Using CTIS to track trends in clinical trial activity at regional and national levels

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Clinical Trials Information System (CTIS) enables nationwide tracking of clinical trials

- Centralised regulatory clinical trial registry
  - Includes all authorised clinical trials of medicinal products for human use in EEA.
  - Provides a single, structured and publicly available source of clinical trials data.
  - Enables nationwide harmonization of data.
  - Supports local, regional, and national strategy development of research funding and infrastructure.

Aim of current data retrieval from CTIS

Publish a national report to inform stakeholders

Compile and disseminate information on authorised trials in Sweden and across Sweden’s six healthcare districts.

Develop a structured dataset of trials authorised in Sweden

- Factual base to use in other business intelligence tools.

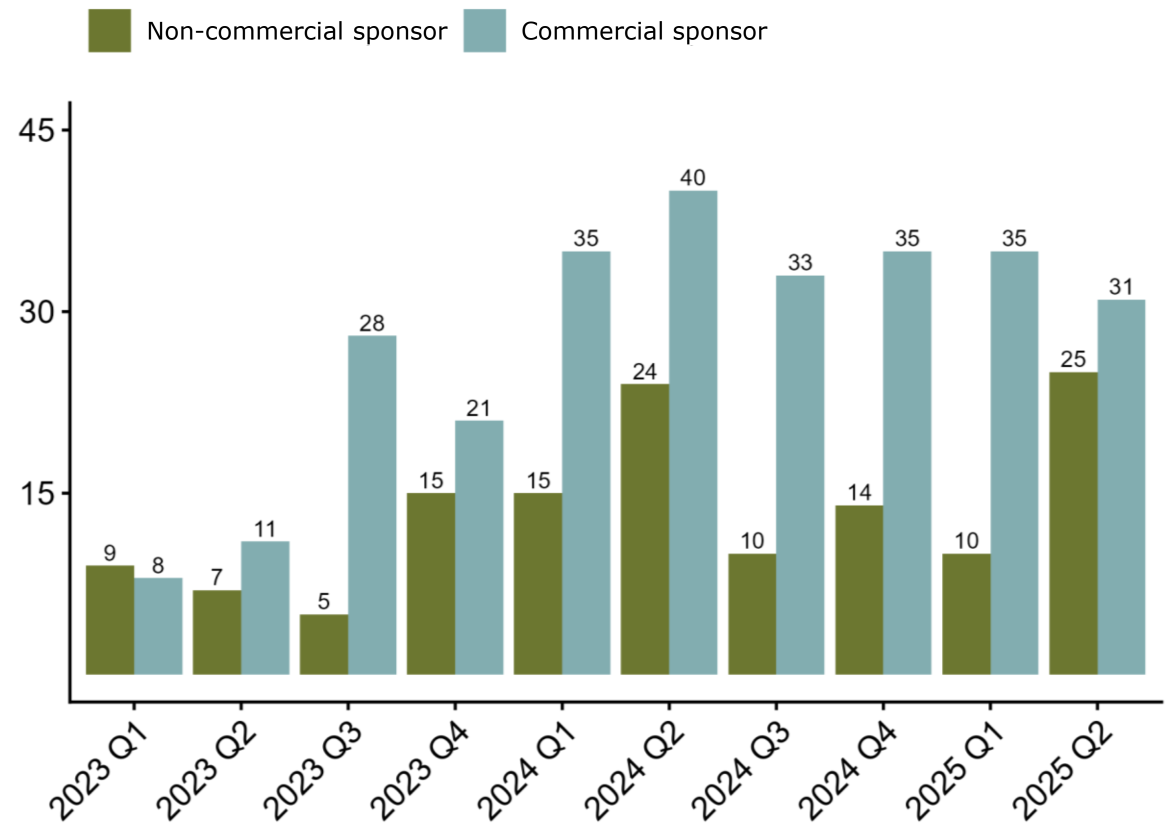
Develop a guide how to *Getting started with CTIS data analysis in R using the ctrdata package*

- Kick-start data analysts to conduct own analyses.

How we currently use CTIS

- Present national data in a harmonised way
- Track national trends over time
- Enable cross-regional comparisons

Number of authorised trials in Sweden (excl. transitional trials)

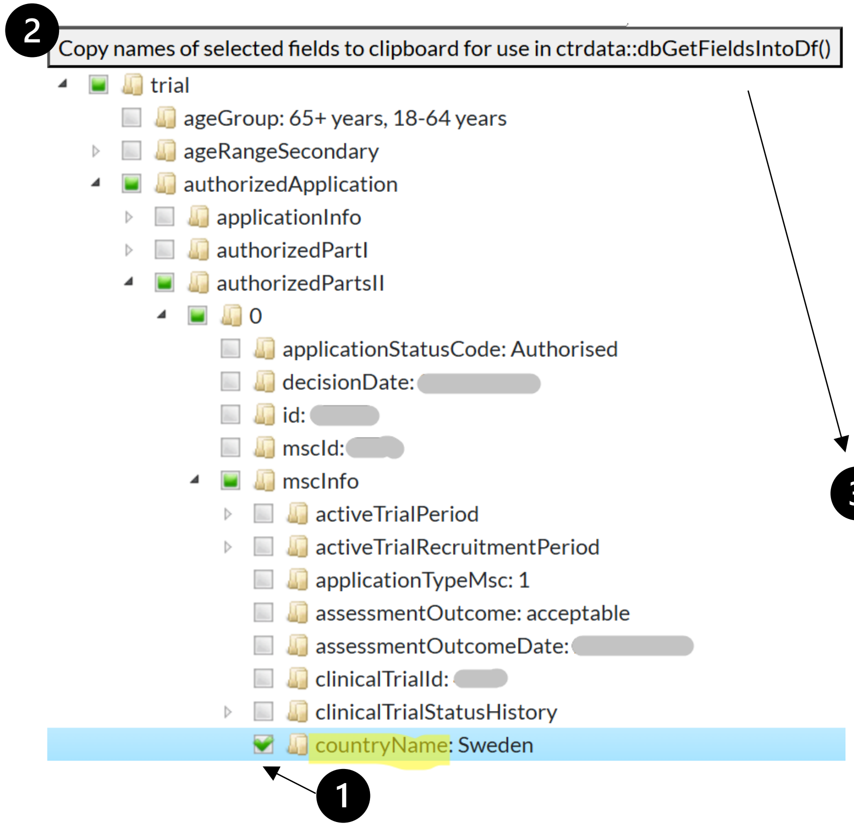


Data source: CTIS, euclinicaltrials.eu, European Medicines Agency (EMA)
Analysis tool: Retrieve and Analyze Clinical Trials in Public Registers_. R, (Herold, 2025)

Tools to learn full CTIS data structure

Find available structured fields online

https://regulatorysciencedata.eu/posts/trialdata/



Make a table of available structured fields

var_full	var_lvl01	var_lvl02	var_lvl03	var_lvl04	var_lvl05
authorizedApplication.authorizedPartsII.mscInfo.countryName	authorizedApplication	authorizedPartsII	mscInfo	countryName	NA
authorizedApplication.authorizedPartsII.mscInfo.trialPeriod.trialEndDate	authorizedApplication	authorizedPartsII	mscInfo	trialPeriod	trialEndDate
authorizedApplication.authorizedPartsII.mscInfo.trialPeriod.trialStartDate	authorizedApplication	authorizedPartsII	mscInfo	trialPeriod	trialStartDate

+1000 unique variables up to eight levels

3 fields = c("authorizedApplication.authorizedPartsII.mscInfo.countryName")

Trial status data per country in CTIS

- New important feature in CTIS to analyse research activity.
  - Not available previously in EU CTR database.

CTIS public webpage

Overall Trial status

Start of trial 10/11/2023 End of trial 16/01/2024 Global end of trial 16/01/2024 Applications

	Trial								Recruitment		
Member state	Current status	Decision date	Last update	Start date	Temporary Halt	Restart	End (or early termination)	Reason for early termination	Start	End	Restart
Sweden	Ended	09/11/2023	09/11/2023	10/11/2023			16/01/2024		10/11/2023	03/01/2024	

Source: CTIS, euclinicaltrials.eu, European Medicines Agency (EMA)

In retrieved data

var_full	var_lvl01	var_lvl02	var_lvl03	var_lvl04
events.trialEvents.events.notificationType	events	trialEvents	events	notificationType

Some challenges noticed

In CTIS, final number of recruited participant is not reported.

- May be mixed up with the field Number of participants enrolled
  (which is planned number of participants)
- Solution → manual follow-up

Type of vulnerable population is not publicly available

- Acknowledging the trade-off between transparency and data availability
- Solution → search words in structured data and in documents

Acknowledgement

CTIS data

euclinicaltrials.eu
European Medicines Agency (EMA)

Retrieve data tool

Retrieve and Analyze Clinical Trials in Public Registers_. R, (Herold, 2025)

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