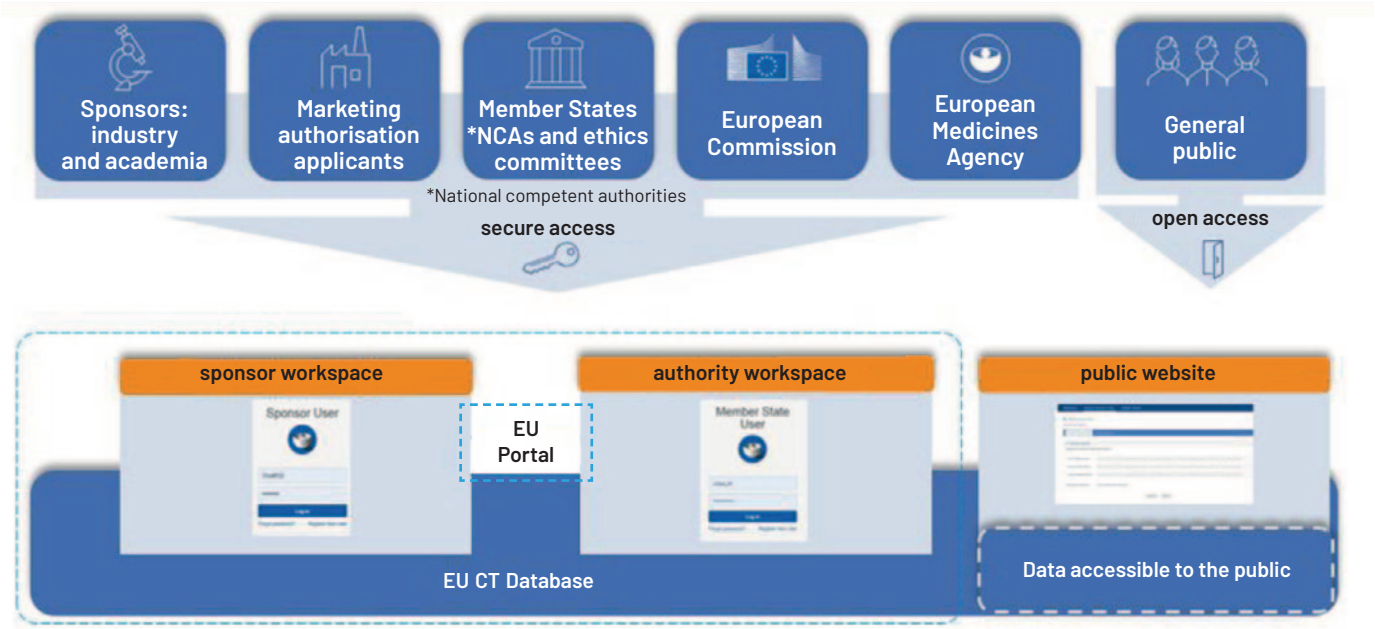

Figure 1. CTIS structure: domains, workspaces, databases

Figure is reproduced from the public EMA document Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS) Version 2.[11]

- **Paediatric Regulation No 1901/2006**[12] deals with medicinal products for paediatric use and drugs that have a potential use in the paediatric population within the EU/EEA. This regulation specifies shorter timelines i.e., 6 months after end of trial (EoT) for disclosure of results from paediatric trials and also for non-paediatric trials that are included in a Paediatric Investigational Plan (PIP).
- **General Data Protection Regulation No 679/2016 (GDPR)**[10] is an essential component of EU privacy and human rights laws. CTR (Article 93) references the GDPR regarding PD, available in the Guidance on protection of PD and CCI.[11,13]
- **Policy 0070**[3] deals with proactive disclosure of documents for products approved as part of an MAA in the EU/EEA through a centralised procedure.

Personal data and commercially confidential information

While the CTR sets aims for transparency through publicly accessible information, it also limits disclosure of PD and CCI. PD is not allowed in documents submitted to the public domain of CTIS unless specifically required by law. Clinical trial participants must be assured (through the informed consent process) that their PD and rights are protected against misuse. The overall rules for protection of PD are governed by the GDPR. Sponsors *may* need to protect CCI. Both PD and CCI should be redacted from the documents that are in scope for public accessibility *before* submitting them to CTIS.

> Both PD and CCI should be redacted from the documents that are in scope for public accessibility *before* submitting them to CTIS.

Responsibilities for PD by clinical trial sponsors and marketing authorisation applicant/holder

As defined by the EC,[14] PD is any information that relates to an identified or identifiable living individual. Separate pieces of information (direct or indirect identifiers), which when collected or combined can lead to the identification of a particular person, also constitute PD. For data to be truly anonymised, the anonymisation must be irreversible.

The processes and requirements governing the handling of PD in CTIS are described in the Joint Controllership Arrangement for CTIS,[15] the guidance on protection of PD and CCI,[11] Annex I,[16] and Question and Answer document.[13] Representatives from the sponsor, marketing authorisation applicant/holder (MAA/MAH) organisation(s) who use CTIS must adhere to the data protection rules and are responsible for protecting PD in publicly accessible documents.[13] As summarised below, four types of PD can arise in CTIS.

- **CTIS registered users:** These users are registered in the database "Identity Access Management" with their name, surname, and email address. This information is only for administrative purposes but is not published.
- **Clinical trial participants:** PD of trial participants may be contained in CTA documents submitted to CTIS, but it should be avoided in documents in scope for publication. PD of trial participants contained in clinical study reports (CSRs) must be protected by redactions and/or other anonymisation techniques.
- **Principal investigator (PI):** Names and professional contact details for the PI are submitted into CTIS and are published. The PI's curriculum vitae is submitted to CTIS but is not published.[1]
- **Sponsor/clinical staff:** Details on the sponsor/MAA/MAH contact point in EU and the legal representative in EU are required in CTIS but are not published.[1] Scientific and public contact points are required and are published;[11] use of generic functional mail addresses and phone numbers is recommended.

Protection principles for CCI

The EMA describes what is considered as CCI along with examples:

Any information which is not in the public domain or publicly available. When its disclosure may undermine the legitimate economic interest or competitive position of the concerned entities, e.g., clinical trial sponsors, MAA/MAH, or service providers.[11]

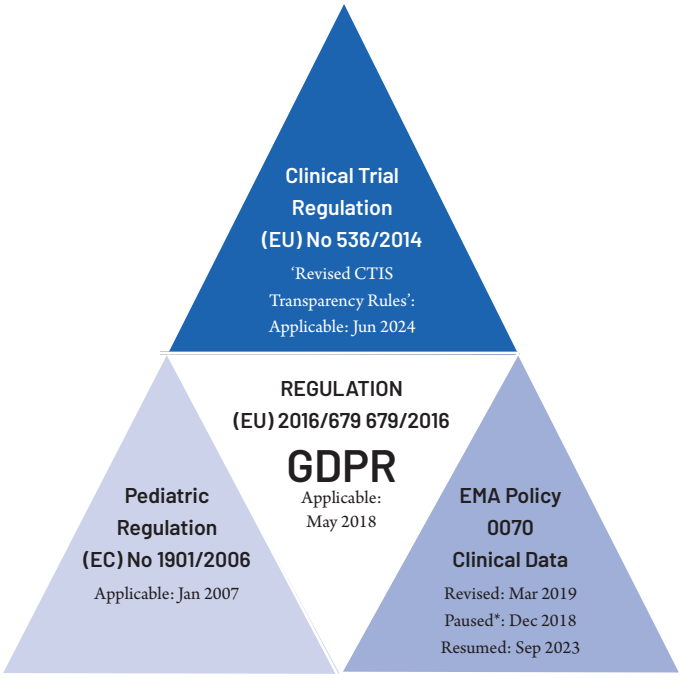

Figure 2. Legal and other requirements for disclosure of clinical trial information

*Activities were paused for all procedures except for clinical trials dealing with COVID-19; paused due to EMA office move from London to Amsterdam.

Table 2. Disclosure requirements* up to *and* after *June 18, 2024

Requirements *up to* June 18, 2024	Requirements *after* June 18, 2024
• All documents publicly accessible *except* for quality-related documents.	• Documents with key relevance for researchers and patients are publicly accessible.
• All versions of documents publicly accessible.	• Only the most recently approved versions of documents are publicly accessible.
• Deferral of document disclosure available to protect CCI.	• Deferral of document is not available. • Redaction of documents is recommended to protect PD and CCI.
• Almost all CTA data fields publicly accessible.	• Fewer CTA structured data fields publicly accessible.
• Historical trials (CTAs submitted *before* June 18, 2024) - publicly accessible for a large number of documents at a timeline that depends on the requested deferral by the sponsor and granted by MS.	• Historical trials (CTAs submitted before June 18, 2024) only structured data from CTIS are made publicly accessible for all trial categories. None of the documents submitted "for publication" before June 18, 2024 will be publicly accessible. • **Note:** Certain updates to a CTA will trigger public accessibility of documents that are in scope of the RTR.

Revised CTIS transparency rules' were adopted by the EMA Management Board on October 5, 2023, and implemented on June 18, 2024.

Abbreviations: CCI, commercially confidential information; CTA, clinical trial application; PD, personal data; RTR, revised CTIS transparency rules

Sources: RTR[1], Guidance on protection of PD and CCI, version 2,[11] and Annex I.[16]

CCI may be protected by redaction in the "for publication" version of documents while the "not for publication" version remains unredacted. It is assumed that as the drug development progresses, less information qualifies as CCI. After a decision on an MAA has been made (i.e., MA approved, rejected, or withdrawn), no information in the CSR should be considered as CCI.[11]

Revised CTIS transparency rules

The recent implementation of the RTR was accompanied by a release of the Guidance document,[11] its Annex I,[16] and other relevant documents,[1] based on the requirements of the CTR.[4] Further specifications are given in documents from the EMA: *CTIS application* fields[17] and *Notifications and results,*[18] which can be used to assess structured data fields and documents for each clinical trial category that incorporates the trial phase of clinical drug development.[19] The main changes in the RTR[1] and their implications as compared with the previous disclosure requirements are described in Table 2.

Structured data fields in CTIS

CTIS contains more structured data fields than the EudraCT database under the CTD. Details on publicly accessible information are available.[17,18] Information entered into the structured data fields in CTIS cannot be redacted and it is important to pay attention to the timing when

Abbreviations

CCI	Commercially confidential information
CHMP	Committee for Medicinal Products for Human Use
CSR	Clinical study report (synonymous for Clinical trial report)
CTA	Clinical trial application
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation (Regulation (EU) 536/214)
EC	European Commission
EEA	European Economic Area (all EU countries plus Iceland, Norway, Lichtenstein)
EMA	European Medicines Agency
EoT	End of trial
EU	European Union
EudraCT	European Union Drug Regulatory Authorities Clinical Trials Database
FDAAA	Food and Drug Administration Amendments Act
GDPR	General Data Protection Regulation
ID	Identification (Subject ID)
MA/MAA/MAH	Marketing authorisation/Marketing authorisation application/Marketing authorisation holder
MS/MSC	Member State/Member State Concerned
PI	Principal investigator
PIP	Paediatric investigation plan
PD	Personal data
Policy 0070	Clinical Data Publication/EMA Policy 0070
RTR	Revised CTIS transparency rules
SmPC	Summary of product characteristics

Table 3. CTIS Documents **"for publication"** *and relevant disclosure timelines*

Documents To be submitted in two versions "for publication" and "not for publication"	**Publication timelines** Category 1 Paediatrics and/or PIP	Category 1 Adults	Category 2 and 3 including integrated ph1 & 2
Protocol, *including patients facing documents*	Upon results' submission	30 months after EU/EEA EoT	First MSC decision
Protocol synopsis			
SmPC, *if available*	Never		That MSC decision
Recruitment arrangements, *including procedures for inclusion and copy of advertising material*			
Subject information and **informed consent form**			
Lay person summary of results	As soon as submitted	30 months after EU/EEA EoT	As soon as submitted
Final summary of results			
Clinical study report, *if available*	As soon as submitted		

Abbreviations: EoT, end of trial; EU/EEA, European Union/ European Economic Area; PIP, paediatric investigation plan; SmPC, summary of product characteristics.

Source: This table is reproduced and slightly modified from the public EMA document Annex I, Table II.[16]

these will become publicly accessible. The timing depends on the category of the clinical trial,[19] the type of information, and whether the trial is in scope for the Paediatric Regulation.[12]

Documents in scope for public disclosure in CTIS

Documents designated as "for publication" and relevant disclosure timelines according to the RTR (see Table 3). Documents must be submitted to CTIS as "disclosure-ready". If redaction is needed to protect PD and CCI, the documents must be submitted as two versions by the sponsor – "for publication" (publicly accessible) and unredacted "not for publication" (for regulatory assessments). To guarantee the correct channelling of the documents, their electronic upload into CTIS must be made in the correct order.

Documents in scope for publication that are expected to contain PD should be checked and redacted, as described below and in Table 4.

- **Clinical trial protocol, protocol synopsis**, and **patients facing documents related to trial endpoints** (such as patient informed consent forms and recruitment arrangements) will be publicly accessible for all trials. For Category 1 trials in paediatrics or trials included in a PIP, the public disclosure will be at the time of summary results submission; for trials in adults, at 30 months after the end of trial (EoT) in the EU/EEA. For Category 2 and 3 trials, public disclosure will occur at the first member state concerned (MSC) decision on the CTA submission.
- **Subject information, informed consent form, recruitment arrangements,** and **SmPC** will be publicly accessible *only* for Category 2 and 3 trials, upon MSC decision on the CTA submission.
- **Lay person summary of results, summary of results,** and **CSR** (if applicable) will be made public as soon as submitted to CTIS; exception to this are Category 1 trials in adults, which will be made public 30 months after EoT in the EU/EEA (Table 3).

Timelines for clinical trial results-related documents

The information in Table 3 shows when the various clinical trial documents become *publicly accessible*. However, the timelines for when the documents are *due for submission* to the regulatory authorities via CTIS are defined in the CTR[4] and in the Paediatric Regulation[11] (Table 5). It is important to distinguish between the two sets of timelines and understand their implications. For example – results summaries for a Category 1 trial in adults will be *publicly accessible* 30 months after EoT; however, for regulatory purposes, such documents need to be *submitted* to CTIS 12 months after EoT.

> Special considerations are noteworthy for CSRs used in an MAA.

Structured data fields and documents *not* destined for public access

A list of structured data fields and documents that are *not* intended for public access is shown in Table VI in Annex I,[16] which specifies documents that are required for *submission* to CTIS and indicates the expectations of the EMA regarding the presence of PD.[17,18]

Special considerations are noteworthy for CSRs used in an MAA. This is because CSRs are in scope for public disclosure according to both the CTR, at a single clinical trial level[4] – and according to the Policy 0070, at a MA dossier level (Table 6). In the CTR, reference is made to Policy 0070 regarding the disclosure of CSRs. A comparison between the two sets of requirements, specifically regarding the CSR, is shown in Table 7. Thus, the earliest public access to CSRs will most likely be in CTIS through the CTR. How such an early public access to the CSR will affect the Policy 0070 process remains

Table 4. Documents* "for publication"*; templates and personal data usually included

Documents **To be submitted in two versions "for publication" and "not for publication"**	**Personal data** **To be anonymised in the doc version "for publication"**	**Websites on the standard templates**
Protocol, including patients facing documents	Personal details of sponsor staff, including signatures	https://www.ema.europa.eu/en/ich-m11-guideline-clinical-study-protocol-template-and-technical-specifications-scientific-guideline
Protocol synopsis		
SmPC, *if available*	Not expected	https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/product-information-templates-human and, for Nationally Authorised Products: https://www.hma.eu/human-medicines/cmdh/templates/qrd.html
Recruitment arrangements, *including procedures for inclusion and copy of advertising material*	Name, surname or identifying element of PI (to be disclosed) or of other individual(s) including trial site personnel	https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorised-under-regulation-eu-no-5362014
Subject information and informed consent form		
Lay person summary of results	Not expected	https://health.ec.europa.eu/document/download/8a42b8f5-4ec3-4667-969c-3dd89ea8b270_en?filename=glsp_en.pdf
Final summary of results	Personal details of sponsor staff, including signatures	
Clinical study report, *if available*	Pseudonymised data of trial participants	https://database.ich.org/sites/default/files/E3_Guideline.pdf

Abbreviations: CTIS, Clinical Trials Information System; CTR, clinical trial report; PI, principal investigator; EoT, end of trial; SmPC, summary of product characteristics.
Source: This table is reproduced from the public EMA document Annex I, Table III.[16]

Table 5.* Submission *timelines for final clinical trial summary results and for lay persons summary of results to MSC via CTIS

Trials with *only adult subjects*

- The timeline for submission of summary documents to CTIS is 12 months after EoT in the EU/EEA.*
- Information on study centre(s) outside the EU/EEA must be captured in the trial protocol and the definition of the global EoT specified, in case the timeline for submission is required to be relative to the global end of trial.
- Documents will be publicly accessible immediately upon submission to CTIS (trial Category 2 and 3 in adults).
- Documents will be publicly accessible at 30 months after the end of the trials in EU/EEA (Category 1 trials in adults).

Trials with *paediatric subjects* and *trials included in a PIP*

- The timeline for submission of summary documents to CTIS is 6 months after trials completion in the EU/EEA.*
- Information on study centre(s) outside the EU/EEA must be captured in the trial protocol and the definition of the global end of the trial specified in case the deadline for submission is required to be relative to the global end of trial.
- The documents will become public immediately upon submission.
- **Note:** The paediatric requirements apply not only to paediatric trials performed in the EU/EEA but also to non-paediatric trials (i.e., adult trials) that are included in a PIP, and under special circumstances, also paediatric trials performed in 'third countries' (outside EU/EEA), as described in Table 6.

Intermediate/Interim (terms used synonymously) trial results summaries

- Intermediate/interim trial results summaries (if specified in the trial protocol) must be submitted to MSC via CTIS when available but will not be publicly accessible.

Abbreviations: EoT, end of trial; EU/EEA, European Union/ European Economic Area; PIP, paediatric investigation plan. Sources: CTR,[4] Paediatric Regulation No 1901/2006,[12] and Annex I, (Table II).[16]
*If a trial has sites outside of EU/EEA, and the global end is required to be considered for such countries, the expected EoT must be described in the trial protocol. Otherwise, the trial results are required 12 months after EoT in EU/EEA.

Table 6. Overall requirements of CTR[4] and EMA Policy 0070[3]

Clinical Trials Regulation (EU) No 536/2014 Clinical Trials Level	EMA Policy 0070 Clinical Data Dossier Level
• All clinical trials performed in EU/EEA.Trials performed outside EU/EEA that are part of PIP. *Note: requirements apply to non-paediatric included in a PIP (i.e. trials in adults).* • Paediatric trials using IMP with EU marketing authorisation and sponsored by MAH, whether or not included in a PIP or whether performed in or outside EU/EEA. • Channel for publication of documents: CTIS Portal applicable: January 31, 2022; Revised: June 18, 2024. Clinical Trials website	• All clinical reports submitted in the regulatory marketing authorisation to EMA. Applies to centrally authorised products only. • Clinical trials performed in EU/EEA or outside EU/EEA ('third countries'). • Channel for publication of documents: EMA Clinical Data publication website. Applicable 2015/Revised 2019. Paused* December 2019; Resumed September 2023. EMA Clinical Data website

*Paused for all procedures except for clinical trials dealing with COVID-19 (paused due to EMA office move from London to Amsterdam)

Abbreviations: CTIS, Clinical Trials Information System; EU/EEA, European Union/ European Economic Area; MAH, marketing authorisation holder; PIP, paediatric investigation plan

Source: Modified from a public EMA document Clinical Data Publication: Comparison with the Clinical Trials Regulation.[20]

to be clarified by the regulators, as summarised in Table 6 and Table 7.

Role of medical writers in clinical trial disclosure activities

Increasing transparency and disclosure of clinical documents has intensified the role of medical writers, from the primary focus of complying with regulatory requirements to also balancing transparency obligations by preparing documents suitable for the public while protecting PD and CCI. Typical documents such as CSR have to be disclosure-ready and disclosure-friendly at the time of creation, with minimal need for time-consuming redaction. Supporting documents regarding the clinical trial disclosure processes and activities are available from the EMA.[19,21]

Supporting documents regarding the clinical trial disclosure processes and activities are available from the EMA.

Minimisation of information and disclosure-ready documents

- Reduce PD and CCI to what is necessary by regulatory requirements. Consider the information that is provided in CTIS in both the structured data fields and the submitted documents. For redacted documents, retain sufficient level of data utility of the information.
- Avoid details of trial participants in patient narratives. Use: month and year for date of birth; relative number of days from trial start; world region instead of a specific country.
- Keep information on clinical trial sponsor and other staff involved to a minimum.
- For scientific and public contact points, use generic functional email and phone number.
- Avoid replicating paragraphs/statements *within* and *between* documents; use cross-references (including electronic links).
- Avoid (or redact) all authors' signatures in documents versions *'for publication'*.
- Use clear naming convention for files to ensure *submitting* documents into the correct electronic slot of CTIS.
- Keep an overview of the company's transparency policy; monitor information made publicly available not only via CTIS but also in the sponsor websites, conference presentations, and global public databases.

PD protection and legal requirements

- PD of trial participants is only allowed if needed for regulatory assessment in the "not for publication" version and must be redacted in the "for publication" version *before* uploading to CTIS.
- Principal investigator names and contact details are legally required and should not be redacted. Redact all signatures. For contact details, use functional non-personal phone numbers and email addresses.
- In documents not destined for publication,[11,16] some PD data may be required for the regulatory assessment; i.e. names and surnames of certain functions/roles are expected in the "not for publication" version, and must be redacted in the "for publication" version, e.g., person issuing the site suitability document and composition of the Data Safety Monitoring Board.[13]
- Remove PD from document metadata (within document properties) *before* submitting to CTIS.

CCI protection

- For CCI identification processes, sponsors should involve experts with relevant scientific and technical skills, including patent legal counsel and follow a consistent decision-making process.
- Follow the principles for CCI protection described for Policy 0070.[3]
- Study protocols become public in most cases immediately after the decision by the first MSC; this implies careful consideration of CCI protection.
- For Category 1 trials in adults, the protocol is disclosed at a later time than for other trials. Nevertheless, consider a situation when a trial ends earlier than planned and thus information is public earlier than anticipated.

Table 7. Specific requirements of CTR[4] and EMA Policy 0070[3] for Clinical Study Reports

Clinical Trials Regulation (EU) No 536/2014	EMA Policy 0070
Scope of MAA documents	
• CSR of trials performed under the CTR and used in an MAA in the EU/EEA.	• Clinical overview, clinical summaries and CSRs of trials globally used for a centralised MAA in the EU/EEA
Scope of content in individual clinical study report documents	
• CSR, as used in the MAA with appendices, except those listing individual patient data.[15]	• CSR body including specific appendices 16.1.1 (trial protocol), 16.1.2 (sample CRF), and 16.1.9 (Statistical Analysis Plan).
Timelines for *submission* and *disclosure* of documents	
• CSR to be *submitted* within 30 days after MAA decision, and made public immediately thereafter.	• Timeline for submission of MAA dossier package depends on the opinion of CHMP. • Package of documents (Clinical Data) is made publicly available after EMA review and approval. • For approved products, public disclosure is expected 60 days after Commission decision; for withdrawn applications 150 days after receipt of the withdrawal letter.
Procedure	
• MAA/MAH to *submit* the CSR appropriately redacted/anonymised for PD and CCI. • CSRs will be publicly accessible immediately upon upload to CTIS. • No Anonymisation Report should be submitted, unless specifically required.	• MAA/MAH to submit the package of documents in scope for Policy 0070, including Anonymisation Report and a set of justification tables (not for publication) for the proposed CCI redactions. • Pre-meeting and consultation contact and process are offered by EMA.
Public access to CSR	
EU Clinical Trials • Clinical Trials website	**Clinical Data** • EMA Clinical Data website

Abbreviations: CCI, commercially confidential information; CSR, clinical study report; CTA, clinical trial application; CTR, Clinical Trials Regulation (Regulation (EU) 536/214); CHMP, Committee for Medicinal Products for Human Use; EU/EEA: European Union/ European Economic Area; MAA, marketing authorisation application; PD, personal data.

CSR - additional considerations

- CSR is likely the document that contains most of the PD information that needs redaction/anonymisation. Details of process alignment for the public disclosure of CSR in scope of the CTR and Policy 0070 are not yet available from the regulators.
- For safety information in the Annual Safety Reports that is potentially also included in the CSR, the Worldwide Unique Case Identification (ID) Number (case ID) and the trial ID should be used for referencing a trial participant rather than the subject ID.[13,22]

Disclaimer

The views expressed in this article are the personal opinions of the authors and do not necessarily reflect the position of the authors' affiliated organisations.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

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