Centrale Commissie Mensgebonden Onderzoek

# CCMO: CTIS Submission Guide INITIAL SUBMISSION

**MOST IMPORTANT TIPS!**

- The last two digits of the EU CT number can be omitted from the documents themselves.
- When uploading the document(s) to CTIS, ensure the language, version and date inputted into CTIS match the language, version and date of the document itself.
- When uploading a redacted and non-redacted version of a document (only possible for some document types): first upload the redacted version to CTIS using the Add Document button, and add the word 'redacted' to the document title. This will then be a "For Publication" document. Then Click on the "+" icon found next to the "For Publication" version, to upload the unredacted version of the document, which will then not be published ("Not for Publication"). If there is no personal data or commercially confident information to redact, then one clean version can be uploaded to CTIS as a "For Publication" document.
- Do not upload duplicate documents, for instance an IMPD that applies to multiple products. Instead, upload the document once in CTIS and submit a referral document in the other placeholders. This way, when the document is updated, it only needs to be updated in one location in CTIS.
- When entering the product details: each different investigational product must be entered as a separate Test:IMP so that it has its own document section. Combination of products under the same Test: IMP is only intended for different strengths of the same product, or multiple products with the same active substance.
- **After submitting a trial in CTIS, your work is not done! The sponsor/delegate is responsible for checking CTIS daily for any Request For Information (RFIs)/communication from the authority regarding the trial. Neither CTIS nor CCMO/MREC will inform you by email. If you receive a RFI in CTIS, make sure you respond to the RFI by the deadline. Otherwise the submission will lapse and you will have to submit again.**

*Please note this information is subject to change.

*For submissions in other Member States Concerned (MSCs), please research the country specific requirements for that MSC (please see Q&A document – Regulation (EU) 536/2014 Annex II and III as well as the Overview part II requirements by MedEthicsEU).

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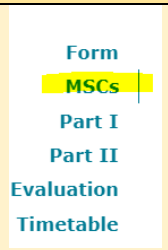
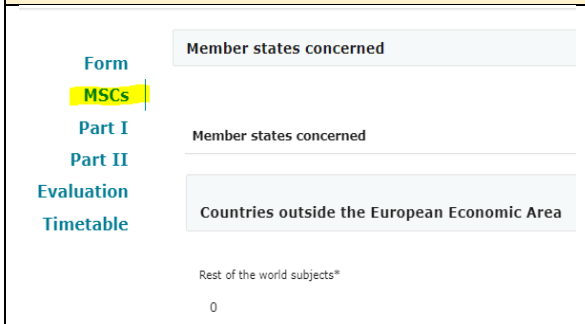
**INITIAL SUBMISSION: Document List**

**Legend**

Blue text: text needs to be completed by sponsor.

Green text: Document subject to publication (depending on trial category). See the Guidance document and Annex 1 found under transparency.

| Location in CTIS | Document & CTCG Naming Convention | Link | Additional Information |
|---|---|---|---|
|  **SECTION MSCs** | | | |
|  | **NA** | **NA** | -Start by adding participating member states within the EEA, number of subjects and if there are 2 or more countries within the EEA participating in the trial, choose the sponsors proposed RMS<br>-Once this section is completed, the Proof of Payment sections per country and Part II sections per country will appear<br>-To add countries and subject numbers outside of the EEA, see Part I – section Countries outside the European Economic Area |

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| **SECTION Form**<br>Form<br>MSCs<br>Part I<br>Part II<br>Evaluation<br>Timetable | | | |
| Form details<br>Initial Application details<br>Cover letter<br>Cover letter * | B1_Cover letter EU CT number | Heads of Medicines Agencies: Clinical Trials Coordination Group (hma.eu)<br><br>Template under Key Documents List.<br>Template name: *Initial application cover letter* | -Mandatory European template – agreed to by all Member States<br>-Clearly describe the location of the Reference Safety Information (RSI)<br>-Mandatory to list all IMPs/AxMPs used as well as information regarding the investigation of medical devices and/or in vitro diagnostics, if applicable |
| Proof of payment of fee<br>Netherlands<br>Proof of Payment | B2_NL-NL_Proof of Payment<br><br>(NL-NL= country code, language code) | CCMO Website - Proof of Payment<br>NL<br>EN | - Mandatory template<br>- Complete all fields (except KvK if not applicable)<br>- Ensure that a reference, purchase or order number is included in section Payment Characteristics (not the EU CT number) |

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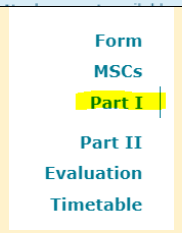
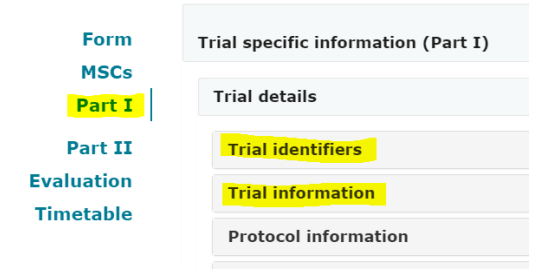
|  | B3_Compliance with the Regulation Statement | CCMO Website - GDPR<br>NL<br>EN | -Recommended template<br>-Full title and EU CT number should be listed |
| **PART I**<br>  | | | |
|  | NA | EudraLex - Volume 10 - European Commission (europa.eu)<br><br>-See Annex II of the *Questions and Answers Document – Regulation (EU) 536/2014* | -Enter all information in English and add the Dutch translations for the full and public study title (Part I, Trial Identifiers) and for the Medical condition, Objectives, Inclusion/Exclusion criteria, Endpoints (Part I, Trial Information) |

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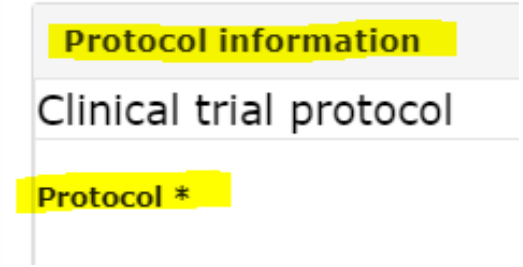
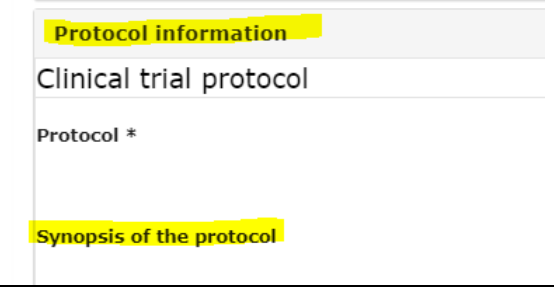
|  | D1_Protocol EU CT number | CCMO Website - Protocol<br>NL<br>EN | -Template available<br>-PDF preferred. PDF needs to be searchable<br>-To be published for all trial categories (different timelines apply). Therefore a "For Publication" version (with redactions) and a "Not for Publication" version (without redactions) can be submitted. If no redactions are needed, submit a "For Publication" version only |
|  | D1_ NL-NL_Protocol synopsis EU CT number<br><br>(NL-NL= country code, language code) | CCMO Website - Protocol<br>NL<br>EN | -Template available<br>-Recommended to write this in layman terms, should be 2-3 pages long<br>-Submit a synopsis in English and Dutch<br>- Add a sponsor version and date within the document for filing purposes<br>--To be published for all trial categories (different timelines apply). |

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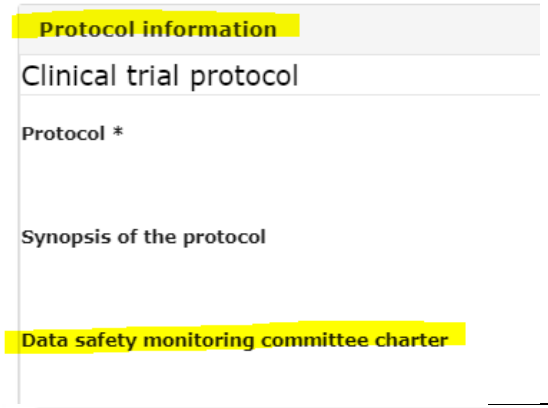
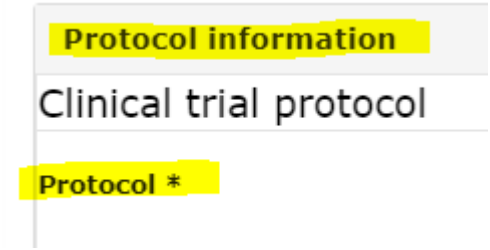
|  | D3_DSMB Charter<br>EU CT number | CCMO Website - Protocol<br>NL<br>EN | -If applicable |
|  | D4_NL-NL_Patient facing document xxx<br><br>(NL-NL= country code, language code) | CCMO Website - Protocol<br>NL<br>EN | - Patient-facing documents are documents, other than recruitment material or subject information sheets, presented to clinical trial participants after they have signed the ICF. These documents should not be submitted, unless they are **used to measure study endpoints as described in the protocol, such as questionnaires and diaries,** which then should be submitted in the Protocol section in Part I.<br>-To be published for all trial categories (different timelines apply). |

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*For submissions in other Member States Concerned (MSCs), please research the country specific requirements for that MSC (please see Q&A document – Regulation (EU) 536/2014 Annex II and III as well as the Overview part II requirements by MedEthicsEU).

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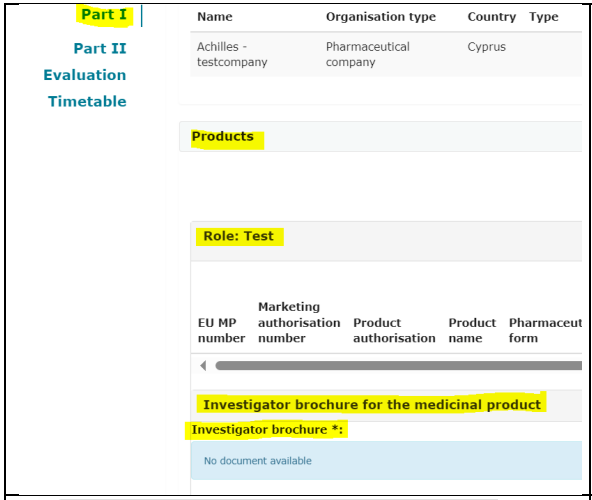
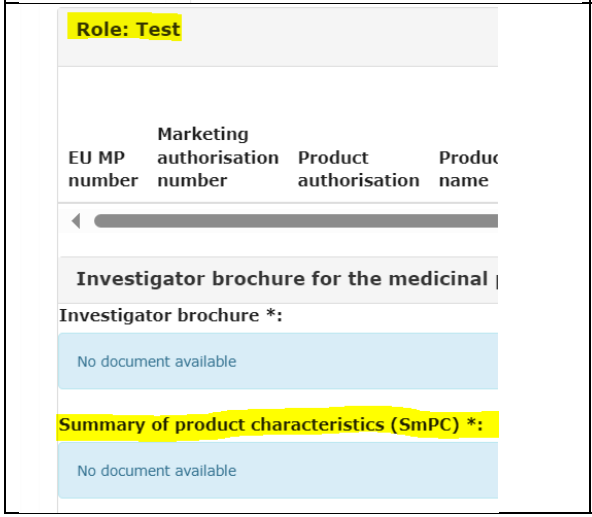
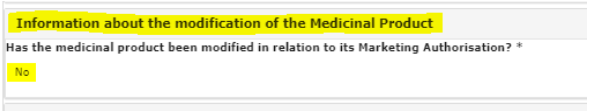
|---|---|---|---|
|  | E1_IB Product name | CCMO Website - IB<br>NL<br>EN | -If applicable<br>-PDF needs to be searchable<br>-Should not be older than 1 year<br>-Needs to contain a clearly identifiable section called “Reference Safety Information” (RSI)<br>-If the product is authorized and non-modified, no IB is needed |
|  | E2_SmPC Product name | CCMO Website - IB<br>NL<br>EN | -If applicable<br>-If the test product is **authorized and non-modified**, only a SmPC is needed for submission<br>-If the test product is **authorized but modified**, more documentation is expected (see Table 1: Content of the simplified IMPD in the Clinical Trials Regulation). Be sure to describe any modifications made to an authorized product here in CTIS<br>  <br>-The RSI should be section 4.8<br>-To be published for category 2 and 3 trials |

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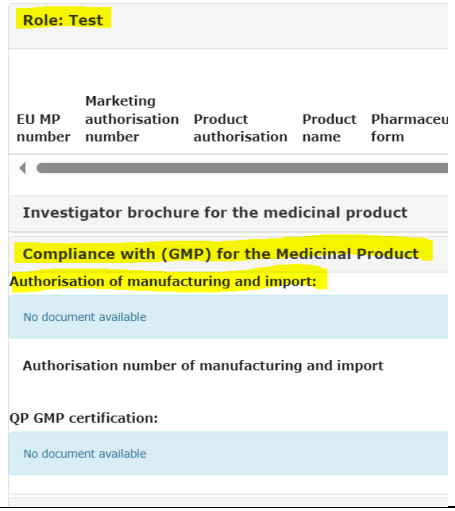
|  | F1_ MIA product name abbreviated name manufacturer/importer | CCMO Website – GMP Documents<br>NL<br>EN | -If applicable-The inspection date on the MIA should not be older than 3 years. If the MIA is older than 3 years, also submit a Certificate of GMP compliance with an inspection date that is not older than 3 years. |

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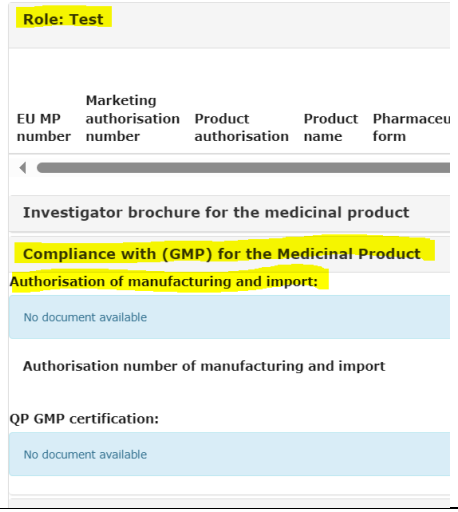
|  | F2_QP GMP declaration product name abbreviated name manufacturer/importer | CCMO Website – GMP Documents<br>NL<br>EN | -If applicable -The MIA number listed in the MIA for the QP-releaser needs to match the MIA number listed in the QP declaration. |
|  | F3_ Other statements/licences product name abbreviated name manufacturer/importer | CCMO Website – GMP Documents<br>NL<br>EN | -If applicable<br>-If the MIA is older than 3 years, also submit a Certificate of GMP compliance with an inspection date that is not older than 3 years.<br>-Eg import licence or Certificate of GMP compliance |

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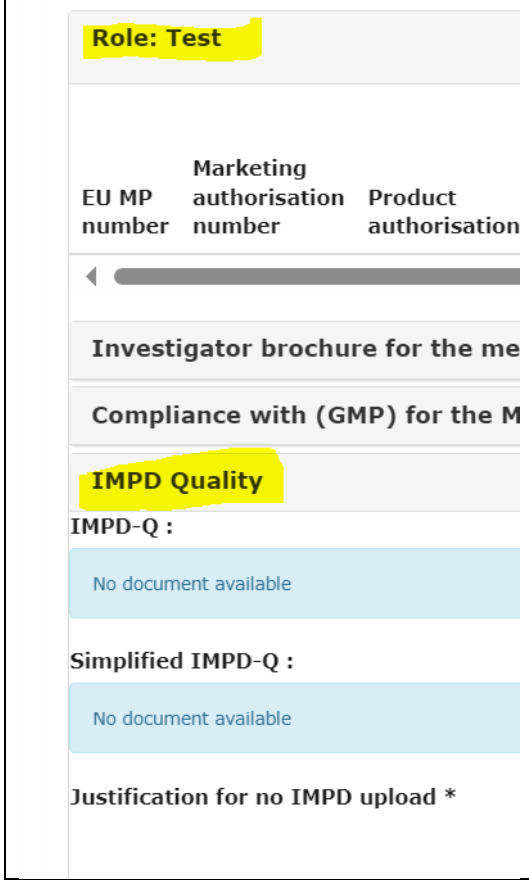
|  | G1_IMPD_Q product name<br>*OR*<br>G1_Simplified IMPD_Q product name | CCMO Website - IMPD<br>NL<br>EN | -If applicable<br>-Template available<br>-PDF needs to be searchable<br>-If document is too large for CTIS, break it into 3 separate parts: drug substance, drug product and appendices<br>-If no IMPD or Simplified IMPD is uploaded, a justification will need to be provided in this section<br>-If there is an authorized but modified product (including re-packaging and/or re-labelling), ensure this is added to CTIS under “Information about the modification of the Medicinal Product”. A SmPC and a sIMPD should be submitted. The cover letter should also provide a justification for conducting a trial with clinical batches when the batches intended for commercial use are already authorized. |

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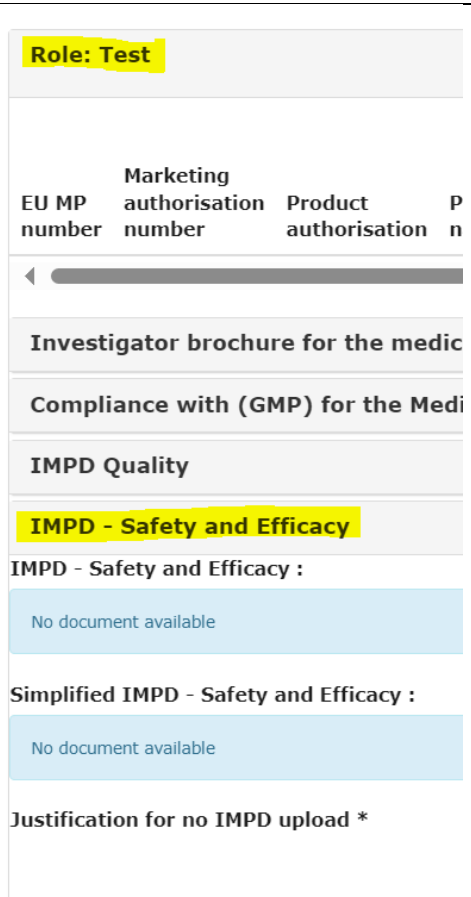
|  | G1_IMPD_E-S product name<br>*OR*<br>G1_Simplified IMPD E-S product name | CCMO Website - IMPD<br>NL<br>EN | -If applicable<br>-Template available<br>-PDF needs to be searchable<br>-Upload a placeholder and refer to the IMPD-Q or IB or SmPC if needed (do not upload the same document twice)<br>-If no IMPD or Simplified IMPD is uploaded, a justification will need to be provided in this section |

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*For submissions in other Member States Concerned (MSCs), please research the country specific requirements for that MSC (please see Q&A document – Regulation (EU) 536/2014 Annex II and III as well as the Overview part II requirements by MedEthicsEU).

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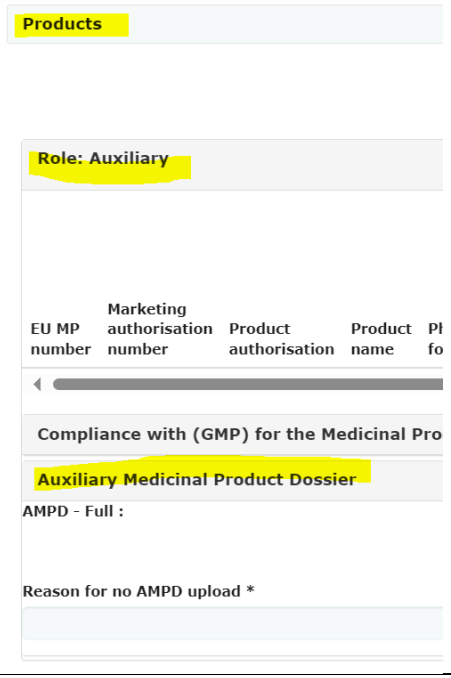
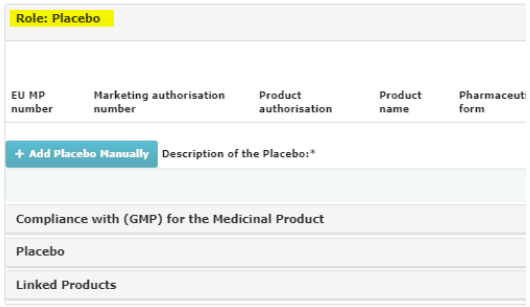
|  | H1_AxMPD product name<br><br>E2_SmPC Product name | CCMO Website – AxMPD<br>NL<br>EN<br><br>CTAG recommendations on AxMPs in clinical trials (europa.eu) | -If applicable<br>-Auxiliary medicinal products (AxMPs) that are unmodified authorized, should not be entered in CTIS but only mentioned in cover letter<br>-Only AxMPs that are unauthorized or modified, authorized should be entered in CTIS |
|  | -See CTCG naming conventions depending on documents submitted | CCMO Website - IMPD<br>NL<br>EN | -If applicable |

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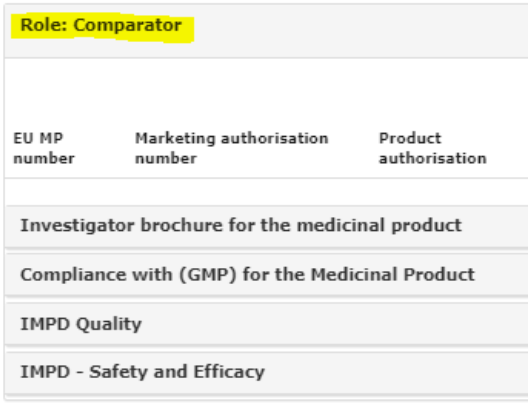
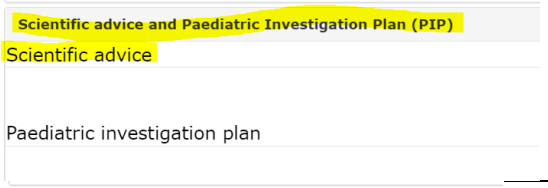
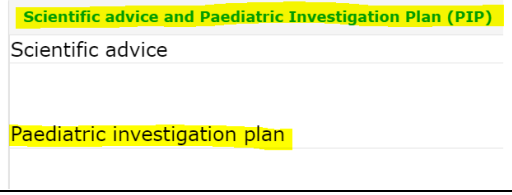
|  | -See CTCG naming conventions depending on documents submitted | CCMO Website<br>NL<br>EN | -If applicable |
|  | I1_Scientific advice name organization | CCMO Website – Scientific advice and PIP<br>NL<br>EN | -If applicable |
|  | I2_PedCo opinion | CCMO Website – Scientific advice and PIP<br>NL<br>EN | -If applicable |

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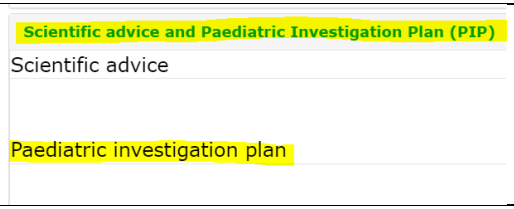
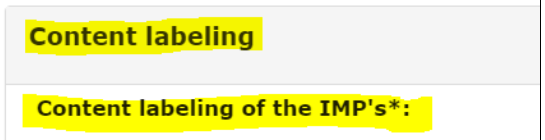
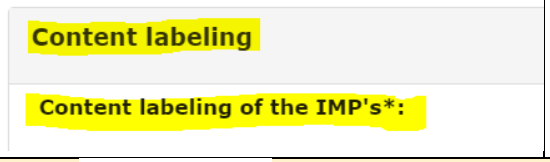
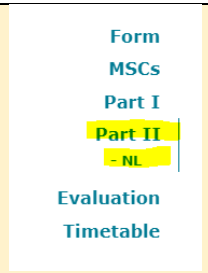
|  | I3_EMA PIP decision name agency | CCMO Website – Scientific advice and PIP<br>NL<br>EN | -If applicable |
|  | J1_NL-NL_Label IMP_ product name<br><br>(NL-NL= country code, language code) | CCMO Website – Labels<br>NL<br>EN | -If applicable<br>-Specify if immediate/outer label (within document and in title if needed)<br>-See Annex VI of the CTR |
|  | J2_ NL-NL_Label AxMP_product name<br><br>(NL-NL= country code, language code) | CCMO Website – Labels<br>NL<br>EN | -If applicable<br>-Specify if immediate/outer label (within document and in title if needed) |
| **PART II**<br>  | | | |

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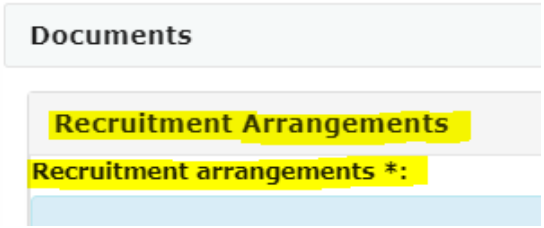
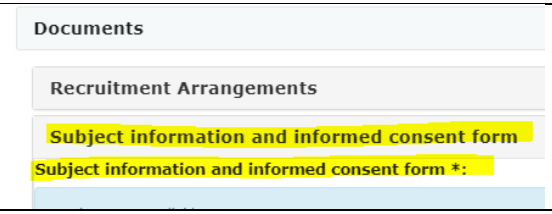
|  | K1_Recruitment arrangements | CCMO Website – Recruitment<br>NL<br>EN | -Mandatory template<br>- Add a sponsor version and date within the document for filing purposes<br>-To be published for category 2 and 3 trials |
|  | K2_ NL(NL)_Recruitment material_description<br><br>(NL-NL= country code, language code) | CCMO Website – Recruitment<br>NL<br>EN | -Only submit Dutch, patient-facing documents. English recruitment material will not be assessed<br>-Besides the SIS-ICF all information and/or description of procedures related to informed consent that is given to the subjects *before* their decision to participate or abstain from participation shall be submitted together with the SIS-ICF (document code L2). **Recruitment materials are the only other patient-facing documents that may be submitted in Part II (document code K2, section Recruitment arrangements).** Any other patient-facing documents provided to patients *after* they have signed the informed consent should not be submitted.<br>-To be published for category 2 and 3 trials |
|  | L1_ NL-NL_SIS and ICF_description<br><br>(NL-NL= country code, language code) | CCMO Website - ICF<br>NL<br>EN | -Templates available based on age<br>-PDF recommended. PDF needs to be searchable<br>-Submit Dutch documents<br>-To be published for category 2 and 3 trials |

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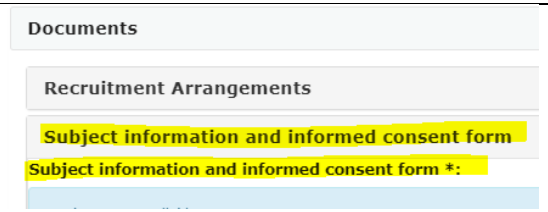
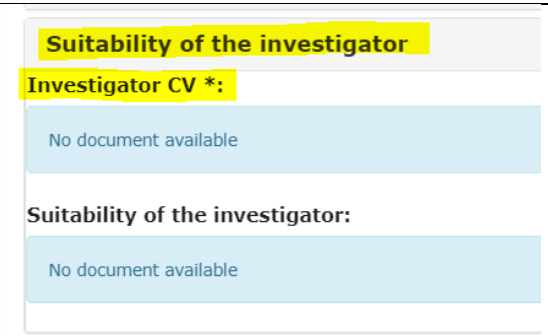
|---|---|---|---|
|  | L2_ NL-NL_Other subject information material_description<br><br>(NL-NL= country code, language code) | CCMO Website - ICF<br>NL<br>EN | -Besides the SIS-ICF all **information and/or description of procedures related to informed consent that is given to the subjects *before* their decision to participate or abstain from participation** shall be submitted together with the SIS-ICF (document code L2). Recruitment materials are the only other patient-facing documents that may be submitted in Part II (document code K2, section Recruitment arrangements). Any other patient-facing documents provided to patients *after* they have signed the informed consent should not be submitted.<br>-Submit Dutch documents<br>-To be published for category 2 and 3 trials |
|  | M1_CV Investigator name investigator and clinical trial site | CCMO Website – Suitability of the Investigator<br>NL<br>EN | -Template available<br>-Needs to be dated and not older than 2 years<br>-1 Principal Investigator per site<br>-No GCP certificates should be submitted. Relevant training should be evident from the CV |

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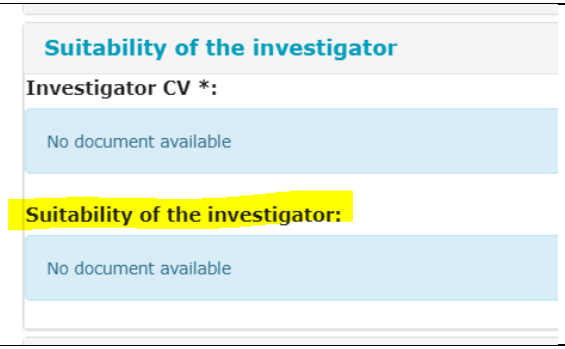
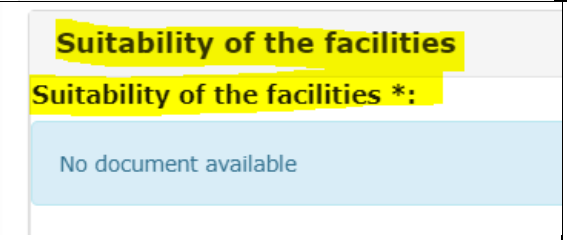
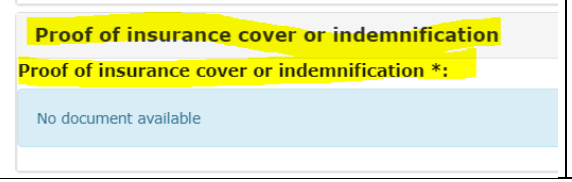
|  | M2_DoI Investigator name investigator and clinical trial site | CCMO Website – Suitability of the Investigator<br>NL<br>EN | -Mandatory Declaration of interest (DoI) template<br>-1 DoI per site |
|  | N1_Site suitability form name clinical trial site | CCMO Website – Suitability of the facilities<br>NL<br>EN | -Most up-to-date VGO form must be used<br>-Must be signed<br>-Complete form but submit page 1 only<br>-1 form per site<br>-For the liability insurance section, choose either site or sponsor, not both<br>-Clinical Trial Agreements should not be submitted |
|  | O1_Trial participant insurance certificate | CCMO Website – Insurance<br>NL<br>EN | - WMO participant insurance (bewijs proefpersonenverzekering)<br>-Check that this is not expired |
|  | O2_Proof of coverage sponsor or investigator name sponsor/trial site | CCMO Website – Insurance<br>NL<br>EN | -Liability insurance which covers general liability or both general and product liability<br>-Not required if each site has their own insurance and this is clearly stated on page one of the VGO form |

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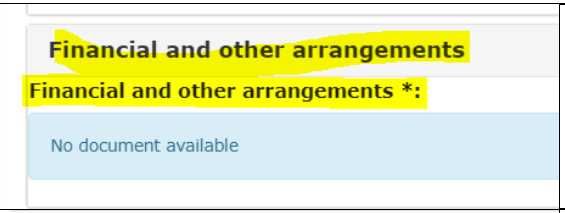
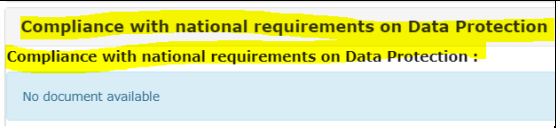
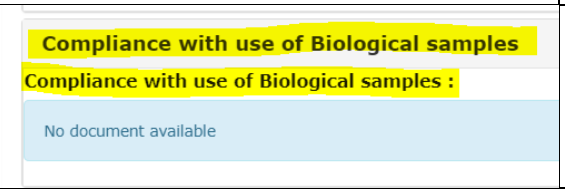
|  | P1_Compensation trial participants, investigator, funding and other arrangements | CCMO Website – Financial arrangements<br>NL<br>EN | -Mandatory template<br>- Add a sponsor version and date within the document for filing purposes |
|  | R1_Compliance on the collection and use of personal data | CCMO Website – National Data protection<br>NL<br>EN | -Mandatory template<br>- Add a sponsor version and date within the document for filing purposes |
|  | S1_Compliance on the collection, use and storage of biological samples | CCMO Website – Biological samples<br>NL<br>EN | -Mandatory template<br>-If no biological samples will be used in the study, upload a pdf stating this in this section<br>- Add a sponsor version and date within the document for filing purposes |

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