Annex - CTCG Best Practice Guide for sponsors of multinational clinical trials under Directive 2001/20/EC that will transition to Regulation (EU) No 536/2014 – adopted at CTCG plenary June 27 2023

The following information should be provided in the cover letter of applications for transitioning a Clinical Trial authorised under the Directive 2001/20/EC to the Clinical Trial Regulation[1]

The protocol for transition is ____fully harmonised /___ consolidated (tick) across all Member States Concerned. I hereby declare that the content of this version of the protocol (version x, dated x) has been approved in the following Member States, and does not contain any substantial changes.

Harmonised Protocol (version x, date x)

Member State	Date of approval		
	National Competent Authority	Ethics Committee	Name of Ethics Committee

(add rows as appropriate)

Consolidated Protocol (version x, date x)

In case of a consolidated protocol, complete the table below describing Member State-specific aspects (e.g. restricted trial population, particular local requirements etc.) and where they are specified (i.e. annex number or protocol section number)

Member State	Version and Date of the protocol approved per Member State on which the consolidated protocol is based	Date of approval			National specific aspect	
		National Competent Authority	Ethics Committee	Name of Ethics Committee	Content	Page reference/location

(add rows as appropriate)

[1] *The content of this document (with the table(s) completed) should be included in the cover letter of the clinical trial dossier for multinational clinical trials that transition from the Directive 2001/20/EC to the Regulation (EU) No 536/2014. The cover letter without signature to be submitted in CTIS should be an exact copy of the version signed by the sponsor or legal representative of the sponsor.*

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Non-substantial changes

The following **non-substantial changes** in line with Annex IV of CLINICAL TRIALS REGULATION (EU) NO 536/2014 QUESTIONS & ANSWERS document have been included as compared to approved Part I documents.

Specify non-substantial changes in different documents in separate lists, e.g. protocol, and briefly describe the non-substantial changes in each of them

Document type, e.g. protocol (version x, date y)

Non-substantial changes

(add rows as appropriate)

Add tables, each with the name of the document as header (e.g. IB, IMPD) as appropriate if needed for non-substantial changes in line with Annex IV of the European Commission Q&A for other Part I documents.

Other documents than the minimum Part I transition dossier approved in some but not all MSCs under the CTD

If the Part I Dossier contains documents in addition to the minimum dossier approved by some, but not all MSCs (e.g. DSMB Charter, see CTCG Best Practice Guide for sponsors of multinational clinical trials under Directive 2001/20/EC that will transition to Regulation (EU) No 536/2014), these should be clearly described in the cover letter with information in which Member State the document was approved under CTD. For clarity, Part II documents approved under the CTD are recommended to be listed in a similar way per MSC.

Member State	Type of document	Version and Date of the document approved per Member State	Date of approval		Comment
			National Competent Authority (if applicable)	Ethics Committee (if applicable)	

(add rows as appropriate)

Declaration

I hereby declare that all documents common to all Member States Concerned (i.e. documents within the Part I dossier) are the same and have been approved by all Member States under CTD or are described in detail above. I also declare that all Part II submitted documents have been approved by the respective Member State under CTD.