

# The SIGMA Consortium: a new era of collaboration to study the safety and effectiveness of medical interventions

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## BACKGROUND

- European research institutions have a proven track record of collaboration, including those that involve federated analyses. In order to further solidify the collaboration, the SIGMA Consortium was launched with the aim to integrate expertise and data from multiple European Research Centres.
- This new collaborative research initiative, designed to be the best 'go-to' organisation for comprehensive and rigorous methodological research, is being launched to enable multi-country studies that use common analyses to study responses to treatments in large populations.
- We hereby provide an overview of the vision, goals, and experience of the SIGMA Consortium—an alliance of research centres of excellence in pharmacoepidemiology in Europe.
- The SIGMA Consortium currently includes 11 institutions from Denmark, France, Germany, Italy, the Netherlands, Spain and the United Kingdom (Figure 1).
- Members of the SIGMA Consortium have extensive collective experience in collaborating in more than 55 multi-country studies. All members are dedicated to excellence in research by adhering to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology and promoting scientific independence and transparency.
- SIGMA members have experience working with a variety of real-world data, including prescription/dispensing, hospital and primary care, laboratory, cancer, and pregnancy data for more than 100 million persons across Europe (Table 1).
- Study funder institutions can contact the SIGMA Office ([info@sigmaconsortium.eu](mailto:info@sigmaconsortium.eu)) for research requests. Each request will be distributed to all SIGMA members with interest and availability to participate in the study in the role(s) of Coordinating Centre, Principal Investigator Centre, and/or Research Site (Figure 2).

## OVERVIEW

- The SIGMA Consortium is formed by several European universities and other leading research institutions with extensive expertise and experience in the conduct of pharmacoepidemiologic real-world evidence research under the principles of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP).

Figure 2. Study request process and formation of study team

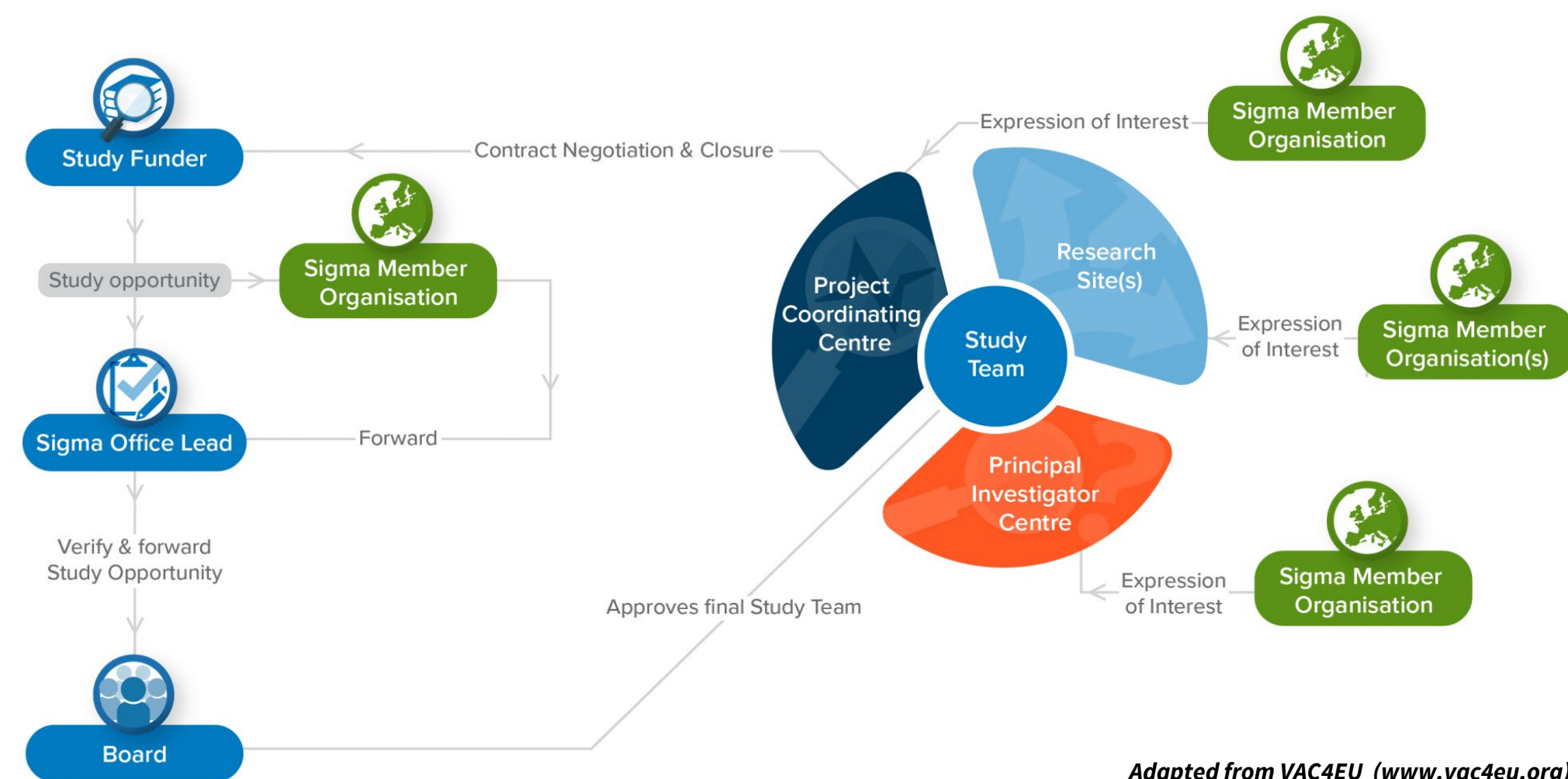


Figure 1. Members of the SIGMA Consortium

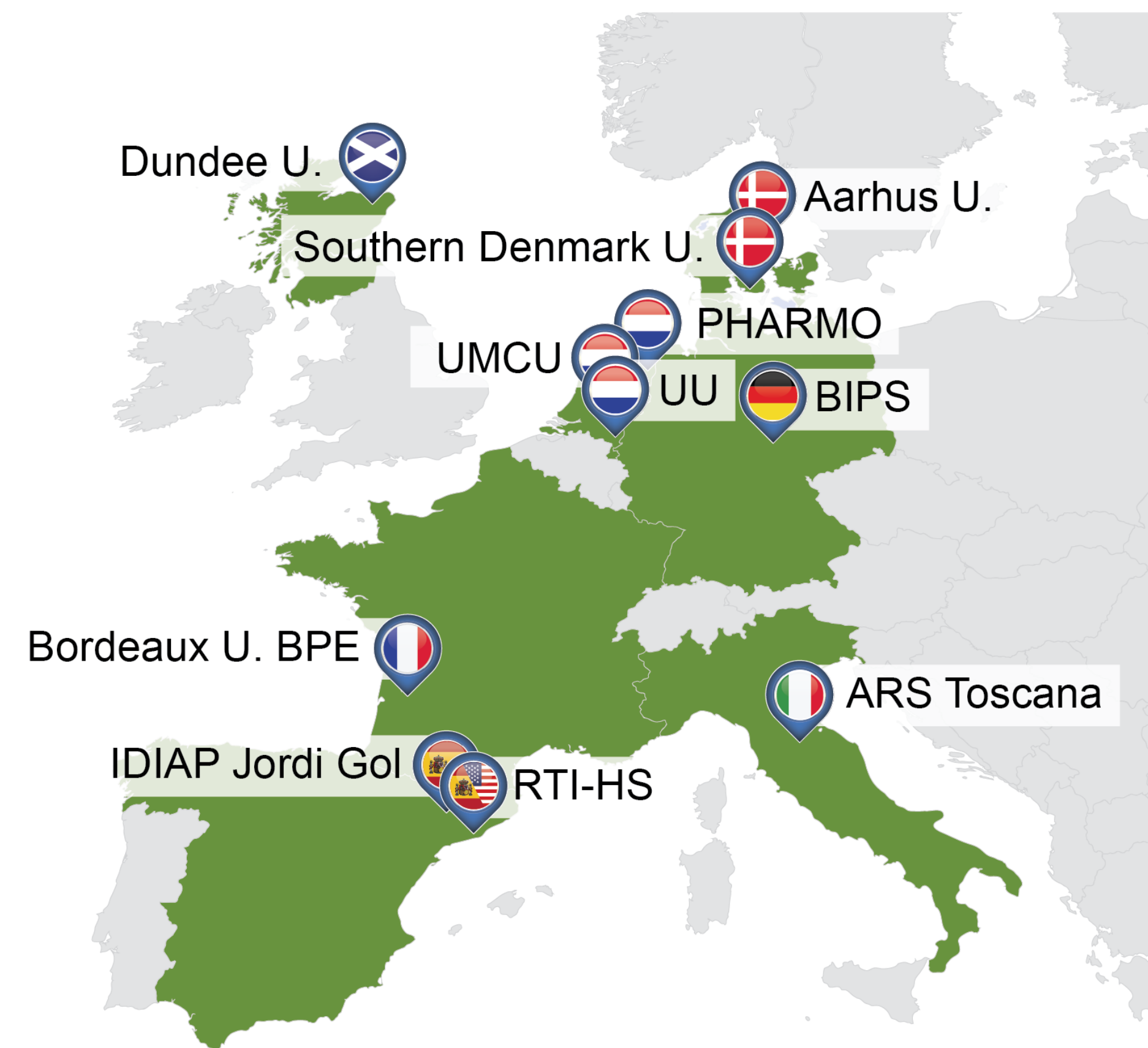


Table 1. Data availability

Name of database <sup>a</sup>	ARS Toscana	Danish Health Registers	GePaRD	SNDS	SIDIAP	PHARMO	PIS
Country	Italy	Denmark	Germany	France	Spain	Netherlands	Scotland
Type of database	Claims	EMR	Claims	Claims	EMR	EMR	EMR
Prescription/dispensing data	✓	✓	✓	✓	✓	✓	✓
Hospital data	✓	✓	✓	✓	✓	✓	✓
Primary care data			✓		✓	✓	
Laboratory data		✓		✓	✓	✓	✓
Cancer data	✓	✓	✓	✓	✓	✓	✓
Pregnancy data	✓	✓	✓	✓	✓	✓	✓
Emergency data	✓	✓	✓	✓		✓	✓

ARS = Agenzia regionale di sanità della Toscana; EMR = electronic medical records; GePaRD = German Pharmacoepidemiological Research Database; SNDS = French National Healthcare System database; SIDIAP = Sistema d'Informació per al Desenvolupament de la Investigació en Atenció Primària; PIS = Prescribing Information System.

## SUMMARY

- The SIGMA Consortium aspires to serve as a trusted hub for the planning, design, analyses, interpretation, and dissemination of European pharmacoepidemiologic, real-world evidence studies, providing a one-stop shop for research services.
- Based on the long-standing collaborative experience of its members, the SIGMA Consortium is a powerful tool to facilitate coordination with its partners and to ensure rational and efficient use of resources.
- SIGMA also constitutes a unique source of extensive shared experiences in the field of advanced pharmacoepidemiology in Europe, which can be easily deployed.
- The SIGMA Consortium's vision is to provide best-quality evidence on the use, benefits, and harms of medications, vaccines, and medical devices for the betterment of public health and patient care.

## CONTACT INFORMATION

Please contact the SIGMA office for study requests or questions at:  
[info@sigmaconsortium.eu](mailto:info@sigmaconsortium.eu)  
 Or visit the website:  
<https://sigmaconsortium.eu/>

SIGMA CONSORTIUM MEMBERS:

