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European Medicines Agency

Table I [1] – 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		Not expected However if personal data is provided it should be only in	-	**Yes**	

[1] 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)				
subsequent applications (i.e. SM, additional MSC)		the document version not for publication			
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with GDPR EU Regulation 2016/679		Name and surname of individual(s) issuing the statement only in the document version not for publication	Clinical trial sponsors	**Yes**	https://health.ec.europa.eu/system/files/2022-09/compliance_reg2016_679_template_en.pdf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where required by specific Member States only: name, surname and signature of individual only in the document version not for publication	-	**Yes**	
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Substantial Modification)*		Not expected However if personal data is provided it should be only in the document version not for publication	-	**Yes**	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					

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)				
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 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**	

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)				
	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 document version not for publication.	If any: Trial participants/ Other	**Yes**	
	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

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)				
	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 the document version not for publication. It may exceptionally include pseudonymised data of trial participants only in the document version not for publication.	If any: Trial participants/ Other	**Yes**	
	(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)	Name, surname and signature of the qualified person (QP) only in version not for publication.	Qualified person (QP)	**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)				
	In the Union that the manufacturing complies with Good Manufacturing Practice (GMP)				
	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 participants only in the document version not for publication.	If any: Trial participants/ Other	**Yes**	
	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**	

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)				
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 <u>other</u> 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
	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 <u>other</u> individual(s) including trial site personnel is provided, it	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)				
		should be only in the document version not for publication			
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
	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	Head of the clinic/ institution or by	**Yes**	https://ec.europa.eu/health/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-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)				
		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.	some other responsible person		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
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

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)				
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 modifications or addition of a new MSC, as applicable.)*	*Any documentation provided by the sponsor to reply to request for information (RFI) raised during the evaluation of an application that do not apply to quality aspects*	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. Any other name and surname should be 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)	**Yes**	
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**	

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)				
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 events, urgent safety measures, serious breaches*	Structured data fields	Not Expected	-	**Yes**	Structured data fields
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**	

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)				
	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 intermediate data analysis**	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**	
	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 exceptionally 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 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	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

Category	Definition of category	Acceptable values in application dossier data field "Trial phase"	Comment
	• Low intervention clinical trial		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	
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	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"

Deferral group	Trial category permitting deferral	Conditions for deferral
I conclusion or conditions to any application type		

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.