EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2015
EMA/768628/2014

# 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.** |

# 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 |

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

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

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

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|---|---|---|---|---|---|---|---|---|---|
| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | ***the clinical trial:*** | 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*** | | ***Contact point designated by the sponsor for further information*** | | Decision on trial | Decision on trial | Decision on trial | Decision on trial | Decision on trial | Decision on trial |

| CT Field ID | WHO ICTR P 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 |
| | | ***on the trial*** | | | | | | | |
| 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** | | | | | | | |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | **AUTHORITY**<br>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 |

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

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

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

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|---|---|---|---|---|---|---|---|---|---|
| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | | | | | Phase III at decision on trial | trial<br>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<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 |

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

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|---|---|---|---|---|---|---|---|---|---|
| | | | | 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 –<br>Phase I/II after MA/10yy after trial<br>Phase III at decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III at decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 |
| | | ***The IMP is a:*** | | | | | | | |
| 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 –<br>Phase I/II after MA/10yy after trial<br>Phase III at decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III at decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | 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<br>Phase III at decision on trial | Non-therapeutic trial after MA/10yy after trial<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III at decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 –<br>Phase I/II after MA/10yy after trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after | Decision on trial Or deferral to 12 months after the trial | Decision on trial |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | device) | | | | Phase III at decision on trial | trial<br>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<br>Phase III at decision on trial | IMP without MA – Non-therapeutic trial after MA/10yy after trial<br>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<br>Phase III at decision on trial | IMP without MA – Non-therapeutic trial after MA/10yy after trial<br>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 |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | 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<br>Phase III – at decision on trial | Non-Therapeutic after MA/10yy after trial<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III – at decision on trial | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III – at | IMP without MA –<br>Non-therapeutic trial after MA/10yy after trial<br>Therapeutic trial | In accordance with proposal one, two, three or four | Decision on trial |

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|---|---|---|---|---|---|---|---|---|---|
| | | | | 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 |
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| | | | | 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 |
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| | | | | 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 |
| | | ***investigation*** ***MedDRA code, version, level, term and SOC*** | 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 |
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| | | | | 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 ICTR P 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 ICTR P 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 |
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| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | ***trial*** | | | | | | | |
| 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 ICTR P 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 |
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| | | | | 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 ICTR P 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 |
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| | | | | 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 ICTR P 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 |
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| | | | | 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 |
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| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | trial | | | | | | trial | |
| ***E.8.6*** | | ***Trial involving sites outside the EEA*** | | | | | | | |
| 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 |
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| | | | | 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 |
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| | | | | 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 |
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| | | | | 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 |
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| | | | | 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 |
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| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | ***subjects to be included*** | | | | | | | |
| 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 |
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| | | | | One | Two | Three | Four | Phase I healthy volunteers | Phase IV/ low-intervention trials |
| | | normal treatment of that condition) | | | | | | | |
| ***G.4*** | | ***Investigator networks to be involved in the trial*** | | | | | | | |
| 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<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III – at decision on trial | IMP without MA –<br>Non-Therapeutic after MA/10yy after trial<br>Therapeutic - at | In accordance with proposal one, two, three or four | Decision on trial<br>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<br>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<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | In accordance with proposal one, two, three or four | Decision on trial<br>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<br>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<br>IMP with MA Decision on trial | years after end of trial<br>IMP with MA Decision on trial | years after end of trial<br>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<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | In accordance with proposal one, two, three or four | Decision on trial<br>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<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | In accordance with proposal one, two, three or four | Decision on trial<br>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<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | In accordance with proposal one, two, three or four | Decision on trial<br>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<br>Decision on trial<br>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<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>IMP with MA Decision on trial | IMP without MA – after MA or 10 years after end of trial<br>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 –<br>Phase I/II after MA/10yy after trial<br>Phase III at decision on trial | IMP without MA –<br>Non-therapeutic after MA/10yy after trial<br>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.* | ***INTRODUCTION AND GENERAL PRINCIPLES*** | | | | | | |
| *B.* | ***COVER LETTER*** | 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.* | ***MODIFICATION APPLICATION FORM*** | 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.* | ***DESCRIPTION OF THE MODIFICATION*** | 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 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 |
| ***E.*** | ***SUPPORTING INFORMATION*** | 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.*** | ***UPDATED EU APPLICATION FORM*** | 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<br>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)<br>(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 |