



## **CCMO: CTIS Submission Guide First Substantial Modification (SM) after Transition (page 2) + SM (page 21)**

### **MOST IMPORTANT TIPS!**

- When uploading updated document(s) to CTIS, ensure the version and date inputted into CTIS match the version and date of the document itself.
- When uploading an updated document, click on the “Update” (paper) icon found next to the previous version of the document. Make sure that a redacted document is uploaded on top of the previous redacted document and that the non-redacted document is uploaded on top of the previous non-redacted document.
- **After submitting a trial in CTIS, your work is not done! The sponsor/delegate is responsible for checking CTIS daily for any Requests 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).

### FIRST SUBSTANTIAL MODIFICATION (SM) AFTER THE TRANSITION (if applicable\*): Document List

\*This type of SM is only applicable for studies previously submitted under the Clinical Trials Directive (CTD) and then transferred to the Clinical Trials Regulation (CTR) via CTIS. For the first SM after the transition, the dossier needs to be completed as if it were an initial submission and documents need to be made compliant with the CTR.

\*The documents for this SM will include:

- **New documents for the CTR (that need to be assessed),**
- Updated CTD documents (that need to be assessed), and/or
- Already approved under the CTD documents (submitted unchanged in CTIS)

\*For further guidance, please see the [CTCG website](#) – Key Document List – documents:

- *CTCG Best Practice Guide to sponsors updating the application dossier Part I after CTR transition\_vs 2.0*
- *Annex III First SM Part II after transition\_vs.\_1.0*

#### 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](#).

**Orange text:** New document for CTR

Location in CTIS	Document & Naming Convention	Link	Additional Information
<b>FORMS</b> <ul style="list-style-type: none"> <li>Form</li> <li>MSCs</li> <li>Part I</li> <li>Part II</li> <li>Evaluation</li> <li>Timetable</li> </ul>			

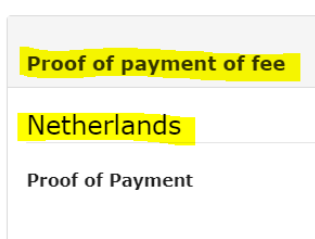
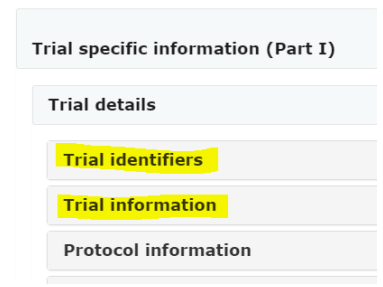
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<p><b>Form</b></p> <p>MSCs</p> <p>Part I *</p> <p>Part II</p> <p>Evaluation</p>	<p>Form details</p> <p>Substantial modification details</p> <p>Cover letter *</p>	<p>B1_Cover letter SM# EU CT number</p>	<p><a href="#">Heads of Medicines Agencies: Clinical Trials Coordination Group (hma.eu)</a></p> <p>Template under Key Documents List – First SM: document requirements after transition. Template name: <i>Annex I Cover letter template First SM after_vs 2.0</i></p>	<p>-Mandatory European template- agreed to by all Member States</p> <p>-If the IB/SmPC is updated, the cover letter should clearly indicate if the Reference Safety Information (RSI) is modified and if so, where the RSI is located.</p>
<p><b>Form</b></p> <p>MSCs</p> <p>Part I *</p> <p>Part II</p> <p>Evaluation</p> <p>Timetable</p>	<p>Form details</p> <p>Substantial modification details</p> <p>Cover letter *</p> <p> Cover-letter </p> <p>English · Cover letter · System vers submission date 19/07/2024 · Version 1 · 19/07/2024</p> <p>Modification description *</p>	<p>B1_Description of the modification</p>	<p><a href="#">Heads of Medicines Agencies: Clinical Trials Coordination Group (hma.eu)</a></p> <p>Template under Key Documents List – First SM: document requirements after transition. Template name: <i>Annex II Substantial modification template</i></p>	<p>-Mandatory European template- agreed to by all Member States</p> <p>-Clearly indicate which documents are</p> <ul style="list-style-type: none"> <li>• New (and need to be assessed)</li> <li>• Updated (and need to be assessed)</li> <li>• Already approved under the CTD and submitted unchanged in CTIS</li> </ul>

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		<i>First SM after transition_ vs 2.0</i>	
 <p>Proof of payment of fee</p> <p>Netherlands</p> <p>Proof of Payment</p>	<p>B2_NL-NL_Proof of Payment</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website - Proof of Payment</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p>-Mandatory template</p> <p>-Complete all fields (except KvK if not applicable)</p> <p>-Ensure that a reference, purchase or order number is included in section Payment Characteristics (not the EU CT number)</p>
<div style="display: flex; align-items: center;"> <div style="margin-right: 20px;"> <p>Form</p> <p>MSCs</p> <p><b>Part I</b></p> <p>Part II</p> <p>Evaluation</p> <p>Timetable</p> </div> <div> <p><b>PART I</b></p> </div> </div>			
 <p>Form</p> <p>MSCs</p> <p><b>Part I</b></p> <p>Part II</p> <p>Evaluation</p> <p>Timetable</p> <p>Trial specific information (Part I)</p> <p>Trial details</p> <p>Trial identifiers</p> <p>Trial information</p> <p>Protocol information</p>	NA	<p><a href="#">EudraLex - Volume 10 - European Commission (europa.eu)</a></p> <p>-See Annex II of the <i>Questions and Answers Document – Regulation (EU) 536/2014</i></p>	<p>-If not yet done, 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)</p>

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<p><b>Protocol information</b></p> <p>Clinical trial protocol</p> <p><b>Protocol *</b></p>	<p>D1_Protocol EU CT number</p>	<p>CCMO Website - Protocol</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p><b>-If the protocol is not yet in line with the requirements of the CTR and does not yet list the EU CT number on the first page, submit an updated protocol</b></p> <p>-PDF preferred. PDF needs to be searchable</p> <p>-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</p>
<p><b>Protocol information</b></p> <p>Clinical trial protocol</p> <p>Protocol *</p> <p><b>Synopsis of the protocol</b></p>	<p>D1_ NL-NL_Protocol synopsis EU CT number</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website - Protocol</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p><b>NEW DOCUMENT FOR CTR!</b></p> <p>-Template available, should be 2-3 pages long</p> <p>-Recommended to write this in layman terms</p> <p>-Submit a synopsis in English and Dutch</p> <p>--To be published for all trial categories (different timelines apply).</p>

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<p><b>Protocol information</b></p> <p>Clinical trial protocol</p> <hr/> <p>Protocol *</p> <p>Synopsis of the protocol</p> <p><b>Data safety monitoring committee charter</b></p>	<p>D3_DSMB Charter EU CT number</p>	<p>CCMO Website - Protocol</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>-If a DSMB Charter was submitted and authorized under the CTD, provide this document, unchanged, in CTIS. If updates have been made for this submission, make this clear in the modification description document and submit clean and track changes versions.</p>
<p><b>Protocol information</b></p> <p>Clinical trial protocol</p> <hr/> <p><b>Protocol *</b></p>	<p>D4_NL-NL_Patient facing document xxx</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website - Protocol</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>-If patient facing documents were submitted and authorized under the CTD, provide the documents, unchanged, in CTIS. If updates have been made for this submission, make this clear in the modification description document and submit clean and track changes versions.</p> <p>-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 <b>used to measure study endpoints as described in the protocol</b>,</p>

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			<p>such as questionnaires and diaries, which then should be submitted in the Protocol section in Part I.</p> <p>-To be published for all trial categories (different timelines apply).</p>																													
<p><b>Part I</b></p> <p><b>Part II</b> Evaluation Timetable</p>	<table border="1"> <thead> <tr> <th>Name</th> <th>Organisation type</th> <th>Country</th> <th>Type</th> </tr> </thead> <tbody> <tr> <td>Achilles - testcompany</td> <td>Pharmaceutical company</td> <td>Cyprus</td> <td></td> </tr> </tbody> </table> <p><b>Products</b></p> <p><b>Role: Test</b></p> <table border="1"> <thead> <tr> <th>Marketing</th> <th>Product</th> <th>Product</th> <th>Pharmaceut</th> </tr> <tr> <th>EU MP</th> <th>authorisation</th> <th>Product</th> <th>Pharmaceut</th> </tr> <tr> <th>number</th> <th>number</th> <th>authorisation</th> <th>name</th> </tr> <tr> <th></th> <th></th> <th></th> <th>form</th> </tr> </thead> <tbody> <tr> <td colspan="4"> <p><b>Investigator brochure for the medicinal product</b></p> <p><b>Investigator brochure *:</b></p> <p>No document available</p> </td> </tr> </tbody> </table>	Name	Organisation type	Country	Type	Achilles - testcompany	Pharmaceutical company	Cyprus		Marketing	Product	Product	Pharmaceut	EU MP	authorisation	Product	Pharmaceut	number	number	authorisation	name				form	<p><b>Investigator brochure for the medicinal product</b></p> <p><b>Investigator brochure *:</b></p> <p>No document available</p>				E1_IB Product name	<p>CCMO Website - IB</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p>-If applicable</p> <p>-Should not be older than 1 year. Needs to be updated annually. Alternatively the sponsor can submit a sponsor statement in the IB section in CTIS stating that the yearly evaluation did not lead to any substantial changes including changes of the trial benefit/risk.</p> <p>-Needs to contain a clearly identifiable section called “Reference Safety Information” (RSI)</p> <p>-PDF needs to be searchable</p>
Name	Organisation type	Country	Type																													
Achilles - testcompany	Pharmaceutical company	Cyprus																														
Marketing	Product	Product	Pharmaceut																													
EU MP	authorisation	Product	Pharmaceut																													
number	number	authorisation	name																													
			form																													
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<p><b>Role: Test</b></p> <table border="1"> <thead> <tr> <th>EU MP number</th> <th>Marketing authorisation number</th> <th>Product authorisation</th> <th>Product name</th> </tr> </thead> <tbody> <tr> <td colspan="4">Investigator brochure for the medicinal product</td> </tr> <tr> <td colspan="4">Investigator brochure *:</td> </tr> <tr> <td colspan="4">No document available</td> </tr> <tr> <td colspan="4"><b>Summary of product characteristics (SmPC) *:</b></td> </tr> <tr> <td colspan="4">No document available</td> </tr> </tbody> </table>	EU MP number	Marketing authorisation number	Product authorisation	Product name	Investigator brochure for the medicinal product				Investigator brochure *:				No document available				<b>Summary of product characteristics (SmPC) *:</b>				No document available				E2_SmPC Product name	CCMO Website - IB <a href="#">NL</a> <a href="#">EN</a>  <a href="#">CTAG recommendation on AxMPs (europa.eu)</a>	-If applicable -Update only if needed -The RSI should be section 4.8 -To be published for category 2 and 3 trials
EU MP number	Marketing authorisation number	Product authorisation	Product name																								
Investigator brochure for the medicinal product																											
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<p><b>Role: Test</b></p> <p>Marketing EU MP authorisation Product Product Pharmaceu number number authorisation name form</p> <p>Investigator brochure for the medicinal product</p> <p><b>Compliance with (GMP) for the Medicinal Product</b></p> <p><b>Authorisation of manufacturing and import:</b></p> <p>No document available</p> <p>Authorisation number of manufacturing and import</p> <p>QP GMP certification:</p> <p>No document available</p>	<p>F1_ MIA product name abbreviated name manufacturer/importer</p>	<p>CCMO Website – GMP Documents <a href="#">NL</a> <a href="#">EN</a></p>	<p>-If applicable -If new batches are expected after the authorization under the CTR, update the documentation related to compliance with GMP for the IMP for those batches</p>
<p><b>Role: Test</b></p> <p>Marketing EU MP authorisation Product Product Pharmaceu number number authorisation name form</p> <p>Investigator brochure for the medicinal product</p> <p><b>Compliance with (GMP) for the Medicinal Product</b></p> <p>Authorisation of manufacturing and import:</p> <p>No document available</p> <p>Authorisation number of manufacturing and import</p> <p><b>QP GMP certification:</b></p> <p>No document available</p>	<p>F2_ QP GMP declaration product name abbreviated name manufacturer/importer</p>	<p>CCMO Website – GMP Documents <a href="#">NL</a> <a href="#">EN</a></p>	<p>-If applicable -Update only if needed</p>

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<p><b>Role: Test</b></p> <p>Marketing EU MP authorisation number    Product authorisation    Product name    Pharmaceu form</p> <p>Investigator brochure for the medicinal product</p> <p><b>Compliance with (GMP) for the Medicinal Product</b></p> <p><b>Authorisation of manufacturing and import:</b></p> <p>No document available</p> <p>Authorisation number of manufacturing and import</p> <p>QP GMP certification:</p> <p>No document available</p>	<p>F3_ Other statements/licences product name abbreviated name manufacturer/importer</p>	<p>CCMO Website – GMP Documents <a href="#">NL</a> <a href="#">EN</a></p>	<p>-If applicable -Eg import licence or Certificate of GMP compliance -Update only if needed</p>
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<p><b>Role: Test</b></p> <p>EU MP number      Marketing authorisation number      Product authorisation</p> <p>Investigator brochure for the me</p> <p>Compliance with (GMP) for the M</p> <p><b>IMPD Quality</b></p> <p>IMPD-Q :</p> <p>No document available</p> <p>Simplified IMPD-Q :</p> <p>No document available</p> <p>Justification for no IMPD upload *</p>	<p>G1_IMPD_Q product name OR G1_Simplified IMPD_Q product name</p>	<p>CCMO Website - IMPD</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>-If applicable -Update only if needed -PDF needs to be searchable</p>
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<p><b>Role: Test</b></p> <p>Marketing authorisation number    Product authorisation number    P n</p> <p>Investigator brochure for the medic</p> <p>Compliance with (GMP) for the Medi</p> <p>IMPD Quality</p> <p><b>IMPD - Safety and Efficacy</b></p> <p>IMPD - Safety and Efficacy :</p> <p>No document available</p> <p>Simplified IMPD - Safety and Efficacy :</p> <p>No document available</p> <p>Justification for no IMPD upload *</p>	<p>G1_IMPD_E-S product name OR G1_Simplified IMPD E-S product name</p>	<p>CCMO Website - IMPD <a href="#">NL</a> <a href="#">EN</a></p>	<p>-If applicable -Update only if needed -PDF needs to be searchable</p>
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<p><b>Products</b></p> <p><b>Role: Auxiliary</b></p> <p>Marketing EU MP authorisation number    Product number    Product authorisation    Product name    PI fo</p> <p>Compliance with (GMP) for the Medicinal Pro</p> <p><b>Auxiliary Medicinal Product Dossier</b></p> <p>AMPD - Full :</p> <p>Reason for no AMPD upload *</p>	H1_AxMPD <b>product name</b>	CCMO Website – AxMPD <a href="#">NL</a> <a href="#">EN</a>  <a href="#">CTAG recommendation on AxMPs (europa.eu)</a>	-If applicable -Update only if needed
<p><b>Scientific advice and Paediatric Investigation Plan (PIP)</b></p> <p><b>Scientific advice</b></p> <p>Paediatric investigation plan</p>	I1_Scientific advice <b>name organization</b>	CCMO Website – Scientific advice and PIP <a href="#">NL</a> <a href="#">EN</a>	-If applicable -If scientific advice was submitted and authorized under the CTD, provide the document, unchanged, in CTIS

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<p><b>Scientific advice and Paediatric Investigation Plan (PIP)</b></p> <p>Scientific advice</p> <hr/> <p><b>Paediatric investigation plan</b></p> <hr/>	I2_PedCo opinion	CCMO Website – Scientific advice and PIP <a href="#">NL</a> <a href="#">EN</a>	-If applicable
<p><b>Scientific advice and Paediatric Investigation Plan (PIP)</b></p> <p>Scientific advice</p> <hr/> <p><b>Paediatric investigation plan</b></p> <hr/>	I3_EMA PIP decision <b>name</b> <b>agency</b>	CCMO Website – Scientific advice and PIP <a href="#">NL</a> <a href="#">EN</a>	-If applicable -If a PIP was submitted and authorized under the CTD, provide the document, unchanged, in CTIS
<p><b>Content labeling</b></p> <hr/> <p><b>Content labeling of the IMP's*:</b></p> <hr/>	J1_NL-NL_Label IMP_ <b>product</b> <b>name</b>  (NL-NL= country code, language code)	CCMO Website – Labels <a href="#">NL</a> <a href="#">EN</a>	-If applicable -If new batches are expected after the authorization under the CTR, update the labels as per CTR Annex VI
<p><b>Content labeling</b></p> <hr/> <p><b>Content labeling of the IMP's*:</b></p> <hr/>	J2_NL-NL_Label AxMP_ <b>product</b> <b>name</b>  (NL-NL= country code, language code)	CCMO Website – Labels <a href="#">NL</a> <a href="#">EN</a>	-If applicable -If new batches are expected after the authorization under the CTR, update the labels

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PART II	<p>Form MSCs Part I <b>Part II</b> - NL - Evaluation Timetable</p>			
	<p>Country specific details (<b>Part II - Netherlands</b>)</p> <p><b>Trial sites</b></p> <p><b>Trial sites</b></p>	NA	NA	<p>-Ensure all sites that are still active and that were approved under the CTD as well as the approved Principal Investigator (PI) for each site is listed in this section. If new sites will be introduced during the first SM after the transition, add the trial site and PI here as well.</p>
	<p><b>Documents</b></p> <p><b>Recruitment Arrangements</b></p> <p><b>Recruitment arrangements *:</b></p>	K1_Recruitment arrangements	CCMO Website – Recruitment <a href="#">NL</a> <a href="#">EN</a>	<p><b>NEW DOCUMENT FOR CTR!</b></p> <p>-Mandatory template</p> <p>-Add a sponsor version and date within the document for filing purposes</p> <p>-If recruitment has ended, add a pdf document stating this instead of the mandatory template</p> <p>-To be published for category 2 and 3 trials</p>

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<p>Documents</p> <p>Recruitment Arrangements</p> <p>Recruitment arrangements *:</p>	<p>K2_NL(NL)_Recruitment material_description</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website – Recruitment</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p>-Only submit Dutch documents</p> <p>-If recruitment materials were submitted and authorized under the CTD, provide the documents, unchanged, in CTIS. If updates have been made for this submission, make this clear in the modification description document and submit clean and track changes versions.</p> <p>-Besides the SIS-ICF all information and/or description of procedures related to informed consent that is given to the subjects <i>before</i> their decision to participate or abstain from participation shall be submitted together with the SIS-ICF (document code L2). <b>Recruitment materials are the only other patient-facing documents that may be submitted in Part II (document code K2, section Recruitment arrangements).</b> Any other patient-facing documents provided to patients <i>after</i> they have signed the informed consent should not be submitted.</p> <p>-To be published for category 2 and 3 trials</p>
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<p>Documents</p> <p>Recruitment Arrangements</p> <p>Subject information and informed consent form</p> <p>Subject information and informed consent form *:</p>	<p>L1_ NL-NL_SIS and ICF_description</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website - ICF</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p>-Update if needed. If updates have been made for this submission, make this clear in the modification description document and submit clean and track changes versions.</p> <p>-PDF needs to be searchable</p> <p>-Submit Dutch documents</p> <p>-To be published for category 2 and 3 trials</p>
<p>Documents</p> <p>Recruitment Arrangements</p> <p>Subject information and informed consent form</p> <p>Subject information and informed consent form *:</p>	<p>L2_ NL-NL_Other subject information material_description</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website - ICF</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p>-If these documents were submitted and authorized under the CTD, provide the documents, unchanged, in CTIS. If updates have been made for this submission, make this clear in the modification description document and submit clean and track changes versions.</p> <p>-Besides the SIS-ICF all <b>information and/or description of procedures related to informed consent that is given to the subjects <i>before</i> their decision to participate or abstain from participation</b> 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</p>

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			<p>arrangements). Any other patient-facing documents provided to patients <i>after</i> they have signed the informed consent should not be submitted.</p> <p>-Submit Dutch documents</p> <p>-To be published for category 2 and 3 trials</p>
<p><b>Suitability of the investigator</b></p> <p><b>Investigator CV *:</b></p> <p>No document available</p> <p><b>Suitability of the investigator:</b></p> <p>No document available</p>	M1_CV Investigator name investigator and clinical trial site	<p>CCMO Website – Suitability of the Investigator</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p>-Provide the CV(s) (submitted and authorized under the CTD) unchanged in CTIS</p> <p>-1 Principal Investigator per site</p> <p>-No GCP certificates should be submitted. Relevant training should be evident from the CV</p>
<p><b>Suitability of the investigator</b></p> <p><b>Investigator CV *:</b></p> <p>No document available</p> <p><b>Suitability of the investigator:</b></p> <p>No document available</p>	M2_DoI Investigator name investigator and clinical trial site	<p>CCMO Website – Suitability of the Investigator</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p><b>NEW DOCUMENT FOR CTR!</b></p> <p>-Mandatory Declaration of interest (DoI) template for trial sites previously approved under the CTD. Also mandatory for any new trial sites.</p> <p>-1 DoI per site</p>

\*Please note this information is subject to change.

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<p><b>Suitability of the facilities</b></p> <p>Suitability of the facilities *:</p> <p>No document available</p>	<p>N1_Site suitability form name clinical trial site</p>	<p>CCMO Website – Suitability of the facilities</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>-Provide the Research Declaration / VGO (submitted and authorized under the CTD) unchanged in CTIS.</p> <p>-Submit page 1 only</p> <p>-1 form per site</p> <p>-Clinical Trial Agreements should not be submitted</p>
<p><b>Proof of insurance cover or indemnification</b></p> <p>Proof of insurance cover or indemnification *:</p> <p>No document available</p>	<p>O1_Trial participant insurance certificate</p>	<p>CCMO Website – Insurance</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>- WMO participant insurance (bewijs proefpersonenverzekering)</p> <p>-Provide the participant insurance (submitted and authorized under the CTD) unchanged in CTIS. However, if the insurance is/is almost expired, submit an updated document</p>
<p><b>Proof of insurance cover or indemnification</b></p> <p>Proof of insurance cover or indemnification *:</p> <p>No document available</p>	<p>O2_Proof of coverage sponsor or investigator name sponsor/trial site</p>	<p>CCMO Website – Insurance</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>-Liability insurance which covers general liability or both general and product liability</p> <p>-Not required for submission in CTIS if each site has their own insurance and this is clearly stated on page one of the VGO form</p> <p>-Provide the liability insurance (submitted and authorized under the CTD) unchanged in CTIS. However, if the insurance is/is almost expired, submit an updated document</p>

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<p><b>Financial and other arrangements</b></p> <p>Financial and other arrangements *:</p> <p>No document available</p>	<p>P1_Compensation trial participants, investigator, funding and other arrangements</p>	<p>CCMO Website – Financial arrangements</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p><b>NEW DOCUMENT FOR CTR!</b></p> <p>-Mandatory template</p> <p>- Add a sponsor version and date within the document for filing purposes</p>
<p><b>Compliance with national requirements on Data Protection</b></p> <p>Compliance with national requirements on Data Protection :</p> <p>No document available</p>	<p>R1_Compliance on the collection and use of personal data</p>	<p>CCMO Website – National Data protection</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p><b>NEW DOCUMENT FOR CTR!</b></p> <p>-Mandatory template</p> <p>- Add a sponsor version and date within the document for filing purposes</p>
<p><b>Compliance with use of Biological samples</b></p> <p>Compliance with use of Biological samples :</p> <p>No document available</p>	<p>S1_Compliance on the collection, use and storage of biological samples</p>	<p>CCMO Website – Biological samples</p> <p><a href="#">NL</a></p> <p><a href="#">EN</a></p>	<p><b>NEW DOCUMENT FOR CTR!</b></p> <p>-Mandatory template</p> <p>-Add a sponsor version and date within the document for filing purposes</p> <p>-If no biological samples will be used in the study, upload a pdf stating this in this section instead of the mandatory template</p>

\*Please note this information is subject to change.

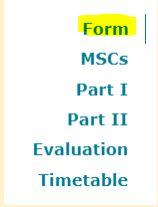

\*For submissions in other Member States Concerned (MSCs), please research the country specific requirements for that MSC (please see [Q&A document – Regulation \(EU\) 536/2014](#) Annex II and III as well as the [Overview part II requirements](#) by MedEthicsEU).

## SUBSTANTIAL MODIFICATION (SM): Document List

### Legend

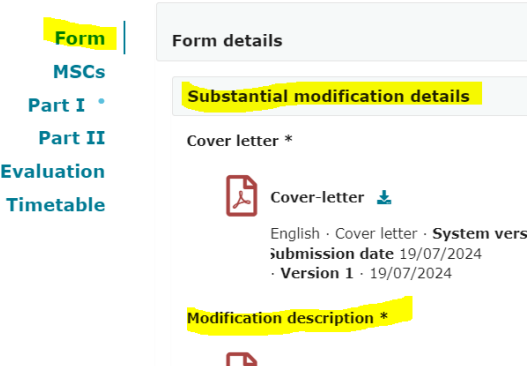
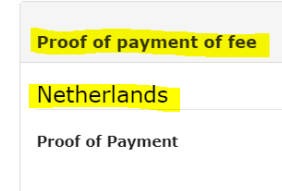
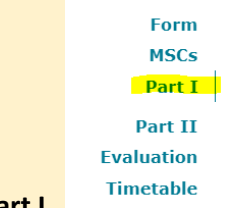
**Blue text:** text needs to be completed by sponsor.

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

Location in CTIS	Document & Naming Convention	Link	Additional Information
 <p>FORMS</p>			
 <p>Form details</p> <p>Substantial modification details</p> <p>Cover letter *</p>	<p>B1_Cover letter SM#</p> <p>EU CT number</p>	<p><a href="#">Heads of Medicines Agencies: Clinical Trials Coordination Group (hma.eu)</a></p> <p>Template under Key Documents List – Substantial Modification (SM). Template name: <i>Cover letter</i></p>	<p>-Mandatory European template- agreed to by all Member States</p> <p>-Clearly describe the location of the RSI if updated</p>

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	<p>B1_Description of the modification</p>	<p><a href="#">Heads of Medicines Agencies: Clinical Trials Coordination Group (hma.eu)</a></p> <p>Template under Key Documents List – Substantial Modification (SM). Template name: <i>Modification description</i></p>	<p>-Mandatory European template- agreed to by all Member States</p>
	<p>B2_NL-NL_Proof of Payment</p> <p>(NL-NL= country code, language code)</p>	<p>CCMO Website - Proof of Payment</p> <p><a href="#">NL</a> <a href="#">EN</a></p>	<p>-Mandatory template -Complete all fields (except KvK if not applicable) -Ensure that a reference, purchase or order number is included in section Payment Characteristics (not the EU CT number)</p>
			

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<p>Form MSCs <b>Part I</b> Part II Evaluation Timetable</p> <p>Trial specific information (Part I)</p> <p>Trial details</p> <p><b>Trial identifiers</b></p> <p><b>Trial information</b></p> <p>Protocol information</p>	NA	<p><a href="#">EudraLex - Volume 10 - European Commission (europa.eu)</a></p> <p>-See Annex II of the <i>Questions and Answers Document – Regulation (EU) 536/2014</i></p>	<p>-If not yet done, 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)</p>
Any updated documents	<p>Add “_TC” or “_SoC” to the end of your document name</p> <p>Example: D1_Protocol EU CT number_TC</p> <p>D1_Protocol EU CT number_SoC</p>		<p>- If you are submitting an updated protocol, IB or IMPD, always submit a searchable track changes version <i>and</i> a summary of changes version.</p> <p>-If you are submitting an updated ICF, always submit a searchable track changes version.</p> <p>-For all other documents (for eg, K1, P1, etc) always submit a track changes version, if possible.</p> <p>-Ensure any updated documents have a sponsor version and date within the document for filing purposes</p>

\*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).