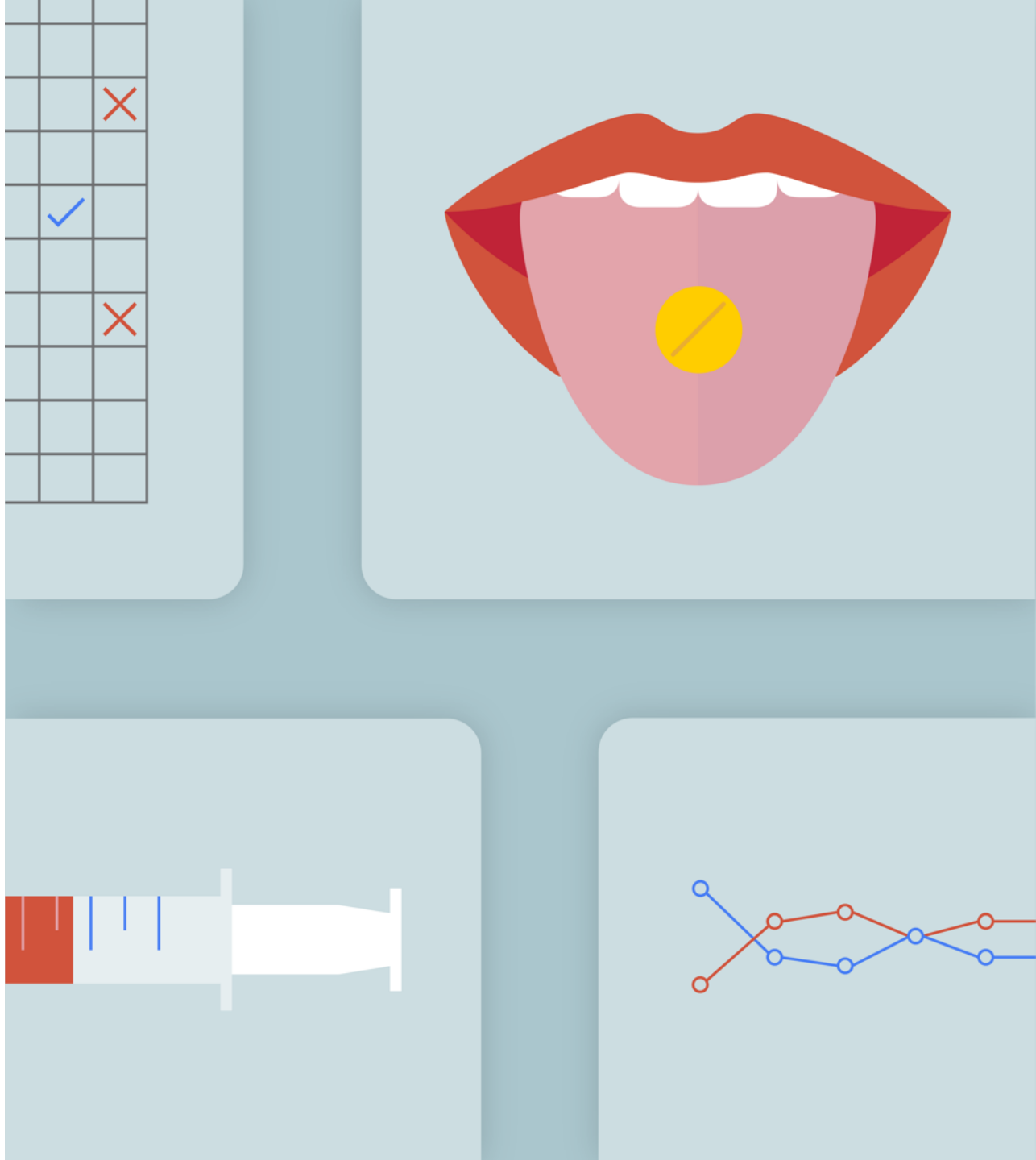
Prof. Helga Gardarsdottir, PharmD, PhD, FISPE

HMA-EMA Catalogues of real-world data sources and studies

The researcher/academic perspective

30 April 2026



Utrecht University

Pharmacoepidemiology
and Clinical Pharmacology

Useful from the perspective of …

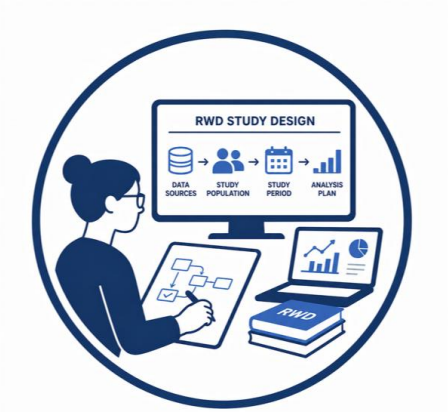
Learning & Education

The individual researcher

Collaborations

Icons generated by ChatGPT

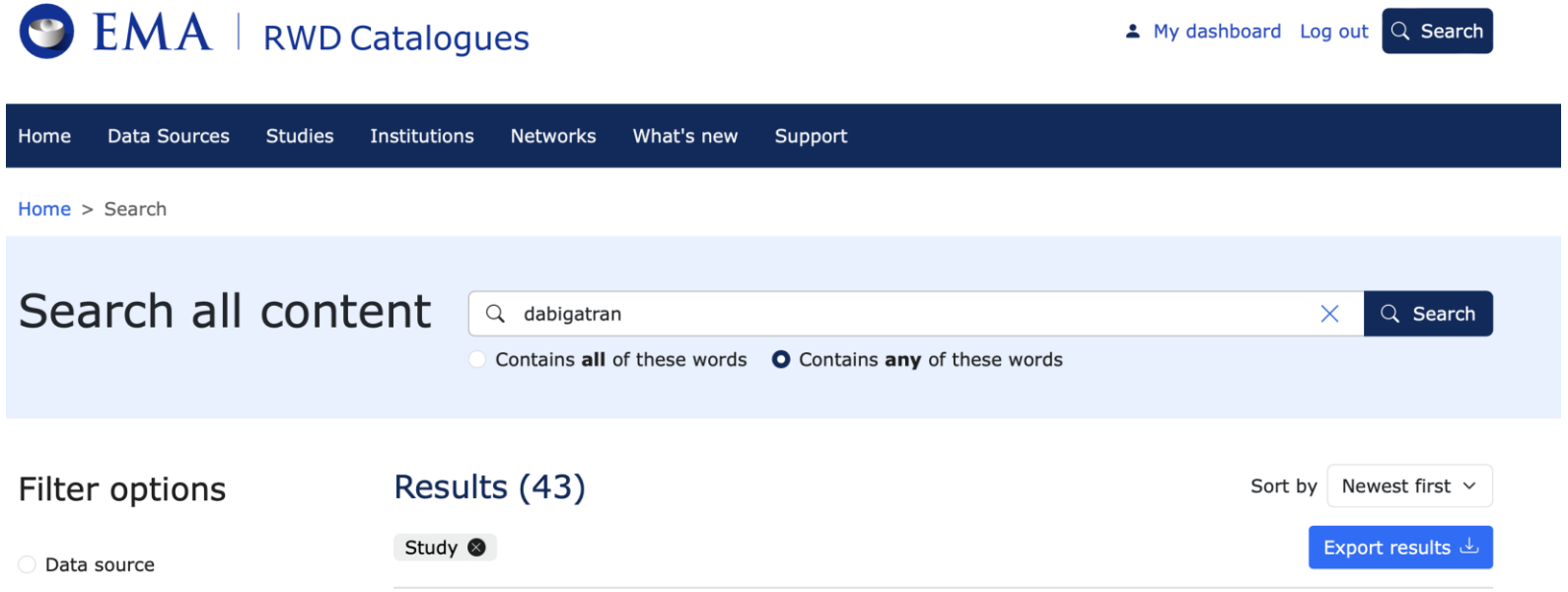
Icons generated by ChatGPT



Potential questions of interest:

- How many and what type of studies have been conducted for the **medicine in question**?
- In what **study population** is the use of the medicine studies?
- What type of **outcomes** are studies for the specific medicine?
- What type of **data sources** are used in these studies?

Icons generated by ChatGPT



Information on other **medicines** included in these studies (apixaban, rivaroxaban, etc)

What **medical condition** does the study involve – e.g. Atrial fibrillation

The **scope** of these studies - e.g., drug utilisation, comparative effectiveness or assessment of risk minimization

The true added value

- Openly accessible protocols (and protocol amendments) which provide detailed protocol level information on specific study design choices
- Can provide more granularity information when compared to methods section of publications that are bound by limited word count
- Help informing decisions on study design, both in general but also when the aim is replication to allow for more valid comparisons between studies where we want to align methodologies at the cross-study level.

An example …

EMA | RWD Catalogues

Log in Search

Home Data Sources Studies Institutions Networks Support

Home
> Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU

First published: 23/11/2016 **Last updated:** 23/05/2024

EU PAS number: EUPAS16014

Study Finalised

Subscribe Download as PDF

Administrative details Methodological aspects Data management

Page content

Study identification

PURI	https://redirect.ema.europa.eu/resource/46296
EU PAS number	EUPAS16014
Study ID	46296
Official title and acronym	Characterising the risk of major bleeding in patients with Non-Valvular Atrial Fibrillation: non-interventional study of patients taking Direct Oral Anticoagulants in the EU
DARWIN EU® study	No
Study countries	Denmark France Germany Netherlands Spain
Study description	This study is using longitudinal data collected in 8 electronic health care databases from six EU countries to characterize the risk of major bleeding in Direct Oral Anticoagulant (DOAC) users in a real-world setting to help

Study timelines

Date when funding contract was signed	Actual: 01/09/2016
Study start date	Actual: 01/01/2008
Date of interim report, if expected	Actual: 12/02/2018
Date of final study report	Actual: 05/10/2018

Study protocol

Initial protocol

20161101_DOAC_bleedingProtocol_Forreview

English (1.03 MB - PDF) View document

Updated protocol

20180601_AMENDED_PROTOCOL_DOAC_bleeding_EUPAS16014_version 3.0

https://catalogues.ema.europa.eu/catalogue-rwd-sources

8 Research question and objectives

The objectives of this proposal are to measure:

Objective 1. The risk of major bleeding, such as gastrointestinal bleeding, intracranial bleeding and haemorrhagic stroke, associated with use of DOACs when compared to other oral anticoagulants (OACs), i.e. vitamin K antagonists (VKAs), in patients with non-valvular atrial fibrillation (NVAF) overall and in relevant clinical and demographical subgroups in a real-life setting. These include patients with chronic kidney disease, with hepatic impairment, the elderly (>=75 years), patients with low or high body weight (<50kg or >100kg) and patients treated with contraindicated or potentially hazardous co-medications as listed in sections 4.3, 4.4, and 4.5 of the SmPC of each product. Risk estimates will be provided for all DOACs as a group, as well as for each DOAC separately and in comparison to VKA.

Detailed description for the handling of drug exposure when using real world data

- How do we consider a patient having switched based on RWD use pattern?
- When do we consider a patient having discontinued use?

8 Research question and objectives

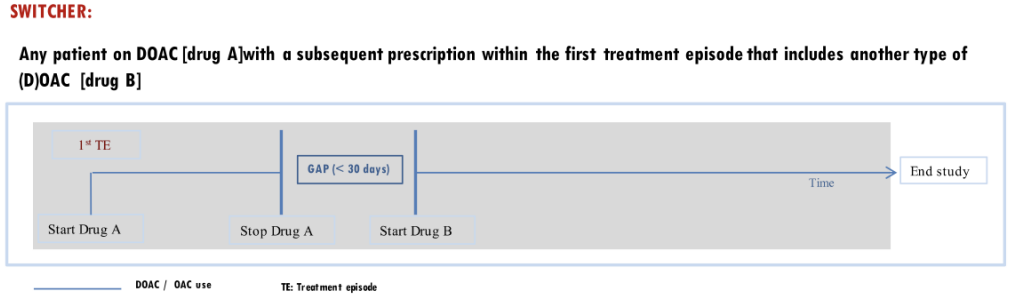
The objectives of this proposal are to measure:

Objective 1. The risk of major bleeding, such as gastrointestinal bleeding, intracranial bleeding and haemorrhagic stroke, associated with use of DOACs when compared to other oral anticoagulants (OACs), i.e. vitamin K antagonists (VKAs), in patients with non-valvular atrial fibrillation (NVAF) overall and in relevant clinical and demographical subgroups in a real-life setting. These include patients with chronic kidney disease, with hepatic impairment, the elderly (>=75 years), patients with low or high body weight (<50kg or >100kg) and patients treated with contraindicated or potentially hazardous co-medications as listed in sections 4.3, 4.4, and 4.5 of the SmPC of each product. Risk estimates will be provided for all DOACs as a group, as well as for each DOAC separately and in comparison to VKA.

Detailed description for the handling of drug exposure when using real world data

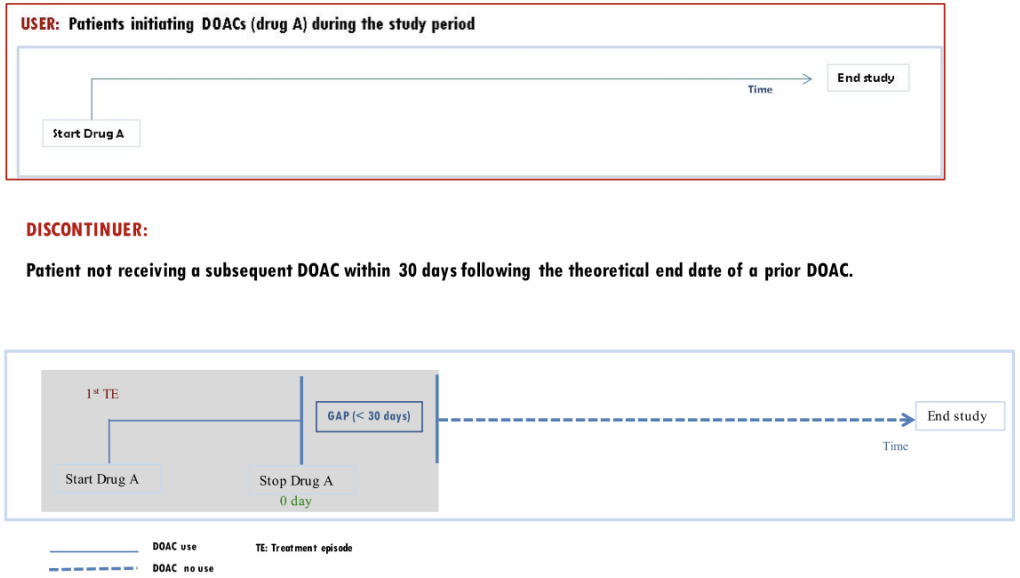
- How do we consider a patient having switched based on RWD use pattern?
- When do we consider a patient having discontinued use?

Figure 9.1. Switching to another antithrombotic agent



c) *Discontinuation*. Patients will be considered to have discontinued therapy if they do not receive a subsequent DOAC within 30 days following the theoretical end date of a prior DOAC.

Figure 9.2. DOAC usage patterns; users, and discontinuers



d) *Treatment duration*, defined as the time on therapy, will be calculated as the number of days on therapy between receiving the initial DOAC and the discontinuation of therapy (see 9.3c Variables, Treatment episodes), or switch of

The HMA EMA Catalogues provide a link between data sources and associated studies

Data sources

Data source(s)	Clinical Practice Research Datalink Danish registries (access/analysis) The Information System for Research in Primary Care (SIDIAP) BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)
Data sources (types)	Administrative healthcare records (e.g., claims) Disease registry Drug dispensing/prescription data Electronic healthcare records (EHR)

- Information on what type of data is included in the data source (e.g., primary care, secondary care, hospitalisations)
- The catalogue does not provide direct access to the data source
- Contact information for the specific data source

Administrative details

Data source ID	21501
Name of data source	BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)
Data source acronym	BIFAP
Data holder	Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency for Medicines and Medical Devices, AEMPS)
Data source type	Hospital discharge records Pharmacy dispensing records Primary care medical records
Main financial support	Funding by own institution
Care setting	Hospital inpatient care Primary care – GP, community pharmacist level Primary care – specialist level (e.g. paediatricians)
Data source website	http://www.bifap.org/index_EN.html

Contact details

Miguel-Angel Macia mmacia@aemps.es

Main

mmacia@aemps.es

Edurne Lazaro elazaro@aemps.es

Alternate

elazaro@aemps.es

When a data source has been identified – what could be the next steps

Make contact to confirm that the database is **suitable** to answer your research question

If deemed suitable, you will also want information regarding:

- The official **application process** for use of data (application forms, assessment by internal review board, timelines and estimated delivery)
- What type of **documentation** is needed for such an application (e.g. protocol, information about applicant and how the work is financed)
- How is the data **delivered/accessed** (can the data leave the country? Or is it accessed and analysed remotely through e.g., virtual desktop infrastructure)
- Are there any **financial aspects** that need to be covered
- Other requirements (e.g., comply with publication procedures)

Useful from the perspective of …

Collaborations

- Many of today's clinical and regulatory questions require broader assessment that goes beyond the single country and/or a single data source
- The catalogues are useful to identify multiple data sources in a single country (outpatient, inpatient, registry) or from multiple countries
- They can be used to identify collaborators based on the needs of the specific research project
- Currently goes beyond including only European studies and data sources

Icons generated by ChatGPT

But also importantly …

The EU's open science policy

Open Science is at the centre of European research policy. Policies, initiatives and structures are developed and implemented to open up European science and research to make them more efficient and productive, seamless, transparent and robust as well as responsive to policy and society needs and expectations.

Highly needed in our field to generate trust in the work we do.

- A central, well-structured infrastructure where researchers can pre-register their studies
- Provides a registration number for use in manuscripts or funding proposals, making them findable
- Currently goes beyond only regulator mandated studies, or European studies

To conclude

The catalogues are a valuable source when designing and understanding Real world data studies that assess effects of medicines

They can be used at the level of educating young researchers, for the individual researcher and also for global

They are a valuable tool that can support us researchers in complying with the current Open Science practices that are needed to support trust in our work

Email: H.Gardarsdottir@uu.nl