



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CHMP Guideline on registry-based studies - [LINK](#)

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Glossary

- **Patient registry** (in line with US FDA and US Agency for Healthcare Research and Quality)
"Organised system that collects uniform data (clinical and other) to identify specified outcomes for a population defined by a particular disease, condition or exposure. The term 'patient' highlights the focus of the registry on health information. It is broadly defined and may include patients with a certain disease, pregnant or lactating women or individuals presenting with another condition such as a birth defect or a molecular or genomic feature."
- **Registry-based study**
"Investigation of a research question using the data collection infrastructure or patient population of one or several patient registries. A registry-based study is a clinical trial or a non interventional study as defined in Article 2 of Regulation (EU) No 536/2014"
- **Registry-based randomised clinical trial**
"Randomised clinical trial embedded in the data collection infrastructure of one or several patient registries"



Methods and processes - *Planning a registry-based study*

Feasibility analysis

- To be performed by the MAA/MAH or research organisation initiating the registry-based study in collaboration with registry holders to facilitate the discussion with regulators and other parties
- Can help answer essential questions on suitability to use the infrastructure of the registry for a specific registry-based study. If any doubts, another study design could be a better choice.
 - ✓ Is the governance model in place appropriate?
 - ✓ Is the registry population appropriately representative?
 - ✓ Are the requirements for additional informed consent feasible?
 - ✓ Is primary data collection feasible, e.g. in terms of collecting and reporting safety data?
 - ✓ Are the collected data sufficient for the purpose of the study ?
 - ✓ Is the time lag for the availability of the data suitable?
 - ✓ Are the data of demonstrated quality?

Methods and processes - *Planning a registry-based study*

Feasibility analysis, including checklist describing the registry, analysis of the availability of the data elements needed for the study and analysis of the capacity to collect any additional ones if needed

Examples of information to be provided

Data on the numbers of registered patients, active patients and patient flows	Potential selection bias due to incl./exclusion criteria
Analysis of the quality and completeness of the available data elements	Potential confounding if some data elements are not available
Any data privacy and governance-related issues	Analytical issues that may arise
Processes in place for AEs/ADRs	Overall evaluation of the suitability of the registry for the specific study

Potential difficulties acknowledged (e.g. burdensome for small registries, need for collaboration with MAA/MAH without contract, quickly outdated) **but added value, e.g.:**

- Time saving (preliminary discussions with registry holders/regulators, feasibility analysis fit in protocol)
- Quality of outputs (choice of the most suitable registry/-ies, limitations of registry-data already known before start and can be adjusted for)



Any questions?

Further information

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