EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ENCePP – Working Groups

Update on current activities

Presented by: Stefanie Prilla

ENCePP Steering Group meeting, 19 February 2010

Working Group 1

Research standards & guidance

Subgroup 1: Methodological Research Standards (MRS), *Chair: Bert Leufkens*

Subgroup 2: Existing Recommendations & Guidelines, *Chair: Susana Perez-Gutthann*

Main activities in 2009

- Develop the Checklist of MRS  *–> public consultation*
- Further develop the Inventory of PE Guidelines (general application as well as more specific) & first steps to develop Guide on Methodological Research Standards

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Inventory of existing PE Guidelines

	Organization & Guideline short title	Document/Link
1	**ISPE - Good PEpi Practices**	Good Pharmacoepidemiology Practices http://www.pharmacoepi.org/resources/guidelines_08027.cfm
2	**IEA - Good Epi Practice**	Good Epidemiology Practice http://www.dundee.ac.uk/iea/download/GEPNov07.pdf
3	**CIOMS - Ethical GL for PEpi Studies**	International Ethical Guidelines for Epidemiological Studies http://www.cioms.ch/080221feb_2008.pdf
4	**STROBE - Reporting of Observational Studies**	von Elm E. et al. - The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies. Ann Intern Med. 2007;147:573-577 Vandenbroucke J.P. et al. - Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. Ann Intern Med. 2007;147:W-163–W-194.
5	**AHRQ - Patient Registries**	Registries for Evaluating Patient Outcomes: A User's Guide http://effectivehealthcare.ahrq.gov/repFiles/PatOutcomes.pdf
6	**ISPOR - Checklist for Retrospective DB studies**	Motheral B, Brooks J, Clark MA, Crown WH, Davey P. A Checklist for Retrospective Database Studies - Report of the ISPOR Task Force on Retrospective Databases. Value Health 2003; 6(2): 90-97 www.ispor.org/TaskForces/RetrospectiveDBPractices.asp
7	**DGEpi - Good Practices for Secondary Data Analysis**	*Gute Praxis Sekundaerdatenanalyse* (Good Practices for Secondary Data Analysis) of the German Society for Epidemiology (DGEpi) www.dgepi.de/pdf/infoboard/stellungnahme/gps-version2-final.pdf

Inventory of existing PE Guidelines

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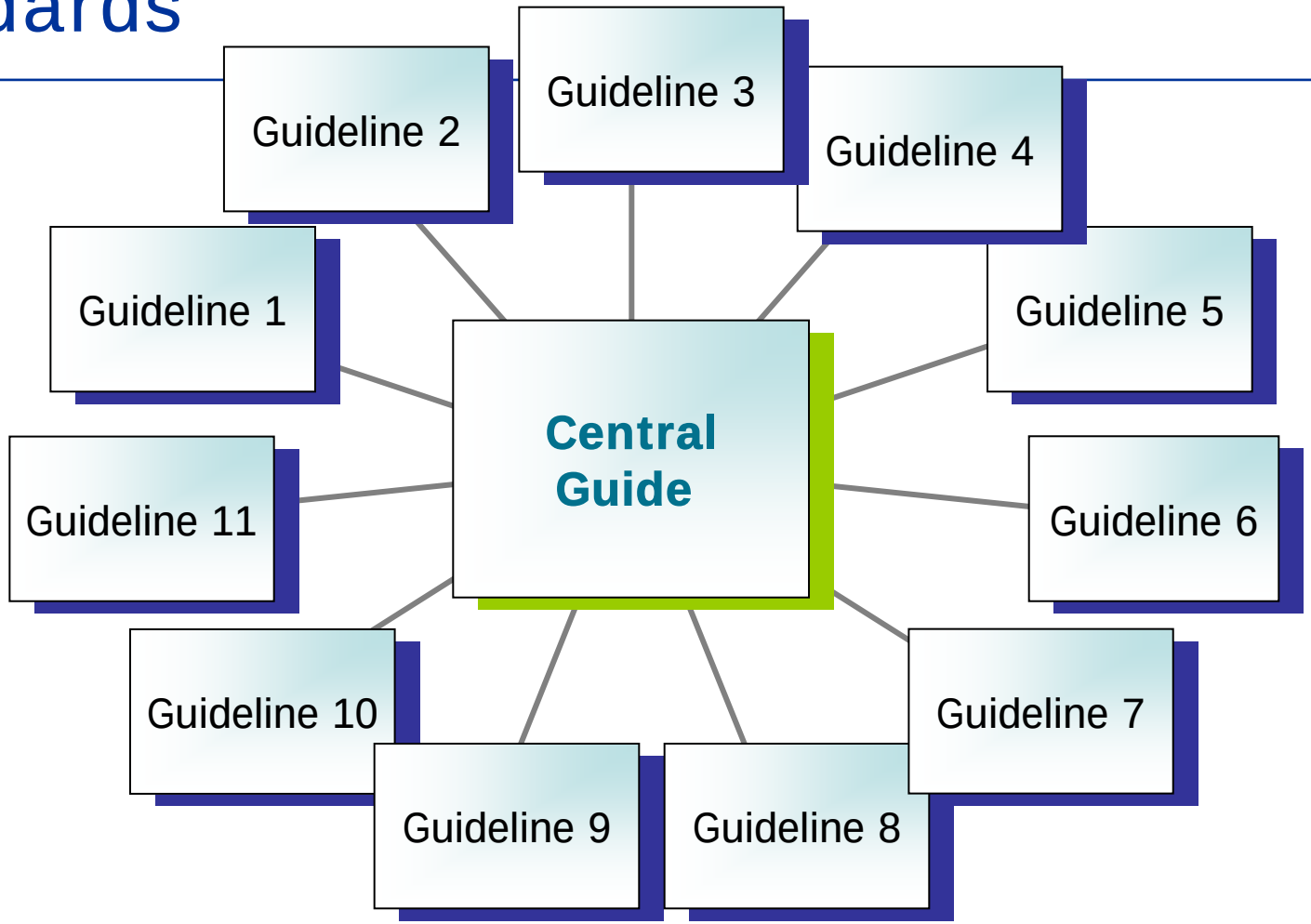
8	**ISPE/ISoP - GL for Publication of AE Reports**	Kelly WN, Arellano FM, Barnes J, Bergman U, Edwards RI, Fernandez AM, et al. Guidelines for Submitting Adverse Event Reports for Publication. Pharmacoepidemiology and Drug Safety 2007(16):581-587. also published in Drug Safety 2007;30(5).
9	**EuroDURG - Drug Utilisation Research Quality Indicators**	Hoven JL, Haaijer-Ruskamp FM, Vander Stichele RH; DURQUIM Scientific Committee. Indicators of prescribing quality in drug utilization research: report of a European meeting (DURQUIM, 13-15 May 2004). Eur J Clin Pharmacol. 2005 Jan;60(11):831-4. http://www.eurodurg.com/durquim.htm: Recommendations of an European Expert Meeting on indicators of prescribing quality in drug utilization research (Recommendations on Methodology)
10	**MOOSE - Reporting of Epi Meta-analyses**	Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, Moher D, Becker BJ, Sipe TA, Thacker SB. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000;283(15):2008-12.
11	**FDA - Good PhV Practices**	Guidance for Industry - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
	EC/EMEA - GL on PV	Volume 9A of The Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Human Use http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-9/pdf/vol9a_09-2008.pdf
	FDA/EMEA - other specific GL	

Guide on Methodological Research Standards



Scope of the Guide

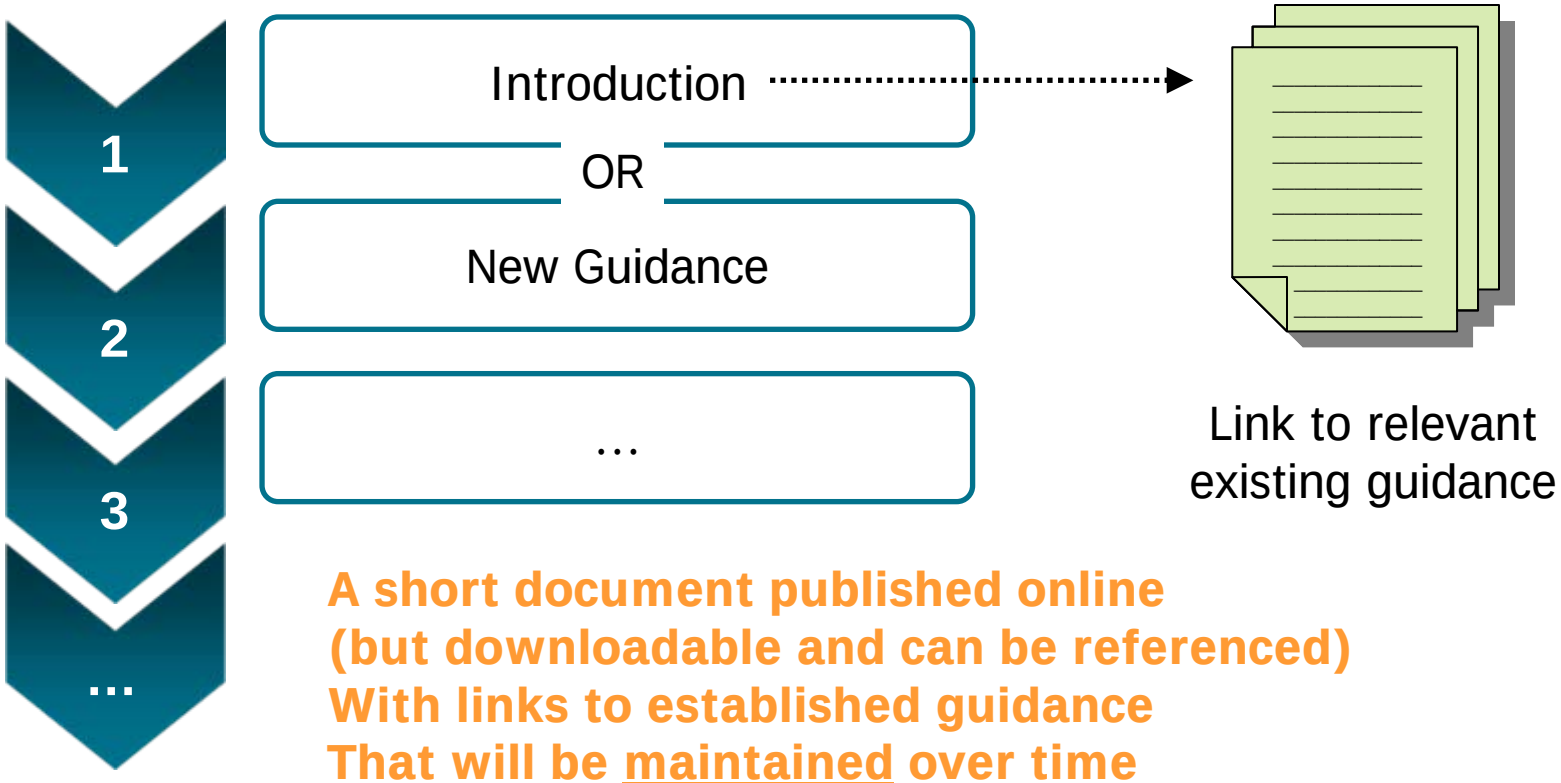
Based on Inventory of Guidance and Guidelines for PE & PhV research

"Overarching" existing guidance; no need to reinvent the wheel

Note: keep in mind much guidance is found in standard reference epidemiology textbooks

Provide new guidance for areas where no or not sufficient guidance is available

Structure of the Guide



A short document published online
(but downloadable and can be referenced)
With links to established guidance
That will be maintained over time
And expanded to cover gaps in current guidance

Development of the Guidance

- Identify different sections of the Guide (areas of operational/methodological research)
- Match existing guidelines with the need for Guidance = Sections of the Guide
- Development of summary recommendations for each domain of study development and conduct
  - If guidance available: short introduction & link to appropriate existing guidance
  - If no guidance available: development of new guidance according to the needs

Meeting of WG on 10 December

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Identify authors !

Next steps

Review of outline, guidance, and authors

- By February 15, 2010

Review by ENCePP (call for authors)

- By March 15, 2010

Final outline and authors document

- By April 10, 2010

First draft summary of sections

- By May 15, 2010

WG meeting in London (date tbc)

Working Group 2

Transparency & Independence

Chair: Helen Dolk

Subgroup 1: Code of Conduct
Chair: Helen Dolk

Subgroup 2: Registry of studies
Chair: Joan-Ramon Laporte

Main activities in 2009

- Develop the Code of Conduct *–> public consultation*
- Development of data fields for the Registry of studies

Working Group 3 - EU data sources & methodological approaches for multi-source studies

Chair: Miriam Sturkenboom

Main activity in 2009: Development of data entry form (questionnaire) for data sources for the ENCePP Database of Research Resources

- List of key points for the Database
- First draft questionnaire: March 2009
- Consultation process: Drafting Group WG3 (April 2009), Working Group (May 2009), ENCePP (June 2009)
- Final draft: July 2009 (presented at ENCePP Plenary in Sept 2010

Registry of Data Sources
Status Update

Planned for 2nd release of resource database (Q 1 2010)

Same structure & features as Inventory of centres

Access to centres and data sources through common portal: Resource database

Link from centres database to data sources and vice versa

Working Group 4

EU PhV & PhEpi research centres in ENCePP

Chair: Mary Teeling

Main activity in 2009: Development of data entry form (questionnaire) for centres for the ENCePP Database of Research Resources

- Identification of key information of the centres to be collected
- First draft questionnaire - Drafting Group WG3, Working Group, ENCePP (September 2009)
- Final draft: September 2009

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ENCePP – Database of Research Resources

Demonstration

Presented by: Stefanie Prilla

ENCePP Steering Group meeting, 19 February 2010

Version 1.0 – released in January 2010

'Special' features

- Download .pdf version of the questionnaire

Note: only electronic applications will be accepted !

- 'Save & exit' of questionnaire
- 'Review' data entries & 'edit' if necessary
- 'Search' database by name, country, resources and research area

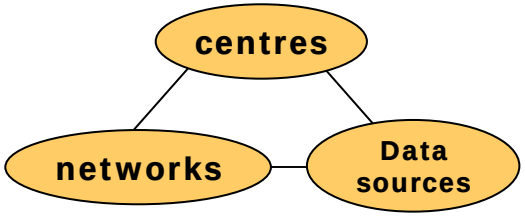
Planned Version 2.0

When? Q1 2010

e-Database of data sources

Additional features

- Interlink of resources



- Extended search functions
- Downloadable profile of centre / search results
- Interactive map of Europe to access database of resources
- Network forum

http://www.encepp.eu