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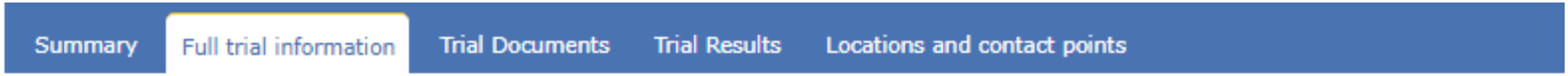
CTIS public portal: Full trial information



This section includes the full information of the trial, as submitted by the sponsor at time of clinical trial application. See the table below for a lay language explanation of each field, while a plain-language description of medical terms is provided in the EMA Medical Terms Simplifier.

Trial information is 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 timelines of specific fields and documents vary for 'Category 1' trials and for integrated phase I and II trials. You can see the trial category and phase under the 'trial information' table of the present section and the exact timelines under the 'part I' section of this file. Note that information on the sponsor and site(s) are located in the section 'Locations and Contact points', while documents of the trial application can be viewed in the section 'Trial documents'.

Note that this section only shows all those fields that are filled in and can be displayed: fields that would be shown as empty (either because they do not contain data, or because of the applicable publication rules) are not displayed at all.

By selecting 'Download clinical trial' at the top right, you can download the full trial details (HTML file) and documents (PDF files). To save the 'trial details' HTML file as a PDF, select the three dots at the top right of your browser, choose 'Print' and then 'Save as PDF'.

Term	Definition
Medical condition	
Medical condition	The disease or health problem being studied or treated in the clinical trial.
Is the medical condition considered to be a rare disease?	A rare disease is a medical condition that affects a small number of people, typically fewer than 1 in 2,000 individuals. These diseases are often chronic, serious, and sometimes life-threatening. Due to their rarity, they may be harder to diagnose and treat. Examples include cystic fibrosis and Huntington's disease. More information here.
Therapeutic area	The specific field of medicine or healthcare that the clinical trial focuses on, such as oncology (cancer), cardiology (heart), or neurology (brain), provided through a standardised coded format.
Participants	
Age range	The age of participants that are involved in the trial.
Age range secondary identifier	A more specific age range of participants, within the already indicated age range.
Are participants male/female	The gender of participants.
Clinical trial group	The kind of participants (e.g. healthy volunteers, patients).
Vulnerable population	The presence in of population groups that are considered vulnerable as per legislation (e.g. incapacitated subjects, minors, pregnant and breastfeeding women, additional national measures, and participants in emergency situations.
Participation criteria	
Principal inclusion criteria	The main conditions or requirements that participants must meet to be allowed to join the clinical trial, such as their specific health status. They are in addition to the ones already listed in the 'participants' section and refer to age and gender.
Principal exclusion criteria	The conditions or factors that would prevent someone from joining the clinical trial, such as having a certain medical condition or taking specific medications.

Term	Definition
Clinical Trial identifiers	
Full title	The official, detailed title of the clinical trial, often technical and specific.
Public title (title in lay language)	A simplified version of the trial's title, often shorter, written in plain language so it can be easily understood by the general public.
Protocol code	A unique identifier or code given to a clinical trial by the sponsor.
WHO universal trial number (UTN)	A unique number assigned by the World Health Organization, at the sponsor's request. It is not a registration number, and it aims to facilitate the unambiguous identification of clinical trials worldwide. More information here.
ClinicalTrials.gov identifier (NCT number)	A unique registration number assigned to clinical trials listed on the ClinicalTrials.gov database.
ISRCTN number	A unique identifier for clinical trials listed in the ISRCTN (International Standard Randomised Controlled Trial Number) registry.
Additional registries	Any other database or system where the clinical trial is registered, together with its registration identifier.
Transition trial	
A transition trial in the EU/EEA refers to a clinical trial that has been transitioned from the legal framework of the Clinical Trials Directive 2001/20/EC to the Clinical Trials Regulation (EU) 536/2014, which is the legal basis for the Clinical Trials Information System (CTIS). The Clinical Trials Directive was the law under which trials were conducted before 31 January 2022, once the Clinical Trials Regulation came into force. Any trial that is foreseen to be ongoing beyond 31 January 2025 needs to be compliant with the Clinical Trials Regulation. Trials recorded under the Clinical Trials Directive can be viewed on the EU Clinical Trial Register.	
Trial category	
Trial phase	The stage in clinical research where a new treatment is tested. Phases can be: • Phase I (Human Pharmacology): to collect data on safety, tolerability, and how the treatment behaves in the body (pharmacokinetics and pharmacodynamics). Typically, it involves a small group of healthy volunteers or patients.

Term	Definition
	• Phase II (Therapeutic exploratory): to collect preliminary data on whether the treatment works and additional safety data, including side effects and optimal dosing, generally performed on a larger group of patients who have the disease or condition the medicine is intended to treat • Phase III (Therapeutic confirmatory): to confirm the effectiveness of the medicine, monitor side effects, compare it to standard treatments, and gather comprehensive safety information, it involves a large group of patients. • Phase IV (Therapeutic use): to monitor the long-term medicine's safety and effectiveness in the general population after it has been approved and marketed. The term 'integrated' is used in case a trial involves both phases.
Trial category	The type of publication category, which mainly depends on the trial phase: Category 1 trials include phase 1 trials, Category 2 trials include phase I, phase II and integrated phase I and II, phase III and integrated phase II and III trials, while Category 3 trials include integrated phase III and IV trials, phase IV trials and low intervention clinical trials. More detailed description of each category can be found in table V of this document.
Justification for trial category	The reasoning behind why the trial falls into a specific category.
Medical condition(s) MedDRA information	
A classification of the medical condition(s) involved in the trial using the MedDRA (Medical Dictionary for Regulatory Activities) system, which standardises terms related to diseases and treatments.	
Objectives	
Trial scope	The overall focus of the clinical trial, e.g. Safety, Efficacy, Pharmacokinetic, Pharmacodynamic.
Main objective	The primary aim of the clinical trial, such as testing a treatment's effectiveness or safety.
Secondary objective(s)	Additional aim(s) of the clinical trial, which provide(s) additional valuable information.
Endpoints	
Primary end points	The key outcomes that the clinical trial is designed to measure, like improvements in symptoms or the effectiveness of a treatment.

Term	Definition
Secondary end points	Additional outcomes measured in the trial that provide extra information beyond the primary end points.
Study design	
The overall plan or structure of the clinical trial, including how it is conducted, the type of study (e.g., randomised, double-blind), and how participants are assigned to different treatments.	
Products	
Trials registered on CTIS are trials on medicinal products. Trials on medical devices or observational clinical trials are not in scope of this system. The characteristics of the investigational medicinal product(s) used in the trial are displayed in this section. Different product roles can be displayed on the left hand side of the table: test (the product that is subject to investigation), comparator (a product used as a comparison to the trial medicine, to evaluate its effectiveness or safety), placebo (a substance designed to have no therapeutic effect and is used as a control in the trial), auxiliary (the name of any additional products used in the trial to support the study which are not the main treatment being tested). The product name as well as the name of its active ingredient (active substance) are displayed, together with their authorisation status (authorised or still under development), as applicable. To view further details on each product, you can click on the left of its relevant table.	
Dosage and administration Details	This field describes the medicinal product's pharmaceutical form (e.g. tablet, injection, or capsule), route of administration (i.e. how it is given to participants, such as orally, by injection, or topically), and specifies the maximum duration of treatment, the maximum daily dose allowed, and the maximum total dose allowed.
Information on specific paediatric formulation, and on orphan designation	This field specifies whether the product is specifically designed for children. Moreover, it indicates if the medicinal product has been granted orphan drug status for treating a rare disease. More information here. In case of orphan designation, the designation number for orphan drug is displayed (i.e. the specific number assigned to the product when it receives orphan drug designation).

Term	Definition
Product classification (ATC), Any Active substance – classification and any additional characteristics	Code, Name and Level based on the Anatomical Therapeutic Chemical (ATC) code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO). More information can be found here. This field describes the classification of the active ingredient in the medicinal product based on its therapeutic properties, synonyms and other descriptive names. If applicable, a few other product's characteristics are listed here (e.g. recombinant for monoclonal antibodies).
Product and active substance IDs/codes	Lists the name(s) of the product used, its unique identifier in the European Union, the unique identifier assigned to the active substance in the EU (EU Active Substance Code) and the relevant codes that are assigned by the sponsor the product and/or active substance. The Authorisation number of manufacturing and import refers to the official number confirming that the medicinal product complies with Good Manufacturing Practices (GMP) regulations.
Product authorisation details and Information about the modification of the medicinal product	If the product is authorised, this field specifies the company or entity that holds its marketing authorisation, the country where the medicinal product has received its marketing authorisation, any authorisation procedure number and the official number assigned when a medicinal product is approved for sale in a specific country. This field also indicates if the medicinal product has been changed or altered from its original form as approved in its marketing authorisation and details of any changes made to the medicinal product compared to its original approved version.
The field 'Excluded MSCs' refers to Member States Concerned (MSCs) where the product is not used.	
Advanced therapy medicinal product	
The advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes, tissues or cells. Details on each kind of therapy are provided, including its description, origin and type. More information on ATMPs and how they are authorised can be found here.	
Product used in combination with a device	

Term	Definition
If the medicinal product is used with a medical device as part of the clinical trial, this field specifies its unique identifier and official trade name, description, type (e.g. diagnostic), together with any European conformity (CE) mark showing it meets EU safety and performance standards, and the organisation responsible for certifying that the device meets regulatory requirements (Device notified body).	
Individual Participant Data	
The intended sharing of deidentified individual clinical trial participant-level data (IPD). In case the IPD will be shared, the 'plan description' field specifies what IPD will be shared, when, by what mechanism, with whom and for what types of analyses.	
Scientific Advice and Paediatric Investigation Plan	
Scientific Advice	If applicable, this field lists the competent authorities (national agencies or the European Medicines Agency (EMA)) that have provided scientific advice to sponsors on how to design and conduct their clinical trials, ensuring that the trial meets regulatory standards and provides reliable data. More information on EMA scientific advice can be found here.
Paediatric Investigation Plan	A Paediatric Investigation Plan (PIP) is a detailed development plan required by the European Medicines Agency (EMA) that outlines how a new medicine or treatment will be tested for safety, efficacy, and quality in children. It ensures that medicines are researched and approved for use in children, as well as adults. More information on PIP can be found here.
Associated clinical trial	
This field allows sponsors to refer to data generated in another clinical trial.	
References	
Sources that are cited or used to support or provide context for various aspects of the clinical trial. References can be used to ensure that the trial is based on solid, validated research or regulatory advice, providing credibility and context to the trial's design, conduct, and outcomes.	

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.