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Acronyms

Acronym	Description
Art. 29 WP	The Article 29 Working Party was set up under Article 29 of Directive 95/46/EC. The Art. 29 WP is the independent European working party that dealt with issues relating to the protection of privacy and personal data until 25 May 2018 (entry into application of the GDPR).
ASR	Annual Safety Reporting
CCI	Commercially Confidential Information
CTs	Clinical Trials
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
EU	European Union

Acronym	Description
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)
IAM	Identity Access Management
MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MSs	Member States
MSC	Member State Concerned
NCAs	National Competent Authorities
OMS	Organisation Management Service
RFI	Request for information
RMS	Reporting Member State
XEVMPD	Extended EudraVigilance Medicinal Product Dictionary

Definitions

In this guidance document 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.[1]
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).

[1] 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 rigour 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[2].
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

[2] 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
	• Storage limitation • Integrity and confidentiality (security) • 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.
Deferral mechanism	Functionality of CTIS to allow CTIS users to delay the publication of clinical trials data and document, with the aim to protect commercially confidential information.
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

Definition	Description
	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) 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,

Definition	Description
	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 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.[3]
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[4]. 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).

[3] 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.

[4] With the exceptions defined by the present guidance

Table I [5] – Data and documents uploaded by the trial sponsor and Marketing Authorisation Applicants/Holders that provide Clinical Study Reports (CSRs)

This is not an exhaustive list but indicative to identify easily data and documents that might contain 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]. Personal data of the author of a document appearing in the file properties should be removed from any file before being uploaded in CTIS.

The term 'Clinical Trial Sponsors' in tables I and II applies to sponsors or entities working on behalf of the sponsors, like Clinical Research Organisations (CROs).

Data and documents		**Categories of personal data captured in CTIS**	**Categories of data subjects**	**Disclosed**	**Template (if available)**
Data and document category/type	Specific documents (if applicable)				
Cover letter - for the application dossier for initial application and subsequent applications (i.e. SM, additional MSC)		Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	
Statement of compliance with GDPR EU Regulation 2016/679		Name and surname of individual(s) issuing the statement only in the document version not for publication	Clinical trial sponsors	**Yes**	https://health.ec.europa.eu/system/files/2022-09/compliance_reg2016_679_template_en.pdf
Proof of payment *(per MSC)*		Not expected However, where required by specific Member States only: name, surname and	-	**Yes**	

[5] This applies to full text documents submitted in an initial clinical trial application, or extract only provided in Substantial Modifications, as applicable

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
		signature of individual only in the document version not for publication			
Modification description *(only for Substantial Modification)*		Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	
Supporting information documentation *(only for Substantial Modification)*		Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	
Part I – Clinical trials details and sponsor details					
Clinical trials documents	**Protocol & amendments including Master Protocols -** *each version and modification that has occurred*	Name and surname of a minimum amount of sponsor staff only in the document version not for publication	Clinical Trials Sponsors	**Yes**	https://www.ema.europa.eu/en/ich-m11-guideline-clinical-study-protocol-template-technical-specifications-scientific-guideline
	Patient facing documents	Not expected	-		
	Protocol Synopsis	Name and surname of a minimum amount of sponsor staff only in the document version not for publication	Clinical Trials Sponsors	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
	Data Safety Monitoring Committee Charter	Name and surname of members of the Data Safety Monitoring Commitee only in the version not for publication	Members of the Committee	**Yes**	
	Justification for low interventional trial	Not expected	-	**Yes**	
	Study design	Not expected	-	**Yes**	
	Summary of scientific advice	Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	
	Summary of scientific advice - quality	Not expected However if personal data is provided note that this document type is exempt from publication	-	**No**	
	Paediatric Investigational Plan (PIP) opinion/decision	Not expected However if personal data is provided it should be only in the document version not for publication. It may exceptionally include pseudonymised data of trial participants only in the	If any: Trial participants/ Other	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
		document version not for publication.			
	Written agreement from the sponsor - *of any previous submitted applications that are associated with this clinical trial*	Name and surname of individual(s) only in version not for publication	Clinical Trials Sponsors	**Yes**	
	Sponsor Contact point in the Union	Name and surname	Clinical Trials Sponsors	**No**	Structured data field
	Sponsor Legal representative in the Union	Name and surname	Clinical Trials Sponsors	**Yes**	Structured data field
	Scientific and public sponsor contact point	Expected to be functional, not including personal data	Clinical Trials Sponsors	**Yes**	Structured data field
Part I – Medicinal Product details					
Medicinal product documents *for test/comparator/auxiliary/ placebo, as applicable*	**Summary of Medicinal Product Characteristics (SMPC)**	Not expected	-	**Yes**	
	Investigator brochure (IB)	Not expected However if personal data is provided it should be only in	If any: Trial participants/ Other	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
		the document version not for publication. It may exceptionally include pseudonymised data of trial participants only in the document version not for publication.			
	(GMP) Authorisation of manufacturing and import	Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	
	(GMP) 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) only in version not for publication.	Qualified person (QP)	**Yes**	
	Quality (IMPD-Q) *Full or simplified*	Not expected	-	**No**	
	Safety and Efficacy (IMPD-S&E) *Full or simplified*	Not expected However if personal data is provided it should be only in the document version not for publication. It may exceptionally include pseudonymised data of trial	If any: Trial participants/ Other	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
		participants only in the document version not for publication.			
	Auxiliary medicinal product dossier (AMPD)	Not expected	Not expected	**No**	
	Placebo medicinal product dossier - quality (IMPD-Q)	Not expected	Not expected	**No**	
	Content of the labelling of the investigational medicinal products	Not expected However if personal data is provided it should be only in the document version not for publication	Not expected	**Yes**	
Part II					
Recruitment arrangements	**Procedures for inclusion of subjects** - *provide a clear indication of what the first act of recruitment is.*	Not expected However, if name and surname of the principal investigator is provided, then it should be in the document version for publication. If name, surname or identifying element of other individual(s) including trial site personnel is provided it should be only in the document version not for publication	Trial site personnel	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
	Copies of the advertising material - *including any printed materials, and audio or visual recordings*	Not expected	-	**Yes**	
Subject information and informed consent form	**Subject information and informed consent form -** *including each version and modification that has occurred*	Not expected However, if name and surname the principal investigator is provided it should be in the document version for publication. If name, surname or identifying element of other individual(s) including trial site personnel is provided, it should be only in the document version not for publication	Trial site personnel	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable
Suitability of the principal investigator	**Principal Investigator (PI) Curriculum Vitae (CV)**	Name and surname of the principal investigator should be available in the version for publication. Where required by specific Member States only: signature of the principal investigator should be only in the document version not for publication	Principal Investigator	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
	Suitability of the investigator other than the investigator's CV	Name and surname of the principal investigator should be available in the version for publication. Where required by specific Member States only: signature of the principal investigator should be only in the document version not for publication Any other personal data should be only in the document version not for publication	Principal Investigator/ Other	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable
Suitability of the facilities	**Suitability of the trial site**	Name and surname of the head of the clinic/institution or other responsible person issuing the document on site suitability should be in version for publication. Signature of the person should be included only in version not for publication.	Head of the clinic/ institution or by some other responsible person	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable
Proof of insurance cover or indemnification		Any name, surname and potential signatures already present on document, or when required in specific member states, should be only in the version not for publication.	Third party	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
Financial and other arrangements		Not expected However if any personal data is provided note that this document type is exempt from publication	Clinical Trials Sponsor / Head of the clinic/ institution or other responsible person	**No**	
Compliance with national requirements on data protection		Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	
Compliance with the use of biological sample		Not expected	-	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-that-will-be-authorised-under-regulation-eu-no-5362014-once-it-becomes-applicable
Principal investigator (PI) details	Structured data field	Name and surname, site affiliation, functional contact details.	Principal Investigator	**Yes**	Structured data field
RFI responses structured data	Structured data field	Not expected	-	**Yes**	Structured data field
Documents to support responses to the RFI other than quality *(For validation, part I/part II, on any application of the trial initial authorisation, substantial*	*Any documentation provided by the sponsor to reply to request for information (RFI) raised during the evaluation of an application that do*	Name and surname of the principal investigator, head of the clinic/institution or other responsible person issuing the site suitability declaration and sponsor legal representative in version for publication.	Clinical Trial Sponsor Principal Investigator Head of the clinic/ institution or other responsible person	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
modifications or addition of a new MSC, as applicable.)	*not apply to quality aspects*	Any other name and surname should be only in the document version not for publication	Other individual(s)		
Documents to support responses to the RFI on quality or other elements of the dossier not subject to publication *(for any application, as applicable)*	*Any documentation provided by the sponsor to reply to request for information (RFI) raised during the evaluation of an application in relation to quality or other elements of the dossier not subject to publication*	Not expected However if any personal data is provided, such as name and surname of the Qualified Person, note that this document type is exempt from publication	Not expected	**No**	
Documents to support responses to sponsor opinion requests	*Sponsor opinion requested as part of corrective measure*	Not expected However if any personal data is provided note that this document type is exempt from publication	-	**No**	
Documents to support responses to request from *ad hoc* assessment	*Additional information requested by the sponsor as part of an ad hoc assessment*	Not expected However if any personal data is provided note that this document type is exempt from publication	-	**No**	
Notifications - *of temporary halt, early termination, unexpected*	Structured data fields	Not Expected	-	**Yes**	Structured data fields

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
events, urgent safety measures, serious breaches					
Notifications - *of temporary halt, early termination, unexpected events, urgent safety measures, serious breaches, third countries inspection reports*	*Notifications related documents*	Not expected If any personal data is provided should be in the document version not for publication, except those personal data that can be published. It may exceptionally include pseudonymised data of trial participants only in the document version not for publication	Clinical Trial Sponsor Principal Investigator Head of the clinic/ institution or other responsible person Other individual(s) Exceptionally: Trial participants	**Yes**	
	Inspection reports of third country authorities	Names, surnames, signatures of third countries inspectors, personal data of sponsor staff, trial site personnel or pseudonymised data of trial participants: all applicable personal data should be only in the version not for publication.	Third countries inspectors, Clinical trial sponsor Personal data of trial participants	**Yes**	
Trial results	**Summary of results or**	Personal data of sponsor staff, signatures and	Clinical Trial Sponsor	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
	intermediate data analysis	pseudonymised data of trial participants should be only in the document version not for publication	Trial participants		
	Layperson summary of the results	Not expected	-	**Yes**	https://ec.europa.eu/health/system/files/2021-10/glsp_en_0.pdf
	Clinical study reports	Personal data of sponsor staff, signatures and pseudonymised data of trial participants should be only in the document version not for publication	Clinical Trial Sponsor Trial participants	**Yes**	ICH-E3 STRUCTURE AND CONTENT OF CLINICAL STUDY REPORTS

Table II – Data and documents uploaded by the Authorities, including MSC (National Competent Authorities & Ethics Committees) and European Commission

This is not an exhaustive list but indicative to identify easily data and documents that might contain 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].

Data and documents		**Categories of personal data captured in CTIS**	**Categories of data subjects**	**Disclosed**	**Template (if available)**
Data and document category/type	Specific documents (if applicable)				
Draft Assessment Reports for part I and part II		Not expected However if any personal data is provided note that this document type is exempt from publication	Not expected	**No**	Yes, in CTIS
Final Part I assessment report *For initial and other applications, as applicable*		Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	They can be based on the draft AR available in CTIS
Final Part II assessment report *For initial and other applications, as applicable*		Not expected However it may include name and surname of the principal investigator, person	Clinical Trial Sponsor Principal Investigator	**Yes**	They can be based on the draft AR available in CTIS

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
		issuing the site suitability declaration in the version for publication. Any other names and surnames should only be mentioned in the document version not for publication.	Head of the clinic/ institution or other responsible person Other individual(s)		
Documents to support requests for information (RFI) to sponsor *for validation, part I/part II assessment, on any application of the trial (initial authorisation, substantial modifications or addition of a new MSC), as applicable.*	*Any documentation provided by the MSC together with request for information (RFI) raised during the evaluation of an application*	Not expected However it may include name and surname of the principal investigator, person issuing the site suitability declaration in the version for publication. Any other names and surnames may only be mentioned in the document version not for publication.	Clinical Trial Sponsor Principal Investigator Head of the clinic/ institution or other responsible person Other individual(s)	**Yes**	
Documents to support RFI on quality or other elements of the dossier not	*Any documentation provided by the MSC together with*	Not expected	-	**No**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
subject to publication *(for any application, as applicable)*	*request for information (RFI) raised during the evaluation of an application in relation to quality or other elements of the dossier not subject to publication*	However, if personal data is provided (of the qualified person for GMP, for example) note that this document type is exempt from publication			
Documents to support a request for sponsor opinion in a corrective measure	*Sponsor opinion requested by the MSC as part of corrective measure*	Not expected, However if personal data is provided note that this document type is exempt from publication	-	**No**	
Documents to support a corrective measure	*MSC documents in a corrective measure*	Not expected However if personal data is provided it should be in the document version not for publication	-	**Yes**	
Documents to support an *ad hoc* assessment	*Additional information provided by the MSC as part of an ad hoc assessment*	Not expected However if personal data is provided it should be only in the document	Not expected Personal data of trial participants	**No**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
		version not for publication. It may <u>exceptionally</u> include pseudonymised data of trial participants only in the document version not for publication			
Inspection report		Names, surnames, signatures of EU/EEA inspectors, personal data of sponsor staff/site personnel or pseudonymised data of trial participants: all applicable personal data should be only in the version not for publication. PI/head of the institution personal data can be published	EU inspectors, sponsor staff or personal data of trial participants	**Yes**	

Data and documents		Categories of personal data captured in CTIS	Categories of data subjects	Disclosed	Template (if available)
Data and document category/type	Specific documents (if applicable)				
Assessment reports for serious breaches, urgent safety measures, unexpected events		Not expected However if personal data is provided it should be only in the document version not for publication. It may exceptionally include pseudonymised data of trial participants only in the document version not for publication	Not expected Personal data of trial participants	**Yes**	
Union control plans/programmes/reports		Not expected	-	**Yes**	

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

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
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, strengths and routes of administration

Category	Definition of category	Acceptable values in application dossier data field "Trial phase"	Comment
			for an existing product that already has a marketing authorisation 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 IV – Deferral groups and trial categories permitting deferral including conditions

Deferral group	Trial category permitting deferral	Conditions for deferral
Main characteristics*	Category 1	Clinical trial is not part of PIP Clinical trial does not include paediatric population (<18 years of age)
Notifications**	Category 1	Clinical trial is not part of PIP Clinical trial does not include paediatric population (<18 years of age)
Clinical trial results summary for intermediate data analysis	Category 1	Clinical trial is not part of PIP Clinical trial does not include paediatric population (<18 years of age)
Clinical trial results summary, Lay person summary	Category 1	Clinical trial is not part of PIP Clinical trial does not include paediatric population (<18 years of age) Clinical trial is not crisis preparedness trial acc. article 17 of Regulation (EU) 123/2022
Protocol & Scientific Advice Summary	Category 1 Category 2 Category 3	Clinical trial is not crisis preparedness trial acc. article 17 of Regulation (EU) 123/2022
IMPD S&E sections and Investigator's Brochure	Category 1 Category 2 Category 3	
Sponsor responses to RFI	Category 1 Category 2 Category 3	

Deferral group	Trial category permitting deferral	Conditions for deferral
Subject information sheet / Informed Consent	Category 1 Category 2	
RFI sent to sponsor (RMS part I, MSC part II)	Category 1 Category 2 Category 3	RMS / MSC deferral option only if sponsor opted for deferral for group "Sponsor responses to RFI"
Assessment report(s) part I, part II, disagreement to part I conclusion or conditions to any application type	Category 1 Category 2 Category 3	RMS / MSC deferral option only if sponsor opted for deferral of "Protocol & Scientific Advice Summary", and/or "IMPD S&E sections and Investigator's Brochure"

Main characteristics* is a compilation of data elements of the clinical trials populated at the time of completion of the clinical trial application in CTIS. Main characteristics include, amongst others: trial title, inclusion and exclusion criteria of the trial, primary and secondary endpoints, information on the medicinal products used in the trial, part II details. These main characteristics can only be deferred for category 1 trials, and have different publication timepoint compared to the protocol where are also contained.

Notifications** include serious breaches, unexpected events, urgent safety measures and third countries inspection reports.