20 September 2024
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CTIS public portal: summary

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

This section includes a summary of the clinical trial you selected, including information on recruitment, start/end dates, safety notifications and corrective measures. See the table below for a lay language explanation of each field.

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. Start/end dates of the trial, recruitment dates and information on temporary halt and early termination are inserted by the sponsor: if they are not displayed, it means that those events did not occur (yet) or that the relevant information still needs to be inserted by the sponsor. Information on any occurred safety notification appears upon their assessment and on any corrective measure upon their application. 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 publication category in the section 'Full trial information' and the exact timelines in the 'part I' section of this file.

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
Trial information *This section outlines the main characteristics of the trial. For a full overview, refer to the section 'Full trial information'.*	
Medical condition(s)	The disease, illness, or health problem affecting the body or mind, which is being studied in a clinical trial.
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. • 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.
Protocol code	A unique identifier or code given to a clinical trial by the sponsor.
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, when 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 Trial Directive can be viewed on the EU Clinical Trial Register.

Term	Definition
Sponsor	The person, company, institution or organisation that takes responsibility for the initiation, management and for setting up the financing of a clinical trial. There are two main types of sponsors: Commercial Sponsors (e.g., pharmaceutical companies) and Non-commercial Sponsors (e.g., Universities or academic research centres).
Age range	The range of ages (e.g., 18-65 years) of people allowed to participate in a clinical trial.
Participants type	Specifies whether the trial is conducted on people who do not have the medical condition being studied (i.e. healthy volunteers) and/or on people with that specific medical condition (i.e. patients).
Locations	Country(/-ies) of the European Union/European Economic Area (EU/EEA) where the clinical trial is authorised and conducted.
Main objective	The primary aim of the clinical trial, such as testing a treatment's effectiveness or safety. Any secondary objective, if present, is listed in the 'Full trial information' section.
Overall trial status *The dates specified in this section are mostly inserted by the sponsor. If no date is displayed, it means that the event has not yet occurred, or that it was not yet recorded by the sponsor.*	
Start of trial	Date from which participants may start to be enrolled in a clinical trial and the trial begins.
End of trial	The date when the clinical trial stops collecting data from participants, and no further trial-specific treatments are given.
Global end of trial	The date when the clinical trial is considered complete worldwide, including in all participating countries or locations outside of the EU/EEA.
'Applications' tab	This section specifies the different kinds of applications the sponsor has made on the clinical trial, their dates of submission, assessment and decision, and the outcome. When 'Not Authorised' is displayed, it means that the trial application was not approved and therefore the trial is not conducted. When 'Authorised with condition' is displayed, it means the trial was approved and can be conducted, however special conditions may apply.

Term	Definition
Member State	Refers to any country that is part of the European Union (EU) or the European Economic Area (EEA) responsible to authorise and oversee clinical trials, ensuring that they comply with ethical, safety, and regulatory standards.
Current status	The present stage of the clinical trial in each member state. Statuses can be: • Authorised, recruitment pending: the trial is authorised, but recruitment is not yet opened • Authorised, recruiting: the trial is authorised, recruitment opened but no one has been recruited yet • Ongoing, recruiting: the trial is ongoing, recruitment opened, and the first participant has been recruited • Ongoing, recruitment ended: the trial is ongoing but no longer recruiting • Temporarily halted: the trial was temporarily halted by the sponsor • Suspended: the trial was suspended by the regulatory authority • Ended: the clinical trial stops collecting data from participants, and no further trial-specific treatments are given. • Revoked: the trial authorization has been revoked by the regulatory authority of the member state • Not authorised: the trial application was not approved and therefore the trial is not conducted • Expired: the authorization of the clinical trial is expired, and the trial cannot be conducted
Decision date	The date when the decision to authorise or not authorise a clinical trial application was made.
Last update	The most recent date when information about the clinical trial was updated.
Start date	The official date when the clinical trial begins in a Member State and is open for recruitment
Temporary halt	A pause in the clinical trial, where activities or treatments could be stopped for a period of time, for example due to safety concerns.
Restart	The resumption of a clinical trial after it was temporarily halted, allowing activities to continue.
End (or early termination)	The official completion date of the clinical trial in the relevant Member State, or when the trial is stopped earlier than initially planned in its protocol.
Reason for early termination	The explanation of the reason a clinical trial was stopped early, such as safety issues, lack of effectiveness, or financial issues.

Term	Definition
Recruitment start	The date when the first participant has been recruited.
Recruitment end	The date when the clinical trial stops recruiting participants.
Recruitment restart	The date when participant recruitment resumes after it was paused or halted.
Trial duration	
Estimated recruitment start date in EU/EEA	The date when a clinical trial is foreseen to begin enrolling participants in countries within the European Union (EU) and European Economic Area (EEA), as estimated at the time of authorisation of its application.
Estimated end of trial date in EU/EEA	The date when the clinical trial is foreseen to be completed in the EU/EEA, as estimated at the time of authorisation of its application.
Estimated global end date of the trial	The date when the clinical trial is foreseen to be finished worldwide, across all locations and countries involved, including those outside of the EU/EEA, as estimated at the time of authorisation of its application.
Source of monetary support or material support	The organisation, company, or group that provides funding (money) or necessary resources (materials or equipment) for the clinical trial.
Notifications *The following events could occur during the conduct of a clinical trial and are notified by the sponsor to the Member State that authorised the trial and is responsible for their assessment.* *Further details can be viewed by clicking on 'View details' and then scrolling up on your browser.*	
Serious Breach	A violation of the clinical trial's rules (e.g., the applicable version of the trial's protocol, or the Clinical Trial Regulation (EU) 536/2014) that may impact participants' safety or quality of the collected data.
Unexpected event	An occurrence during the clinical trial that was not anticipated and could affect its benefit-risk balance.
Urgent safety measure	An immediate action taken during the trial to protect participants' safety in response to an unexpected event that is likely to seriously affect the benefit-risk balance.
Temporary halt	A temporary stop to the conduct of a trial which was not foreseen in the trial's application.

Term	Definition
Corrective measures	
These measures occur when a Member State requested a modification of a clinical trial application or status, often after a breach or safety concern has been identified. This element is not numbered; you need to click on this field to see whether a corrective measure was applied to the trial.	
Further details can be viewed through clicking on 'View details' and then scrolling up on your browser.	