

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

Josephina G. Kuiper<sup>1</sup>, Carla Franzoni<sup>2</sup>, Vera Ehrenstein<sup>3</sup>, Rosa Gini<sup>4</sup>, Ulrike Haug<sup>5</sup>, Nicholas Moore<sup>6</sup>, Cécile Droz-Perroteau<sup>6</sup>, Bonaventura Bolíbar<sup>7,8</sup>, Maria Giner-Soriano<sup>7,8</sup>, Jesper Hallas<sup>9</sup>, Thomas MacDonald<sup>10</sup>, Miriam C. Sturkenboom<sup>11</sup>, Olaf H. Klungel<sup>12</sup>, Susana Perez-Gutthann<sup>2</sup>, Ron M. Herings<sup>1</sup>

<sup>1</sup>PHARMO Institute for Drug Outcomes Research, Utrecht, the Netherlands; <sup>2</sup>RTI Health Solutions, Barcelona, Spain; <sup>3</sup>Aarhus University, Aarhus, Denmark; <sup>4</sup>Agenzia Regionale di Sanità, Florence, Italy; <sup>5</sup>Leibniz-Institut für Präventionsforschung und Epidemiologie, Bremen, Germany; <sup>6</sup>Bordeaux PharmacoEpi, INSERM CIC1401, Université de BORDEAUX, Bordeaux, France; <sup>7</sup>Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain; <sup>8</sup>Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Spain; <sup>9</sup>University of Southern Denmark, Odense, Denmark; <sup>10</sup>University of Dundee, Dundee, Scotland; <sup>11</sup>University Medical Centre Utrecht, Utrecht, the Netherlands; <sup>12</sup>Utrecht University, Utrecht, the Netherlands

## 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.

## 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

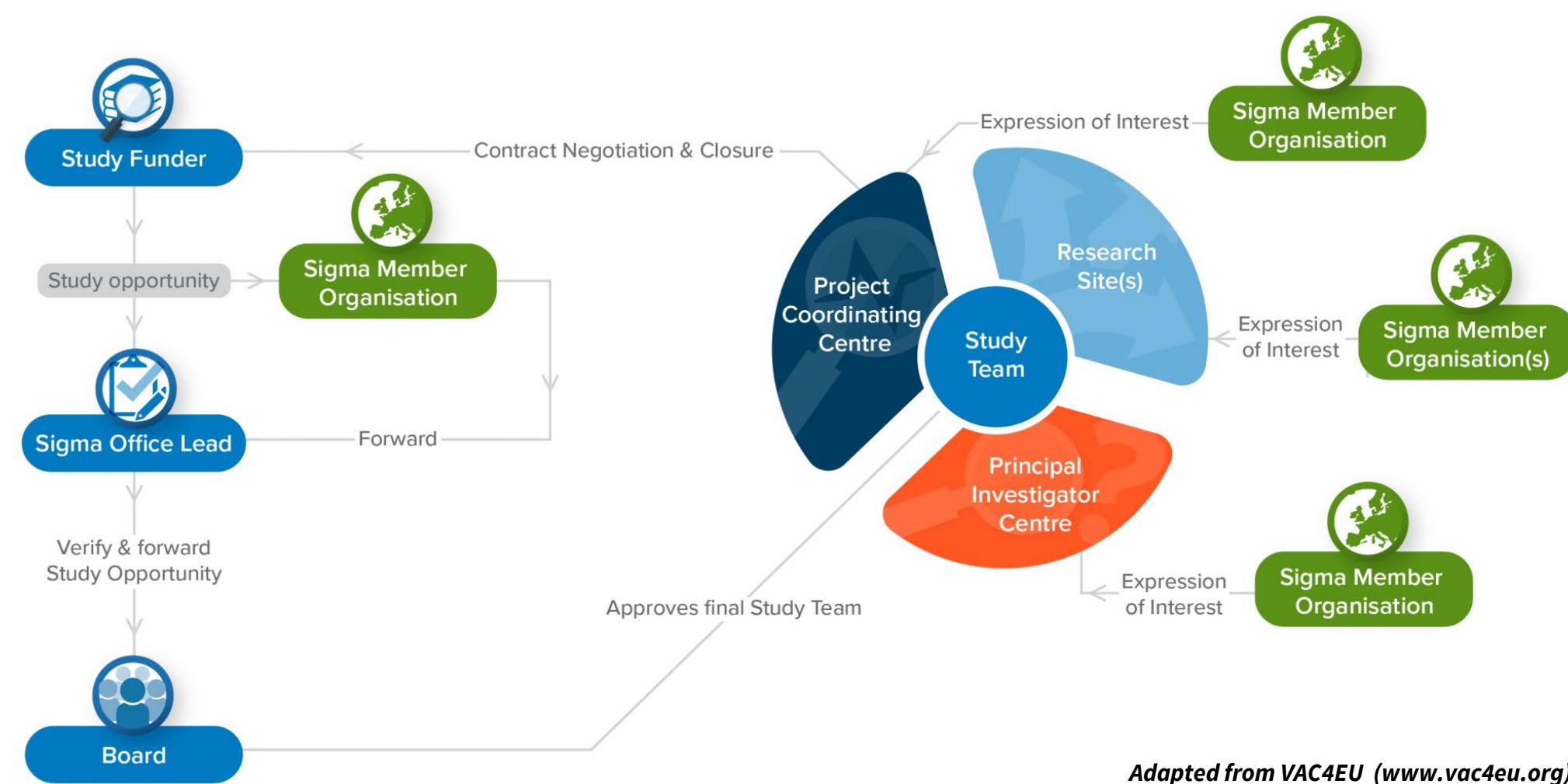


Figure 1. Members of the SIGMA Consortium

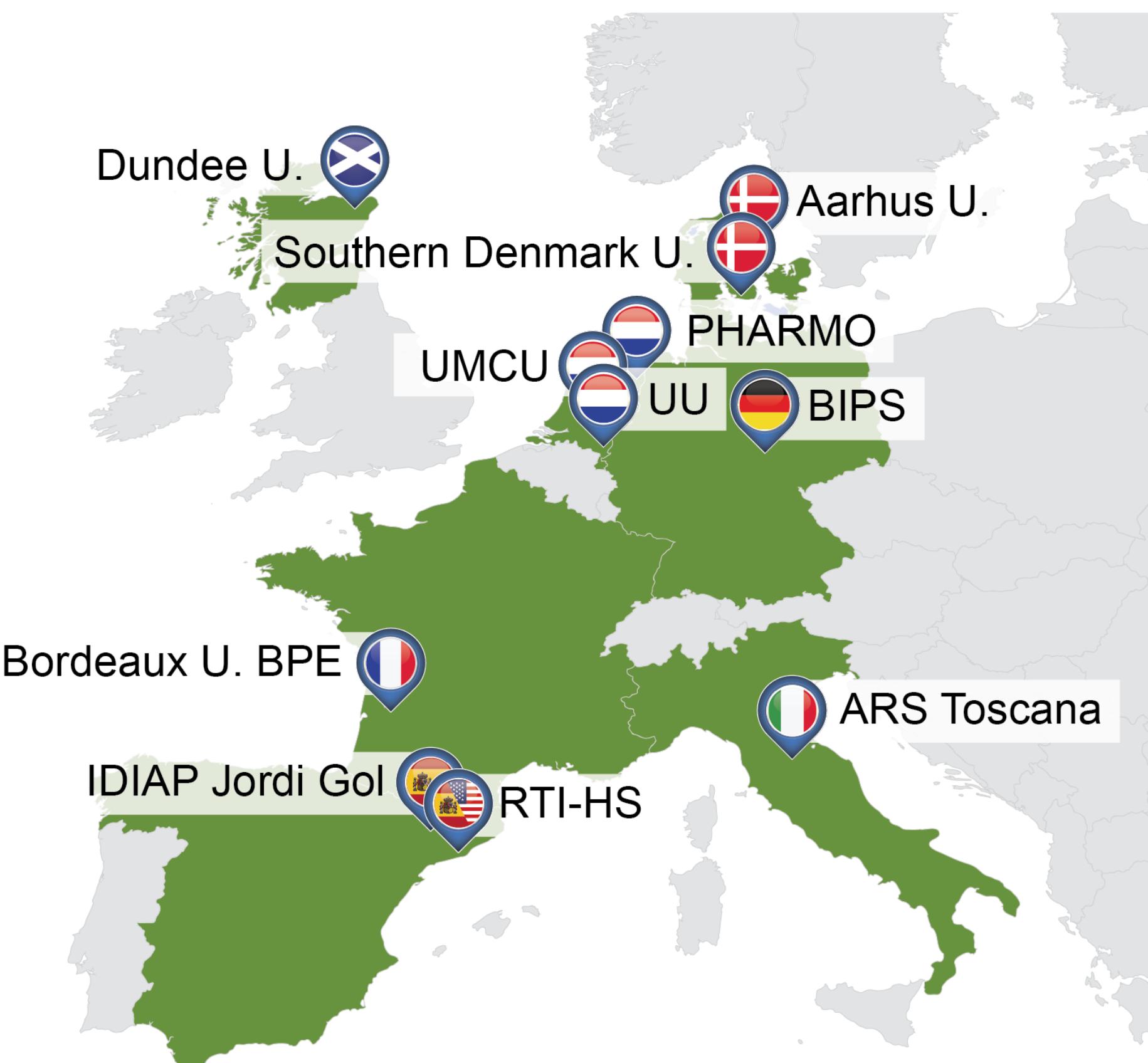


Table 1. Data availability

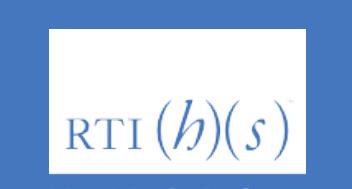
Name of database <sup>a</sup>	ARS Toscana	Danish Health Registers	GePaRD	SNDS	SIDIAP	PHARMO	PIS
Country	Italy	Denmark	Germany	France	Spain	Netherlands	Scotland
Type of database	Claims	EMR	Claims	Claims	EMR	EMR	EMR
Prescription/dispensing data	✓	✓	✓	✓	✓	✓	✓
Hospital data	✓	✓	✓	✓	✓	✓	✓
Primary care data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

## SIGMA CONSORTIUM MEMBERS:



## 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/>