2024 ISPE ANNUAL MEETING

August 24-28

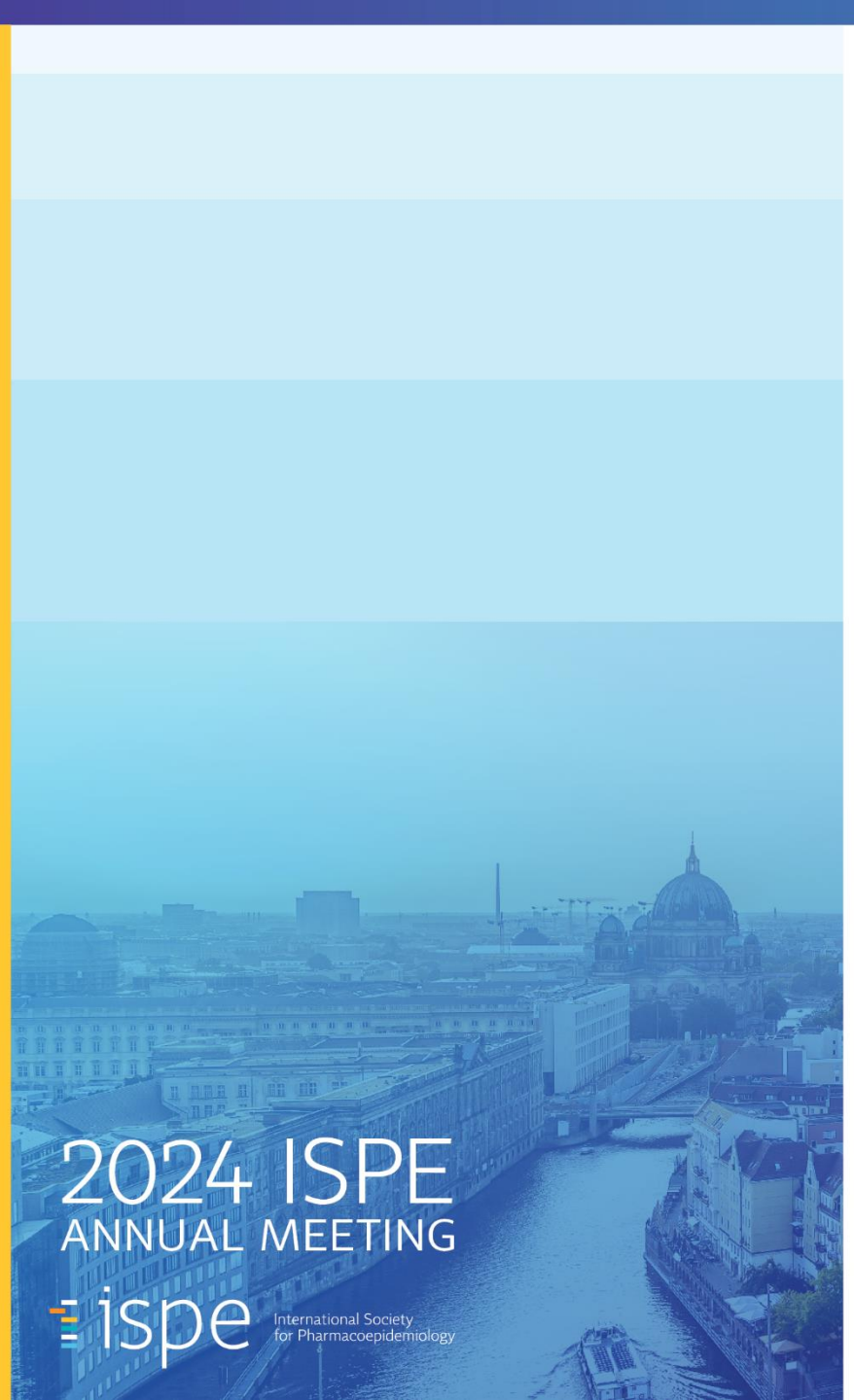
BERLIN, GERMANY

ESTREL CONGRESS CENTER

Celebrating 40 years of
Advancing Pharmacoepidemiology

ispe2024.org

ispe International Society for Pharmacoepidemiology



enepp

European Network of Centres for Pharmacoepidemiology

15+ years of ENCePP What has been achieved, what's next, and what's in for ISPE

Tuesday, August 27, 2024

4:15 PM – 5:45 PM CEST

Conv Hall I C

Todays' panel

K. Arnold Chan

- TriNetX, Cambridge, USA
- ISPE representative on the ENCePP Steering Group

Catherine Cohet

- European Medicines Agency, Amsterdam, NL
- ENCePP Steering Group co-chair

Helga Gardarsdottir

- Utrecht University, NL
- ENCePP Steering Group co-chair

Rosa Gini

- ARS Toscana, Florence, Italy
- Chair of ENCePP WG2 (Independence and transparency)

Gianmario Candore

- Bayer, Berlin, Germany
- Industry representative on the ENCePP Steering Group

Massoud Toussi

- Cytel, France
- ENCePP WG1 (research standards & guidance) and WG3 (databases)

Carla Torre

- U. of Lisbon, Portugal
- Representing EMA's CHMP and MWP on the ENCePP Steering Group

Disclosures

K. Arnold Chan is a full-time employee of TriNetX and has equity of the company

Catherine Cohet has no conflict of interest. The views expressed in this presentation are personal views and may not be understood or quoted as being made on behalf of, or reflecting the position of the European Medicines Agency or one of its committees or working parties

Helga Gardarsdottir has no conflict of interest

Rosa Gini is employed by ARS Toscana, a governmental research agency that conducts/participates in funded studies compliant with the ENCePP Code of Conduct

Gianmario Candore is an employee of Bayer AG. The views and opinions expressed in this presentation are those of the presenter and should not be understood or quoted as being made on behalf of Bayer AG or EFPIA/EUCOPE

Massoud Toussi is a full-time employee of Cytel Inc and has equity of the company. His views and opinions expressed in this presentation shall not be considered as being made on behalf of Cytel Inc.

Carla Torre has no conflict of interest

Where do you come from?

- ❑ Pharma company/SME
- ❑ Regulatory / HTA / Public Health
- ❑ Academia
- ❑ CRO
- ❑ Patient/HCP
- ❑ Other

Where do you come from?

- ❑ Europe
- ❑ Outside of Europe

What is your knowledge of ENCePP?

- Extensive - I'm familiar with the network and the ENCePP tools
- Average - I have a high-level understanding of what is ENCePP and how the network can contribute to my work
- Limited/none

What is ENCePP?

Principles

- Brings together **expertise** and **resources** in pharmacoepidemiology and pharmacovigilance across Europe since 2007
- Coordinated by EMA, with overall aim to **strengthen monitoring** of the benefit/risk of medicinal products, through **facilitating** conduct of high quality, multicentre, independent **non-interventional studies**
- Comprised of research **centres** and **networks**, participation is voluntary

Session Objectives

- To inform on recent ENCePP **updates** and their potential benefits for the ISPE community
- To position the **current work** of ENCePP in a fast-changing and more global environment
- To exchange views with **ISPE** members on future directions for ENCePP

- **Part 1** (40 min): 4 speakers, 10 minutes each

- **Part 2** (40 min): Panel and interactive session

ENCePP throughout the years and where are we going?

Helga Gardarsdottir

Governance

Steering Group

- Defines and safeguards the objectives and principles of ENCePP and decides on operational tasks of the network (work plan)
- Elected representatives from the network and centres, and nominated representatives (EMA, EMA committees/WPs, learned societies, industry trade associations, FDA, Health Canada

Current working groups

- WG1 – Research Standards and Guidance
- WG2 – Independence and Transparency
- WG3 – Data sources and multi-source studies

Ad hoc **Special Interest Groups** (upon need, specific research or methods topics)

ENCePP Steering Group (27 members in total)

- Up to 10 elected from the ENCePP network
- 3 representatives from EMA
- 11 appointed
  - Heads of Medicines Agencies (HMA)
  - Committee for Medicinal Products for Human Use (CHMP)
  - Committee for Orphan Medicinal Products (COMP)
  - Pharmacovigilance Risk Assessment Committee (PRAC)
  - CHMP's Patient and Consumers Working Party (PCWP)
  - Methodological working party (MWP)
  - Representative from an HTA body
  - International Society of Pharmacoepidemiology (ISPE)
  - International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
  - International Society of Pharmacovigilance (ISoP)
  - Representative from industry
- Other regulatory bodies
  - Food and Drug Administration (FDA)
  - Health Canada

European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 13 May 2009
Doc. Ref. EMEA/233267/2009

ENCePP Work Plan 2009
(European Network for Centres of Pharmacoepidemiology and Pharmacovigilance)

I. MAIN GOAL AND OBJECTIVES

The aim is to have in place by the end of the year an **operational network system** that would allow the conduct of **"ENCePP studies"**[1]

Specifically, the main objectives for 2009 are to take the necessary steps and further develop the core aspects of ENCePP to achieve the goal for 2009 as specified above:

Essential deliverables for a functional ENCePP network

- a Checklist of operational research standards covering the core elements and methodological aspects in Pharmacoepidemiology and Pharmacovigilance research
- the Code of Conduct (CoC) setting out rules and requirements for investigators and sponsors/funders when planning/conducting/reporting ENCePP studies in order to achieve a maximum level of transparency and scientific independence in the research process
- establish a Database and start populating it with (i) data sources that can be used for Pharmacoepidemiology and Pharmacovigilance research and (ii) research centres participating in ENCePP. The Inventories shall be made publicly available to facilitate access for possible sponsors/funders of Pharmacoepidemiology and Pharmacovigilance research
- create a Database that can be populated with post-authorisation studies
- agree the mandate, tenure, etc to enable the appointment of the ENCePP Steering Group (to replace the interim governance body ENCIAG)

The first workplan in 2009

- (Methodological) Standards & study checklist
- Establish a Code of conduct to facilitate transparency & scientific independence
- Database of:
  - Data sources
  - Research centres
- Database of post-authorisation studies
- Governance

Ten years later...


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ten years of ENCePP. Time to celebrate and move forward

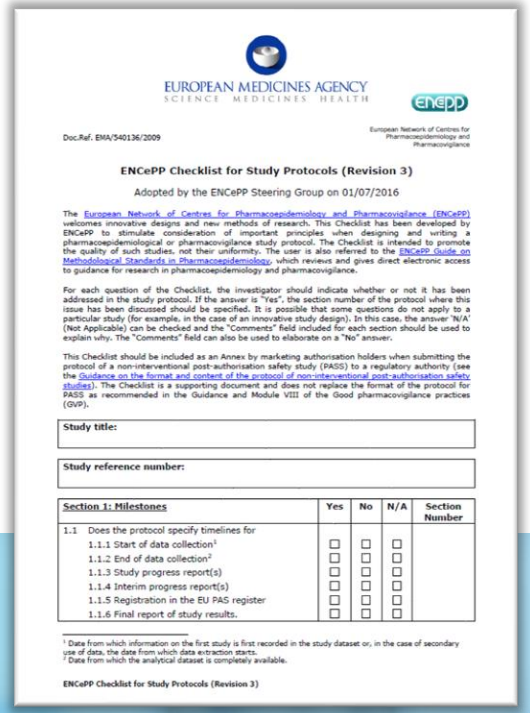
Introduction

ICPE Prague, 25 August, 2018

Presented by Xavier Kurz, EMA, co-Chair of ENCePP Steering Group
& Susana Perez-Gutthann, FISPE, RTI-HS, Member of ENCePP Steering Group and Deputy Chair 2012-2016

An agency of the European Union

- (Methodological) Standards
  - 7th revision, >4000 views
- Database of:
  - Data sources → 127
  - Research centres & Networks → 172
- Database of post-authorisation studies → 1333
- Checklist of study protocols & Code of conduct


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Doc.Ref. EMA/540136/2009

ENCePP Checklist for Study Protocols (Revision 3)

Adopted by the ENCePP Steering Group on 01/07/2016

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) welcomes innovative designs and new methods of research. This Checklist has been developed by ENCePP to stimulate consideration of important principles when designing and writing a pharmacoepidemiological or pharmacovigilance study protocol. The Checklist is intended to promote the quality of such studies, not their uniformity. The user is also referred to the ENCePP Guide on Methodological Standards in Pharmacoepidemiology, which reviews and gives direct electronic access to guidance for research in pharmacoepidemiology and pharmacovigilance.

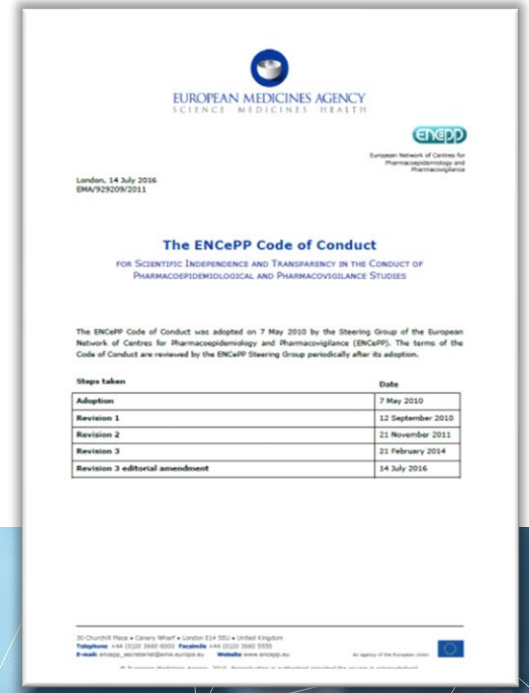
For each question of the Checklist, the investigator should indicate whether or not it has been addressed in the study protocol. If the answer is 'Yes', the section number of the protocol where this issue has been discussed should be specified. It is possible that some questions do not apply to a particular study (for example, in the case of an innovative study design). In this case, the answer 'N/A' (Not Applicable) can be checked and the "Comments" field included for each section should be used to explain why. The "Comments" field can also be used to elaborate on a "No" answer.

This Checklist should be included as an Annex by marketing authorisation holders when submitting the protocol of a non-interventional post-authorisation safety study (PASS) to a regulatory authority (see the Guidance on the format and content of the protocol of non-interventional post-authorisation safety studies). The Checklist is a supporting document and does not replace the format of the protocol for PASS as recommended in the Guidance and Module VIII of the Good pharmacovigilance practices (GVP).

Study title:
Study reference number:

Section 1: Milestones	Yes	No	N/A	Section Number
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection[1]	☐	☐	☐	
1.1.2 End of data collection[2]	☐	☐	☐	
1.1.3 Study progress report(s)	☐	☐	☐	
1.1.4 Interim progress report(s)	☐	☐	☐	
1.1.5 Registration in the EU PAS register	☐	☐	☐	
1.1.6 Final report of study results.	☐	☐	☐	

[1] Date from which information on the first study is first recorded in the study dataset or, in the case of secondary use of data, the date from which data extraction starts.
[2] Date from which the analytical dataset is completely available.


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

London, 14 July 2016
EMA/929209/2011

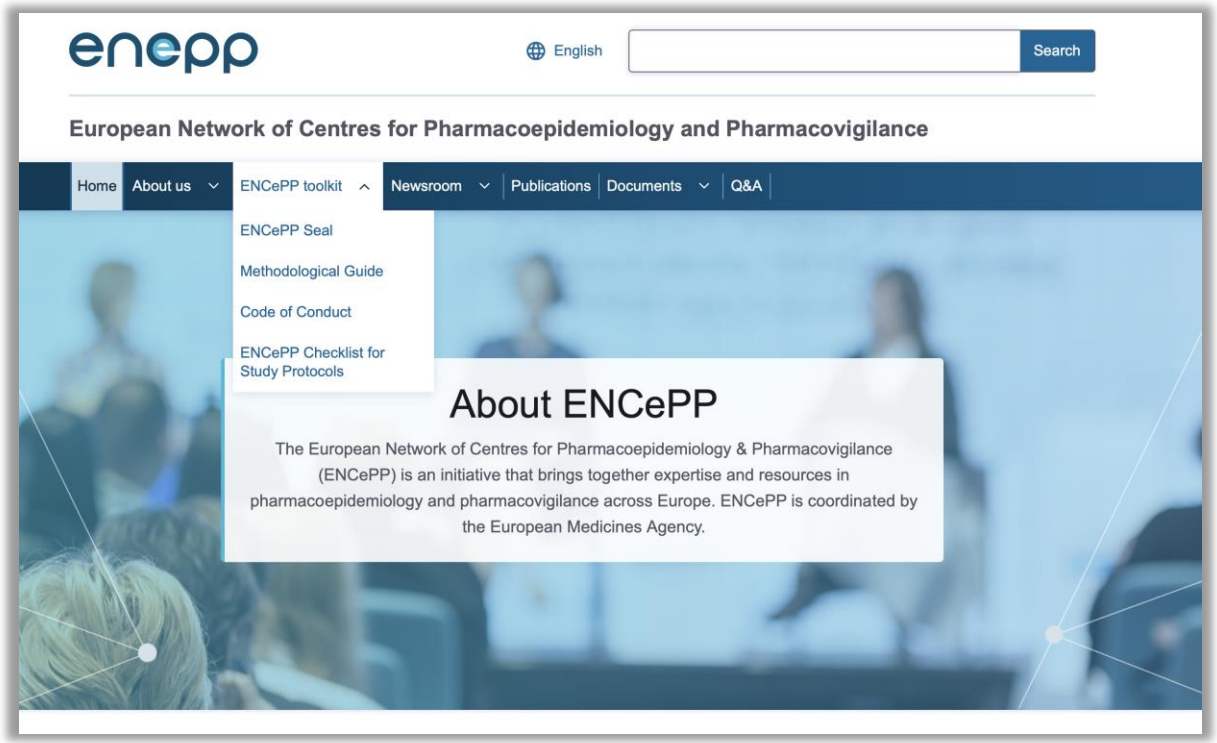
The ENCePP Code of Conduct

FOR SCIENTIFIC INDEPENDENCE AND TRANSPARENCY IN THE CONDUCT OF PHARMACOEPIDEMIOLOGICAL AND PHARMACOVIGILANCE STUDIES

The ENCePP Code of Conduct was adopted on 7 May 2010 by the Steering Group of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The terms of the Code of Conduct are reviewed by the ENCePP Steering Group periodically after its adoption.

Steps taken	Date
Adoption	7 May 2010
Revision 1	12 September 2010
Revision 2	21 November 2011
Revision 3	21 February 2014
Revision 3 editorial amendment	14 July 2016

Today



- (Methodological) Standards
  - 11th revision, >9500 views (since 15 Feb)
- Database of:
  - Data sources → 227
  - Research centres & Networks → 205
- Database of post-authorisation studies → 2899
- Checklist of study protocols & Code of conduct

- Launch Q1 2024 of a new URL: https://encepp.europa.eu
- Catalogues (database) migrated to the EMA website

HMA-EMA Catalogues of RWD sources and studies

ENCePP Resources Database

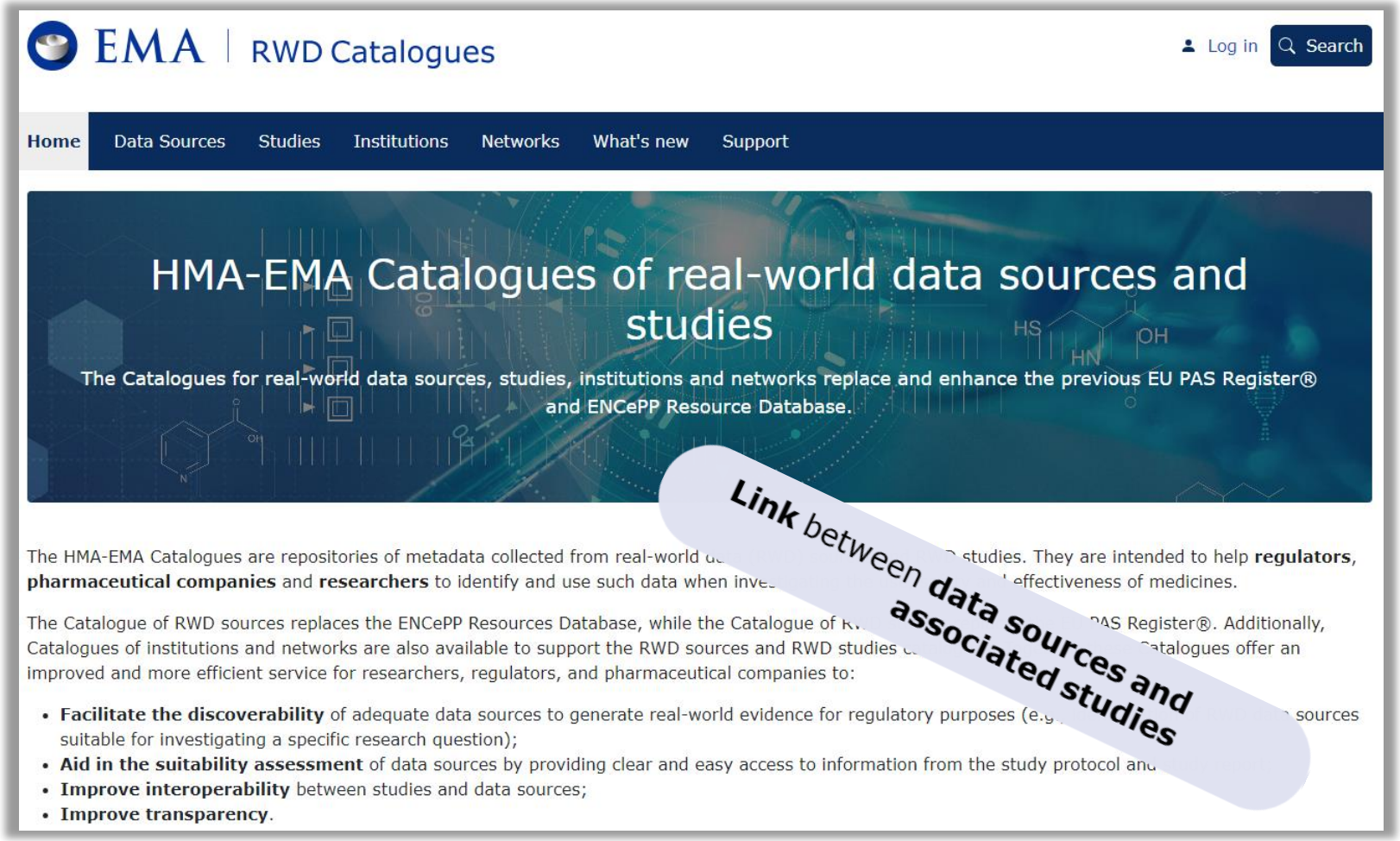
↓

Catalogue of real-world data sources

EU PAS Register

↓

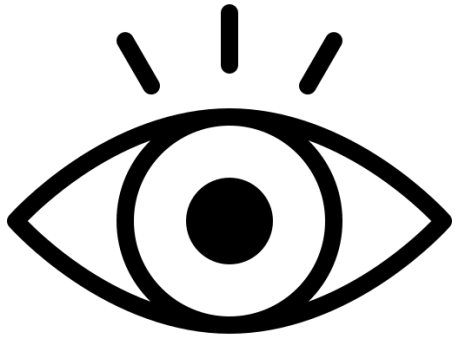
Catalogue of real-world data studies



ENCePP Workplan 2024-2026

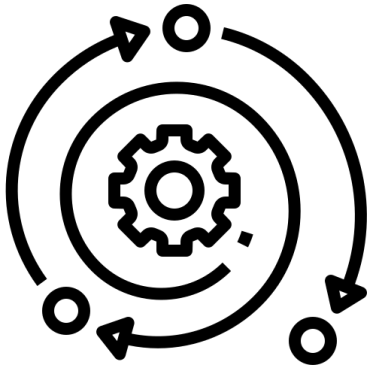
Governance

* Terms of reference for working groups and SIGs
* Review of mandates



Visibility

* ENCePP website
* Podcasts
* Social media
* Publication(s)



Impact

* Assess needs (w/ Utrecht Uni)
* Collaboration w/ learned Societies
* Update/reinforce ENCePP Tools
* Partner w/Public bodies in EU candidate countries

https://encepp.europa.eu/documents/work-plans

www.flaticon.com/free-icons
Governance icons created by Ida Desi Mariana
Eye icons created by Freepik
Impact icons created by noomtah

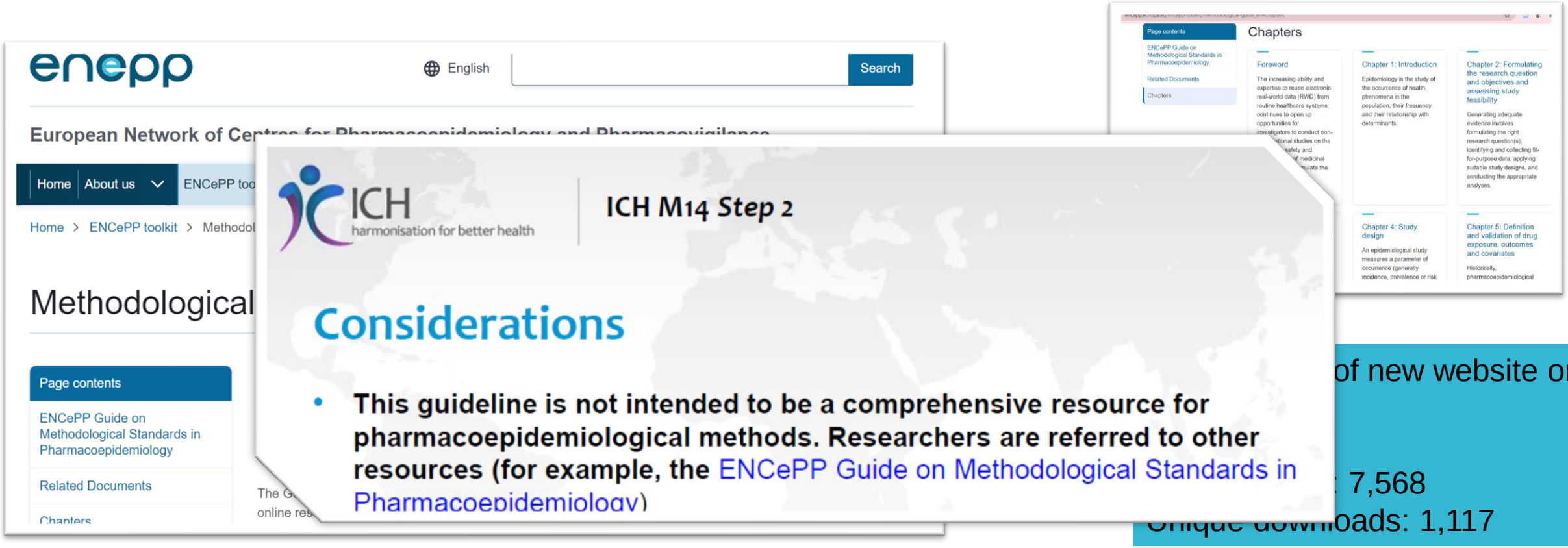
The role of the ENCePP working groups

Rosa Gini

Working Groups

- Carry on the Work plan
- Active members, on voluntary basis
- Historical groups
  - Methods: Methodological Guide (chair: Alejandro Arana)
  - Transparency and Independence: Code of Conduct, Catalogue of studies (chair: Rosa Gini)
  - (Multidatabase) studies: analysis of studies (chair: Gianluca Trifirò)

Methodological Guide



of new website on

7,568

Unique downloads: 1,117

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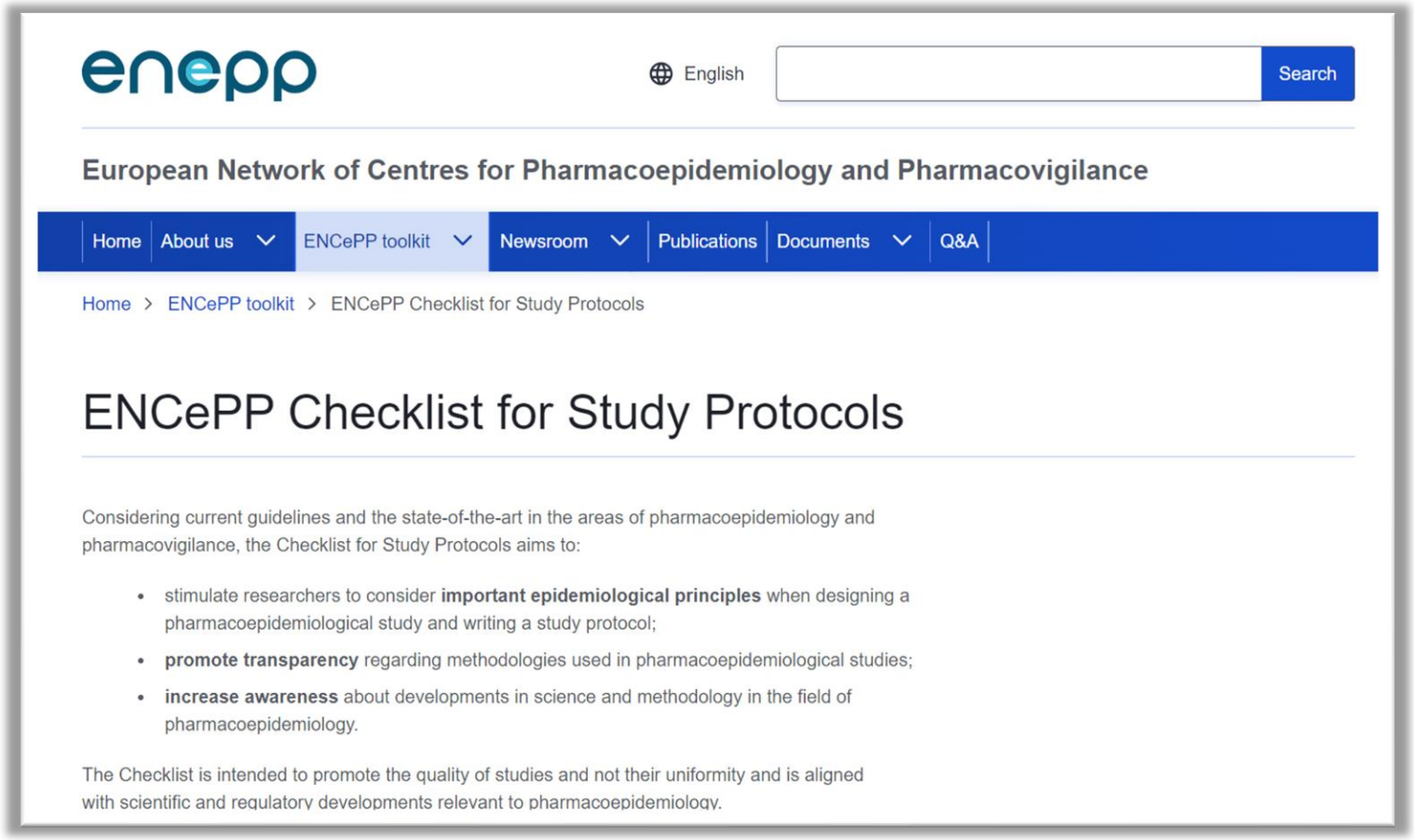
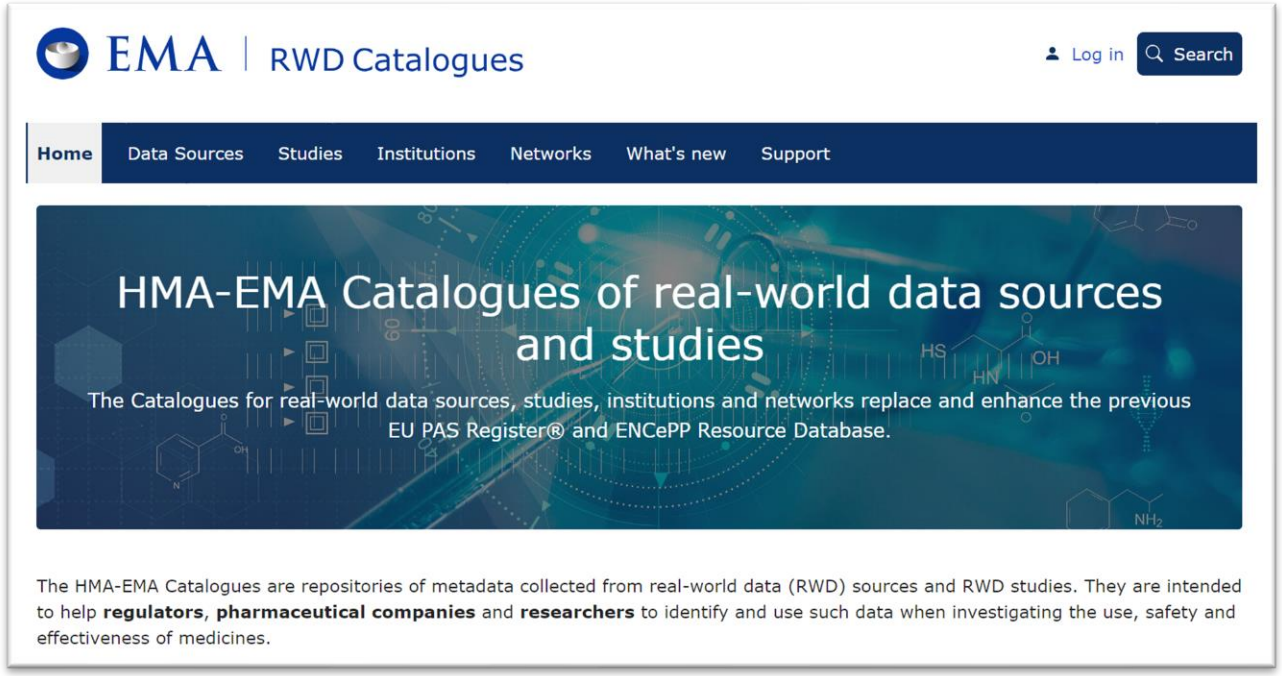
Methodological guide continuously reflects the status of the scientific debate in ISPE

ENCePP Checklist for study protocols



Incorporated in HARPER

The pathway to the HMA-EMA Catalogues



Now a key asset of HMA-EMA, was born from ENCePP e-Register and Resource Database

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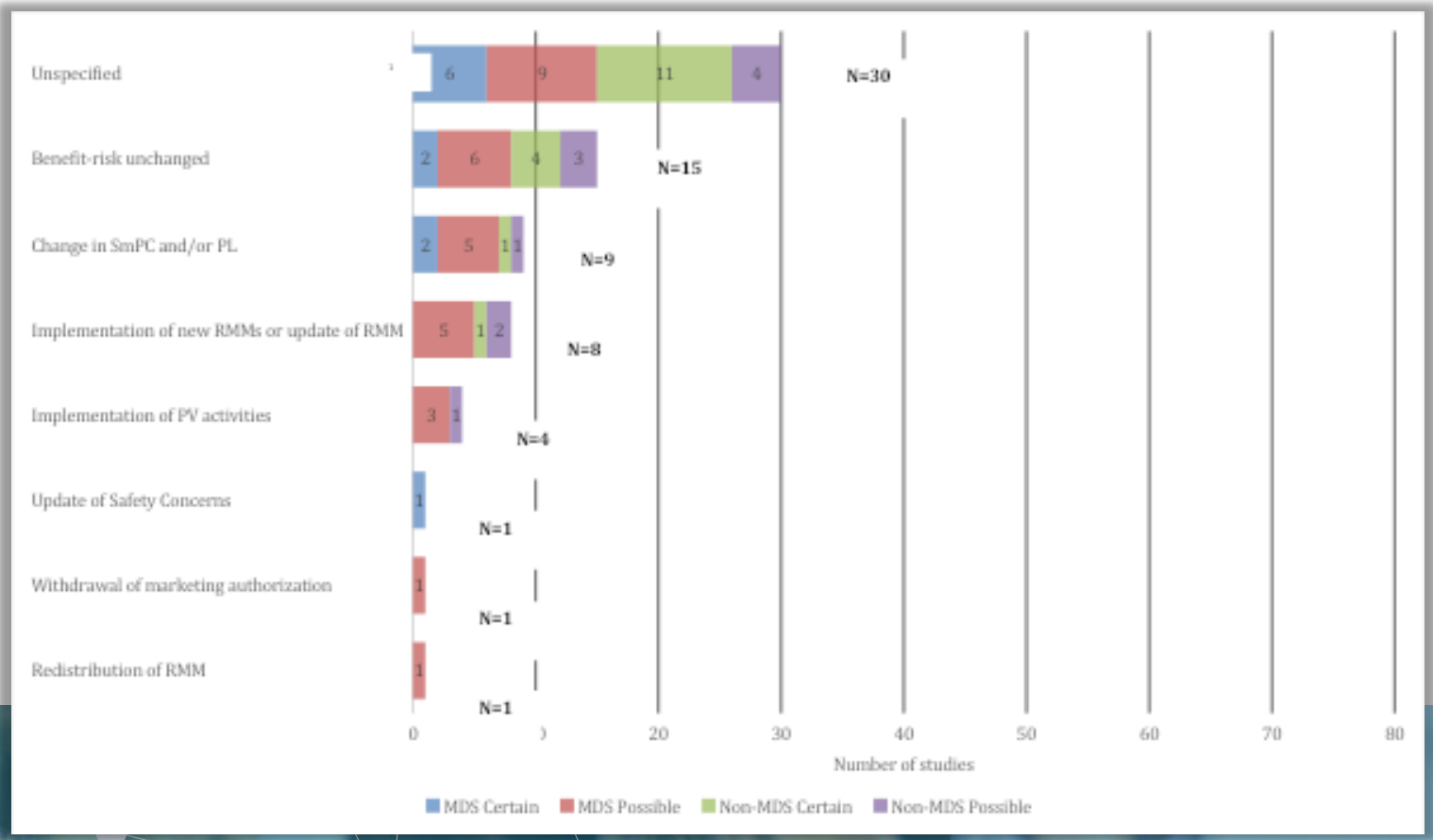
Non-European Real World data sources and studies can be registered

Understanding registered studies (1)

Almas M, Girardi A, Crisafulli S, Gvozdanovic K, Hakkarainen KM, Hyeraci G, Hoogendoorn WE, Rillmann B, Roberto G, Vitturi G, Trifirò G. *Regulatory Outcomes of non-interventional PASS.* Manuscript in preparation

Regulatory outcome types following submission of PASS report (categories are not mutually exclusive) among 39 PASS with regulatory outcomes



Before the HMA-EMA Catalogues introduced persistent identifiers, the was not a unique identifier of studies to allow follow up in minutes of regulatory committee meetings

When studies could be tracked, the regulatory decision was often '*unspecified*'

Most common outcome: benefit/risk unchanged, change in leaflet, new risk minimization maesures

Understanding registered studies (2)

Poulentzas G, Lalagkas PN, Toussi M, Landi A, Gardarsdottir H, Wei L, Barone-Adesi F, Ucciero A, Crisafulli S, Trifirò G, Kontogiorgis. *Use of secondary data in observational studies and its relationship with economic development of the countries: a study based on the analysis of EU PAS Register.* Manuscript submitted for publication

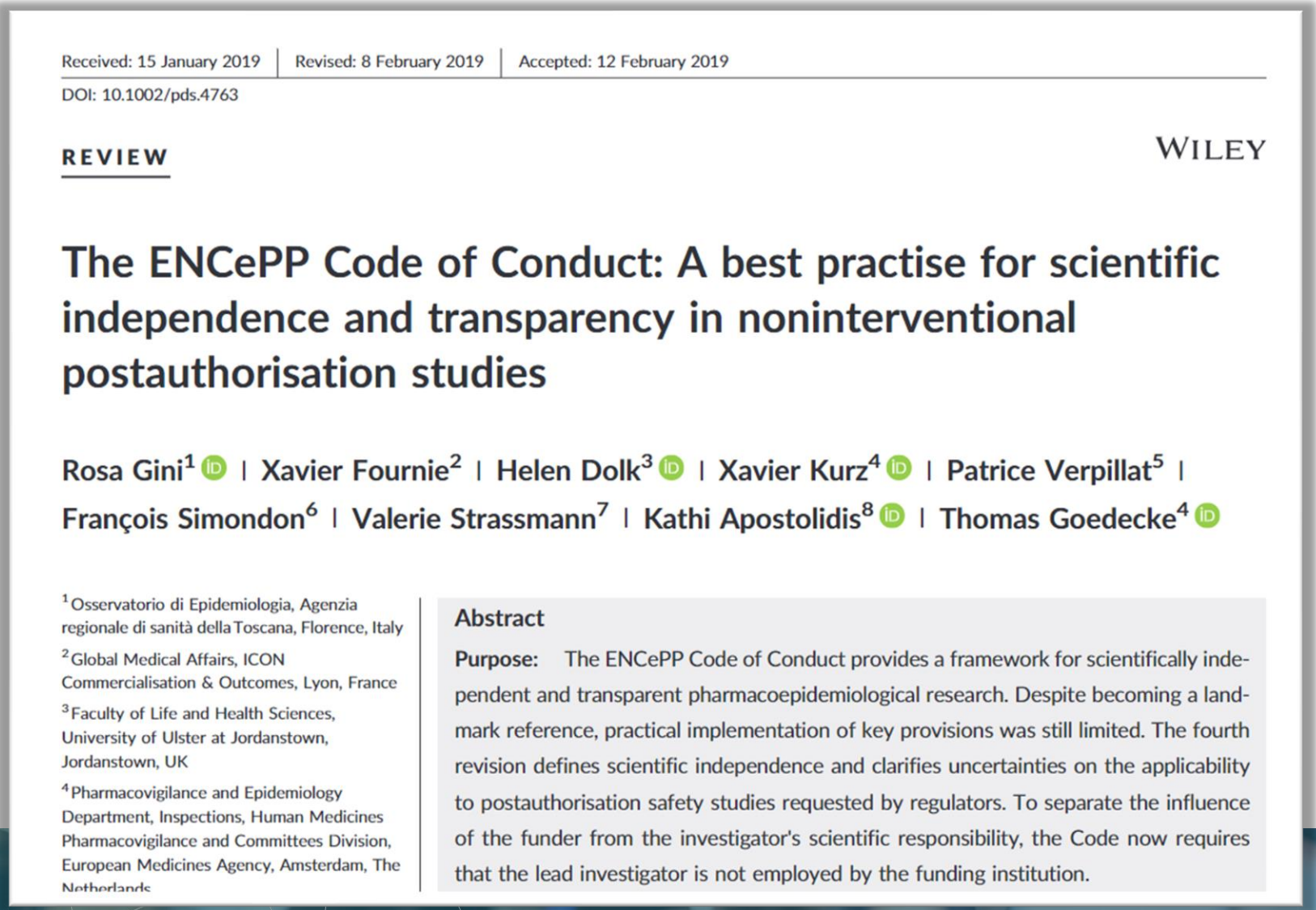
	Number of studies
Studies using secondary data, n	698
Source of secondary data, n (%)	
US & Canada	154 (22.1)
From 1 European country	317 (45.4)
From >1 European countries	185 (26.5)
From both US & Canada and European countries	42 (6.0)
Scope, n (%)	
Risk assessment	373 (53.4)
Drug utilization	268 (38.4)
Effectiveness evaluation	153 (21.9)
Disease epidemiology	118 (16.9)

Country	Index number	Country	Index number	Country	Index number
U.S.A.	0.79	Croatia (EU member)	0.57	Belgium	0.50
Finland	0.73	Italy	0.56	Switzerland	0.49
United Kingdom	0.73	Ireland	0.55	Romania	0.48
Denmark	0.67	Bulgaria	0.55	Slovakia	0.47
Estonia	0.65	Lithuania	0.54	Portugal	0.47
Sweden	0.64	Germany	0.53	Poland	0.46
Spain	0.62	Norway	0.53	Greece	0.45
Netherlands	0.60	Slovenia	0.52	Russia	0.44
France	0.58	Turkey	0.50	Hungary	0.42
Canada	0.58	Latvia	0.50	Austria	0.42

$$\text{Index Number} = \frac{\text{Number of studies with secondary or mixed data}}{\text{Number of observational studies}}$$

Many studies entering these analysis are non-European, some conclusions may be generalizable

The ENCePP Code of Conduct



Received: 15 January 2019 | Revised: 8 February 2019 | Accepted: 12 February 2019

DOI: 10.1002/pds.4763

REVIEW

WILEY

The ENCePP Code of Conduct: A best practise for scientific independence and transparency in noninterventional postauthorisation studies

Rosa Gini[1] | Xavier Fournie[2] | Helen Dolk[3] | Xavier Kurz[4] | Patrice Verpillat[5] | François Simondon[6] | Valerie Strassmann[7] | Kathi Apostolidis[8] | Thomas Goedecke[4]

[1] Osservatorio di Epidemiologia, Agenzia regionale di sanità della Toscana, Florence, Italy

[2] Global Medical Affairs, ICON Commercialisation & Outcomes, Lyon, France

[3] Faculty of Life and Health Sciences, University of Ulster at Jordanstown, Jordanstown, UK

[4] Pharmacovigilance and Epidemiology Department, Inspections, Human Medicines Pharmacovigilance and Committees Division, European Medicines Agency, Amsterdam, The Netherlands

Abstract

Purpose: The ENCePP Code of Conduct provides a framework for scientifically independent and transparent pharmacoepidemiological research. Despite becoming a landmark reference, practical implementation of key provisions was still limited. The fourth revision defines scientific independence and clarifies uncertainties on the applicability to postauthorisation safety studies requested by regulators. To separate the influence of the funder from the investigator's scientific responsibility, the Code now requires that the lead investigator is not employed by the funding institution.

A revision is foreseen to

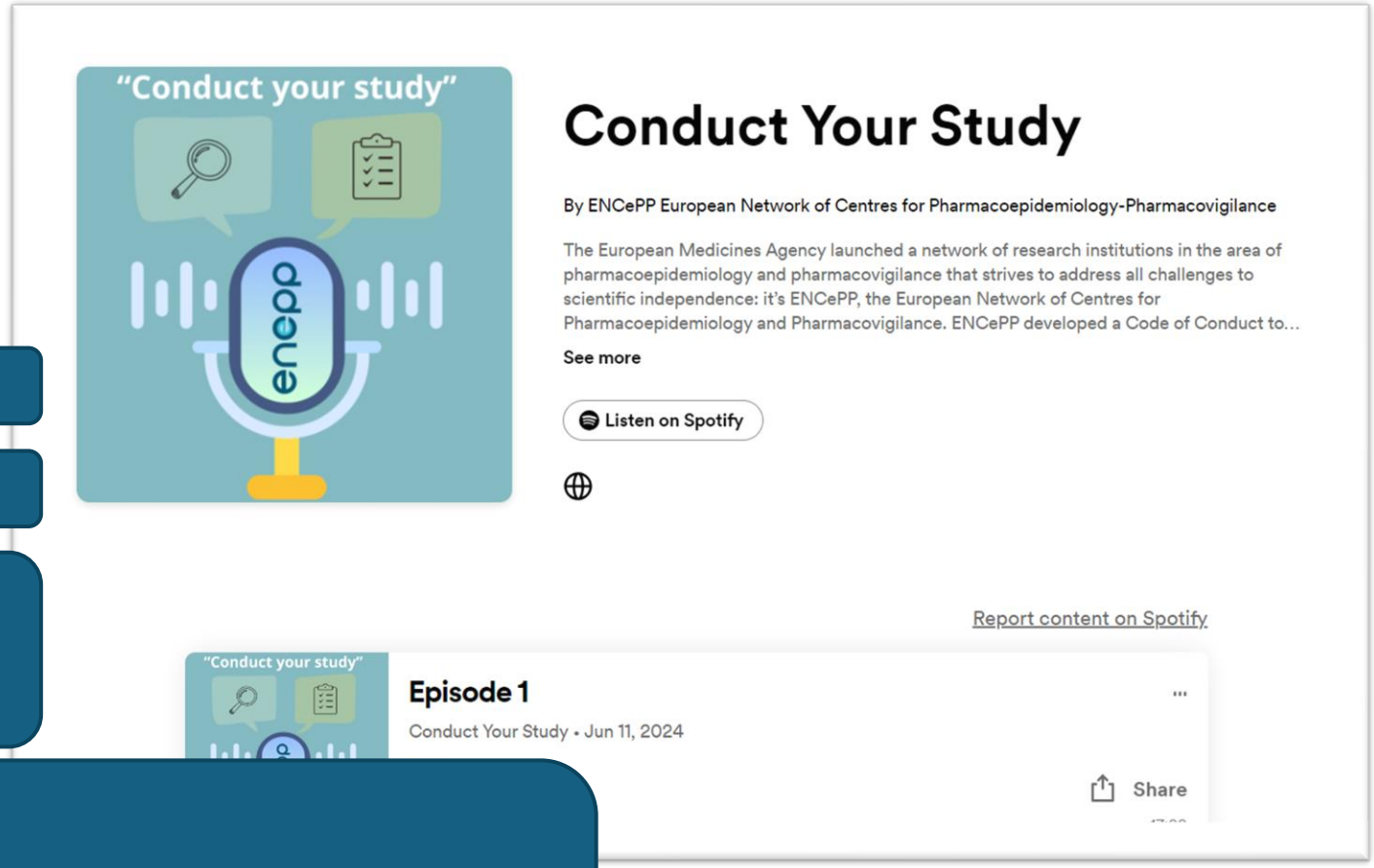
- Replace the EU PAS Register with the new HMA/EMA Catalogue
- Update the Checklist
- Update the transparency measures (e.g., reference to code sharing)

Conduct Your Study: a podcast on the Code of Conduct

Launched in June 2024

First episode: interview to Barbara Mintzes

Upcoming episodes: perspective from investigators, regulators, researchers in pharmaceutical companies…



ispe International Society for Pharmacoepidemiology

Extra-European point of view is incorporated in some episodes

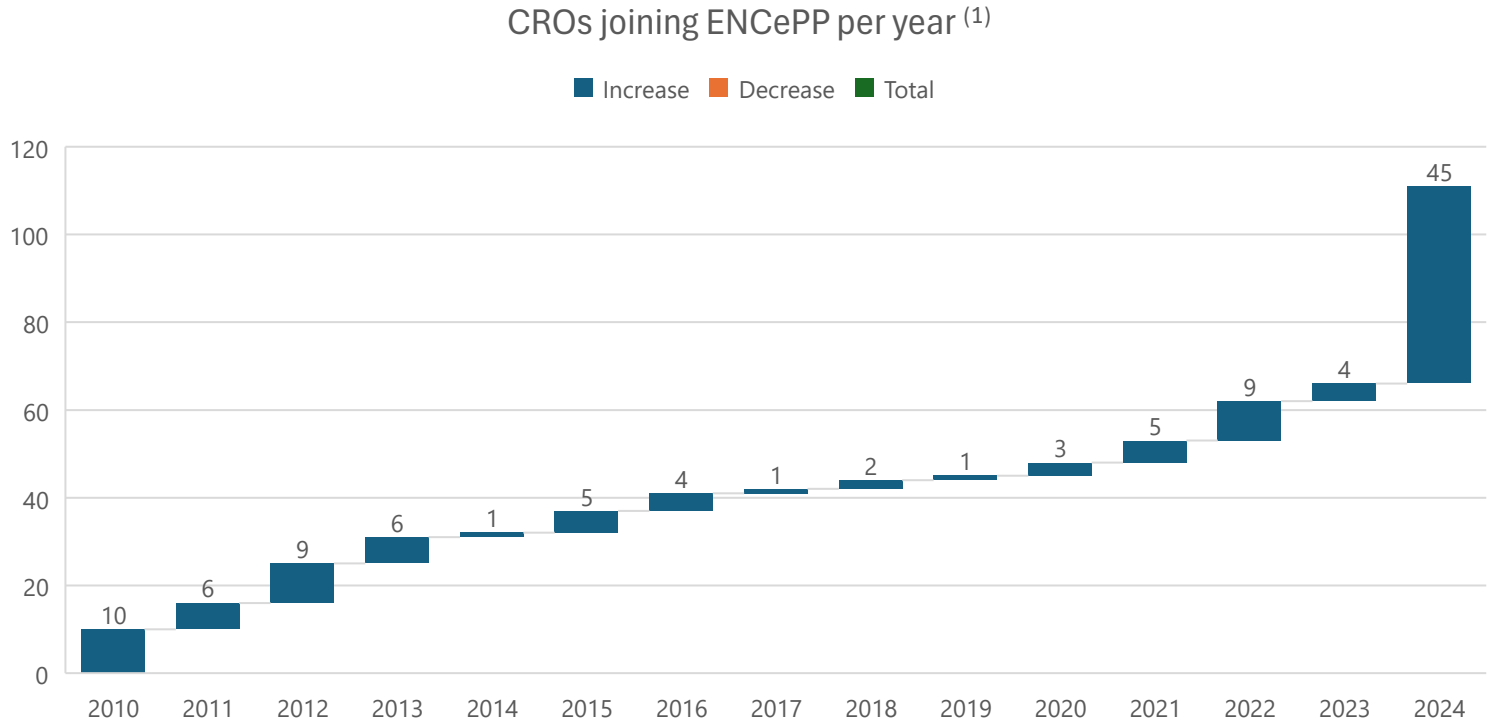
The CRO perspective

Massoud Toussi

CROs membership in ENCePP

CROs have been an integrated part of ENCePP from its beginnings, playing an important role in its mandate and different working groups.

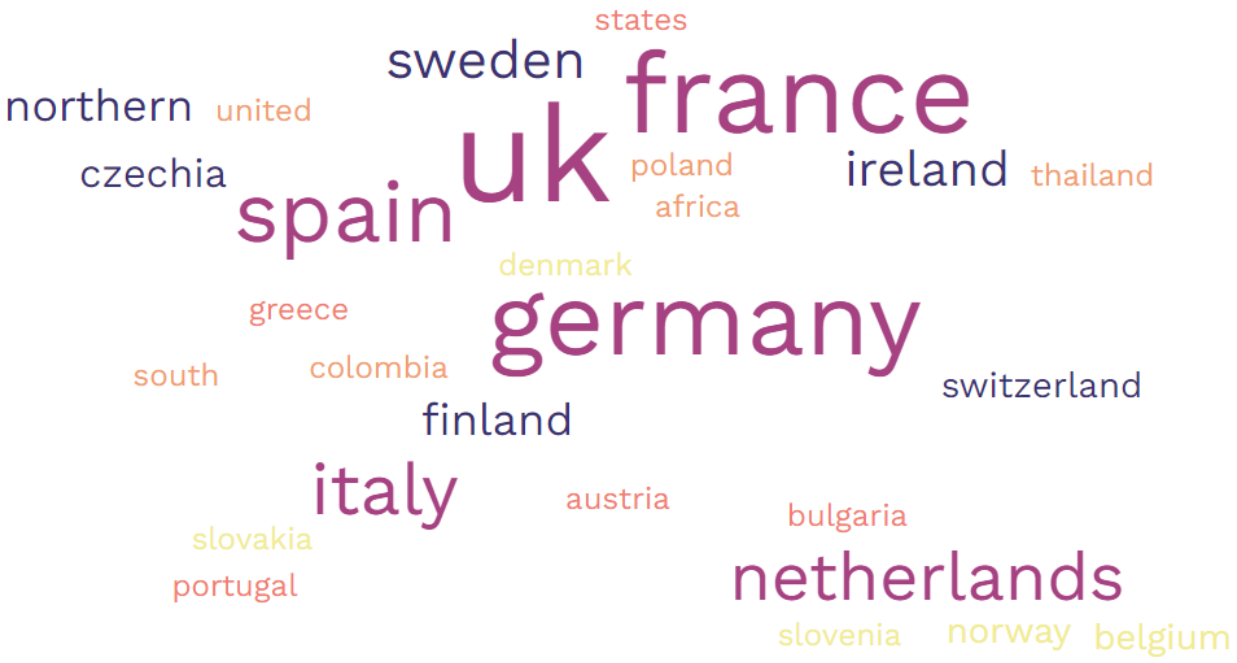
- More than 100 CROs
- Started in 2010 and constantly expanding
- Some CROs represented by more than one affiliate



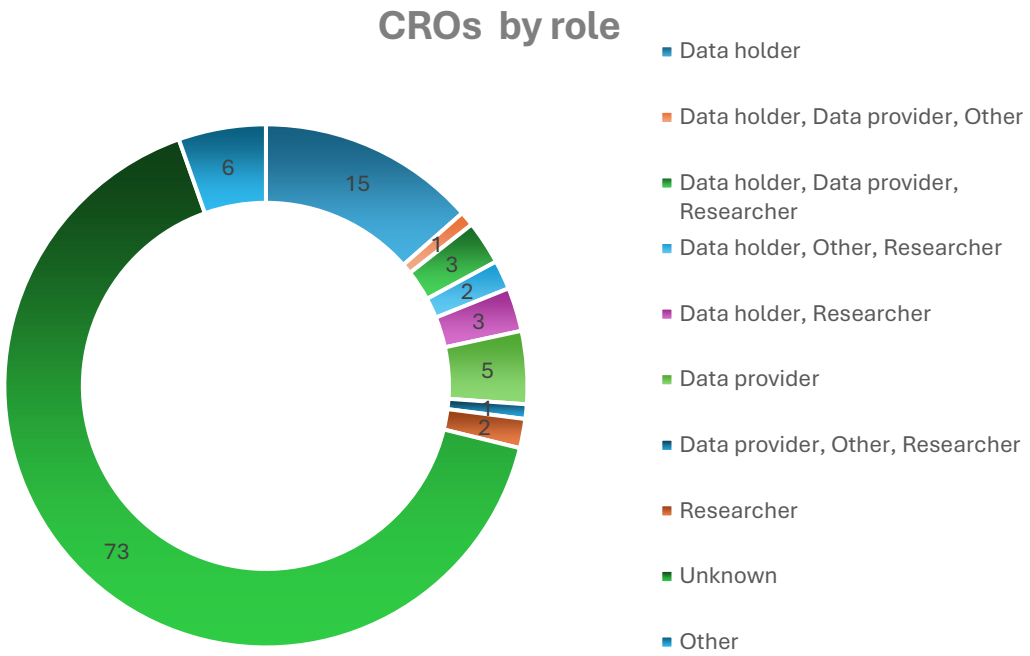
1) The jump in 2024 may be related to the new website release.

Distribution by country and role

CROs from most European countries



A majority of data owners/providers



ENCePP, GVP[1] and PRAC[2]

The triad of ENCePP, GVP and PRAC played a tremendous role in improving the quality of studies conducted by CROs in 2010s. There was a life before, and a life after!

ENCePP (2010)

- ENCePP Toolkit:
- Methodological guide
- ENCePP checklist
- HMA-EMA catalogues (from Feb. 2024)
- Code of Conduct

GVP (2012)

- GVP module VIII
- GVP module XVI
- Protocol template
- Report template
- EU PAS Register

PRAC (2012)

- Critical review of studies
- Encouraging secondary use of data, feasibility studies and new methods

1- Good pharmacovigilance practice, 2- Pharmacovigilance working party

ENCePP contribution to CROs

- **Knowledge sharing**
  - Providing a direct link to the regulator (EMA), allowing the acknowledgment of its expectations
  - ENCePP toolkit
    - Validity of scientific methodology
      - Methodological guide
      - ENCePP checklist
      - Access to a catalogue of studies and data sources
    - Scientific independence
      - Code of conduct
    - Transparency
      - Registration of studies (former EU PAS Register)

- **Capacity building**
  - Networking
    - Connection to other institutions including other CROs, academic institutions, regulators, patient groups, etc.
    - Consortium building
  - COVID-19 pandemic was a turning point in awakening and leveraging this capacity

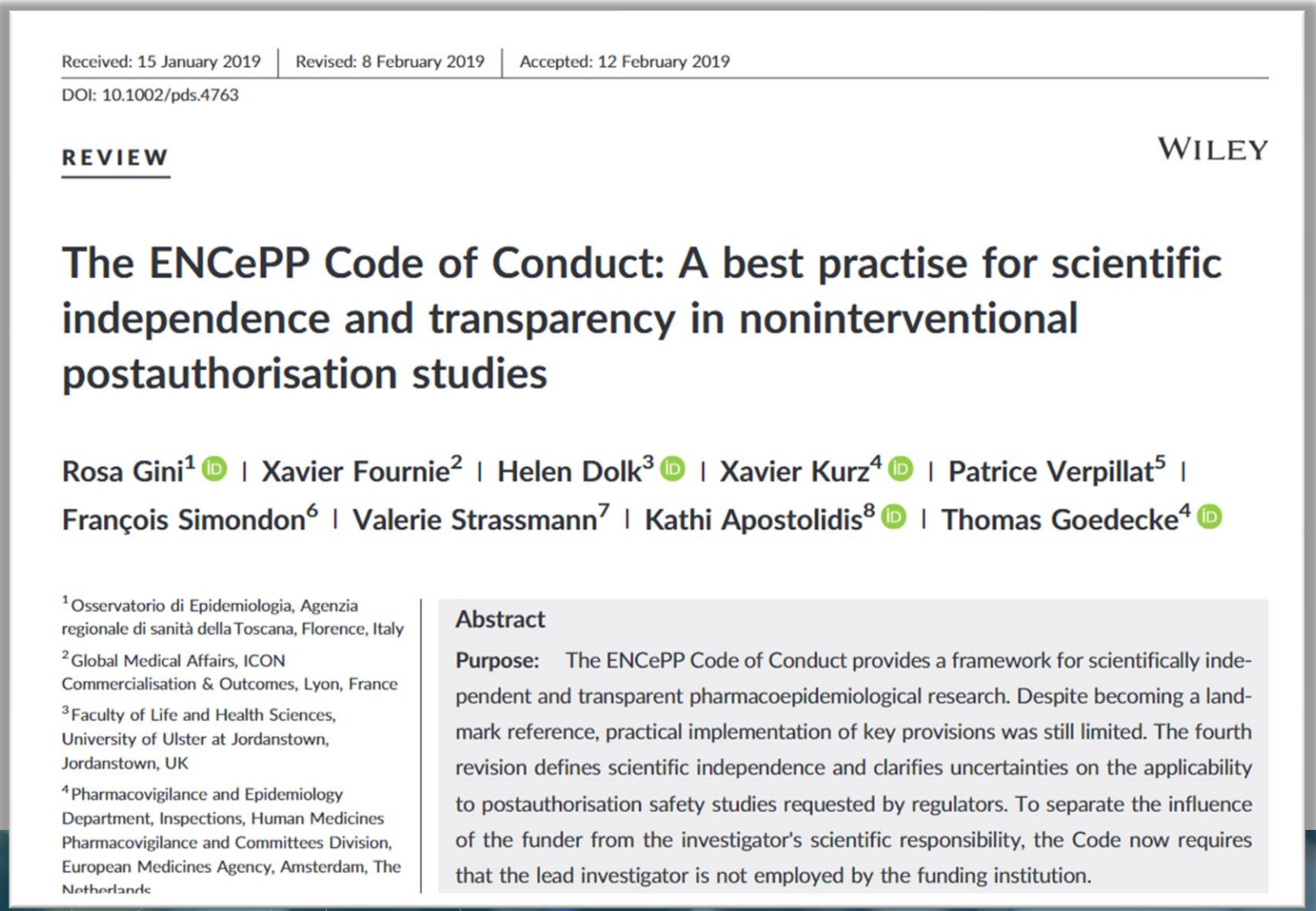
Perspectives

- ENCePP is a unique network
  - Its sponsorship by EMA provides the needed legitimacy to set the pace for research
  - Its inclusiveness of CROs helps a better dissemination of its principles to professionals who conduct studies as their everyday jobs
  - An increasing number of professionals from CROs outside of EU acknowledge the usefulness of ENCePP resources and toolkit

ENCePP and ISPE have similarities in their mandates

- Their collaboration can facilitate the development and dissemination of new methods and best practices.
- A recent example is the recommendation of HARPER protocol template (developed by ISPE/ISPOR RWE Task Force) in the 11th Revision of ENCePP Methodological Guide

The ENCePP Code of Conduct



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Pharmaceutical industry perspective

Gianmario Candore

Outline

- ENCePP and pharmaceutical companies
- Efpia and EUCOPE survey
- Outline possible future perspectives

Efpia: European Federation of Pharmaceutical Industries and Associations; EUCOPE: European Confederation of Pharmaceutical Entrepreneurs

ENCePP and pharmaceutical companies

- Pharmaceutical companies are represented in the **ENCePP Steering Group**
  - The role has evolved from ‘observer’ representing Efpia…
  - …to a **full participation** representing **all industry associations**

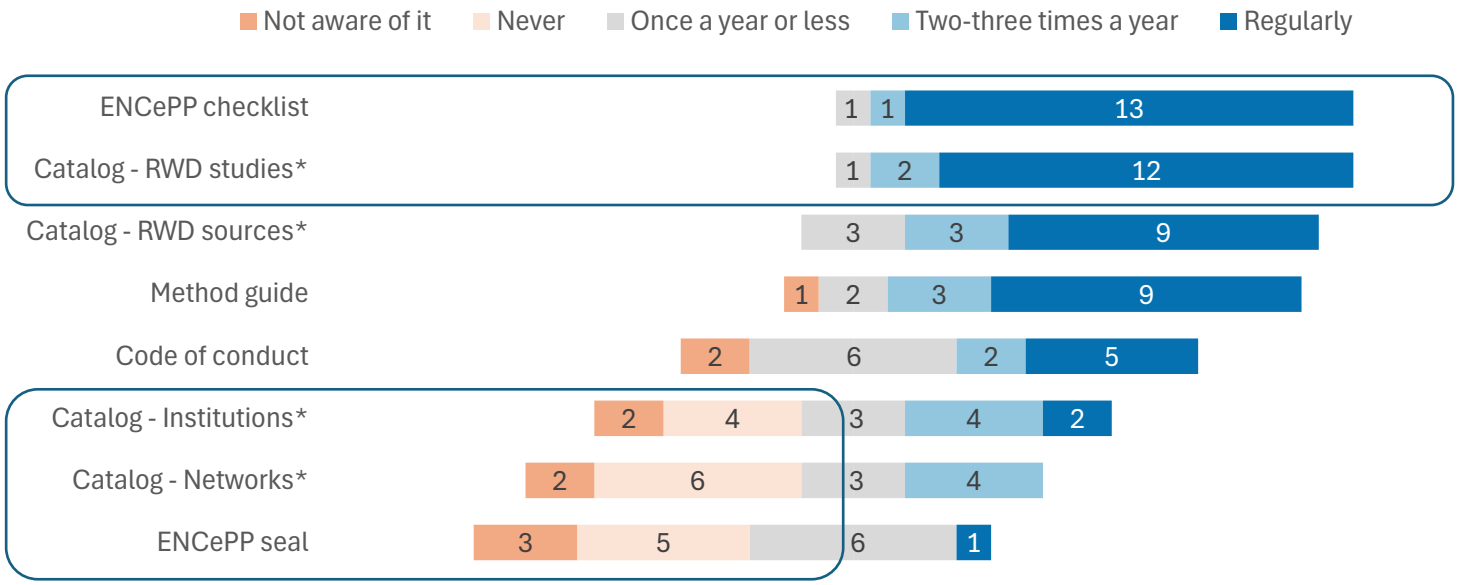
- Pharmaceutical companies are not ENCePP partners, but they are encouraged to make **use of the resources** offered by the network

Survey across Efpia and EUCOPE

- Survey conducted across Efpia and EUCOPE organisations to have an overview on
  - **How often** ENCePP tools are used
  - For what **purpose** they are used and what **value** they provide
  - Orientations for the **future**

- **15 organisations** responded to the survey
- Answers from **different teams/functions** within the same organisation, reflecting the breadth of application of ENCePP resources
  - Epidemiology, Real-Word Data/Evidence, Evidence Generation, Biostatistics, Biomarkers, Clinical Disclosure Office, Health Economics and Outcomes Research, Regulatory Policy & Intelligence
  - For presentation purposes, answers from different functions within the same organisation have been aggregated

How often ENCePP tools and resources are used



- The ENCePP **checklist for study protocol** and the catalogue of **RWD studies** are regularly used by the majority of the organisations (> 80% of respondents)

- There are also tools and resources **not well known**

ENCePP tools and resources
Use and value

Resources	Value provided	For what is used

Catalogue of RWD studies*	Transparency and shared learning	• Inform **evidence generation plans** on specific products/disease areas
		  • Overview of PASS evidence generated/gaps
		• Inform **planning and design of studies**
		  • Overview of research questions, (innovative) methods and study designs
		  • Indication of suitable data sources for specific diseases/research questions
		• Access to **study documents** (protocols, reports) to better inform results interpretation

Catalogue of RWD sources*	Data discoverability	• Early **feasibility landscape** of RWD sources for a study/research
		  • One of the sources used, limitations impact its use
		• Increase **trust and acceptability of data** sources based on known use
		  • Cited in study protocols to support justification of the selected data source

* Previously referred as EU PAS Register and ENCePP Resource Database, managed directly by EMA since 2024. Included for their history with ENCePP

ENCePP tools and resources
Use and value

Resources	Value provided	For what is used	
ENCePP checklist for study protocols	Increase research quality	• Stimulate consideration of important principles when developing a **protocol**, improving its quality (scientific rigour, completeness) and consistency • Facilitate **protocol review** by the internal technical review teams	Part of **company guidance documents** (e.g. referenced in SOP, templates, training)
Methodological guide		• Inform **study planning and conduct** activities (protocol development, statistical analysis plan, study report, study reviews) • **Reference** in methodological discussions	
Code of conduct	Increase research trust	• Provide **accepted principles for collaborating** with external scientific organisations • Provide **guiding principles throughout study conduct** • Alignment with own company standards	

Possible orientations for the future

ENCePP has impacted observational research in the pharmaceutical industry

- Collaboration and communication
  - Continue the collaborative spirit and open dialogue with different stakeholders developed over the last 15 years
    - Tools and added value can be improved based on **different users' feedback**
  - Continue to **raise awareness** and **educate** on resources, added value, and achievements of the network
- Methods
  - **Strong focus** on developing methodological standards to continue enhancing confidence in observational research
  - Be the **reference for new methodological challenges** rising from new data and innovative models/designs
  - **Leverage industry** for input and for highlighting pain points from applied pharmacoepidemiology
- Network
  - **Highlight data sources** successfully used for regulatory decision making (acknowledging this is use case specific)
- HMA-EMA catalogues
  - Be a reference for collecting user's feedback and **drive future developments**
  - **Periodic reports** on the catalogues (e.g. type of designs, trends,…) will also help increasing awareness, quality and utility

Acknowledgments

- Montse Soriano Gabarro
- Sigrid Behr
- All colleagues involved in answering or collecting answers for the survey

Panel discussion and Q&A

- Carla Torre

  → The perspective from the European medicines regulatory network (Committees and Working Parties)

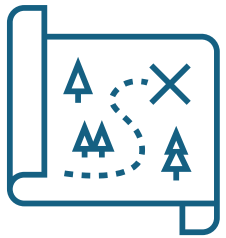
- Catherine Cohet

  → The EMA perspective

Engaging with ISPE

- How can **cross-fertilisation** be enhanced between ENCePP and ISPE?
- What could be common strategic or operational **objectives**? What are potential topics that would benefit from **collaboration**?
- How could the various **structures** of ENCePP and ISPE (annual meeting, SIGs, WGs, webinars…) be leveraged?
- …?

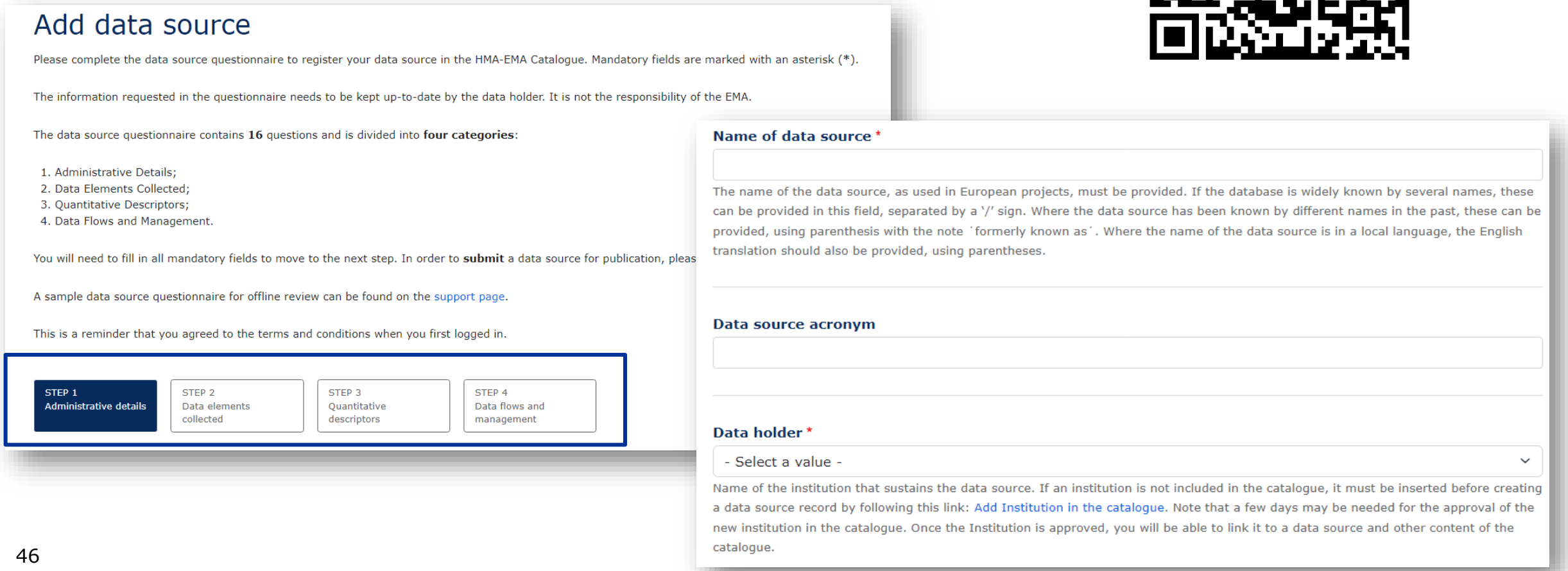
Key messages & next steps



K. Arnold Chan & Catherine Cohet

Help us foster the discoverability of RWD sources!

Add information on your data source directly to the RWD Catalogues or send us an email at ***RWDcatalogues@ema.europa.eu***



Thank you for your participation!

Slides are available via the ISPE app and will be published on the ENCePP website

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