Prospective cohort study to assess the performance of tools to describe the Natural History of CytoMegaloVirus infection and transmission in FAMILIes with children attending daycare centers in France (CMV FAMILI study)

First published: 13/07/2026

Last updated: 14/10/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001054

Study ID

1000001054

DARWIN EU® study

No

Study countries

France

Study description

The primary objective of this study is to assess the performance of polymerase chain reaction (PCR)-based case definition criteria for identifying primary cytomegalovirus (CMV) infection in parents/caregivers who are CMV-seronegative at baseline.

Study status

Planned

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Last updated: 08/07/2025

Institution | Pharmaceutical company

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC
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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 29/01/2026

Study start date
Planned: 30/10/2026

Data analysis start date
Planned: 01/09/2029

Date of final study report
Planned: 31/03/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

CMV Nat Hist NIS104141 Amendment 1 Approved 6.17.2026_final-redaction.pdf
(1.04 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Feasibility analysis

Method development or testing

Data collection methods:

Primary data collection

Study design:

This is a prospective, longitudinal cohort study in which participants are enrolled through DCCs in France. The study will include two sequential phases: a pilot phase and a main phase. Both phases will use the same overarching design, sample collection schedule, and recruitment framework.

Main study objective:

The primary objective of this study is to assess the performance of PCR-based case definition criteria for identifying primary CMV infection in parents/caregivers who are CMV-seronegative at baseline.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Cytomegalovirus infection

Population studied

Short description of the study population

This study will include parents/caregivers (ages 18 to 49) of children attending participating day-care centers (DCCs) in France, as well as their children who are attending the DCC. Children with known congenital CMV infection and/or disease and parents of children with known congenital CMV infection and/or disease are excluded.

Age groups

- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Estimated number of subjects

3.000

Study design details

Setting

This study will include parents/caregivers of children attending participating DCCs in France, as well as their children who are attending the DCC. The primary setting for the study is DCCs located within the catchment areas of participating local laboratories to ensure feasibility of longitudinal sample collection.

Outcomes

The primary outcome of the study will be primary CMV infection in adults. Primary CMV infection is defined as seroconversion, i.e. appearance of CMV Immunoglobulin G (IgG) and/or Immunoglobulin M (IgM) antibodies, using a commercial serology assay or the Sponsor’s serology assay in parents/caregivers who were CMV-seronegative at baseline.

Data analysis plan

All analyses will be descriptive or exploratory; no hypothesis testing is planned. Continuous variables will be summarized using mean, standard deviation, median, interquartile range, and range where appropriate. Categorical variables will be summarized using counts and percentages where appropriate. Time-to-event analyses will use Kaplan-Meier methods to estimate cumulative incidence where appropriate. Incidence rates will be calculated per 100 person-years, with 95% confidence intervals. Analyses will be stratified by variables of interest (e.g., sex, age, household size) where appropriate. All analyses will be conducted using validated statistical software.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

after creation of study variables