



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

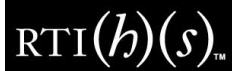


European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

WG1. Research Standards and Guidances

Presented by: **Alejandro Arana, MD, MPH, FISPE**
ENCePP Working Group 1. Research Standards and Guidances

Director, Epidemiology



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Participants

WG Members:

Alfonso Carvajal, Xavier Fournie, Helga Gardarsdottir, Victor Kiri, Ursula Kirchmayer, Olaf Klungel, Gillian Hall, Susana Perez-Gutthann, Yvonne Lis, Federica-Edith Pisa, Annie Reglat, Massoud Toussi, Rachael Williams, Vera Ehrenstein, Alfonso Carvajal, Alejandro Arana

SG sponsor:

Maria Teresa Herdeiro

EMA:

Xavier Kurz



Assess the need to update ISPE Guidelines for good database selection and use in pharmacoepidemiology research (ENCePP SG request)

- Information from Yola Moride that there is no plan at ISPE to review the guidelines
- Guidelines considered good and complete- minor changes may be needed
- WG1 members to review guidelines and provide comments to authors (Gillian Hall) by end January 2007
- A checklist will be developed and offered to database custodians to organise information



EMA Scientific guidance on post-authorisation efficacy studies: impact for ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Guide considered to cover a broader spectrum.

ENCEPP Guide has more detailed information on methods

EMA Guidance to be referenced in the ENCePP Guide

Pragmatic trials section of ENCePP Guide to be expanded

No other impact



6th revision. ENCePP Guide on Methodological Standards in Pharmacoepidemiology

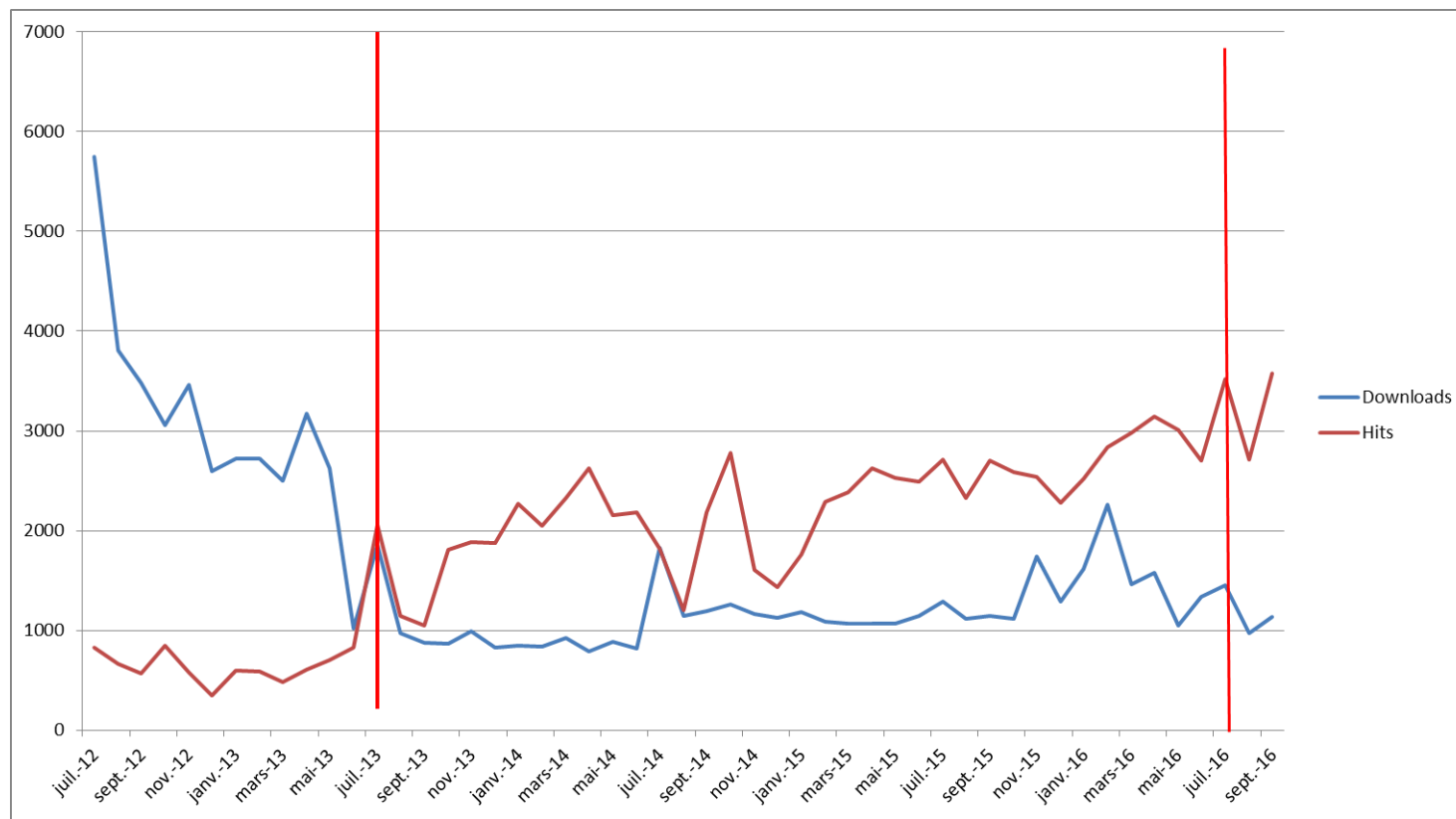


Results from on-line survey

#	Please specify your suggestion(s) for improvement:
1	This site is wonderful ! Thank you !
2	For survey purposes, it would great to highlight changes from the previous to the new version of the guide.
3	Section 4.2.2. Bias and confounding could benefit from streamlining and a more formal approach currently it reads as a collection of anecdotes and lacks clear structure. A more formal classification could be e.g. into "information bias", "selection bias" and confounding and then explanation of specific subtypes within this general category.
4	Content and frequency of progress and interim reports from PASS.
5	conceptual content on the principles of causal inference is missing, in my opinion
6	Prospective research



Results from hits: most popular deliverable



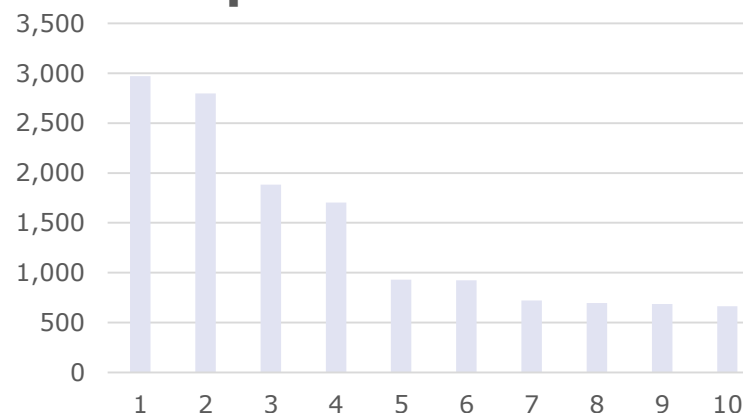


Hits by chapters

as of 16 NOV 2016

- ▶ 1*: Statistical plan (5)
- ▶ 2*: Bias and confounding (4.2.2)
- ▶ 3*: Signal detection methodology and application (4.6)
- ▶ 4*: Immortal time bias (4.2.2.2.1)
- ▶ 5**: Confounding by indication (4.2.2.2.3)
- ▶ 6: Randomised clinical trials Vs observational studies (9.1.3.1)
- ▶ 7: General aspects of study protocols (1)
- ▶ 8: Guidance on conducting systematic reviews and meta-analyses (Annex1)
- ▶ 9: Study design and methods (4)
- ▶ 10: Case-only designs (4.2.3.2)

Top 10 Hits 2016



*: same ranking in 2015
**: Quality management was ranking #5 in 2015 (Vs 12 in 2016)



6th revision. ENCePP Guide on Methodological Standards in Pharmacoepidemiology: Update

Primary data collection, including use of social media

Registries: clarification of terminology needed – *routine* data collection

Signal detection. Examples PROTECT

Large pragmatic trials. Examples

Bias

Dissemination and reporting vs. Communication

Vaccines



HTA

HTA integration in WG1 and guide for methodological standards (specific chapter in collaboration with HTA experts?)

Scope. Review EUnetHTA Position papers on Study design and Research standards for possible impact on ENCePP Guide

Call for collaboration by HAS France and EUnetHTA JA3. François Meyer & Irena Guzina