



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Big Data – ENCePP Research Center Perspective

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Health Solutions



Disclosure & Perspectives

- **Employed** at **RTI Health Solutions**, RTI is an independent non-for-profit research institute working for government and private and other institutions including pharma companies. As employee, my work includes research, advisory roles and regulatory deliverables, mostly funded by pharma.
- Past employment 1990-2007: R&D Pharma epidemiology in Pfizer, Pharmacia, Novartis, Ciba-Geigy



Current member and Past Co-Chair of the Steering Committee of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (**ENCePP**) and past Co-Chair of the working group on **Research Standards**



Past President and long-time service as officer of International Society for Pharmacoepidemiology (**ISPE**), including chair public policy committee (**Good Pharmacoepidemiology Practice**)

The views and opinions expressed in the following slides are those of the presenter and should not be attributed to any of above organizations

What is ENCePP?

ENEPP

An initiative that **brings together expertise and resources** in pharmacoepidemiology and pharmacovigilance across Europe

ENEPP

Aims to **strengthen the monitoring of the benefit:risk balance of medicinal products**

ENEPP

Comprises research centres and networks referred to as '**ENCePP partners**'

ENEPP

Globally acknowledged for its expertise and outputs



European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance



Who are the ENCePP partners?

Centres (>190)

- Public (university, hospital, government, charities)
- Others (CROs, consultants)

Networks (>25)

- International
- National

Special interests: psychiatry, rheumatology, respiratory, effectiveness, teratology, pharmacogenetics, congenital abnormalities, women's health, paediatrics, psoriasis, severe cutaneous adverse reactions to drugs;

Data sources (150)



ENCePP guiding principles and tools

Transparency

 EU PAS Register

Registration of studies

Publication of protocols and results

Independence

Clear roles and responsibilities of all parties involved for public health benefit

 *Code of Conduct*

Standards

Stimulate consideration of important principles in study design



Methodological Standards Guide



Checklist for Study Protocols



Code of Conduct

Epidemiology / RWE and Big Data



Pharmacovigilance, Risk-management, Benefit-risk Assessment, Comparative Effectiveness, Disease Knowledge

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- Patient population
 - Indication safety issues
 - Chemical class
 - Preclinical safety
 - Clinical pharmacology
 - Expected patient safety profile: patients, drugs
 - Modeling and simulations
 - ODA/PIP
 - Risk-management plan
 - RWE trial arms and contextualization
 - Patient and drug characteristics, off label use
 - Safety in general use, long-term and special population safety
 - Risk-minimization evaluation
 - Effectiveness
 - New indications, and labeling extensions

ENCePP research community & Big Data Initiative

- **Priorities**

- Availability of good quality data for state-of-the-art epidemiologic research
- Foster application of solid epidemiologic methods
- Integrate innovation as part of the research process



ENCePP research community & Big Data Initiative

- Opportunities

- increased capture of research quality population data
- increased visibility of our field

- Risks

- confusion between data driven analysis and causal inference research
- failure in the RWE Big Data environment results in lack of trust in our discipline as a whole



ENCePP research community & Big Data Initiative

Area for collaboration: Addressing Common Challenges

- health systems funding cuts and fragmentation reduce health data coverage and completeness
- data protection driven limitations to use of data and share results, e.g., need to mask cells less than five cell as orphan and ultra orphan indications grow
- length of approvals for studies of public health relevance;
- scarce resources in public and private health systems to support data infrastructure and access for research.



ENCePP research community & Big Data Initiative

Area for collaboration: Engagement

- Outreach is more important than ever to identify and involve centers in Europe that can contribute to the evidence generation
- Support methodology and good practice framework across centers with less capacity, and expertise
- End goal is to increase population coverage and quality of data for research in Europe
- Outreach in international collaborations: ISPE, and other research networks in our field



Thank you for your attention

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