EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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CTIS public portal: Trial Documents

Summary | Full trial information | Trial Documents | Trial Results | Locations and contact points

This section includes the documents of the clinical trial application that are subject to publication: protocol, protocol synopsis, Summary of Product Characteristics (if available), Recruitment arrangements, Subject information and informed consent form. Their lay language descriptions are available in the table below.

Trial documents are generally published as soon as the relevant EU/EEA country(/-ies) complete the scientific and regulatory assessment of the trial and make a decision on its authorisation. Publication rules vary for 'Category 1' trials, where the protocol and protocol synopsis are published 30 months after the trial's completion in EU/EEA or, if the trial includes paediatric participants, together with its results which are expected 6 months after the trial's completion in EU/EEA. In addition, recruitment arrangements, subject information and informed consent forms are never published for 'Category 1' trials. The trial category and age of participants can be seen in the section 'Full trial information'.

Note that for trial applications submitted before 18 June 2024 when the revised CTIS transparency rules came into effect, the trial documents are not published and do not appear in this section. You can check the relevant submission date in the 'Summary' section.

Term	Definition
Overall documents for the trial	
Protocol	The detailed plan on how a clinical trial will be conducted. It outlines the trial's objectives, design, procedures, and methods for ensuring participant safety and collecting data. The term 'protocol' encompasses successive versions of the protocol and protocol modifications.
Synopsis of the protocol	The document accompanying the protocol, which includes brief summary of the clinical trial protocol, highlighting the key points like the trial's purpose, design, number of participants, and main procedures.
Summary of Products Characteristics (SmPC)	A detailed document providing information about a medicine, including its uses, dosages, side effects, and safety guidelines. It is present in case a medicine that is already on the market is used in the clinical trial.
Country-specific documents: documents uploaded in CTIS for each country where the trial is located	
Recruitment arrangements	A document describing in detail the procedures for inclusion of subjects and providing a clear indication of what the first act of recruitment is.
Subject information and Informed consent form (ICF)	The information provided to potential participants, explaining the trial in simple terms, including its purpose, risks, and benefits. This is given together with the informed consent form, a document that participants sign to show they understand the trial, including its risks and benefits, and agree to take part voluntarily. It ensures that participation is based on fully informed choice.

Please note that if a trial has ended in some countries while it is ongoing in others where its data and document(s) were modified, the corresponding translations of those data and documents in the ended countries may not correspond with the latest authorised versions in the ongoing countries.