Checklist of required fields per application type

How to create, submit and withdraw a CTA

CTIS Training Programme – Module 10
Version 1.1 – December 2021

Learning Objectives

- In this support document you will find a list of the data and documents that are requested as a minimum in CTIS to be able to proceed with the submission of the different application types.
General information

This document is composed of three sections below, listing the sections, sub-sections and required fields on each type of clinical trial applications (CTA). Find below the legend of the elements included in each section:

- A cloud icon (☁️) indicates that users need to upload a pre-populated document to CTIS.
- A ‘button’ indicates that when users click on that specific button, a pop-up window will allow users to populate the indicated information.
- A ‘check box’ indicates that, if clicked, the user will need to populate specific information.
- A ‘pencil’ indicates that users should click this icon to open a pop-up window where they will be able to edit or complete the specific information.
- An ‘example’ field refers to instances of the particular required field e.g. an authorised product.

Initial Clinical Trial Application

<table>
<thead>
<tr>
<th>Form section</th>
<th>Sub-sections</th>
<th>Required fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial application details</td>
<td>Cover letter</td>
<td>• Cover letter ☁️</td>
</tr>
<tr>
<td>Compliance with regulation</td>
<td>Compliance with Regulation (EU) 2016/679</td>
<td>• Compliance with Regulation (EU) 2016/679 ☁️</td>
</tr>
<tr>
<td>Deferral publication dates</td>
<td>Deferral of clinical trial information</td>
<td>• Short title / Trial category • Justification for trial category / Trial category</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MSC section</th>
<th>Required fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member State Concerned</td>
<td>• +Add member states (button) • Member states • Subjects • Select Proposed RMS</td>
</tr>
<tr>
<td>Part I section</td>
<td>Sub-sections</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------</td>
</tr>
</tbody>
</table>
| Trial details | Trial identifiers | • Full title  
• Public title |
| Trial information | Trial category | • If Low intervention trial (check box) / Justification for the low intervention trial
• Trial phase |
| Medical condition | • Add condition (button) / Medical condition(s)  
• Therapeutic area |
| Main objective | • Trial scope  
• Main objective |
| Eligibility criteria | • Add inclusion criteria (button)  
• Add exclusion criteria (button) |
| End points | • Add primary endpoint (button) |
| Trial duration | • Estimated recruitment start date in EEA  
• Estimated end of trial date in EEA |
| Population of trial subjects | • Age range  
• Gender  
• Clinical trial group  
• (if check box ‘Vulnerable group’ is clicked) Recruitment population group |
| Protocol information | Clinical trial protocol | • Protocol |
| Sponsors | Contact point for Union | • Add contact point for Union (button)  
• Scientific Contact Point  
• Public Contact Point |
| Products | Products | • +Add (button) |
| Role: Test (example) | • +Add (button) / Authorised product (example) |
| Dosage and administration details | • Route of administration  
• Maximum duration of treatment  
• Maximum daily dose allowed  
• Total dose unit of measure |
| Information about the modification of the medicinal product | • Has the medicinal product been modified in relation to its Marketing Authorisation? (check box) |
| Investigator brochure for the medicinal product | • Investigator brochure  
• Summary of product characteristics (SmPC) |
| IMPD Quality* | • IMPD-Q  
• Simplified IMPD-Q  
• Justification for no IMPD upload |
| IMPD - Safety and efficacy* | • IMPD - Safety and Efficacy  
• Simplified IMPD - Safety and Efficacy  
• Justification for no IMPD upload |
| Content labelling | • Content labelling of the IMP’s |

* To view the required fields per IMP please refer to question 2.12 What types of IMP can be added as a test role on the Frequently Asked Questions document of this module.
### Part II sections

<table>
<thead>
<tr>
<th>Sub-sections</th>
<th>Required fields</th>
</tr>
</thead>
</table>
| **Trial sites** | • +Add sites (button)  
• Search organisation (or create an organisation)  
• Edit information (pencil)  
• First name / last name / department / phone / email |

### Country specific details

<table>
<thead>
<tr>
<th>Documents</th>
<th>Required fields</th>
</tr>
</thead>
</table>
| • Recruitment arrangements  
• Subject information and informed consent form  
• Investigator CV  
• Suitability of the facilities  
• Proof of insurance cover or indemnification  
• Financial and other arrangements |

### Additional MSC Clinical Trial Application

<table>
<thead>
<tr>
<th>Form section</th>
<th>Sub-sections</th>
<th>Required fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial application details</td>
<td>Cover letter</td>
<td>• Cover letter</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MSC section</th>
<th>Required fields (if users wish to add MSCs which have not been populated in the pop-up screen after the Add MSC CTA has been created, but not yet submitted)</th>
</tr>
</thead>
</table>
| Member states concerned | • +Add member states (button)  
• Member states  
• Subjects |

<table>
<thead>
<tr>
<th>Part II sections</th>
<th>Sub-sections</th>
<th>Required fields</th>
</tr>
</thead>
</table>
| **Trial sites** | • +Add sites (button)  
• Search organisation (or create organisation)  
• Edit information (pencil)  
• First name / last name / department / phone / email |

<table>
<thead>
<tr>
<th>Documents</th>
<th>Required fields</th>
</tr>
</thead>
</table>
| • Recruitment arrangements  
• Subject information and informed consent form  
• Investigator CV  
• Suitability of the facilities  
• Proof of insurance cover or indemnification  
• Financial and other arrangements |

Substantial Modification Clinical Trial Application

When users create a Substantial Modification, the scope must be selected (Part I only, Part II only, or Part I and Part II) from the dropdown menu in the pop-up screen.

<table>
<thead>
<tr>
<th>Form section</th>
<th>Sub-sections</th>
<th>Required fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substantial Modification details</td>
<td>Cover letter</td>
<td>• Cover letter</td>
</tr>
<tr>
<td></td>
<td>Modification description</td>
<td>• Modification description</td>
</tr>
</tbody>
</table>
Clinical Trials Information System (CTIS).
Support document – Checklist of mandatory fields per application type.

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