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SCIENCE MEDICINES HEALTH

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Draft Appendices to

Draft proposal for an addendum, on transparency, to the "Functional specifications for the EU portal and EU database to be audited" EMA/641479/2014

The detail, in particular of data fields in the clinical trial application form or documents, is subject to change, as the full data set for the new database has not been finalised. These appendices are presented for the purposes of illustrating the potential implementation of the proposals.

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These appendices have been prepared to illustrate the potential implementation of the proposed application of the transparency rules of the clinical trial Regulation.

For each field or document the timing and time-point of publication is completed in the tables below. The differences between the proposals in section 4 are illustrated.

Key:	Green: Public at the first opportunity provided by the legislation e.g. decision on the trial or for results 12 months after the end of the trial.	Amber: Deferred to take account of CCI in relation to IMP MA status and balancing that with the overriding public interest, e.g. after the MA, at start of phase III etc, or to protect the supervision process.	Red: will not be made public due to CCI, personal data protection or protection of supervision process, or draft assessments.
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Appendix 1: The clinical trial application form, and those elements considered to be the "major characteristics of the trial", as referred to in recital 68 including WHO ICTRP data elements

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTRP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
A		Protocol Information							
A.1		Reporting and concerned Member State(s)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
A.2	1	EU trial number	Primary Registry and Trial Identifying Number	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
	2		Date of Registration in Primary Registry	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
A.3	10	Full title of the trial	Scientific Title	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
A.3.1	9	Title of the trial for lay people, in easily understood, i.e. non-technical, language	Public Title	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
A.3.2		Name or abbreviated title of the trial where available		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
A.4.1	3	Sponsor's protocol code number	Secondary Identifying Numbers	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
A.5.1	3	ISRCTN (International Standard Randomised Controlled Trial) Number	Secondary Identifying Numbers	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
A.5.2	3	US NCT (ClinicalTrials.gov registry) number	Secondary Identifying Numbers	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
A.5.3	3	WHO Universal Trial Reference Number (UTRN)	Secondary Identifying Numbers	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
A.5.4	3	Other Identifier - Name	Secondary Identifying Numbers	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
A.5.4	3	Other Identifier -	Secondary Identifying	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		Identifier	Numbers						
A.7		Trial is part of a Paediatric Investigation Plan		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
A.8		EMA Decision number of Paediatric Investigation Plan		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B	3	Sponsor Information							
B.1.1	3	Name of Sponsor		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.1.3.4	3	Country		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.4	4	Source(s) of Monetary or Material Support for	Source(s) of Monetary or Material	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		<i>the clinical trial:</i>	Support						
B.4.1	4	Name of organisation providing support	Source(s) of Monetary or Material Support	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.4.2	4	Country	Source(s) of Monetary or Material Support	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
	5		Primary Sponsor	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
	6		Co-Sponsor(s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5		<i>Contact point designated by the sponsor for further information</i>		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		<i>on the trial</i>							
B.5.1		Name of organisation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.2		Functional name of contact point		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.3		Address:							
B.5.3.1		Street address		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.3.2		Town/ city		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.3.3		Post code		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.3.4		Country		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.4		Telephone number		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
B.5.6		E-mail		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1		REQUEST FOR THE COMPETENT							

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		AUTHORITY This is the section C title							
C.1.1		Sponsor		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1.2		Legal representative of the sponsor		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1.3		Person or organisation authorised by the sponsor to make the application		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1.4		Complete the details of the applicant below even if they are provided elsewhere on		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		the form (this is a title)							
C.1.4.1		Name of organisation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1.4.2		Name of contact person							
C.1.4.2 .1		Given name							
C.1.4.2 .2		Middle name							
C.1.4.2 .3		Family name							
C.1.4.3		Address							
C.1.4.3 .1		Street address		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1.4.3 .2		Town/city		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
C.1.4.3.3		Post code		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
C.1.4.3.4		Country		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
D.2		Status of the IMP to be used in the clinical trial							
D.2.1		IMP to be used in the trial has a marketing authorisation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.2.1.1.1	13	Trade name	Intervention (s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.2.1.1.2		Name of the marketing authorisation holder		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
D.2.1.2		Country which granted the marketing authorisation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.2.5		The IMP has been designated in this indication as an orphan drug in the EU		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.2.5.1		Orphan drug designation number		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3		Description of the IMP							
D.3.1	13	Product name	Intervention (s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTRP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
D.3.2	13	EU Product code	Intervention (s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.4		Pharmaceutical form		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.4.1		Specific paediatric formulation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
D.3.7		Routes of administration for this IMP		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial	IMP without MA – Non-therapeutic trial after MA/10yy after	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
						Phase III at decision on trial	trial Therapeutic trial at decision on trial		
D.3.8	13	INN - Proposed INN	Intervention (s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.9.1		CAS number		Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.9.2	13	Current sponsor code	Intervention (s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
D.3.9.3	13	Other descriptive name	Intervention (s)	Decision on trial	MA or 10 years after the trial	MA or 10 years after the trial	MA or 10 years after the trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.9.4		EU substance Code		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.10		Strength							
D.3.10.1		Concentration unit		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.10.2		Concentration type		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.10.3		Concentration number		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
D.3.11		The IMP contains an:							Decision on trial
D.3.11.1		Active substance of chemical origin		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11.2		Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP))		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		<i>The IMP is a:</i>							
D.3.11.3		Advanced Therapy IMP (ATIMP)		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11.3.1		Somatic cell therapy medicinal product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11		Gene therapy medical		Decision on trial	IMP without MA – after MA or 10	IMP without MA –	IMP without MA –	Decision on trial Or deferral to 12	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
.3.2		product			years after end of trial	Phase I/II after MA/10yy after trial Phase III at decision on trial	Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	months after the trial	
D.3.11 .3.3		Tissue Engineered Product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11 .3.4		Combination ATIMP (i.e. one involving a medical		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial	IMP without MA – Non-therapeutic trial after MA/10yy after	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		device)				Phase III at decision on trial	trial Therapeutic trial at decision on trial		
D.3.11 .3.5		Committee on Advanced Therapies (CAT) has issued a classification for this product			IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11 .3.5.1		CAT classification and reference number			IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
							trial		
D.3.11.4		Combination product that includes a device, but does not involve an Advanced Therapy		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11.5		Radiopharmaceutical medicinal product		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.3.11.6		Immunological medicinal product (such as vaccine, allergen, immune serum)		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on	In accordance with proposal one, two, three or four	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
							trial		
D.3.11.7		Plasma derived medicinal product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
D.3.11.8		Extractive medicinal product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
D.3.11		Recombinant medicinal		Decision on trial	IMP without MA – after MA or 10	IMP without MA –	IMP without MA –	In accordance with proposal	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
.9		product			years after end of trial	Phase I/II after MA/10yy after trial Phase III – at decision on trial	Non-Therapeutic after MA/10yy after trial Therapeutic - at decision on trial	one, two, three or four	
D.3.11.10		Medicinal product containing genetically modified organisms		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
D.3.11.11		Herbal medicinal product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial	In accordance with proposal one, two, three or four	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
						decision on trial	at decision on trial		
D.3.11.12		Homeopathic medicinal product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
D.3.11.13		Another type of medicinal product		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
D.3.11 .13.1		Other medicinal product type		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
D.8		Information on Placebo							
D.8.1		Is a Placebo used in this trial?		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.8.3		Pharmaceutical form of the placebo		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at	IMP without MA – Non-therapeutic trial after MA/10yy after trial	In accordance with proposal one, two, three or four	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
						decision on trial	Therapeutic trial at decision on trial		
D.8.4		Route of administration of the placebo		Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-therapeutic trial after MA/10yy after trial Therapeutic trial at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
E		General information on the trial							
E.1		Medical condition or disease under investigation							

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
E.1.1		Medical condition(s) being investigated		Decision on trial	Decision on trial	Decision on trial	Decision on trial	In accordance with proposal one, two, three or four	Decision on trial
E.1.1.1	12	Medical condition in easily understood language	Health Condition(s) or Problem(s) Studied	Decision on trial	Decision on trial	Decision on trial	Decision on trial	In accordance with proposal one, two, three or four	Decision on trial
E.1.1.2	12	Therapeutic area	Health Condition(s) or Problem(s) Studied	Decision on trial	Decision on trial	Decision on trial	Decision on trial	In accordance with proposal one, two, three or four	Decision on trial
		MedDRA classification							
E.1.2	12	Medical condition or disease under	Health Condition(s) or Problem(s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	In accordance with proposal one, two, three or four	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		<i>investigation MedDRA code, version, level, term and SOC</i>	Studied						
E.1.3	12	Condition being studied is a rare disease	Health Condition(s) or Problem(s) Studied	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.2		Objective of the trial							
E.2.1	19	Main objective of the trial	Primary Outcome(s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.2.2	20	Secondary objectives of the trial	Key Secondary Outcomes	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
E.2.3		Trial contains a sub-study		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.2.3.1		Full title, date and version of each sub-study and their related objectives		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
		Objective of the trial							
E.3	14	Principal inclusion criteria	Key Inclusion and Exclusion Criteria	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.4	14	Principal exclusion criteria	Key Inclusion and Exclusion	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
			Criteria						
E.5		End points							
E.5.1	19	Primary end point(s)	Primary Outcome(s)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.5.1.1		Timepoint(s) of evaluation of this end point		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.5.2	20	Secondary end point(s)	Key Secondary Outcomes	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.5.2.1		Timepoint(s) of evaluation of this end point		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6		Scope of the							

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		<i>trial</i>							
E.6.1	15	Diagnosis	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.2	15	Prophylaxis	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.3	15	Therapy	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.4	15	Safety	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.5	15	Efficacy	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
E.6.6	15	Pharmacokinetic	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.7	15	Pharmacodynamic	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.8	15	Bioequivalence	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.9	15	Dose response	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.10	15	Pharmacogenetic	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.11	15	Pharmacogenomic	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
								months after the trial	
E.6.12	15	Pharmacoeconomic	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.13	15	Others	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.6.13.1	15	Other scope of the trial description	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.7		Trial type and phase							
E.7.1	15	Human pharmacology (Phase I)	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.7.1.1	15	First	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		administration to humans						Or deferral to 12 months after the trial	
E.7.1.2	15	Bioequivalence study	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.7.1.3	15	Other	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.7.1.3.1	15	Other trial type description	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.7.2	15	Therapeutic exploratory (Phase II)	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.7.3	15	Therapeutic confirmatory (Phase III)	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
								trial	
E.7.4	15	Therapeutic use (Phase IV)	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8		Design of the trial							
E.8.1	15	Controlled	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1	15	Randomised	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1.2	15	Open	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1.3	15	Single blind	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
								months after the trial	
E.8.1.4	15	Double blind	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1.5	15	Parallel group	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1.6	15	Cross over	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1.7	15	Other	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.1.7.1	15	Other trial design description	Study Type	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
E.8.2		Comparator of controlled trial							
E.8.2.1		Other medicinal product(s)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.2.2		Placebo		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.2.3		Other		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.2.3.1		Comparator description		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.2.4		Number of treatment arms in the		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		trial						trial	
E.8.6		<i>Trial involving sites outside the EEA</i>							
E.8.6.1		Trial being conducted both within and outside the EEA		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.6.2		Trial being conducted completely outside of the EEA		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.6.3		If E.8.6.1 or E.8.6.2 are yes, specify the regions in which trial		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		sites are planned							
E.8.8		Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
E.8.9		Initial estimate of the duration of the trial							
E.8.9.1		In the EU years/months/ days		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
E.8.9.2		In all countries concerned years/months/days		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
F		Population of trial subjects							
F.1		Age range							
F.1.1		Trial has subjects under 18		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.1		In utero		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.1.1		Number of subjects for this age							

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		range:							
F.1.1.2		Preterm newborn infants (up to gestational age < 37 weeks)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.2.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.3		Newborns (0-27 days)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.3.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.4		Infants and toddlers (28 days-23		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		months)							
F.1.1.4.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.5		Children (2-11years)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.5.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.6		Adolescents (12-17 years)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.1.6.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.2		Adults (18-64		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		years)							
F.1.2.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.3		Elderly (>=65 years)		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.1.3.1		Number of subjects for this age range:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.2		Gender							
F.2.1		Female		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.2.2		Male		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3		Group of trial subjects							
F.3.1		Healthy		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		volunteers							
F.3.2		Patients		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
F.3.3		Specific vulnerable populations		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3.3.1		Women of childbearing potential not using contraception		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
F.3.3.2		Women of child-bearing potential using contraception		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
F.3.3		Pregnant women		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
F.3.3.4		Nursing women		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3.3.5		Emergency situation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3.3.6		Subjects incapable of giving consent personally		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3.3.6.1		Details of subjects incapable of giving consent		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3.3.7		Others		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.3.3.7.1		Details of other specific vulnerable populations		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.4		Planned number of							

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		<i>subjects to be included</i>							
F.4.1		In the member state		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.4.2		For a multinational trial							
F.4.2.1		In the EEA		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.4.2.2	17	In the whole clinical trial	Target Sample Size	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
F.5		Plans for treatment or care after the subject has ended the participation in the trial (if it is different from the expected		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		normal treatment of that condition)							
G.4		<i>Investigator networks to be involved in the trial</i>							
G.4.1		Name of organisation		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
G.4.3.4		Network country		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
H.4		Third country in which the trial was first authorised:		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
H.4.1		First authorised third country		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
N		Conclusion on Part I of the assessment		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
		Ethics committee opinion (per Member State).		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
		Decision on the trial (per Member State).		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
P		End of trial		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
		End of trial status		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
		Date of the global end of the trial		Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
	11	Countries of recruitment in EU	Countries of Recruitment	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
	18	Recruitment status	Recruitment Status	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
	16	Date of first enrolments in EU	Date of First Enrolments	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
	18	Status of recruitment	Recruitment Status	Real time	Real time	Real time	Real time	Decision on trial Or deferral to 12 months after the trial	Real time
	18	End of recruitment	Recruitment Status	Real time	Real time	Real time	Real time	Decision on trial Or deferral to 12	Real time

CT Field ID	WHO ICTRP ID	EU Clinical Trial Register UI Text	WHO ICTR IP Label	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
				One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
								months after the trial	
	18	End of trial	Recruitment Status	End of trial	End of trial	End of trial	End of trial	Decision on trial Or deferral to 12 months after the trial	End of trial

Appendix 2: The contents of the clinical trial initial application dossier

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
A.	INTRODUCTION AND GENERAL PRINCIPLES						
B.	COVER LETTER	Decision on trial	In line with information in initial CTA and application dossier (IMPD-Q not public)	In line with information in initial CTA and application dossier (IMPD-Q not public)	In line with information in initial CTA and application dossier (IMPD-Q not public)	In line with information in initial CTA and application dossier (IMPD-Q not public)	Decision on trial
C.	EU APPLICATION FORM	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial Or deferral to 12 months after the trial	Decision on trial
D.	PROTOCOL	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III – at decision on trial	IMP without MA – Non-Therapeutic after MA/10yy after trial Therapeutic - at	In accordance with proposal one, two, three or four	Decision on trial Or deferral to 12 months after the trial

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
					decision on trial		
E.	INVESTIGATOR'S BROCHURE (IB)	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	In accordance with proposal one, two, three or four	Decision on trial Or deferral to 12 months after the trial
F.	DOCUMENTATION RELATING TO COMPLIANCE WITH GOOD MANUFACTURING PRACTICE (GMP) FOR THE INVESTIGATIONAL MEDICINAL PRODUCT	Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	In accordance with proposal one, two, three or four	Decision on trial Or deferral to 12 months after the trial
G.	INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD – Q section)						
G.	INVESTIGATIONAL MEDICINAL	Decision on trial	IMP without MA – after MA or 10	IMP without MA – after MA or 10	IMP without MA – after MA or 10	In accordance with proposal one, two,	Decision on trial Or deferral to 12

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation	
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials	
	PRODUCT DOSSIER (IMPD – S section)		years after end of trial IMP with MA Decision on trial	years after end of trial IMP with MA Decision on trial	years after end of trial IMP with MA Decision on trial	three or four	months after the trial	
G.	INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD – E section)	Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	In accordance with proposal one, two, three or four	Decision on trial Or deferral to 12 months after the trial	
H.	AUXILIARY MEDICINAL PRODUCT DOSSIER – Q section							
H.	AUXILIARY MEDICINAL PRODUCT DOSSIER – E section	Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	In accordance with proposal one, two, three or four	Decision on trial Or deferral to 12 months after the trial	

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
H.	AUXILIARY MEDICINAL PRODUCT DOSSIER – S section	Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	In accordance with proposal one, two, three or four	Decision on trial Or deferral to 12 months after the trial
I.	SCIENTIFIC ADVICE	Decision on trial	EMA SAWP Public information only	EMA SAWP Public information only	EMA SAWP Public information only	EMA SAWP Public information only Decision on trial Or deferral to 12 months after the trial	EMA SAWP Public information only
I.	PAEDIATRIC INVESTIGATION PLAN (PIP)	Decision on trial	Decision on trial Public summary	Decision on trial Public summary	Decision on trial Public summary	Decision on trial	Decision on trial Public summary
J.	CONTENT OF THE LABELLING OF THE INVESTIGATIONAL MEDICINAL PRODUCTS	Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	IMP without MA – after MA or 10 years after end of trial IMP with MA Decision on trial	In accordance with proposal one, two, three or four	Decision on trial

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
K.	RECRUITMENT ARRANGEMENTS (INFORMATION PER MEMBER STATE CONCERNED)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
L.	SUBJECT INFORMATION, INFORMED CONSENT FORM AND INFORMED CONSENT PROCEDURE (INFORMATION PER MEMBER STATE CONCERNED)	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – Phase I/II after MA/10yy after trial Phase III at decision on trial	IMP without MA – Non-therapeutic after MA/10yy after trial Therapeutic at decision on trial	In accordance with proposal one, two, three or four	Decision on trial
M.	SUITABILITY OF THE INVESTIGATOR (INFORMATION PER MEMBER STATE CONCERNED)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
N.	SUITABILITY OF THE FACILITIES (INFORMATION PER	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
	MEMBER STATE CONCERNED)						
O.	PROOF OF INSURANCE COVER OR INDEMNIFICATION (INFORMATION PER MEMBER STATE CONCERNED)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
P.	FINANCIAL AND OTHER ARRANGEMENTS (INFORMATION PER MEMBER STATE CONCERNED)						
Q.	PROOF OF PAYMENT OF FEE (INFORMATION PER MEMBER STATE CONCERNED)	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial
R.	PROOF THAT DATA	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial	Decision on trial

CT Regulation Annex I	Sections	Proposal products without marketing authorisation					Proposal products without marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV/ low-intervention trials
	WILL BE PROCESSED IN COMPLIANCE WITH UNION LAW ON DATA PROTECTION						

Appendix 3: The contents of the clinical trial substantial modification application dossier

CT Regulation Annex II	Sections	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV or low-intervention
A.	<i>INTRODUCTION AND GENERAL PRINCIPLES</i>						
B.	<i>COVER LETTER</i>	Decision on trial	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	Decision on trial
C.	<i>MODIFICATION APPLICATION FORM</i>	Decision on trial	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	Decision on trial
D.	<i>DESCRIPTION OF THE MODIFICATION</i>	Decision on trial	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier

CT Regulati on Annex II	Sections	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
		One	Two	Three	Four	Phase I healthy volunteers	Phase IV or low- intervention
E.	<i>SUPPORTING INFORMATION</i>	Decision on trial – except for IMPD-Q section	In line with information in initial CTA and application dossier (IMPD-Q not public)	In line with information in initial CTA and application dossier (IMPD-Q not public)	In line with information in initial CTA and application dossier (IMPD-Q not public)	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier
F.	<i>UPDATED EU APPLICATION FORM</i>	Decision on trial	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	In line with information in initial CTA and application dossier	Decision on trial

Appendix 4: Other data and documents submitted to the database

Sections	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
	One	Two	Three	Four	Phase I healthy volunteers	Phase IV or low-intervention
Assessment report Part 1 Q section						
Assessment report Part 1 S section	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	Decision on trial Or deferral to 12 months after the trial
Assessment report Part 1 E section	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	Decision on trial Or deferral to 12 months after the trial
Assessment report Part 2 Q section						
Assessment report Part 2 S section	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	Decision on trial Or deferral to 12 months after the trial
Assessment report Part 2 E section	Decision on trial	IMP without MA – after MA or 10 years after end of	IMP without MA – after MA or 10 years after end of	IMP without MA – after MA or 10 years after end of	IMP without MA – after MA or 10 years after end of	Decision on trial Or deferral to 12 months after the

Sections	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
	One	Two	Three	Four	Phase I healthy volunteers	Phase IV or low-intervention
		trial	trial	trial	trial	trial
Requests for information and responses Q section						
Requests for information and responses S section	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	Decision on trial Or deferral to 12 months after the trial
Requests for information and responses E section	Decision on trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	IMP without MA – after MA or 10 years after end of trial	Decision on trial Or deferral to 12 months after the trial
Withdrawal of application and reasons	Real Time	Real Time	Real Time	Real Time	Real Time	Real Time
Start of trial	Real time	Real Time	Real Time	Real Time	Decision on trial Or deferral to 12 months after the trial	Real Time
First Visit first subject	Real Time	Real Time	Real Time	Real Time	Decision on trial Or deferral to 12 months after the	Real Time

Sections	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
	One	Two	Three	Four	Phase I healthy volunteers	Phase IV or low-intervention
					trial	
End of recruitment	Real Time	Real Time	Real Time	Real Time	Decision on trial Or deferral to 12 months after the trial	Real Time
End of trial (in each MS, All MS, Global)	Real Time	Real Time	Real Time	Real Time	Decision on trial Or deferral to 12 months after the trial	Real Time
Temporary halt	Real Time	Real Time	Real Time	Real Time	Decision on trial Or deferral to 12 months after the trial	Real Time
Restart of the trial Early termination	Real Time	Real Time	Real Time	Real Time	Decision on trial Or deferral to 12 months after the trial	Real Time
Serious breaches	When investigation	When investigation concluded	When investigation concluded	When investigation concluded	When investigation concluded	When investigation concluded

Sections	Proposal for trials on products without marketing authorisation					Proposal for trials on products with marketing authorisation
	One	Two	Three	Four	Phase I healthy volunteers	Phase IV or low-intervention
	concluded					
Corrective measures	When issued to sponsor	When issued to sponsor	When issued to sponsor	When issued to sponsor	When issued to sponsor	When issued to sponsor
Unexpected events which affect risk/benefit	Once assessed	Once assessed	Once assessed	Once assessed	Once assessed	Once assessed
Inspection report	Once inspection report issued unless there is a judicial procedure or MA ongoing	Once inspection report issued unless there is a judicial procedure or MA ongoing	Once inspection report issued unless there is a judicial procedure or MA ongoing	Once inspection report issued unless there is a judicial procedure or MA ongoing	Once inspection report issued unless there is a judicial procedure or MA ongoing	Once inspection report issued unless there is a judicial procedure or MA ongoing

Appendix 5: The summary of results of the trial

CT Regulation Annex IV	Sections	Proposal			
		One	Two	Three	Four
A.	CLINICAL TRIAL INFORMATION				
1.	Clinical trial identification (including title of the trial and protocol number)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
2.	Identifiers (including EU trial number, other identifiers)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
3.	Sponsor details (including scientific and public contact points)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
4.	Paediatric regulatory details (including information whether the clinical trial is a part of a Paediatric Investigation Plan)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
5.	Result analysis stage (including information about	12 months after the	12 months after the	12 months after the	12 months after the

CT Regulation Annex IV	Sections	Proposal			
		One	Two	Three	Four
	intermediate data analysis date, interim or final analysis stage, date of global end of the clinical trial). For clinical trials replicating studies on already authorised investigational medicinal products and used in accordance with the terms of the marketing authorisation, the summary of the results should also indicate identified concerns in the overall results of the clinical trial relating to relevant aspects of the efficacy of the related medicinal product	end of the trial, unless delay scientifically justified in the protocol	end of the trial, unless delay scientifically justified in the protocol	end of the trial, unless delay scientifically justified in the protocol	end of the trial, unless delay scientifically justified in the protocol
6.	General information about the clinical trial (including information about main objectives of the trial, trial design, scientific background and explanation of rationale for the trial; date of the start of the trial, measures of protection of subjects taken, background therapy; and statistical methods used)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
7.	Population of subjects (including information with actual number of subjects included in the clinical trial in the Member State concerned, in the Union and in third countries; age group breakdown, gender breakdown)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
B.	SUBJECT DISPOSITION				
1.	Recruitment (including information on the number of subjects screened, recruited and withdrawn; inclusion and exclusion criteria; randomisation and blinding details; investigational medicinal products used)	12 months after the end of the trial, unless delay scientifically justified	12 months after the end of the trial, unless delay scientifically justified	12 months after the end of the trial, unless delay scientifically justified	12 months after the end of the trial, unless delay scientifically justified

CT Regulation Annex IV	Sections	Proposal			
		One	Two	Three	Four
		in the protocol	in the protocol	in the protocol	in the protocol
2.	Pre-assignment period	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
3.	Post assignment periods	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
C.	BASELINE CHARACTERISTICS				
1.	Baseline characteristics (required) age	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
2.	Baseline characteristics (required) gender	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
3.	Baseline characteristics (optional) study specific characteristic	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay

CT Regulation Annex IV	Sections	Proposal			
		One	Two	Three	Four
		scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol
D.	END POINTS				
1.	End point definitions ⁽¹⁾	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
2.	End Point #1 - Statistical Analyses	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
3.	End Point #2 - Statistical Analyses	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
E.	ADVERSE EVENTS				
1.	Adverse events information	12 months after the end of the trial, unless delay scientifically justified	12 months after the end of the trial, unless delay scientifically justified	12 months after the end of the trial, unless delay scientifically justified	12 months after the end of the trial, unless delay scientifically justified

¹ Information shall be provided for as many end points as defined in the protocol

CT Regulation Annex IV	Sections	Proposal			
		One	Two	Three	Four
		in the protocol	in the protocol	in the protocol	in the protocol
2.	Adverse event reporting group	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
3.	Serious adverse event	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
4.	Non-serious adverse event	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
F.	ADDITIONAL INFORMATION				
1.	Global substantial modifications	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
2.	Global interruptions and re-starts	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay

CT Regulation Annex IV	Sections	Proposal			
		One	Two	Three	Four
		scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol
3.	Limitations, addressing sources of potential bias and imprecisions and caveats	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
4.	A declaration by the submitting party on the accuracy of the submitted information	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol

Appendix 6: The laypersons summary of the trial

CT Regulation Annex V	Sections	Proposal			
		One	Two	Three	Four
1	Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
2	Name and contact details of the sponsor	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
3	General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
4	Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria)	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
5	Investigational medicinal products used	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay

CT Regulation Annex V	Sections	Proposal			
		One	Two	Three	Four
		scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol
6	Description of adverse reactions and their frequency	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
7	Overall results of the clinical trial	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
8	Comments on the outcome of the clinical trial	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
9	Indication if follow up clinical trials are foreseen	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol	12 months after the end of the trial, unless delay scientifically justified in the protocol
10	Indication where additional information could be found	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay	12 months after the end of the trial, unless delay

CT Regulation Annex V	Sections	Proposal			
		One	Two	Three	Four
		scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol	scientifically justified in the protocol

Appendix 7: The clinical study report including its annexes

ICH E3 Table of Contents number	ICH E3 Table of Contents Heading	Proposal			
		One	Two	Three	Four
1.	TITLE PAGE	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
2.	SYNOPSIS	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
3.	TABLE OF CONTENTS FOR THE INDIVIDUAL CLINICAL STUDY REPORT	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
4.	LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
5.	ETHICS	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
6.	INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
7.	INTRODUCTION	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
8.	STUDY OBJECTIVES	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
9.	INVESTIGATIONAL PLAN	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes

ICH E3 Table of Contents number	ICH E3 Table of Contents Heading	Proposal			
		One	Two	Three	Four
10.	STUDY PATIENTS	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
11.	EFFICACY EVALUATION	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
12.	SAFETY EVALUATION	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
13.	DISCUSSION AND OVERALL CONCLUSIONS	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
14.	TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
15.	REFERENCE LIST	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.	APPENDICES				
16.1	STUDY INFORMATION				
16.1.1	Protocol and protocol amendments	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.2	Sample case report form (unique pages only)	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.3	List of IECs or IRBs (plus the name of the Committee Chair if required by the regulatory authority) – Representative written information for patient and	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes

ICH E3 Table of Contents number	ICH E3 Table of Contents Heading	Proposal			
		One	Two	Three	Four
	sample consent forms				
16.1.4	List and description of investigators and other important participants in the study, including brief (1 page) CVs or equivalent summaries of training and experience relevant to the performance of the clinical study	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.5	Signatures of principal or coordinating investigator(s) or sponsor's responsible medical officer, depending on the regulatory authority's requirement	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.7	Randomisation scheme and codes (patient identification and treatment assigned)	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.8	Audit certificates (if available) (see Annex IVa and IVb of the guideline)	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.9	Documentation of statistical methods	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.10	Documentation of inter-laboratory standardisation methods and quality assurance procedures if used	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.11	Publications based on the study	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes
16.1.12	Important publications referenced in the report	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes	30 days after MA process concludes