Instructions are in red/suggestion text in blue.

Delete all coloured text from the completed document.

**EUdraCT no:** Insert Trial Number

**EU CT number:** Insert Trial Number

**Universal trial number:** Insert Universal Trial Number if applicable

**Protocol Number:** Insert Protocol Number if applicable

**Protocol Title:** Insert Protocol Title

Place, date

**Clinical Trial Transition**

The Ethics Committee that granted approval/positive opinion is specify ethics committee, e.g. REK Sør-Øst committee A. For international trials, specify all Ethics Committees.

# For trials including documents that have been harmonised or consolidated

No documents have been harmonised nor consolidated

or

Each of the Part I documents Protocol, Investigator’s brochure (IB) and/or Investigational Medicinal Product Dossier (IMPD) for transition is fully harmonised or consolidated (choose as appropriate) across all Member States Concerned.

I hereby declare that the contents of the submitted version of the respective documents (protocol, IB, IMPD) (version insert version, dated insert date) have been approved in the following Member States, and do not contain any substantial changes.

Harmonised Protocol (version insert version, date insert version)

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

Add rows as appropriate. As applicable, similar tabular information should be provided for the harmonised IB or IMPD.

Consolidated Protocol (version insert version, date insert version)

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. As applicable, similar tabular information should be provided for the consolidated IB or IMPD.

# For trials with Non-substantial changes in Part I documents

No substantial changes of Part I documents have been included since they were last approved by national competent authority(ies) and/or ethics committee(s).

or

The following non-substantial changes in line with Annex IV of CLINICAL TRIALS REGULATION (EU) No 536/2014 QUESTIONS & ANSWERS document have been included with specified changes 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](https://health.ec.europa.eu/document/download/bd165522-8acf-433a-9ab1-d7dceae58112_en?filename=regulation5362014_qa_en.pdf) for other Part I documents.

# For trials with Other documents than the minimum Part I and Part II transition dossier approved in some but not all MSCs under the CTD

This transition only includes the minimum Part I and Part II transition dossier as listed in the table below.

Or

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.

The following documents are submitted as part of the transition

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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

# Auxiliary Medicinal Product used within its marketing authorisation

No Auxiliary Medicinal Product (AxMP) is used in this trial

or

Insert name of Auxiliary Medicinal Product (AxMP) is used within the marketing authorisation.

or

Insert name of Auxiliary Medicinal Product (AxMP) is not used within the marketing authorisation and has therefore been inserted to CTIS by the sponsor.

# 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.

Yours sincerely,

Enter name, do not sign

Applicant Name & function:

Institution/department: