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Annex I: Guidance document on how to approach the protection of personal data and commercially confidential information while using the Clinical Trials Information System (CTIS)

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Table I – Published CTIS Structured Data and relevant disclosure timelines

The detailed list of structured data that are, or are not subject to publication is specified in documents on CTIS application fields and Notifications and Results. Disclosure timelines are provided in this table, and modalities in table IV. To know the type of trials belonging to each Category, refer to table V. An indicative list of structured data that is not subject to publication is provided in table VI.

<table>
<tr><th rowspan="2">Structured data fields</th><th colspan="2">Category 1</th><th rowspan="2">Category 2 integrated ph1&2</th><th rowspan="2">Category 2 & 3
(excl. integr. ph1&2)</th></tr>
<tr><th>Paediatrics and/or PIP</th><th>Adults</th></tr>
<tr><td rowspan="2">CTIS Application fields[1], excluding the ones specified in the row below and in table III</td><td rowspan="2">First MSC decision</td><td>First MSC decision [2]</td><td rowspan="2">First MSC decision</td><td rowspan="3">First MSC decision</td></tr>
<tr><td>30 months after EU/EEA End of Trial</td></tr>
<tr><td>CTIS Application fields: maximum duration of treatment, maximum daily dose allowed, daily dose unit of measure, maximum total dose allowed, Total dose unit of measure</td><td colspan="3">30 months after EU/EEA End of Trial</td></tr>
<tr><td>MSC(s) conclusions and decision outcomes</td><td colspan="4">That MSC decision</td></tr>
<tr><td>Notifications on trial status and recruitment</td><td colspan="4">As soon as submitted by sponsor</td></tr>
<tr><td>Notifications on serious breaches, urgent safety measures, unexpected events</td><td>After MSC assessment</td><td>30 months after EU/EEA End of Trial & MSC assessment</td><td colspan="2">After MSC assessment</td></tr>
<tr><td>Corrective measures (suspension, revocation, modification request)</td><td colspan="4">When applied by MSC(s)</td></tr>
</table>

[1] Any contact detail provided (e.g., scientific and public sponsor contact point, PI) is expected to be a functional or professional contact detail (not personal).
[2] The following fields are disclosed at time of decision for Category 1 trials conducted solely on adult population: public title (= title in lay terms), trial identifiers in registers, protocol code, phase, medical condition, rare disease, therap. Area, Population age, gender, Sponsor details, Details of clinical investigator sites in MSC(s)

Table II – CTIS Documents 'for publication' and relevant disclosure timelines

The detailed list of documents that are, or are not subject to publication is specified in documents on CTIS application fields and Notification and Results. Disclosure timelines are provided in this table, and modalities in table IV (including exceptions applicable to 'historical trials').

Caution: any document inadvertently uploaded 'for publication' into the below document upload sections will be published. Example: if an IB is uploaded into the SmPC section of a Cat 2 or 3 trial, the IB will be made public if not corrected by the sponsor before the decision on the application.

<table>
<tr><th rowspan="3">Documents[3]
to be submitted in two versions 'for publication' and 'not for publication</th><th colspan="3">Publication timelines[4]</th></tr>
<tr><th colspan="2">Category 1</th><th rowspan="2">Category 2 and 3
including integrated ph1&2</th></tr>
<tr><th>Paediatrics and/or PIP</th><th>Adults</th></tr>
<tr><td>Protocol, including patients facing documents[5]</td><td rowspan="2">Upon results' submission</td><td rowspan="2">30 months after EU/EEA EoT</td><td rowspan="2">First MSC decision</td></tr>
<tr><td>Protocol synopsis</td></tr>
<tr><td>SmPC, if available</td><td colspan="2" rowspan="3">Never</td><td rowspan="3">That MSC decision</td></tr>
<tr><td>Recruitment arrangements, including procedures for inclusion and copy of advertising material[6]</td></tr>
<tr><td>Subject information and informed consent form</td></tr>
<tr><td>Lay person summary of results</td><td rowspan="2">As soon as submitted</td><td rowspan="2">30 months after EU/EEA EoT</td><td rowspan="2">As soon as submitted</td></tr>
<tr><td>Final summary of results[7]</td></tr>
<tr><td>Clinical study report, if available[8]</td><td colspan="3">As soon as submitted</td></tr>
</table>

[3] Table III lists the type of personal data generally contained in documents 'for publication', while for an indicative list of documents that are not published: see table VI
[4] To know the type of trials belonging to each Category, refer to table V
[5] Protocol: this is referred to any kind of protocol (including master protocol, sub-protocol, etc.); patients facing documents: see definition in Clinical Trial Regulation 536/2014 Q&A
[6] Recruitment arrangements: provide a clear indication of what the first act of recruitment is; advertising material: this includes any printed materials and audio or visual recordings
[7] Interim results are not made publicly available, only final summary of results are: those documents are distinguished through a dropdown menu of the relevant placeholder
[8] It is the Marketing Authorisation Applicants/Holders that provide Clinical Study Reports (CSRs), within 30 days from the issuing of marketing authorisation, or variation/line extension

Table III – Documents 'for publication': templates and personal data usually included

In this table there is a suggested list of personal data that may be contained in the document version 'not for publication' and shall be removed the relevant 'for publication' version (with exception of PI details). For each document, any available template as per current guidelines is also linked, so that users can know which information is required to be included in the documents, avoiding unnecessary inclusion of CCI.

Documents *to be submitted in two versions 'for publication' and 'not for publication*	**Personal data[9]** *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[10]) 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

[9] Personal data should be provided in the document version 'not for publication' if reduced to a minimum: only when required and necessary to facilitate collaboration within the parties [Article 81(6) referring to 81(2) of the CTR]. Personal data of the author of a document appearing in the file properties should be removed from any file before being uploaded on CTIS.
[10] Name, surname and professional contact details of the Principal Investigator should be included in version 'not for publication' as well as in version 'for publication' (see revised rules)

Table IV – Publication rules of historical trials and of non-authorised applications

This table provides an overview of the modality of disclosure for non-authorised applications, for historical trials applications as well as for all applications submitted to CTIS as of 18 June 2024 (non-historical trials). The 'historical' trials are trials submitted to CTIS before the 18 June 2024, date of applicability of the revised transparency rules.

Note that only the most recent authorised[11] application of any trial, as well as any 'not authorised' initial application, is made publicly available.

Application type	Authorisation outcome	Structured data (most recent version)	Documents (most recent version) submitted as part of the application
Applications published as of 18 June 2024, of trials submitted before 18 June 2024 (historical trials):			
IN, SM, NSM, AMSC	Authorised[11]	Published as per Table I	Not published
SM, AMSC	Not authorised	Not published	Not published
Applications submitted as of 18 June, on trials submitted before 18 June 2024 (historical trials):			
SM	Authorised	Published as per Table I[12]	Published as per Table II
NSM part I		Published as per Table I	Never published
NSM part II		Published as per Table I	Published as per Table II
AMSC	Authorised	Published as per Table I	Part I documents: not published[13] Part II documents: published as per Table II
SM, AMSC	Not authorised	Not published	Not published
Trials submitted as of 18 June 2024 (non-historical trials):			
IN, SM, NSM, AMSC	Authorised[11]	Published as per Table I[12]	Published as per Table II
IN	Not authorised	Published as per Table I	Published as per Table II
SM, NSM, AMSC	Not authorised[11]	Not published	Not published

[11] In case of NSM: 'N/A'
[12] Due to technical reasons, structured data fields are updated depending on which part of the application the specific value is publicly available: for example, fields updated through SM/NSM part I, that affect fields disclosed as part II (e.g. number of subjects), will not be updated, and can only be updated if a part II update of those fields occurs
[13] No part I documents are published in case of AMSC occurring on a historical trial. If the AMSC follows the SM, documents which were published with the SM will remain as they are

Table V – Trial categories and definition of trial phases subject to each category

CTIS disclosure timelines depend mainly on the trial category. In case of category 1 trials, trial population age is also affecting those timelines. In addition, in case of integrated phase 1 and 2 trials, exceptions apply: see table I.

Category	Definition of category	Acceptable values in application dossier data field "Trial phase"	Comment
Category 1	Pharmaceutical development clinical trials: • Phase I clinical trial in healthy volunteers or patients • Phase 0 trial - in healthy volunteers or patients, without therapeutic or prophylactic intent • Bioequivalence and bioavailability trials • Similarity trials for biosimilar product including those conducted in patients where efficacy endpoints are used to determine biosimilarity, where pharmacokinetic and or pharmacodynamic studies are not possible • Equivalence trial for combination products or topical products where a pharmacodynamic or efficacy endpoint is used to determine equivalence, and where pharmacokinetic and or pharmacodynamic studies are not possible.	Human Pharmacology (Phase I) - First administration to humans Human Pharmacology (Phase I) - Bioequivalence Study Human Pharmacology (Phase I) - Other	Category not permitted for clinical trial in emergency situations acc. to article 35 of EU CTR Category not permitted for integrated phase I and phase II trials Only for similarity trials and equivalence trials: the phase selected in the CTIS application could be different than phase I
Category 2	Therapeutic exploratory and confirmatory clinical trials • Phase I and phase II integrated clinical trial • Phase II clinical trial • Phase III clinical trial	Phase I and Phase II (Integrated)- First administration to humans Phase I and Phase II (Integrated)- Bioequivalence Study Phase I and Phase II (Integrated)- Other	Category includes safety and efficacy trials in patients, or target populations for prophylaxis, i.e. carried out for treatment, diagnosis or prevention in the subjects included in the clinical trial during clinical development of a new product or during exploration of new indications, pharmaceutical forms,

Category	Definition of category	Acceptable values in application dossier data field "Trial phase"	Comment
			strengths, and routes of administration for an existing product that already has a marketing authorisation When a protocol sets out a multiphase or adaptive design that falls in both category 1 and 2, the trial should be treated according to category 2. Category not permitted for integrated phase III and Phase IV trials.
Category 3	Therapeutic use clinical trials • Phase III and phase IV integrated clinical trial • Phase IV clinical trial • Low intervention clinical trial	Therapeutic use (Phase IV) Phase III and Phase IV (Integrated)	Category for clinical trial carried out for treatment, diagnosis or prevention in the subjects included in the clinical trial, using an authorised IMP, used in accordance with the terms of the marketing authorisation, or the use of the IMPs is evidence-based and supported by published scientific evidence on the safety and efficacy of those IMPs in any of the Member States concerned

Table VI – CTIS Structured Data and documents that are not subject to publication

The detailed list of structured data and documents that are, or are not subject to publication is specified in documents on CTIS application fields and Notifications and Results. The below is an indicative list that allows to identify easily CTIS data and documents submitted by Sponsors and Authority(ies) (including MSC - National Competent Authorities & Ethics Committees - and European Commission) that are not subject to publication and that might contain commercially confidential information and personal data. Personal data should be provided in CTIS only when required and necessary to facilitate collaboration within the parties [Article 81(6) referring to 81(2) of the Clinical Trials Regulation], further details are provided in the Q&A. Personal data of the author of a document appearing in the file properties should be removed from any file before being uploaded in CTIS.

Location	Data/document type	Categories of personal data captured in CTIS[14]
Structured data submitted by the sponsor		
CTIS Application	Sponsor Contact point for Union Sponsor Legal representative, *if applicable*	Names and surnames of individual(s)
	Justification for no IMPD/AMPD upload, *if applicable* Non substantial modification description, *if applicable* Substantial modification details (information, reason, scope), *if applicable* Justification of application withdrawal, *if applicable*	Not expected ,
Assessment and other sections	Request for information (RFI) responses structured data Sponsor opinion requested as part of intended corrective measure, *if applicable* Sponsor response(s) to request of ad hoc assessment(s), *if applicable* Third country inspection details*, if applicable*	Not expected
Documents submitted by the sponsor		
CTIS Application Form	Cover letter	Not expected
	Proof of payment (per MSC)	Not expected. However, where required by specific

[14] Personal data should be provided in the document version 'not for publication' if reduced to a minimum: only when required and necessary to facilitate collaboration within the parties [Article 81(6) referring to 81(2) of the CTR]. Personal data of the author of a document appearing in the file properties should be removed from any file before being uploaded on CTIS

Location	Data/document type	Categories of personal data captured in CTIS[14]
		Member States (see Q&A): name, surname and signature of individual(s)
	Statement of compliance with GDPR EU Regulation 2016/679 (see template)	Name and surname of individual(s) issuing the statement
	Documents provided only in case of Substantial Modification (modification description, supporting information documentation), *if applicable* Document with supporting information on withdrawal, *if applicable*	Not expected
CTIS Application Part I	Justification for low interventional trial, *if applicable*	Not expected
	Data Safety Monitoring Committee Charter	Name and surname of members of the Data Safety Monitoring Committee, see Q&A
	Study design	Not expected
	Summary of scientific advice Summary of scientific advice – quality	Not expected
	Paediatric Investigational Plan (PIP) opinion/decision	Not expected. It may exceptionally include pseudonymised data of trial participants
	Written agreement from the sponsor - of any previous submitted applications that are associated with this clinical trial	Name and surname of individual(s)

Location	Data/document type	Categories of personal data captured in CTIS[14]
	Medicinal product documents *for test/comparator/auxiliary/placebo, as applicable:* • Investigator brochure (IB) • (GMP) Authorisation of manufacturing and import	Not expected. The IB may exceptionally include pseudonymised data of trial participants
	• Certification by the qualified person (QP) In the Union that the manufacturing complies with Good Manufacturing Practice (GMP)	Name, surname and signature of the qualified person (QP)
	• Quality (IMPD-Q) - Full and simplified	Not expected
	• Safety and Efficacy (IMPD-S&E) - Full and simplified	Not expected. It may exceptionally include pseudonymised data of trial participants
	• Auxiliary medicinal product dossier (AMPD) • Placebo medicinal product dossier - quality (IMPD-Q)	Not expected
	Content of the labelling of the investigational medicinal products	Not expected
CTIS Application Part II	Suitability of the investigator: Principal Investigator (PI) Curriculum Vitae (CV) Suitability of the investigator other than the investigator's CV	Name and surname of the principal investigator and of any other personnel. Where required by specific Member States only, other signatures are to be provided: see Q&A.
	Suitability of the facilities: suitability of the clinical trial site facilities	Name and surname of the head of the clinic/institution or of another responsible person issuing the document on site suitability, including relevant signature(s).

Location	Data/document type	Categories of personal data captured in CTIS[14]
	Proof of insurance cover or indemnification	Name, surname and potential signatures already present on document, if required in specific member state(s): see Q&A
	Financial and other arrangements Compliance with national requirements on data protection Compliance with use of biological sample	Not expected
Assessment and other sections	Documents submitted with responses to the RFI (for validation, part I/part II*, as applicable*): list of changes to the application, General documentation, Quality related documentation, Documents related to the response*, as applicable* Sponsor opinion requested document(s) as part of intended corrective measure*, if applicable* Documents to support response(s) to request of ad hoc assessment(s), *if applicable*	Name and surname of relevant individual(s) (e.g. principal investigator, head of the clinic/institution or other responsible person issuing the site suitability declaration, sponsor legal representative, Qualified Person), as applicable depending on the document type.
Notifications documents submitted during trial duration	Documents submitted as part of notifications uploaded for trial start, end of trial, early termination, temporary halt, restart trial, start recruitment, end recruitment, restart recruitment*, as applicable* Notification supporting documentation, supporting information uploaded for unexpected event(s), serious breach(es), urgent safety measure(s), *as applicable* Third country inspectorate inspection documents (report summary and related document(s)), *if applicable*	Not expected. They may exceptionally include pseudonymised data of trial participants, as applicable. Names, surnames, signatures of third countries inspectors, personal data of sponsor staff, trial site personnel or pseudonymised data of trial participants.

Location	Data/document type	Categories of personal data captured in CTIS[14]
Trial results	Intermediate data analysis summary of results document(s)*, if applicable*	Personal data of sponsor staff, signatures and pseudonymised data of trial participants.
Structured data submitted by the Member State(s) Concerned		
Assessment and other sections	RFIs Validation conclusion details Assessment decision conditions (if any) Ad hoc assessment details*, if applicable* Corrective measure consultation with MSCs, sponsor opinion request, as *applicable* Annual Safety Report RFI*, if applicable*	Not expected
Documents submitted by the Member State(s) Concerned		
Assessment and other sections	Documents to support requests for information (RFI) to sponsor during evaluation of an application (validation, part I/part II assessment), on any element of the dossier, including quality*, as applicable* Draft assessment reports (part I and/or part II *as applicable*) Final assessment reports (part I and/or part II *as applicable*) Authorisation supporting documentation (decision document)*, if applicable* Revert decision supporting documentation, *if applicable* Part I disagreement justification Corrective measure supporting documents: justification document(s), sponsor opinion, investigator opinion, consultation with MSCs related document(s), sponsor opinion request(s) related document(s), *as applicable* Ad hoc assessment related documents: supporting document(s), document(s) added to RFI, summary of assessment and outcome documentation, *as applicable* Inspection report*, if applicable* Assessment reports for serious breaches, urgent safety measures, unexpected events*, if applicable* Union control plans/programmes/reports*, as applicable*	Not expected. However, they could include name and surname of relevant individual(s) (e.g. principal investigator, head of the clinic/institution or other responsible person issuing the site suitability declaration, Qualified Person), as applicable depending on the document type. The inspection report may include names, surnames, signatures of EU/EEA inspectors, personal data of PI, head of the institution, sponsor staff/site personnel

Location	Data/document type	Categories of personal data captured in CTIS[14]
		or pseudonymised data of trial participants. In the assessment report(s) for serious breaches, urgent safety measures and unexpected events, personal data are not expected, however they may exceptionally include pseudonymised data of trial participants

Table VII – Acronyms

In this Guidance document and Annex the following acronyms apply:

Acronym	Description
AMSC	Additional Member State Concerned Application
ASR	Annual Safety Report
CCI	Commercially Confidential Information
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation or 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.
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency, also referred to hereafter as the Agency
EoT	End of Trial date
EU	European Union
EUDPR	Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices, and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (European Data Protection Regulation)
EUPD	European Union Portal and Database
GCP	Good Clinical Practice
GDPR	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

Acronym	Description
IAM	Identity Access Management
IMPD	Investigational Medicinal Product Dossier
MAA	Marketing Authorisation Applicant
MAH	Marketing Authorisation Holder
MSs	Member States
MSC	Member State Concerned
NCA	National Competent Authority
NSM	Non-Substantial Modification Application
OMS	Organisation Management Service
PI	Principal Investigator
RFI	Request for information
SM	Substantial Modification Application
XEVMPD	Extended EudraVigilance Medicinal Product Dictionary

Table VIII - Definitions

In this Guidance document and Annex the following definitions apply:

Definition	Description
Aggregated data	Data about several individuals that have been combined/grouped to present general trends or values without identifying (either directly or indirectly) individuals within the data generated for statistical or research purposes.
Anonymisation	The process of rendering personal data anonymous as described in recital 16 of the EUDPR and recital 26 of the GDPR i.e., namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.
Anonymous data (also called as anonymised)	Information which does not relate to an identified or identifiable natural person or personal data rendered anonymous in such a manner that the data subject is not, or no longer, identifiable.
Article 29 Data Protection Working Party (Art. 29 WP)	The 'Article 29 Working Party' is the short name of the Article 29 Data Protection Working Party established by Article 29 of Directive 95/46/EC. It provided the European Commission with independent advice on data protection matters and helped in the development of a harmonised implementation of data protection rules in the EU Member States. As of 25 May 2018, the Article 29 Working Party ceased to exist, and has been replaced by the European Data Protection Board (EDPB).
Clinical trial information submitted to CTIS	Data (captured in structured data fields) and documents submitted to CTIS in the context of a clinical trial application, during the evaluation of an application and during the clinical trial life cycle including the supervision of the clinical trial and the clinical trials results.
Commercially Confidential Information (CCI)	Any information submitted to CTIS which is not in the public domain, or publicly available, and where disclosure may undermine the legitimate economic interest or competitive position of the concerned entities, e.g. clinical trial sponsors, marketing authorisation applicants/holders or service providers.[15]
Data	'Data' means any digital representation of acts, facts or information and any compilation of such acts, facts, or information, including in the form of sound, visual or audio-visual recording (Article 2 of Data Act).

[15] HMA/EMA recommendations on transparency approved in November 2010 - Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation (EMA/484118/2010). CCI potentially claimed by service providers is unlikely to appear in clinical trial information submitted in CTIS and will be subject to a particular degree of rigor when scrutinizing its existence.

Definition	Description
Database	An organized collection of data stored as multiple datasets.
Dataset	A dataset is a structured collection of data. A table where each column represents a particular variable, and each row corresponds to a different record is an example of a dataset[16].
Data controller (or controller)	''Controller' means the natural or legal person, public authority, agency, or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law.' (Article 4(7) of Regulation (EU) 2016/679). or, as applicable to the entity in question ''Controller' means the Union institution or body or the directorate-general or any other organisational entity which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by a specific Union act, the controller or the specific criteria for its nomination can be provided for by Union law.' (Article 3(8) of Regulation (EU) 2018/1725).
Data minimisation principle	'Personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed.' (Article 5(1)(c) of Regulation (EU) 2016/679 and Article 4(1)(c) of Regulation (EU) 2018/1725).
Data processor (or processor)	''Data processor' means a natural or legal person, public authority, agency, or other body which processes personal data on behalf of the controller.' (Article 4(8) of Regulation (EU) 2016/679 and Article 3(12) of Regulation (EU) 2018/1725).
Data protection principles	Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 prescribe adherence to 7 data protection principles, i.e.: • Lawfulness, fairness, and transparency • Purpose limitation • Data minimisation • Accuracy • Storage limitation • Integrity and confidentiality (security)

[16] See AEPD-EDPS joint paper on 10 misunderstandings related to anonymisation, https://edps.europa.eu/data-protection/our-work/publications/papers/aepd-edps-joint-paper-10-misunderstandings-related_en

Definition	Description
	• Accountability
Data subject	'An identified or identifiable natural person to whom personal data relates. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person.' (Article 4(1) of Regulation (EU) 2016/679 and Article 3(1) of Regulation (EU) 2018/1725). Data subjects applicable to CTR and CTIS are trial participants, CTIS users, principal investigators, sponsor staff, etc.
Disclosure	The act of making data available to one or more third parties.
EU Clinical Trials Information System (CTIS)	The IT platform, including the EU portal and EU database, that allows the exchange of clinical trials information in the European Union. CTIS interacts with other databases such as IAM (Identity Access Management), XEVMPD (Extended EudraVigilance Medicinal Product Dictionary) and OMS (Organisation Management Service) which are also managed by the Agency.
EU Clinical Trials Information System (CTIS) user	The natural person(s) being granted access to the secure domains of CTIS, that submitted the clinical trial information to CTIS in the context of a clinical trial application, or that has access to the system during the evaluation of an application, or during the clinical trial life cycle including supervision of the clinical trial.
EU Portal and Database (EUPD)	In accordance with Articles 80 and 81, and Recitals 66 and 67 of the Clinical Trials Regulation, the Agency has the obligation, in collaboration with the Member States and the Commission, to set up and maintain both a Clinical Trials Portal, as a single-entry point for the submission of data and information relating to clinical trials, and a Clinical Trials Database containing data and information submitted in accordance with that Regulation.
Joint Controller	'Where two or more controllers jointly determine the purposes and means of processing, they shall be joint controllers. They shall in a transparent manner determine their respective responsibilities for compliance with the obligations under this Regulation, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in Articles 13 and 14, by means of an arrangement between them unless, and in so far as, the respective responsibilities of the controllers are determined by Union or Member State law to which the controllers are subject. The arrangement may designate a contact point for data subjects.' (Article 26(1) of Regulation (EU) 2016/679)

Definition	Description
	or, as applicable to the entity in question 'Where two or more controllers or one or more controllers together with one or more controllers other than Union institutions and bodies jointly determine the purposes and means of processing, they shall be joint controllers. They shall in a transparent manner determine their respective responsibilities for compliance with their data protection obligations, in particular as regards the exercising of the rights of the data subject and their respective duties to provide the information referred to in Articles 15 and 16, by means of an arrangement between them unless, and in so far as, the respective responsibilities of the joint controllers are determined by Union or Member State law to which the joint controllers are subject. The arrangement may designate a contact point for data subjects.' (Article 28(1) of Regulation (EU) 2018/1725).
Personal data	''Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'. (Article 4(1) of Regulation (EU) 2016/679 and Article 3(1) of Regulation (EU) 2018/1725).
Special categories of personal data	Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation. (Article 9(1) of Regulation (EU) 2016/679 and Article 10(1) of Regulation (EU) 2018/1725).
Personal data breach	''Personal data breach' means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored, or otherwise processed'. (Article 4(12) of Regulation (EU) 2016/679 and Article 3(16) of Regulation (EU) 2018/1725).
Process, processes, processing	''Processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure, or destruction'. (Article 4(2) of Regulation (EU) 2016/679 and Article 3(3) of Regulation (EU) 2018/1725).
Pseudonymised, pseudonymisation	''Pseudonymisation' means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional

Definition	Description
	information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person'. (Article 4(5) of Regulation (EU) 2016/679 and Article 3(6) of Regulation (EU) 2018/1725).
Publishing	The act of making data publicly available.
Redaction	Masking of text in a document by applying a permanent and unremovable overlay, rendering the text unreadable.
Re-identification	The process of analysing data, or combining it with other data, with the result that individuals become identifiable.
Re-identification risk (or re-identification likelihood, risk of re-identification)	The re-identification risk (or likelihood) is the probability in a given dataset of re-identifying an individual, by turning anonymised data back into personal data through the use of data matching or similar techniques.[17]
Sponsor	The term 'Clinical Trial Sponsors' in the tables of the present Annex applies to sponsors or entities working on behalf of the sponsors, like Clinical Research Organisations (CROs).
Study subject, trial participant	'An individual who participates in a clinical trial, either as a recipient of an investigational medicinal product or as a control'. Article 2(17) of Regulation (EU) No 536/2014. Use is made in the guidance of the term 'trial participant' as an equivalent to 'trial subject/study subject'.
Version of the document 'for publication'	The version of the document provided in CTIS by the users which should not contain commercial confidential information (CCI) and personal data[18]. It is the responsibility of the user to ensure that this version does not contain such information.
Version of the document 'not for publication'	The version of the document provided in CTIS by the users which may contain personal data insofar that this is necessary for the purposes listed in Article 81(2) of the Clinical Trials Regulation and/or commercial confidential information (CCI).

[17] See AEPD-EDPS joint paper on 10 misunderstandings related to anonymisation, https://edps.europa.eu/data-protection/our-work/publications/papers/aepd-edps-joint-paper-10-misunderstandings-related_en.

[18] With the exceptions defined by the present guidance