10 December 2024
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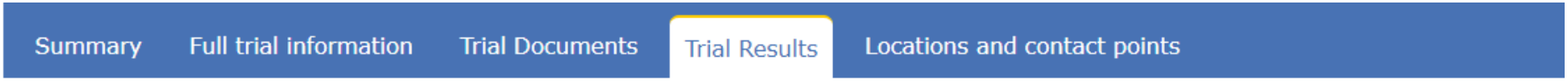
CTIS public portal: Trial Results



This section includes the trial's summary of results and layperson summary of results, as submitted by the sponsor on CTIS, and could include the Clinical Study Report, if submitted by the relevant Marketing Authorisation Holder. See the relevant definitions in the table below.

The summary of results and layperson summary of results are generally expected to be submitted within one year from the trial's completion unless the trial includes paediatric participants, in which case their submission occurs within 6 months from the trial's completion. To know when a trial is ended, refer to the 'Summary' section. Both documents are published as soon as they are submitted, with the exception of results for 'Category 1' trials conducted solely on adults, which are published 30 months after the end of trial date in EU/EEA. You can see the trial category and age of participants in the section 'Full trial information'.

Clinical Study reports (CSRs) are submitted by the marketing authorisation holder (MAH) in case the trial led to a marketing authorisation application of its medicinal product(s). A CSR submission occurs within 30 days from the relevant marketing authorisation decision, and its publication occurs upon submission.

Term	Definition
Layperson summary of results	A simplified version of the trial's summary of results written in plain, non-technical language so that the general public can easily understand the outcomes.
Summary of results	Document providing an overview of the findings of a clinical trial. This document includes key information such as: disposition and characteristics of the trial’s participants, outcomes measured during the trial (e.g., primary and secondary endpoints) and safety data, including any adverse effects. It ensures transparency by making important trial data accessible, contributing to scientific knowledge and the safe use of new treatments.
Clinical Study report	A document that includes all the data and analysis from a clinical trial, accompanying an application for marketing authorisation. It includes trial's objectives, methods and results: for more information on what this report includes, you can refer to this guideline. If this report is not present, it means that no marketing authorisation decision was issued on the trial’s investigational medicinal product (or that the marketing authorisation holder has not submitted it yet).