Characterisation of complex clinical trials in the European regulatory context

First published: 23/10/2025

Last updated: 26/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000786

Study ID

1000000786

DARWIN EU® study

No

Study countries

Austria

Germany

Sweden

Study description

The project aims to identify and categorize Complex Clinical Trials (CCTs). Definitions of “complexity” will be developed based on a review of relevant literature and regulatory documents. Clinical trials registered in the Clinical Trials Information System (CTIS) will be identified and categorized accordingly. The search strategy will combine natural language processing (NLP) and text-mining techniques with manual review.

A Delphi process will be conducted to establish a harmonized framework for CCT categorization, taking into account multiple dimensions of complexity, such as operational, regulatory, methodological, statistical, and ethical aspects. This process will ensure input from experts with diverse backgrounds, including CTIS end-users, CTIS application assessors, and professionals with regulatory, ethical, operational and methodological expertise.

A validation study will assess the accuracy and reliability of both the search strategy and the proposed categorization framework. Based on these findings, the project will provide recommendations for identifying complex trials within CTIS and suggestions for improving future processes to facilitate easier identification. The results, including both technical and conceptual insights, will be disseminated through comprehensive reports and webinars.

Study status

Ongoing

Research institutions and networks

Institutions

Medical University of Vienna

Austria

First published: 01/02/2024

Last updated: 26/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Uppsala University

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Institution

University Medical Centre Göttingen (UMG)

Germany

First published: 26/11/2025

Last updated: 26/11/2025

Institution | Hospital/Clinic/Other health care facility

Austrian Agency of Health and Food Safety

Networks

CONsortium For Innovation in Regulatory Medical Statistics (CONFIRMS)

Contact details

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Study timelines

Date when funding contract was signed

Planned: 18/09/2025

Actual: 18/09/2025

Study start date

Planned: 18/09/2025

Actual: 18/09/2025

Data analysis start date

Planned: 18/09/2025

Actual: 18/09/2025

Date of final study report

Planned: 18/06/2026

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Methodological

Study type:

Not applicable

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Characterisation of complex clinical trials

Data collection methods:

No individual level data collected for the purpose of the study

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.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable