GVP Module VIII
ICH M14

ENCePP Plenary 2022
Wednesday 30 November 2022

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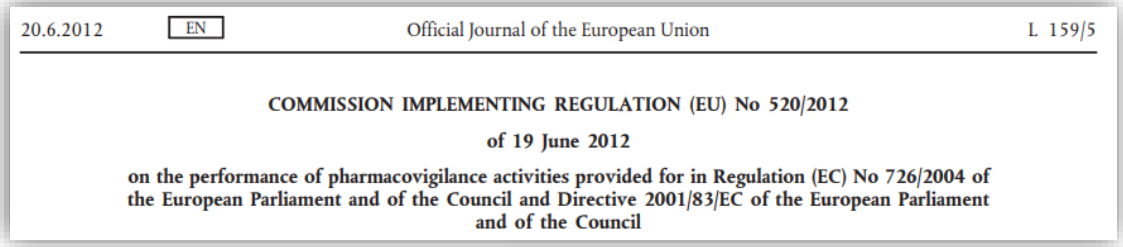
Data Analytics and Methods Taskforce, EMA

Legal obligations
Annex III. 1. Format of the study protocol



20.6.2012 EN Official Journal of the European Union L 159/5

COMMISSION IMPLEMENTING REGULATION (EU) No 520/2012

of 19 June 2012

on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

Set of measures to be applied for implementing the legal obligations
VIII.B.3.1 Format and content of a study protocol

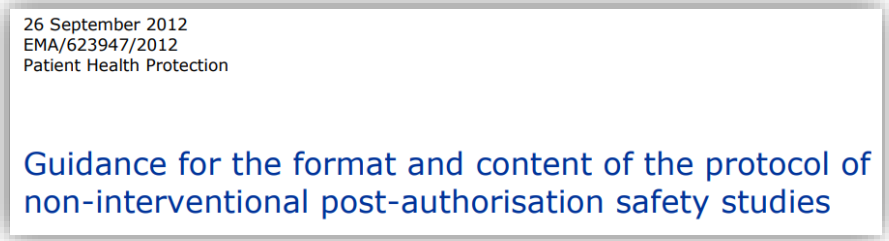
HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 October 2017
EMA/813938/2011 Rev 3*

Guideline on good pharmacovigilance practices (GVP)
Module VIII – Post-authorisation safety studies (Rev 3)

Template with explanations on format and content of each section of PASS protocols submitted by companies



26 September 2012
EMA/623947/2012
Patient Health Protection

Guidance for the format and content of the protocol of non-interventional post-authorisation safety studies

Revision of GVP Module VIII

- Revision required due to entry into force in Jan 2022 of the **new EC Clinical Trial Regulation**
- What will we do?
  - adapt **definitions** (e.g., clinical study, clinical trial, non-interventional study)
  - explore how to **align** with new/updated **guidelines** and international standards (e.g., EMA guideline on registry-based studies, HARPER)
  - add text about **feasibility** and **selection** of **data source(s)**
  - integrate appendix I and addendum I
  - implement changes based on **experience** of PASS assessors
  - opportunity to amend **templates** for format and content of PASS protocol and report
- Will be subject to **public consultation** (2023 or 2024)

Link with HARPER

- Compatible with legal format and content of GVP Module VIII
- Template can already be used in PASS protocols without change of structure

9.1. Study design: recommendation to use study design diagrams

9.2. Setting: rationale, context and table for choices relating to selection of time zero, inclusion/exclusion criteria

9.3. Variables: structured tables for exposure, outcome, follow-up and covariates, and validation; description of algorithms

9.4. Data sources: evaluation of fitness-for purpose of data source

9.7. Data analysis: structured table detailing sensitivity analyses

10. Protection of human subjects: new considerations based on GDPR – use of anonymised or pseudo-anonymised data sources

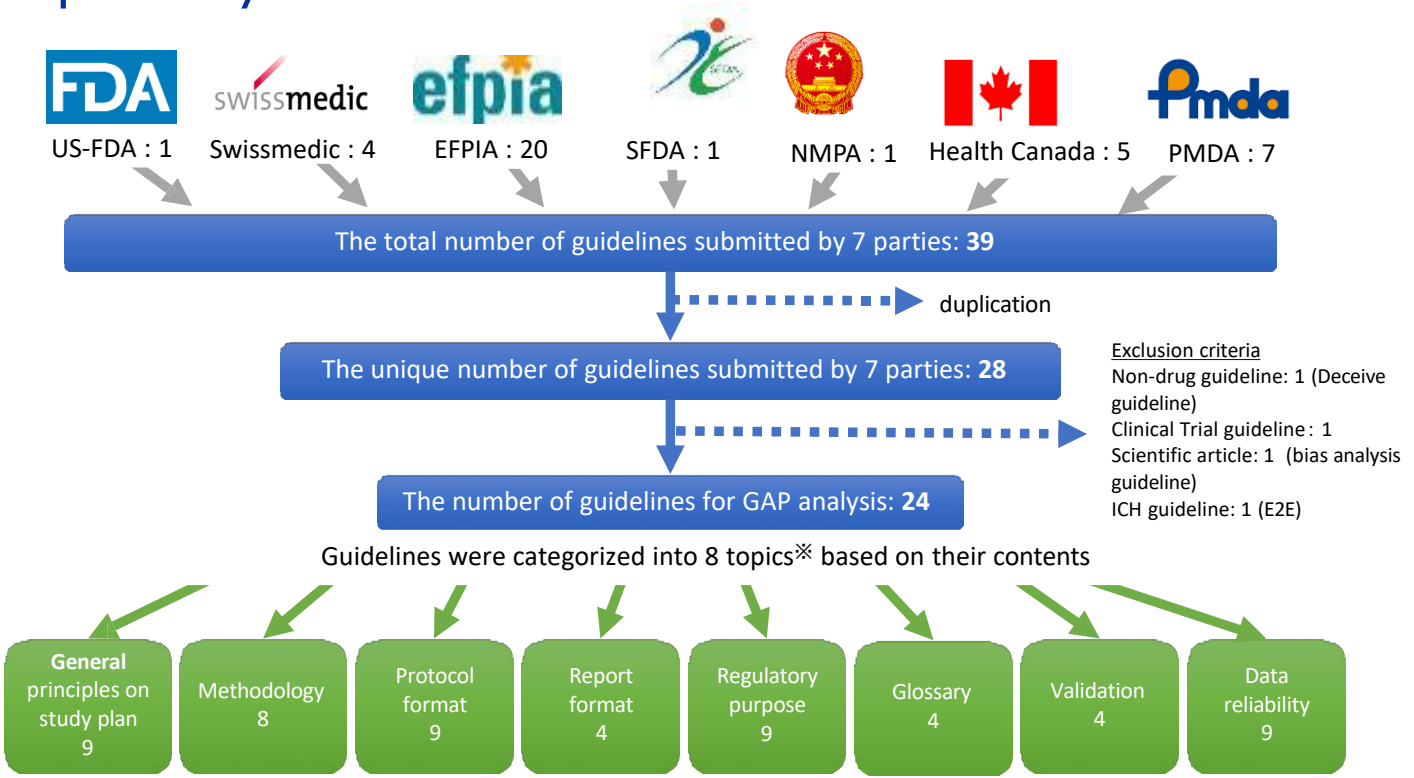
ICH M14

"*General principles on planning and designing **pharmacoepidemiological studies** that utilize RWD for **safety** assessment of a medicine*"

ICH M14 background

- **ICH Reflection paper** on pharmacoepidemiological studies endorsed by ICH Assembly in **June 2019**
  - Harmonise technical and scientific requirements for studies submitted to regulatory agencies
  - Facilitate use of RWD and promote globally-harmonised approach in post-approval safety-related regulatory actions based on most current evidence
- Creation of the **Pharmacoepidemiology Discussion Group** (PEpiDG)
- **Concept paper** recommending establishment of new guideline endorsed in **July 2021**
  - To "*promote faster access of patients to new drugs*", "*increase confidence in PV activities using RWD*", "*accelerate rapid accumulation of safety data*", "*promote sharing of post-marketing safety information among different regulatory agencies, leading to better decision-making*"

PEpiDG Gap Analysis



※ Guidelines describing more than one topic are categorized in multiple relevant topics.

https://www.pmda.go.jp/files/000241195.pdf

ICH M14 background – ctn'd

- ICH M14 Informal Working Group formed in Nov. 2021
- Concept paper endorsed in April 2022
- Working group formalised in May 2022
- Rapporteur: FDA, Regulatory lead: Japan (PMDA)
- Overall aim: to develop harmonized recommendations for post-approval non-interventional studies using RWD on drugs, vaccines and other biologics. Studies with treatment assignment are excluded

ToC

Guideline establishment target date:

January 2025