EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP Steering Group and Working Groups

ENCePP Plenary webinar – 18 November 2021

Presented by Susana Perez-Gutthann and Gianmario Candore – ENCePP SG chairs

An agency of the European Union

Steering Group

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Update on the first year of the new SG

Minutes published on the ENCePP website

New Steering Group started in January 2021

- Three meetings on 18 January, 16 April and 15 June with key topics discussed
  - Discussion and finalisation of the ENCePP mandate (to be published on the ENCePP website)
  - 9th Revision of the ENCePP Guide on Methodological Standards
  - Reactivation of the Working Groups (WG) with renewed composition and recruitment
  - Input in the discussions on rebuilding of catalogues (ENCePP Resource Database, EU PAS Register)
- ENCePP webinar for Academia on 8 March
  - Promote a better understanding of what ENCePP is and how it contributes to improving pharmaco-epidemiological research

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New Steering Group 2021-2023

No.	Representing	Name	Affiliation
1	ENCePP	Cécile Droz-Perroteau	Pharmacoepidemiologist, Director of Bordeaux PharmacoEpi reasearch platform, France
2	ENCePP	Daniel Prieto-Alhambra	Research Co-ordinator for the IMI2 European Health Data and Evidence Network (EHDEN); Erasmus University Medical Center, the Netherlands; Oxford University, UK
3	ENCePP	Francesco Salvo	Associate Professor, Hospital Practitioner, Bordeaux University Hospital, Bordeaux Pharmacovigilance Centre, INSERM Research Centre, France
4	ENCePP	Helga Gardarsdottir	Associate Professor at the Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University, the Netherlands
5	ENCePP	Rosa Gini	Head of the Medical Informatics and Pharmacoepidemiology Unit, ARS Toscana, Regional Agency of Health - Agenzia Regionale di Sanità (ARS), Florence, Italy
6	ENCePP	Susana Perez-Gutthann (Co-Chair)	Vice President, Global Head Epidemiology, RTI Health Solutions, Barcelona, Spain
7	EMA	Ana Hidalgo-Simon	Head of Advanced Therapies, Human Division, European Medicines Agency, Amsterdam, the Netherlands
8	EMA	Gianmario Candore (Co-Chair)	Statistician, Data Analytics and Methods Task Force, European Medicines Agency, Amsterdam, the Netherlands
9	EMA	Andreas Kouroumalis	Scientific Officer, Oncology and Haematology Office, Human Division, European Medicines Agency, Amsterdam, the Netherlands
10	HMA	Kåre Kemp	Head of EU Pharmacovigilance Section, Danish Medicines Agency, Copenhagen, Denmark
11	CHMP	Johann Lodewijk Hillege	Medicines Evaluation Board, Utrecht, The Netherlands
12	COMP	Frauke Naumann-Winter	Federal Institute for Drugs and Medical Devices, Bonn, Germany
13	PRAC	Daniel Morales	GP & Epidemiologist, University of Dundee, United Kingdom; University of Southern Denmark, Denmark
14	PCWP	Iryna Vlasenko	European Chapter of the International Diabetes Federation, Brussels, Belgium
15	ISPE	Arnold K. Chan	Director of the Health Data Research Centre, National Taiwan University, Taiwan
16	ISoP	Gianluca Trifirò	Professor of Pharmacology, Department of Diagnostics and Public Health, University of Verona, Italy
17	ISPOR	Richard J. Willke	Chief Science Officer, International Society for Pharmacoeconomics and Outcomes Research, USA
Observer	EFPIA	Patrice Verpillat	Global Epidemiology, Merck Group, Germany
Observer	FDA	Wei Hua	Associate Director, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Office of Pharmacovigilance and Epidemiology, Division of Epidemiology, U.S. Food and Drug Administration, USA
Observer	FDA	Narayan Nair	Division Director, Division of Epidemiology, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, USA
Observer	Health Canada	Craig Simon	Acting Director, Health Products Surveillance and Epidemiology Bureau, Marketed Health Products Directorate, Health Products and Food Branch, Health Canada, Canada
Scientific adviser	EMA	Catherine Cohet	Pharmacoepidemiologist, Data Analytics and Methods Task Force, European Medicines Agency, Amsterdam, the Netherlands
Statistical adviser	EMA	Chantal Quinten	Biostatistician, Data Analytics and Methods Task Force, European Medicines Agency, Amsterdam, the Netherlands

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Future direction: areas of focus

ENCePP mission to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe

- Strengthening the network
  - Reactivating the Working Groups
- Access to data
  - Input in supporting the data discoverability and data quality recommendations of the Big Data Steering Group
- High quality studies
  - Support the upgrade of the EU PAS Register
  - Support the provision of training curricula in pharmacoepidemiology

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Future direction: areas of focus

- Methods and governance
  - Developing and maintaining methodological standards and governance principles for research in pharmacoepidemiology and pharmacovigilance
  - Strengthening collaborations with existing ENCePP stakeholders and interact with new networks (DARWIN EU, coordinated registry networks,…)
  - Strengthen recommendations on analytic methods on multi-database studies
- New data sources and approaches
  - Ensure the network embraces field like artificial intelligence and pharmacogenomics

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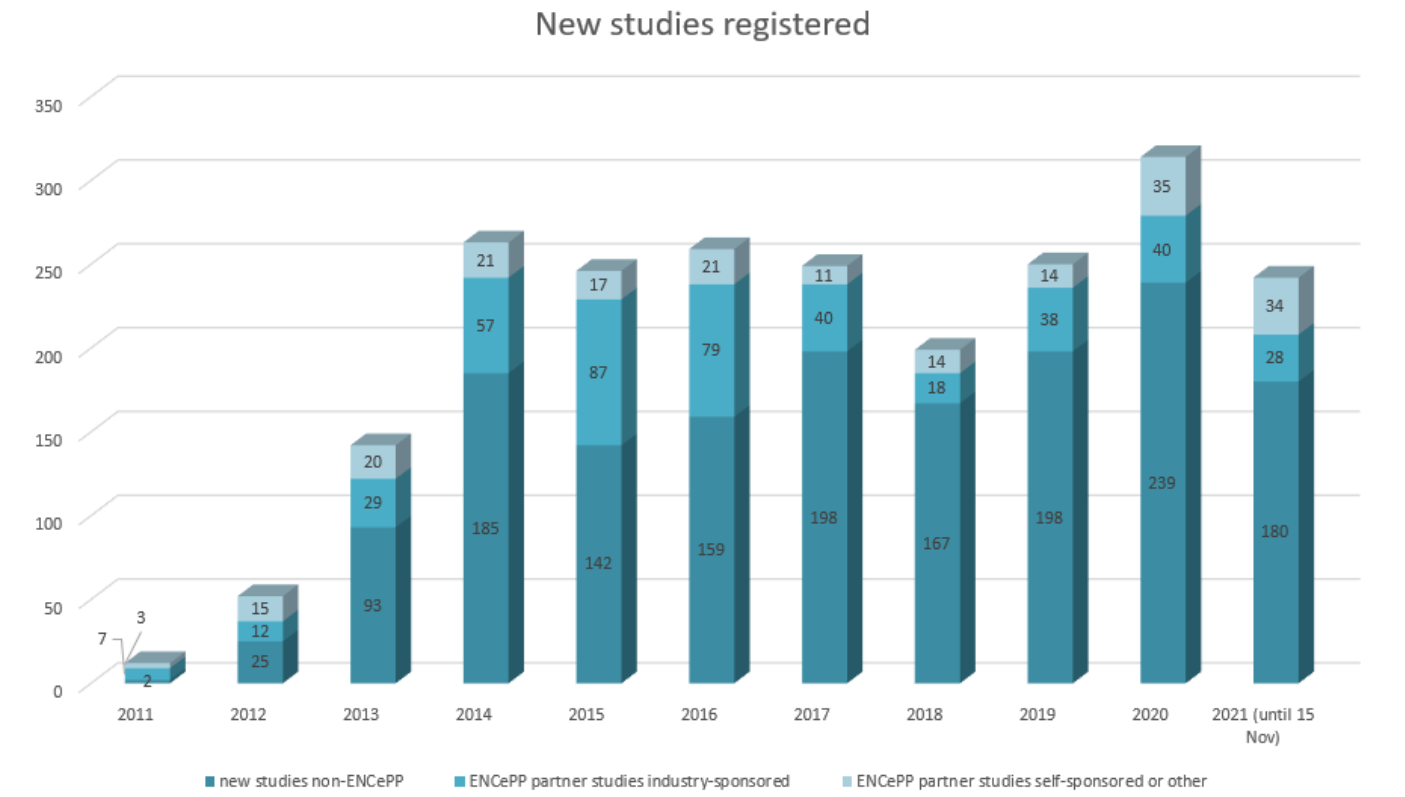
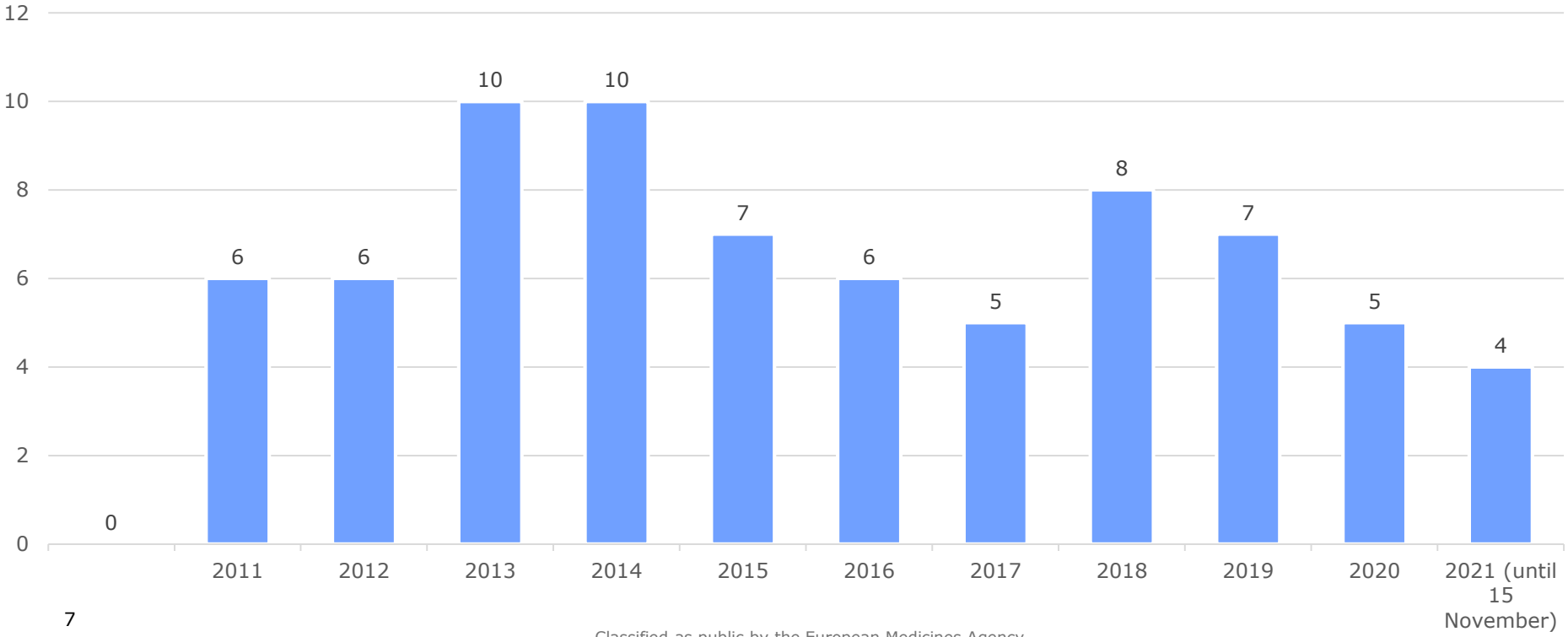
EU PAS Register studies



EU PAS Register – ENCePP seal studies



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Working Groups and Special Interest Groups

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ENCePP Working Groups (WG)

WG1: Research Standards and Guidance

Chair: Alejandro Arana

WG2: Independence and Transparency

Chair: Rosa Gini

WG3: Inventory of EU data sources and methodological approaches for multi-source studies

Chair: Gianluca Trifirò

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ENCePP Special Interest Groups (SIG)

- SIG on Measuring the Impact of Pharmacovigilance Activities
  - Terminated due to completing its mandate

- SIG on Drug Safety in Pregnancy
  - May be reactivated if active interest and contribution

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WG membership process and reactivation of WGs

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January 2021

SG meeting
- Discussion on refreshing WGs
- New SG members join WGs

June 2021

SG meeting
- Discussion on the need to recruit new members
- Agreed to draft a process to renew and accept new members

September 2021

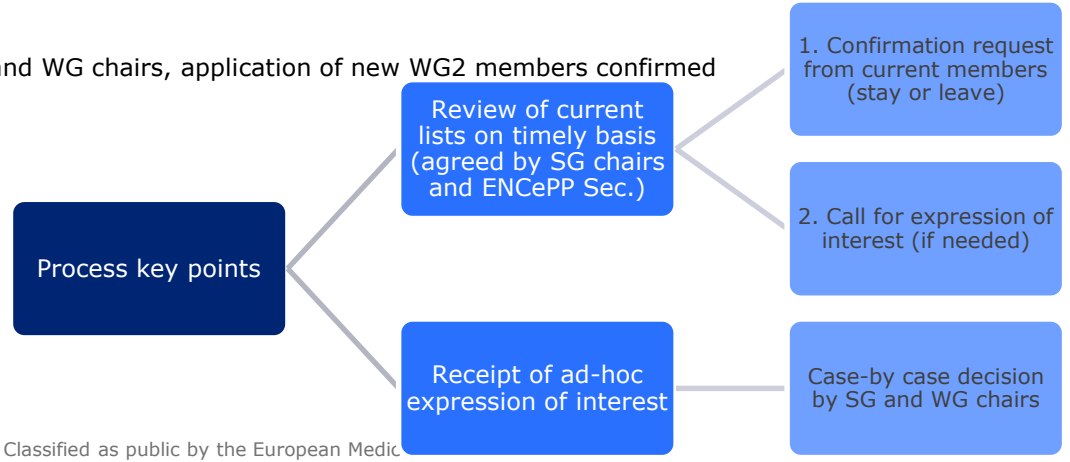
Membership process drafted by ENCePP Secretariat and accepted by SG chairs
Confirmation request sent to current WG members whether they wish to stay or leave

October 2021

WG2 - Call for expression of interest (no expression of interest call for WG1 and WG3 due to the size of the groups)

November 2021

Updated lists approved by SG and WG chairs, application of new WG2 members confirmed



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Update from Working Group 1

ENCePP research standards and guidance

Alejandro Arana

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Mandate and objectives of WG1

Overall mandate

To address methodological aspects of the generation of evidence-based information supporting the needs of regulatory and HTA decision-making

ENCePP research standards and guidances	
Chair:	Alejandro Arana
• Identify areas in which research standards and guidances relevant for ENCePP activities are needed and identify or develop such guidance.	
• Periodically review the ENCePP Checklist for Study Protocols.	
• Periodically review the Guide on Methodological Standards in Pharmacoepidemiology.	
• Monitor the development of accreditation systems and their methodologies.	
• Support training relevant to the ENCePP standards.	
• Support the implementation of new and existing standards.	

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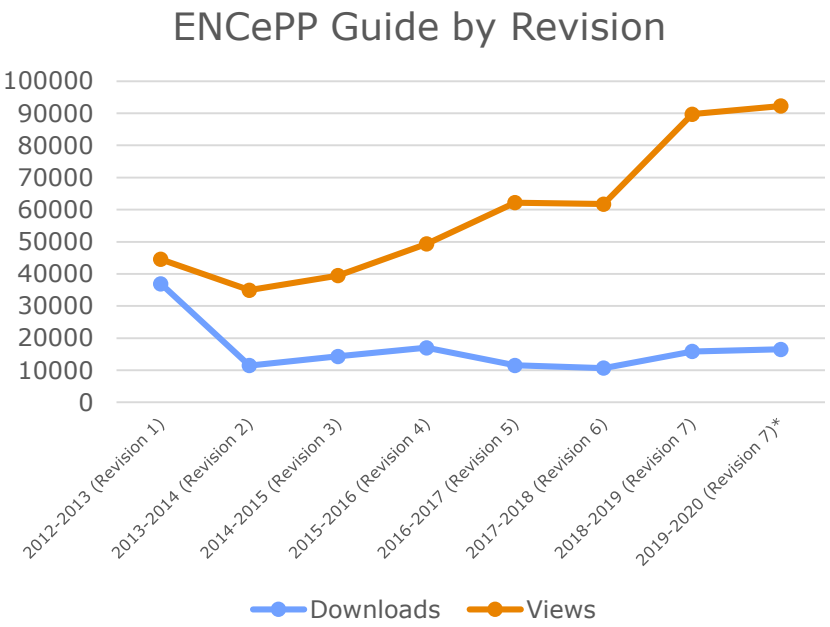
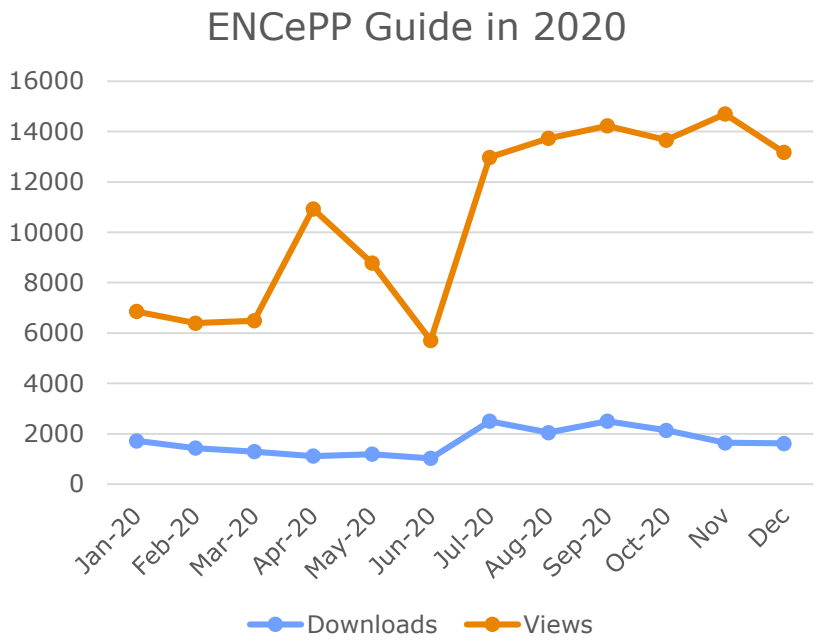
ENCePP Guide





* No revision in 2019 due to Brexit-related Business Continuity Plan

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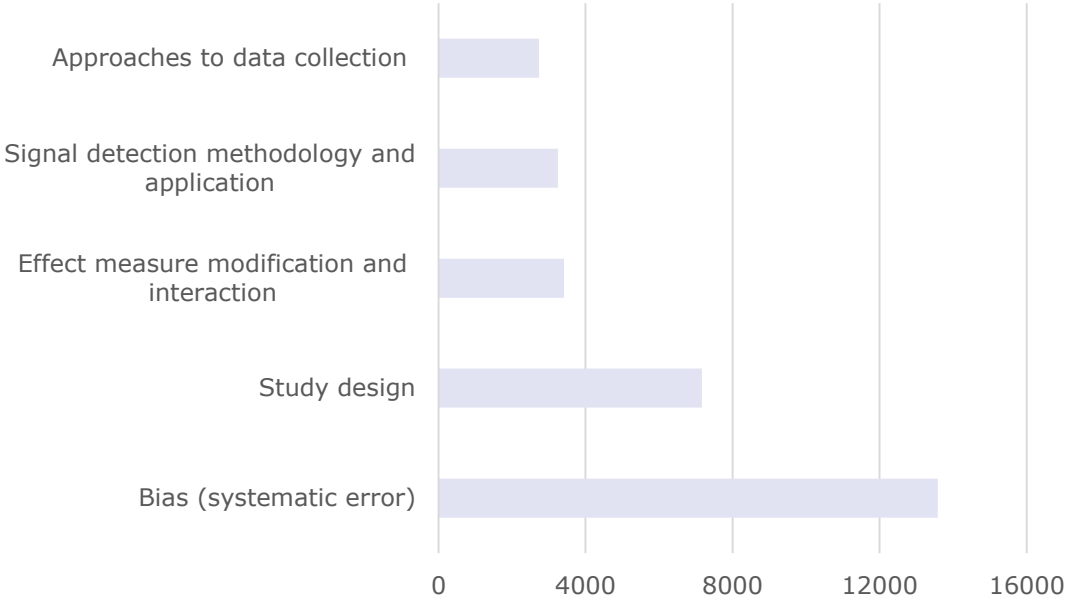
Most viewed topics of the ENCePP Guide in 2020



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9th revision of the ENCePP Guide – released July 2021

- Update of each chapter by the corresponding authors
- Extensive revision of **chapter 5** Study design. Brief description of **basic principles of study design and comparative epidemiology** (reference to standard textbooks)
- Extensive revision of **chapter 14.3**: Design and analysis of pharmacogenetic studies
- Extensive revision of **chapter 7 (now 11)**: Quality management
- New section with recommendations on use of positive and negative control exposures and outcomes
- Collider bias to be developed in Selection bias chapter
- Covid 19 topics
  - Update of the Foreword with reference to high quality studies and to tools and methods relevant for research e.g. ACCESS
  - Relevant studies on Covid vaccinations referred to in chapter 14.2. Vaccine safety and effectiveness

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Update from Working Group 2

Independence and transparency

Rosa Gini

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Working Group 2: independence and transparency

- WG2 has been reconvened after the relocation/pandemic hyatus
- Group members: Rosa Gini (chair, SG liaison), Morten Andersen, Helen Dolk, Stephen Evans, Xavier Fournie, Agnes Kant, Iryna Vlasenko, Martin Daumer, Lia Gutiérrez, Christos Kontogiorgis, Elena Petelos, Evangelia E. Ntzani, Nicolas Deltour
- During the kick-off meeting, two activities have been planned

1. Contribute to EU PAS Register revision to introduce variables aimed at monitoring compliance with the ENCePP CoC provisions
2. Develop guidance on transparency in data analytics documentation: from sharing of raw data, to sharing of analytic programs, to structuring code execution on synthetic datasets

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Update from Working Group 3

Inventory of EU data sources and methodological approaches for multi-source studies

Gianluca Trifirò

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Major achievements

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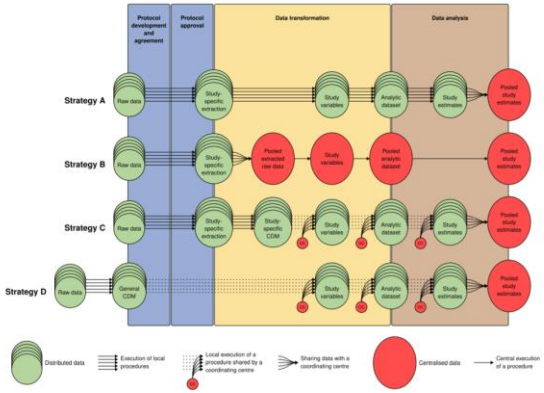
Different Strategies to Execute Multi-Database Studies for Medicines Surveillance in Real-World Setting: A Reflection on the European Model

CLINICAL PHARMACOLOGY & THERAPEUTICS | VOLUME 108 NUMBER 2 | August 2020

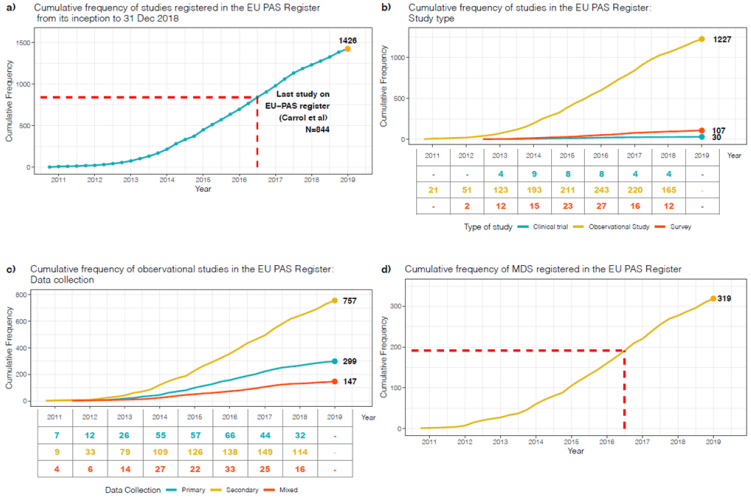
Rona Gini[1]*, Miriam C. J. Sturkenboom[2], Janet Sultana[3], Alison Cave[4], Annalisa Landi[5,6], Alexandra Pacurariu[4], Giuseppe Roberto[1], Tania Schink[7], Gianmario Candore[4], Jim Slattery[4], and Gianluca Trifirò[8] on behalf of the Working Group 3 of ENCePP (Inventory of EU data sources and methodological approaches for multisource studies)



Re-submitted to Pharmacoepidemiology and Drug Safety after minor revisions

Overview of the EU-PAS register post-authorization studies performed in Europe from September 2010 to December 2018

Janet Sultana (1,2)*, Salvatore Crisafulli (3)*, Mariana Almas (4), Ippazio Cosimo Antonazzo (5,6), Esme Baan (7), Claudia Bartolini (6), Maria Paola Bertuccio (3), Fedele Bonifazi (8, 9), Annalisa Capuano (10,11), Antonella Didio (8,9), Vera Ehrenstein (12), Mariagrazia Felisi (8,13), Carmen Ferrajolo (10,11), Andrea Fontana (14), Remy Francisca (7), Annie Fourrier-Reglat (15), Joan Fortuny (16), Rosa Gini (6), Giulia Hyeraci (6), Christel Hoeve (7), Christos Kontogiorgis (17), Valentina Isgrò (18), Panagiotis-Nikolaos Lalagkas (17), Luca L'Abbate (18), Deborah Layton (19), Annalisa Landi (8,9), Silvia Narduzzi (19), Leonardo Roque Pereira (20), Georgios Poulentzas (17), Concetta Rafaniello (10,11), Giuseppe Roberto (6), Giulia Scondotto (3), Liberata Sportiello (10,11), Maddalena Toma (8,9), Massoud Toussi (19), Katia Verhamme (7), Elisabetta Volpe (8,9) and Gianluca Trifirò** (18) on behalf of ENCePP WG3 "Inventory of EU data sources and methodological approaches for multisource studies"



List of suggestions/recommendations for EU-PAS Register improvement from ENCePP WG3

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Plan for 2022 activities

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1. To finalize the specific assessment of studies registered in EU-PAS register

- Multiple database studies (University of Verona and ARS Toscana)
- Regulatory outcomes of registered PASs (IQVIA and PRA Solutions)
- Studies in pregnancy and lactation (UMC Utrecht, IQVIA and University of Thrace)
- Studies in paediatric populations (University of Campania and TEDDY Network)
- International comparison of studies (University of Thrace)
- COVID-19-related observational studies (University of Verona and IQVIA)

2. To liaise with EMA for improvement of EU- PAS register and ENCePP Resource Database

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Any questions?

Further information

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