ICH Pharmacoepidemiology Discussion Group activities

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ICH Pharmacoepidemiology Discussion Group (PEpiDG)

Introduction

ICH Reflection Paper
Endorsed by the ICH Assembly on 5 June 2019

ICH Reflection paper

Strategic Approach to International Harmonization of Technical Scientific Requirements for Pharmacoepidemiological Studies Submitted to Regulatory Agencies to Advance More Effective Utilization of Real-World Data

- The reflection paper was endorsed in June 2019 for advancing more effective utilization of real world data (RWD) in regulatory setting
  - Establishment of Pharmacoepidemiology Discussion Group (PEpiDG)

Background

- Pharmacoepidemiological studies with active use of RWD have globally increased for regulatory submission.
- Some regulatory guidelines related to epidemiological evaluation during the post-marketing stage have been already published in each region (e.g. FDA, ENCePP, PMDA, etc.).
- There is currently no ICH guideline that focuses on pharmacoepidemiological studies.

Objectives

https://www.ich.org/products/reflection-papers.html

- **Harmonize the technical scientific requirements related to pharmacoepidemiological studies submitted to regulatory agencies.**

Members of the PEpi-DG

ANVISA, Brazil	Bill and Melinda Gates Foundation
CDSCO, India	EC, Europe
EFPIA	FDA, United States
Health Canada,Canada	JPMA
MHLW/PMDA, Japan	NMPA, China
PhRMA	SFDA, Saudi Arabia
Swissmedic, Switzerland	TGA, Australia
WHO	

Past Activities of PEpiDG

PEpi-DG was endorsed on June 5th 2019.

Nov. 2019

First web-conference

All members proposed topics for harmonization.

Mar. 2020

Second web-conference

Conducted GAP analysis.

Aug. 2020

Third web-conference

Discussed results of GAP analysis and prioritized topics

Oct. 2020

Third web-conference

Discussed the first opportunity proposal

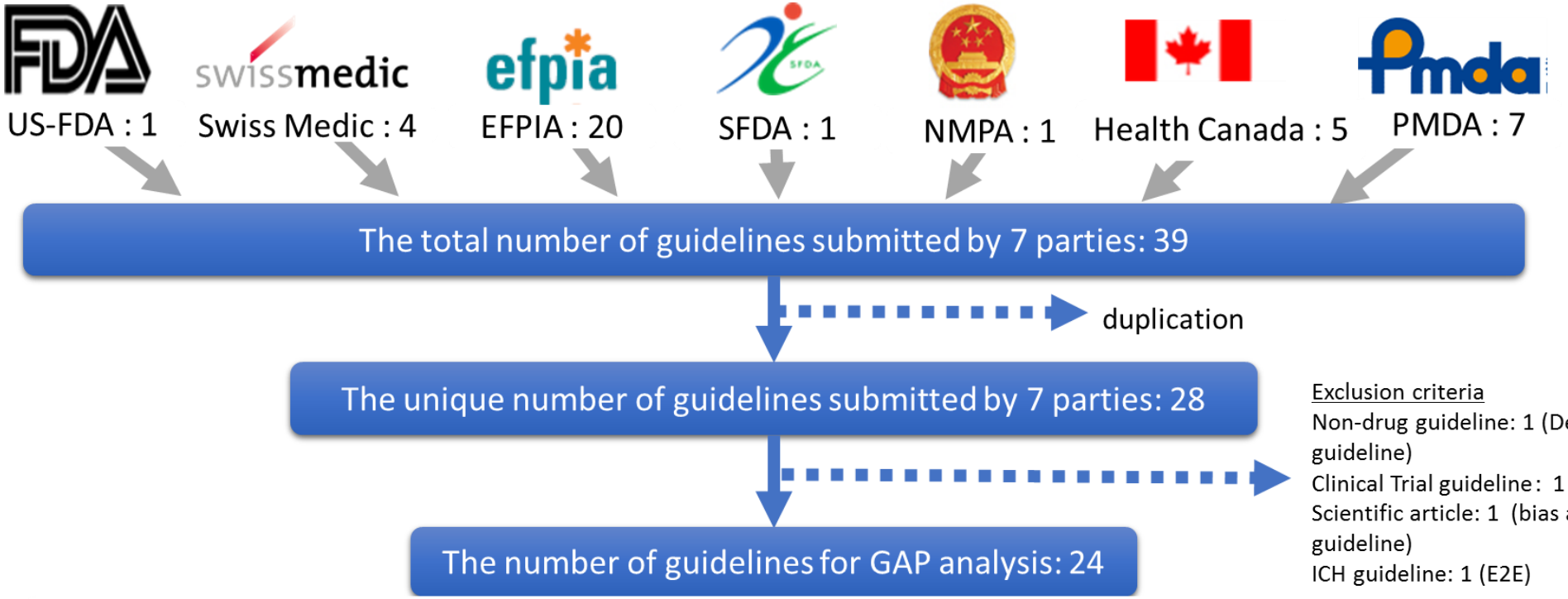
Dec. 2020: Submit the first opportunity proposal on
"General principles on planning and designing pharmacoepidemiological studies that utilize real-world data for safety assessment of a medicine"

GAP analysis

<Objectives>

- To figure out which topics have been already published or well described in many regions
- To help our discussions for prioritizing topics in ICH

GAP analysis - Methods



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

Overview of guidelines for GAP analysis

Topics	Total number of regions	Total number of guidelines	# of guidelines published by						
			US-FDA	EMA/ ENCePP	NMPA	MHLW/ PMDA	Health Canada	SFDA	ISPE
Protocol format	5	9	1	2	0	2	1	1	2
Purpose of RWD/RWE utilization	5	9	4	2	1	1	1	0	0
General principles on study plan	4	9	2	1	0	2	1	0	3
Methodology	4	8	2	2	1	1	0	0	2
Data reliability	4	9	3	1	0	3	1	0	1
Reporting format	3	4	0	1	0	1	0	1	1
Validation	3	4	1	1	0	1	0	0	1
Glossary	2	4	3	0	1	0	0	0	0

Most epidemiological topics have been already described in more than three regions' guidelines.

Results - General principles on study plan

- Number of guidelines (regions): **9 (4)**
- Total number of key items: **9**
- The number of key items described in three or more regions' guidelines: **8**
- Index of conformity: **8/9 * 100 = 89%**

Note:
Many key items were described in the regulatory guidelines of multiple regions.

Table. List of all key items in this topic.

Key items	Number of Regulatory guidelines (Number of regions)
General considerations	4 (4)
Database selection	6 (4)
Design considerations	5 (4)
Target population	4 (4)
Exposure definition	5 (4)
Outcome definition	5 (4)
Analyses	5 (4)
Data management	4 (4)
Limitation	1(1)

The first opportunity proposal

- Based on the results of the gap analysis, the PEpiDG has prioritized a list of potential topics to include in an ICH guideline to facilitate an international harmonized approach for the submission of high-quality RWD and RWE to regulatory agencies.
- As a result, PEpiDG reached a consensus that the establishment of an ICH guideline on the general principles of planning and designing pharmacoepidemiological studies that use RWD in the context of drug safety assessment is the highest priority for promoting an internationally harmonized approach on the use of such studies for regulatory purpose.
  - This is because,
    1) there are sufficient regulatory use cases accumulated on this topic
    2) the guideline will cover fundamental issues and overarching principles which will support other important topic areas with the potential for harmonization, such as aspects of “protocol and report format” and “methodology”.

Objectives of the proposal

- The proposed guideline will outline recommendations on general considerations when utilizing RWD for drug safety assessments, such as: data source selection, study design, definitions of target populations, exposure and outcome(s), and analytic approaches.
- The guideline will promote faster access of patients to new drugs by giving more confidence for pharmacovigilance activity with RWD and accelerating rapid accumulation of safety data in an internationally harmonized way in real world setting.
- It also promotes sharing post-marketing safety information among different regulatory agencies, leading to better decision making.

Future activities

- The first proposal was endorsed by the ICH assembly in June 2021
  - Move forward to the formal establishment of Expert Working Group
- PEpiDG will continue discussions about what other topics would be needed in ICH

- **PMDA web site**

http://www.pmda.go.jp/english/index.html

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Thank you very much for your kind attention !!