Current trends in global pharmacovigilance

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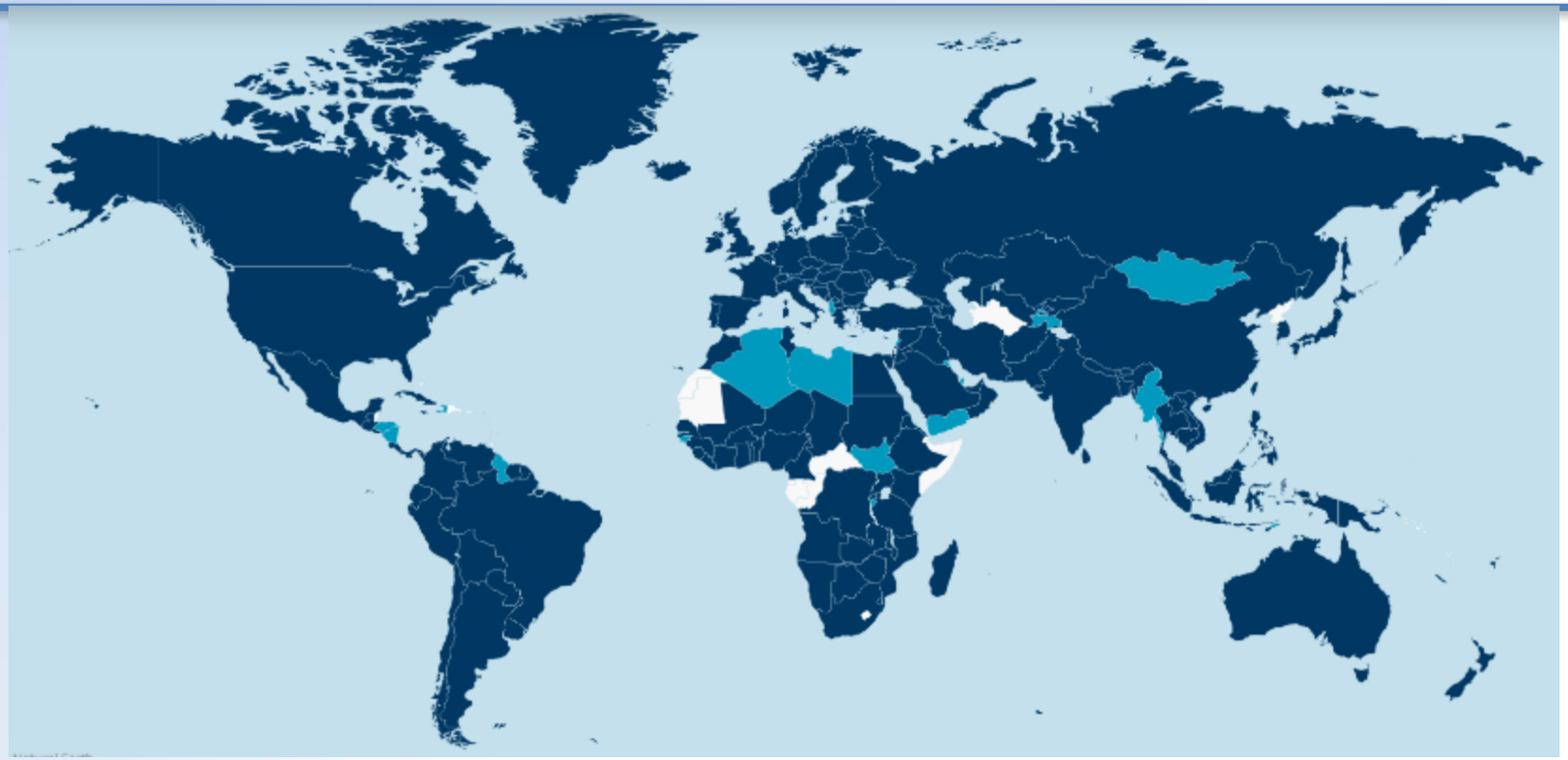
International Society of Pharmacovigilance, ISoP
London, UK

Presentation outline

- WHO
  - HQ
  - UMC
- Regulatory harmonization
- Technological development
- Academia
- Patient involvement
- Scientific progress
- Integration

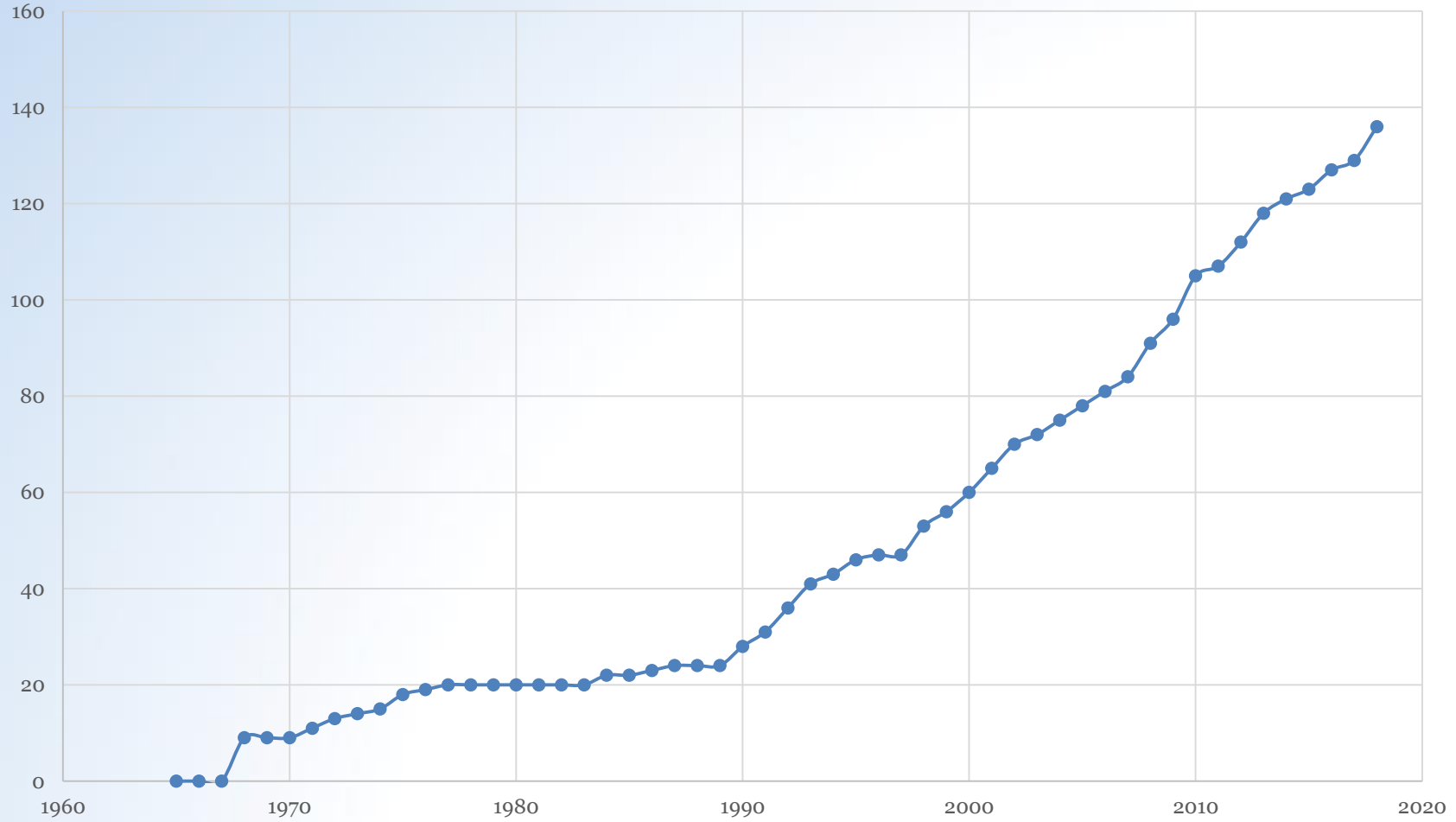
WHO PIDM Member Countries (September 2019)



Full members: 136
Associate members: 30
Total: 166

WHO PIDM members

Member countries cumulative



As of 2019-04-23

Safety and Vigilance: Medicines Group, WHO-Geneva

Coalition of Interested Partners

Strengthening Regulatory Systems

Current challenge

- Many organizations involved
- Lack of co-ordination

- Inefficient use of resources
- Duplication of efforts
- Inconsistent standards and actions

Strengthening Regulatory Systems

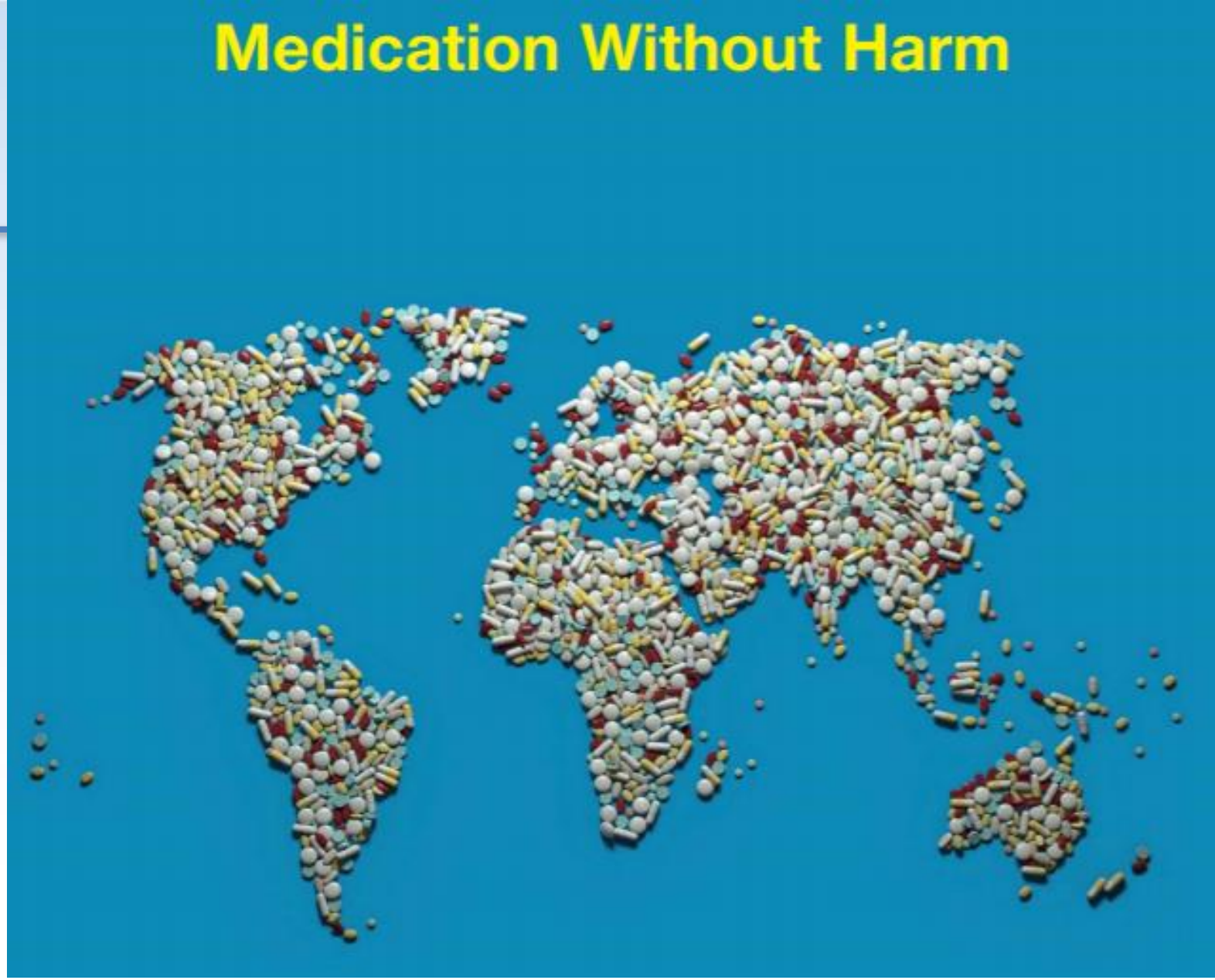
Goal

- Establish a network of partners who will collaborate to achieve better coordination, efficiency and outcomes in regulatory strengthening in Member States or regions to achieve better public health outcomes

- Coalition of Interested Partners (CIP)
  - Wise use of resources, wealth of expertise
  - Better outcome and impact
  - Improved capacity and sustainability
  - Sharing and adoption of best practices

WHO Global Patient Safety Challenge

- Campaign focusing on medication error prevention
- Launched in March 2017
- Managed by Patient Safety Programme
- Minimum coordination with WHO pharmacovigilance programme



Patient Safety: a global health priority

On the first-ever World Patient Safety Day on 17 September 2019, WHO will launch a global campaign to create awareness of patient safety and urge people to show their commitment to making healthcare safer.

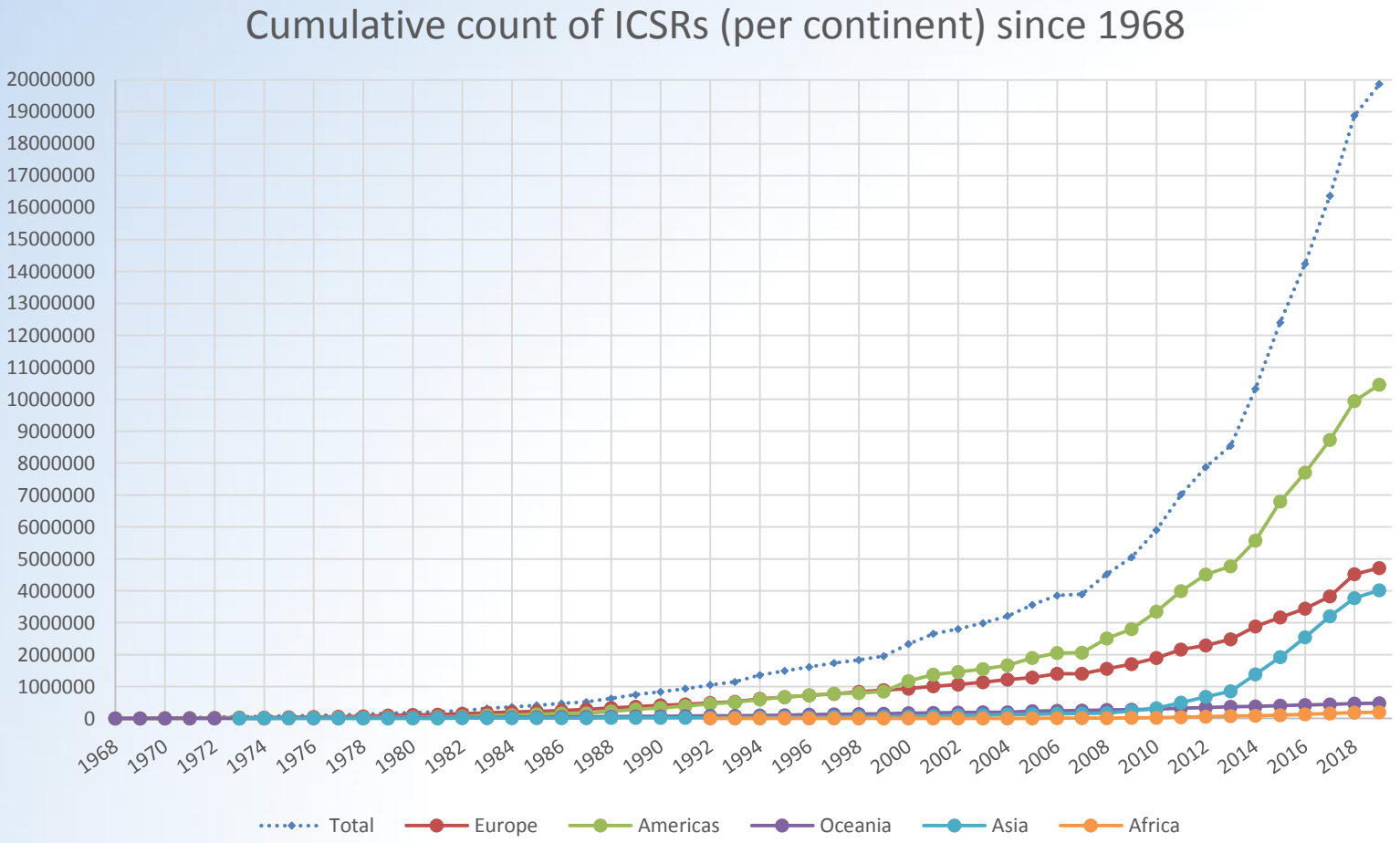
World Patient Safety Day 17 September 2019

Speak up for patient safety!

Announced by World Health Assembly May 2019

Uppsala Monitoring Centre - the staff

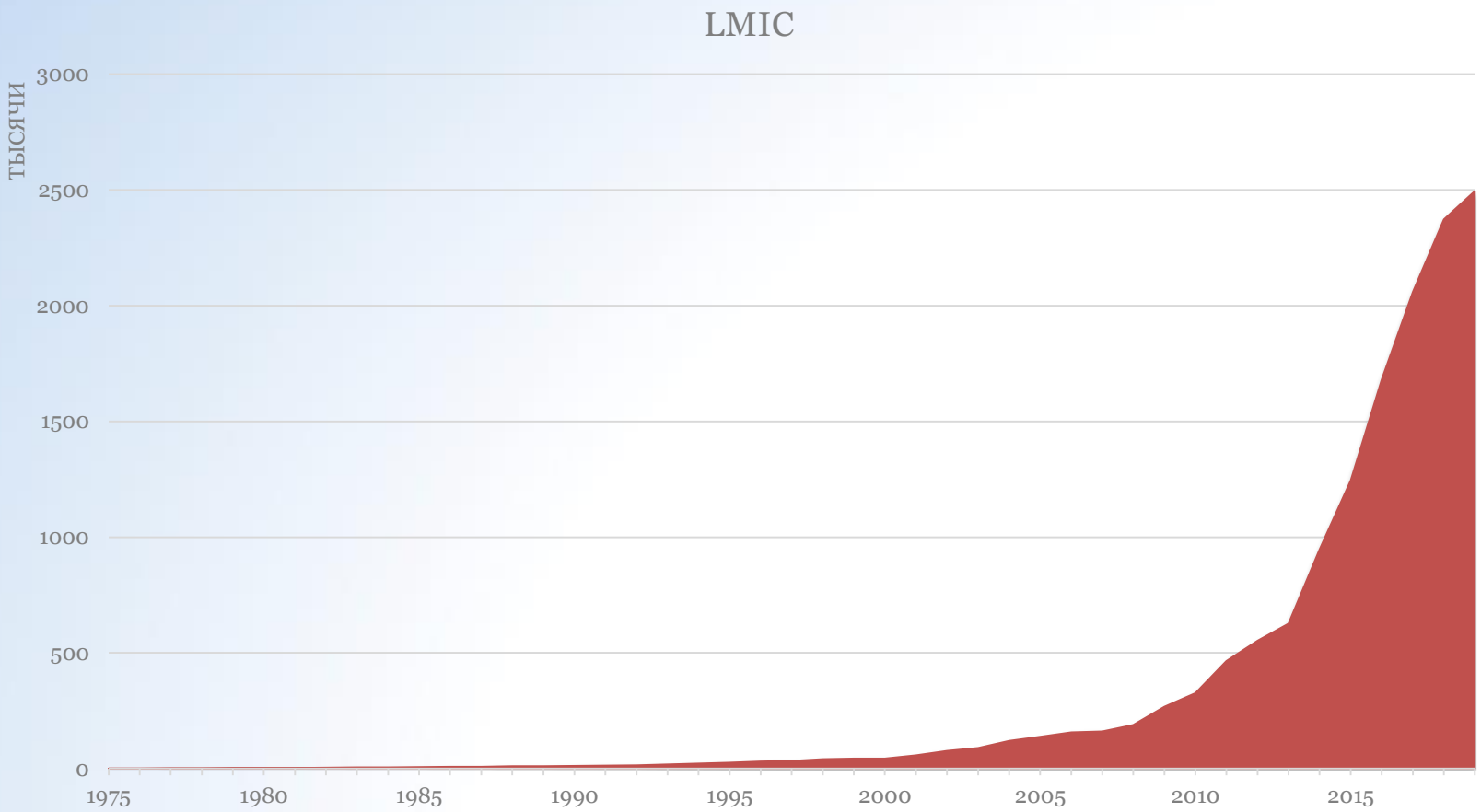
VigiBase - Number of ICSRs



Almost 20 million
Individual Case Safety Reports (ICSRs)

As of 2019-04-23

VigiBase - LMIC Contribution



As of 2019-04-23

- Regulatory harmonization

ICH Guidelines for PV

E2A	• Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
E2B(R3)	• Clinical Safety Data Management: Data Elements for Electronic Transmission of ICSRs
E2C(R2)	• Periodic Benefit-Risk Evaluation Report (PBRER)
E2D	• Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
E2E	• Pharmacovigilance Planning
E2F	• Development Safety Update Report

PV regulations for pharma industry

https://www.ema.europa.eu/en/human-regulatory/post-authorisation

Fora for regulatory harmonization

Asia-Pacific Economic Cooperation (APEC)

Eurasian Economic Union

Gulf Central Committee for Drug Registration (GCC)

Pan American Network for Drug Regulatory Harmonization (PANDRH)

Association of South-East Asian Nations (ASEAN)

African Medicines Regulatory Harmonization

Regional networks assessed in scientific studies

Received: 22 March 2018 | Revised: 23 October 2018 | Accepted: 28 November 2018
DOI: 10.1002/pds.4717

ORIGINAL REPORT

WILEY

Current status of pharmacovigilance regulatory structures, processes, and outcomes in the Asia-Pacific region: Survey results from 15 countries

Drug Safety (2018) 41:1285–1302
https://doi.org/10.1007/s40264-018-0708-5

SPECIAL ARTICLE

CrossMark

Enhancing Pharmacovigilance Capabilities in the EU Regulatory Network: The SCOPE Joint Action

Anna Radecka[1] · Louise Loughlin[1] · M
Marina Dimov Di Giusti[4] · Marina Les
June Raine[1]

Published online: 21 August 2018
© The Author(s) 2018

Abstract
In November 2013, a team of European
in Europe (SCOPE) Joint Action. Fund
involved Member States, SCOPE gathe
pharmacovigilance systems to meet th

Hilda Ampadu *et al. Globalization and Health* (2018) 14:109
https://doi.org/10.1186/s12992-018-0431-0

Globalization and Health

RESEARCH Open Access

Organizational capacities of national

CrossMark

Drug Saf
DOI 10.1007/s40264-017-0510-9

CrossM

ORIGINAL RESEARCH ARTICLE

Drug Safety
https://doi.org/10.1007/s40264-019-00807-4

REVIEW ARTICLE

Check for updates

Pharmacovigilance Systems in Arab Countries: Overview of 22 Arab Countries

Thamir M. Alshammari[1,2] · Neslihan Mendi[3] · Khalidah A. Alenzi[4] · Yazed Alsowaida[1,5]

© Springer Nature Switzerland AG 2019

AN and Selected
ive Signal

percent of ASEAN countries util
help detect signals from ADR rep
in the other non-ASEAN count
hat the development of a QSDA w

- Technological development

New ways of collecting data Reporting APP

WEB-RADR

Partnership with WHO

- Introduced in Burkina Faso, Zambia, UAE, Ethiopia and others

Other APP developed by Indian PvPI

- Offered to others in region

Real time data recording

Wearables

Real World Evidence

- Introduction of electronic healthcare records globally
- Health insurance claims data
- Patient registers

- Automatic extraction of case safety information
  - Trigger tools and biomarkers

Big Data for pharmacovigilance

Therapeutic Advances in Drug Safety

Hypothesis-free signal detection in healthcare databases: finding its value for pharmacovigilance

Ther Adv Drug Saf

2019, Vol. 10: 1–9

DOI: 10.1177/2042098619864744

Andrew Bate, Ken Hornbuckle, Juhaeri Juhaeri, Stephen P. Motsko

Social Media

Drug Safety
https://doi.org/10.1007/s40264-019-00858-7

SPECIAL ARTICLE

Recommendations for the Use of Lessons from IMI WEB-RADR

John van Stekelenborg[1] · Johan Ellenius[2] · Simo
Juergen Dietrich[6] · Sara Gama[7] · David Lewis[7,8] · Vi
Gregory Powell[11] · Alicia Ptaszyńska-Neophytou[12]
Munir Pirmohamed[14,15]

Key Points

General social media, as exemplified by sample data from Facebook and Twitter, are not recommended for broad statistical signal detection.

Social media channels may provide a useful adjunct to pharmacovigilance activities in specific niche areas such as exposure during pregnancy and abuse/misuse of medicines.

Future enhancement of adverse event recognition algorithms may broaden the scope and utility of social media over time.

Technological development

- Use of artificial intelligence and machine learning
- Natural language processing
- Robotic process automation

ISoP Seminar – Intelligent Automation in Pharmacovigilance

Pre-service PV training for HCP

Drug Saf
DOI 10.1007/s40264-014-0216-1

SPECIAL ARTICLE

Teaching Pharmacovigilance: the WHO-ISoP Core Elements of a Comprehensive Modular Curriculum

Jürgen Beckmann · Ulrich Hagemann · Priya Bahri · Andrew Bate · Ian W. Boyd · Gerald J. Dal Pan · Brian D. Edwards · I. Ralph Edwards · Kenneth Hartigan-Go · Marie Lindquist · John McEwen · Yola Moride · Sten Olsson · Shanthi N. Pal · Rachida Soulaymani-Bencheikh · Marco Tuccori · Claudia P. Vaca · Ian C. K. Wong

1 Introduction

The importance of pharmacovigilance (PV) for safe medicines and their safe use has increasingly been recognised

other complementary remedies, used to prevail. A
of publications, guidelines and information abou
observed or further investigated adverse drug r
(ADRs) from all over the world creates a growing

2018

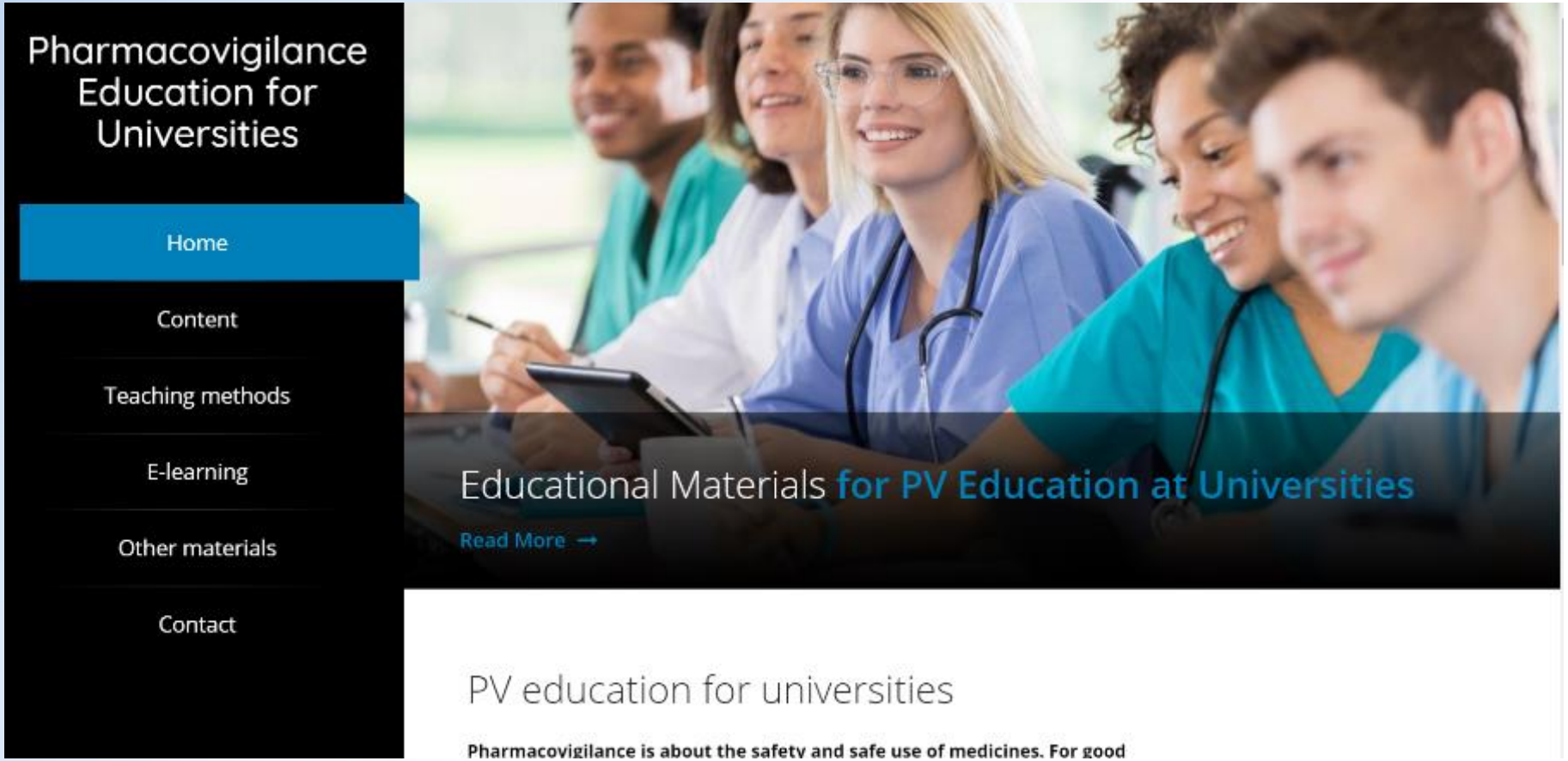
Drug Saf
https://doi.org/10.1007/s40264-018-0681-z

CURRENT OPINION

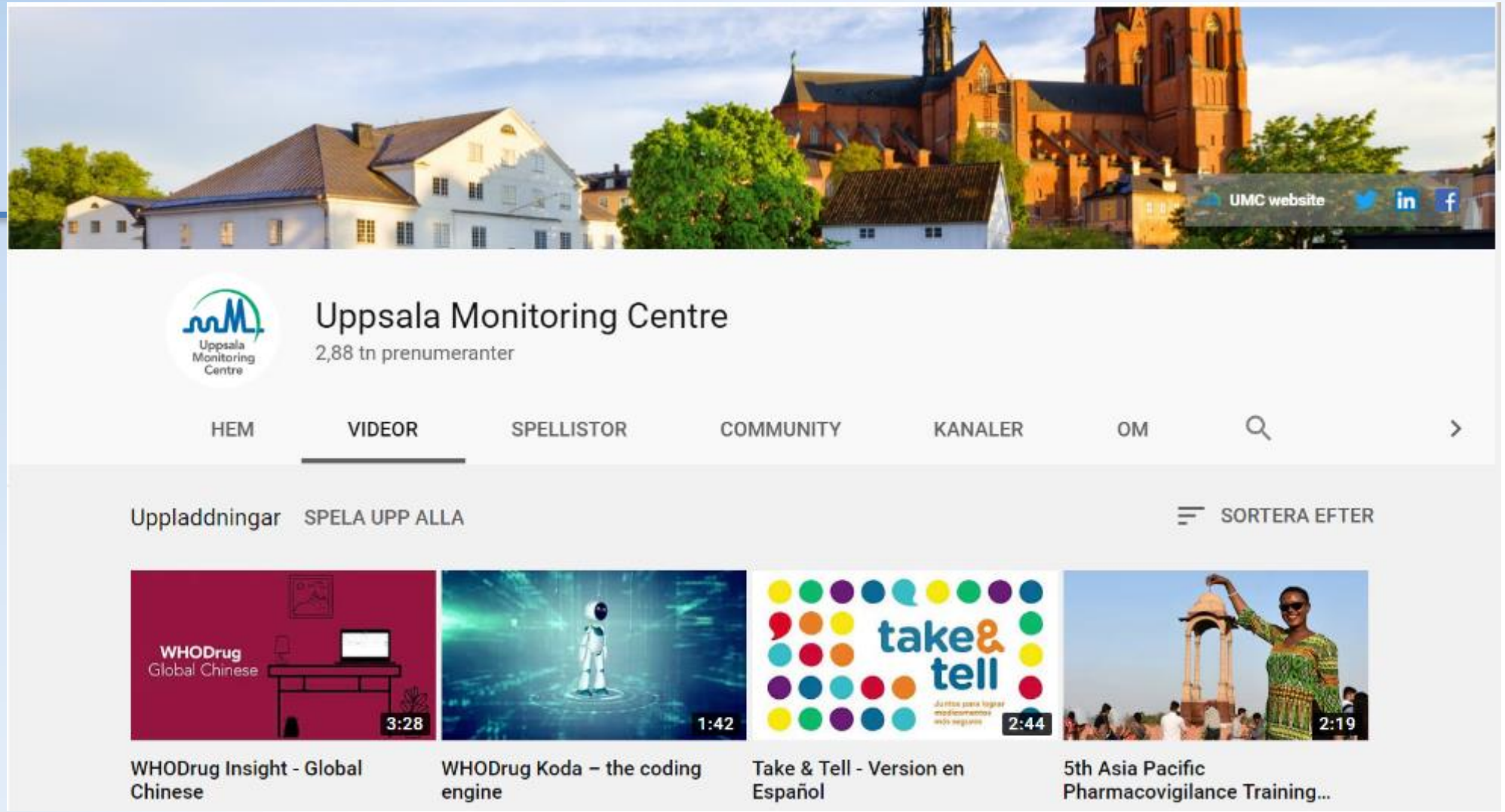
What Future Healthcare Professionals Need to Know About Pharmacovigilance: Introduction of the WHO PV Core Curriculum for University Teaching with Focus on Clinical Aspects

Rike van Eekeren[1,2] · Leàn Rolfes[1,2] · Andries S. Koster[3] · Lara Magro[4] · Gurumurthy Parthasarathi[5] · Hussain Al Ramimmy[6] · Tim Schutte[7,8] · Daisuke Tanaka[9] · Eugène van Puijenbroek[1,2] · Linda Härmark[1]

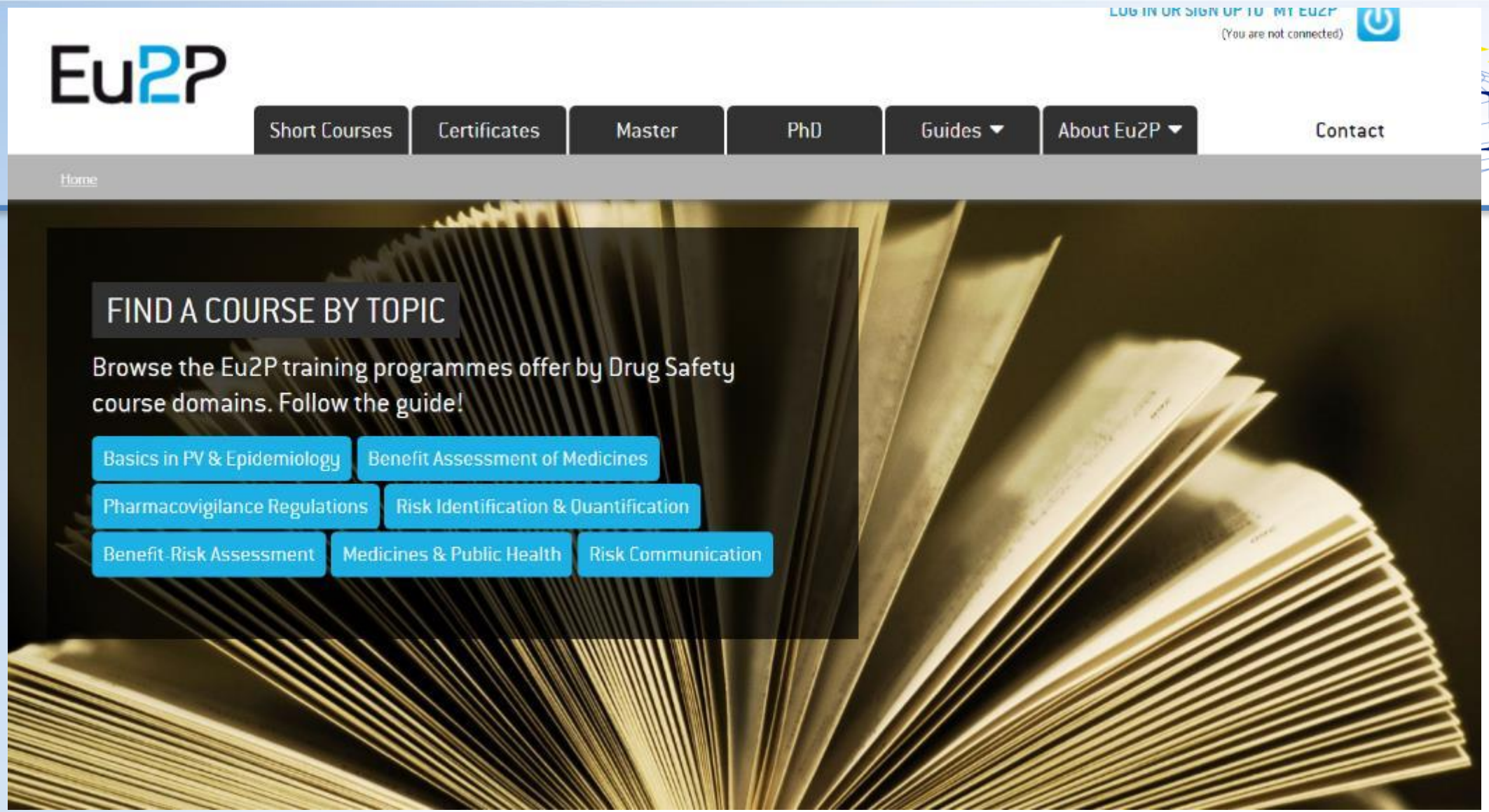
www.pv-education.org



Netherlands Pharmacovigilance Centre Lareb, 's-Hertogenbosch, the Netherlands, E-mail: info@lareb.nl



https://www.youtube.com/channel/UC1SmOUUe6noAWVY4P2JEljw/videos



Partnership of 7 universities + 2 regulatory agencies + 15 pharma companies

- Patient involvement

A Reneaissance of PV

Drug Saf
DOI 10.1007/s40264-016-0441-x

CURRENT OPINION

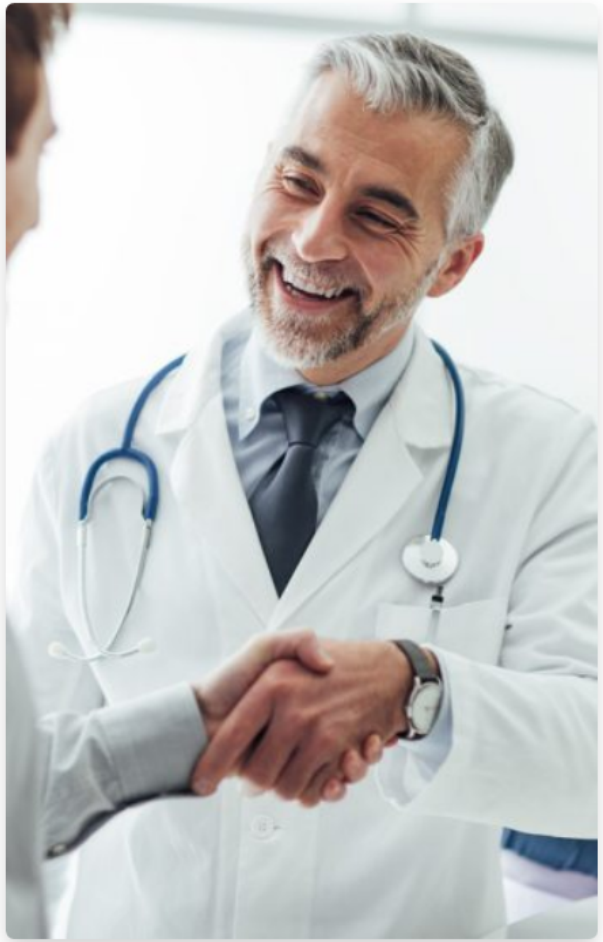
Patient-Reported Safety Information: A Renaissance of Pharmacovigilance?

Linda Härmark[1] · June Raine[2] · Hubert Leufkens[3] · I. Ralph Edwards[4] · Ugo Moretti[5] · Viola Macolic Sarinic[6] · Agnes Kant[1]

Abstract The role of patients as key contributors in pharmacovigilance was acknowledged in the new EU pharmacovigilance legislation. This contains several efforts to increase the involvement of the general public, including

similar associations and they give more detailed information regarding quality of life including psychological effects and effects on everyday tasks. Current methods used in pharmacovigilance need to optimise use of the information

CIOMS WG XI - Patient Involvement in development and safe use of mediciens



Working Group XI – Patient Involvement

CIOMS has developed international guidelines in many key areas of safety of medicines for decades. While the patient is recognized as a key stakeholder in CIOMS guidelines, their role in existing and previous guidelines has been defined primarily by other stakeholders. However, some patient input experience was recently obtained by CIOMS when formulating guidance in CIOMS Working Group (WG) IX on Practical Approaches for Risk Minimisation of Medicinal Products.

CIOMS is now launching a Working Group with the purpose of elaborating pragmatic approaches **for involvement of patients as key stakeholders in the development and safe use of medicines**. Specific aspects of this involvement will include patient input to the development of medicines in areas of medical need; the collection and reporting of safety information; input to benefit-risk assessment; the use of technologies involving patients for safety communication between stakeholders including patients, healthcare professionals, pharmaceutical companies, regulators and academia. The aim will be to formulate Points to Consider for the optimal consideration of patient perspectives and preferences to support the safe and effective use of medicines throughout their life cycle. Such patient involvement from discovery to clinical and market use of medicines, is expected to improve the health of individual patients and the public. The ambition is to address a wide range of the challenges which we believe would benefit from further practical guidance and advice

The task for the CIOMS group would be to develop criteria and guidelines on patient involvement in drug development, pharmacovigilance and risk management as well as several other areas where harmonized and pragmatic patient-centred approaches should be adopted.

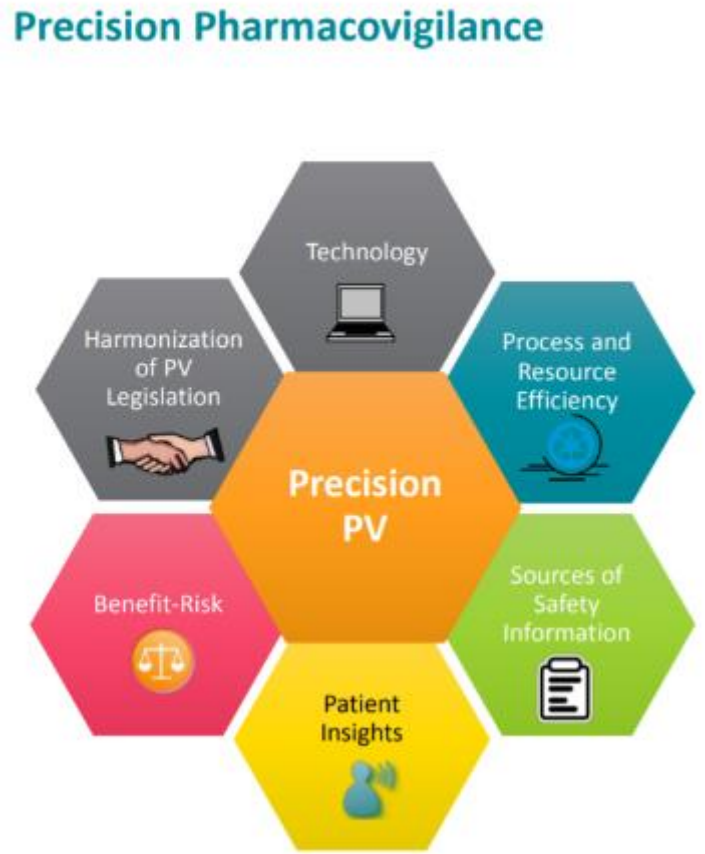
The new WG will be composed of key stakeholders **including patient organizations, industry, regulators and academia**, with potential additional representation from ethicists and Health Care Professionals groups, to address the present challenges, knowledge and practice gaps related to patient involvement in development and safe use of medicines in order to formulate pragmatic consensus-based recommendations. Furthermore, collaborative efforts aimed at capitalizing on existing initiatives and avoiding duplicative efforts would strengthen the WG in order to provide output that is as comprehensive as possible.

It is anticipated that the WG will operate for three years (from 2018 to 2021). In person meetings are contemplated 2-3 times per year. The first meeting took place 19-20 April 2018 in Geneva. Finalization of the vision about the concrete tasks of the new WG work will take place during the first meeting of the WG in presence of all stakeholders.

- Preventive pharmacovigilance

Precision pharmacovigilance

- Segmentation of risks
  in populations
- Predicting individual risks



Source: Vicky Edwards, EFPIA

Pharmacogenetics-based Pharmacovigilance

HLA Genotyping Results

	CBZ	Cases (n=13)	Controls (n=26)	Odds Ratio (OR)
HLA-B*1502	Positive	13	3	**181** (8.7 to 3785) $p=6.9*10^{-8}$
	Negative	0	23	

Sensitivity= 13/13 = 100%

Specificity= 23/26 = 88.5%

- Data from HSA's study supports strong association between CBZ-induced SJS and TEN and HLA-B*1502

- Power of study to reject null hypothesis of no association at 0.05 significance level is >99%

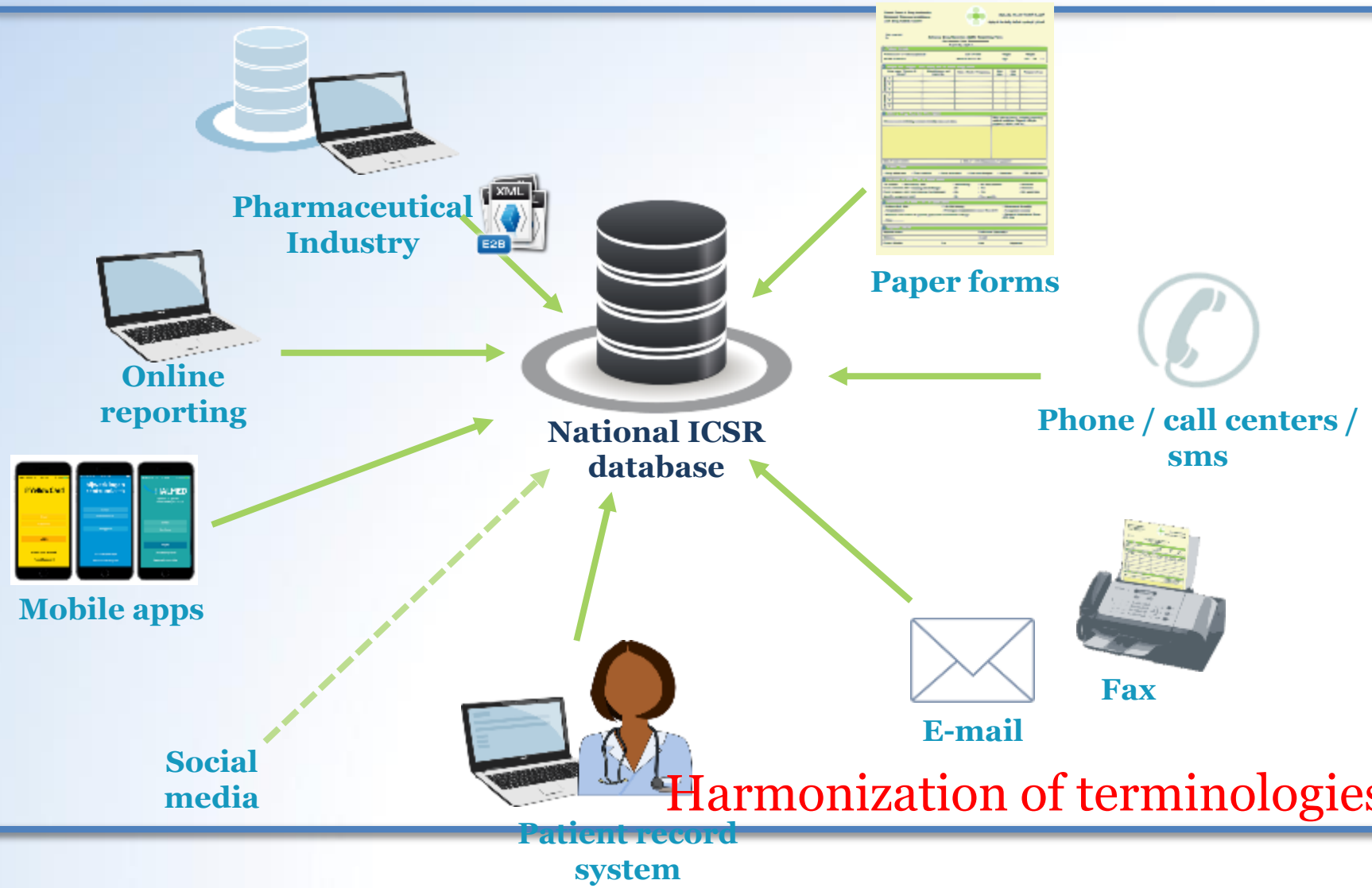
Sensitivity: test ability to identify true positives (those who will get SJS and TEN)
Specificity: test ability to identify true negatives (those who will not get SJS and TEN)

CBZ-induced SJS/TEN cases Significance to Public Health

Awarded Mrs Tan Shook Fong – PSS Innovation and Scientific Research Award 2015

- Integration

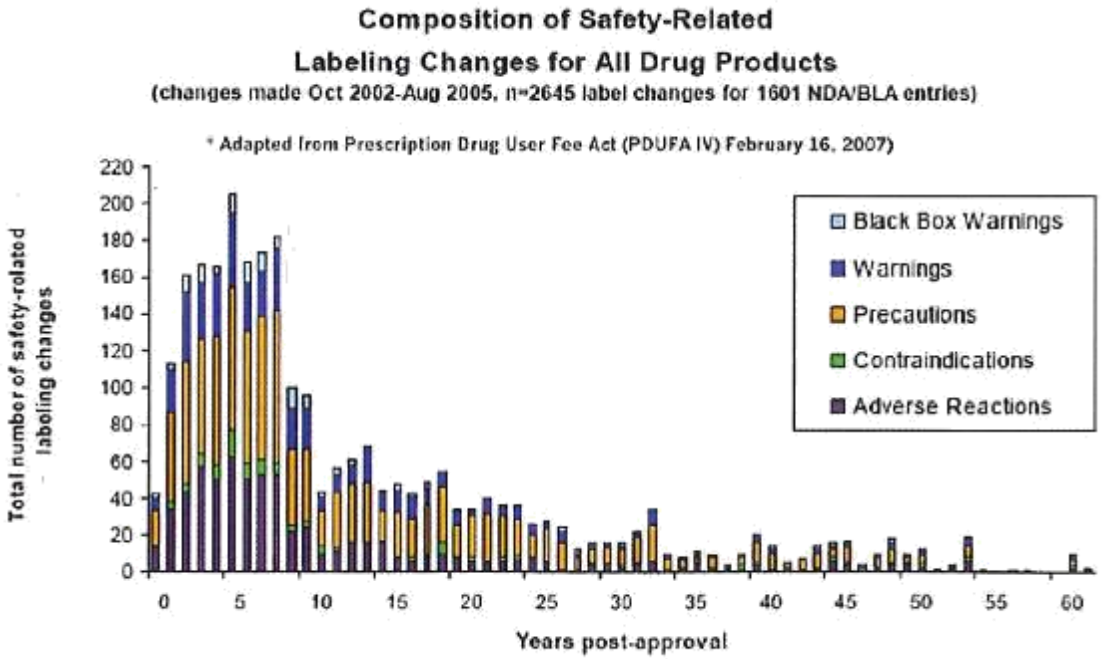
Integrating different sources of information



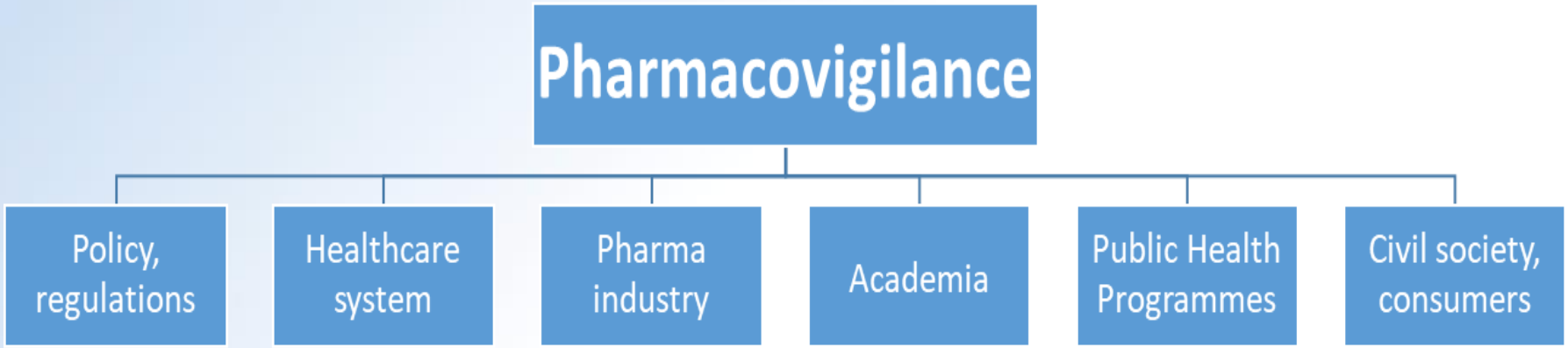
Harmonization of terminologies and formats

An integrated life-cycle approach

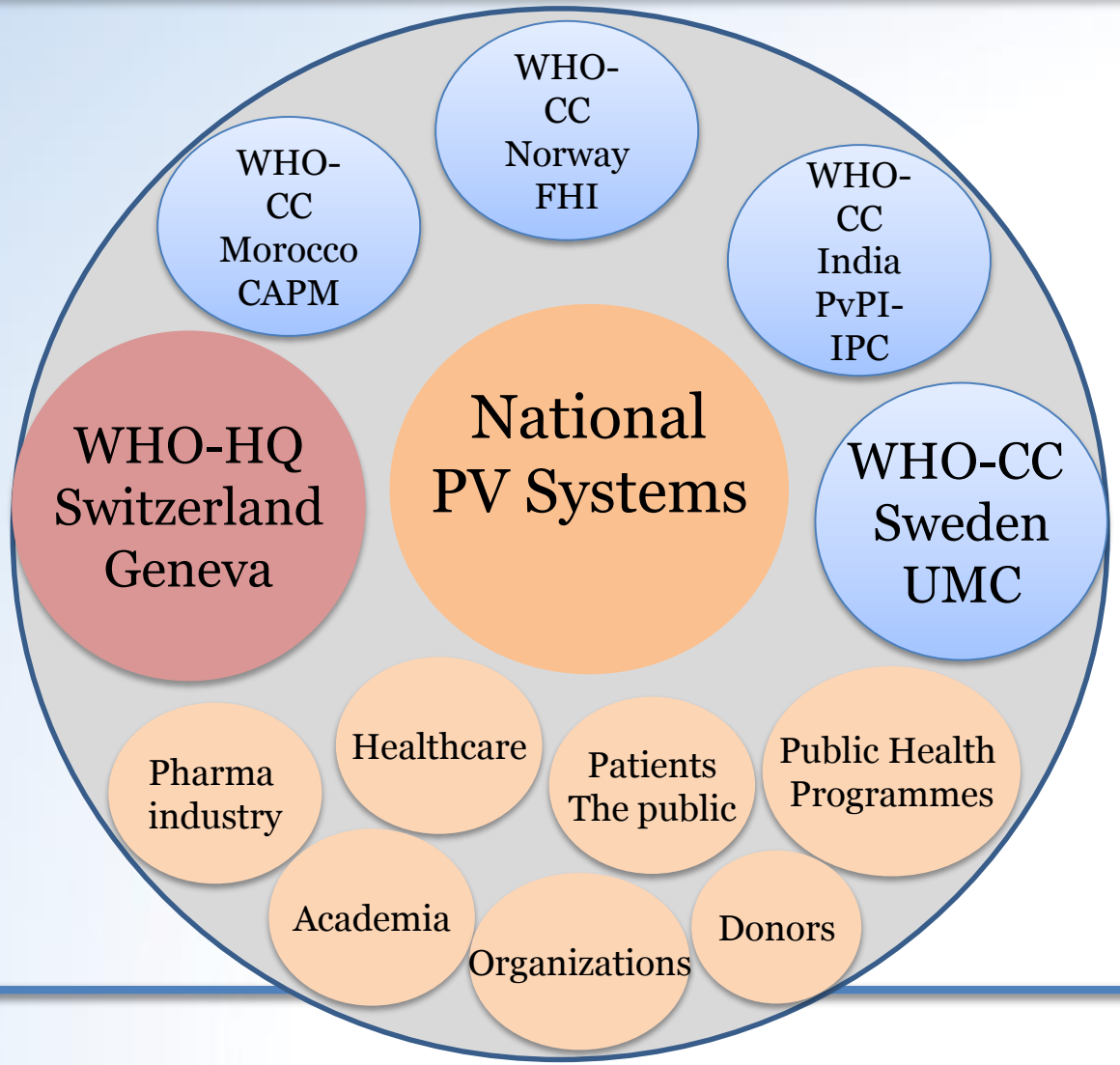
Phase	I	II	III	IV
Number exposed	10	100	1-2000	Millions
Patient type	Healthy volunteers	Highly selected	Selected	Real life
Identifiable risk	1:1	1:10	1:100	1:1000 to 1: 10 000



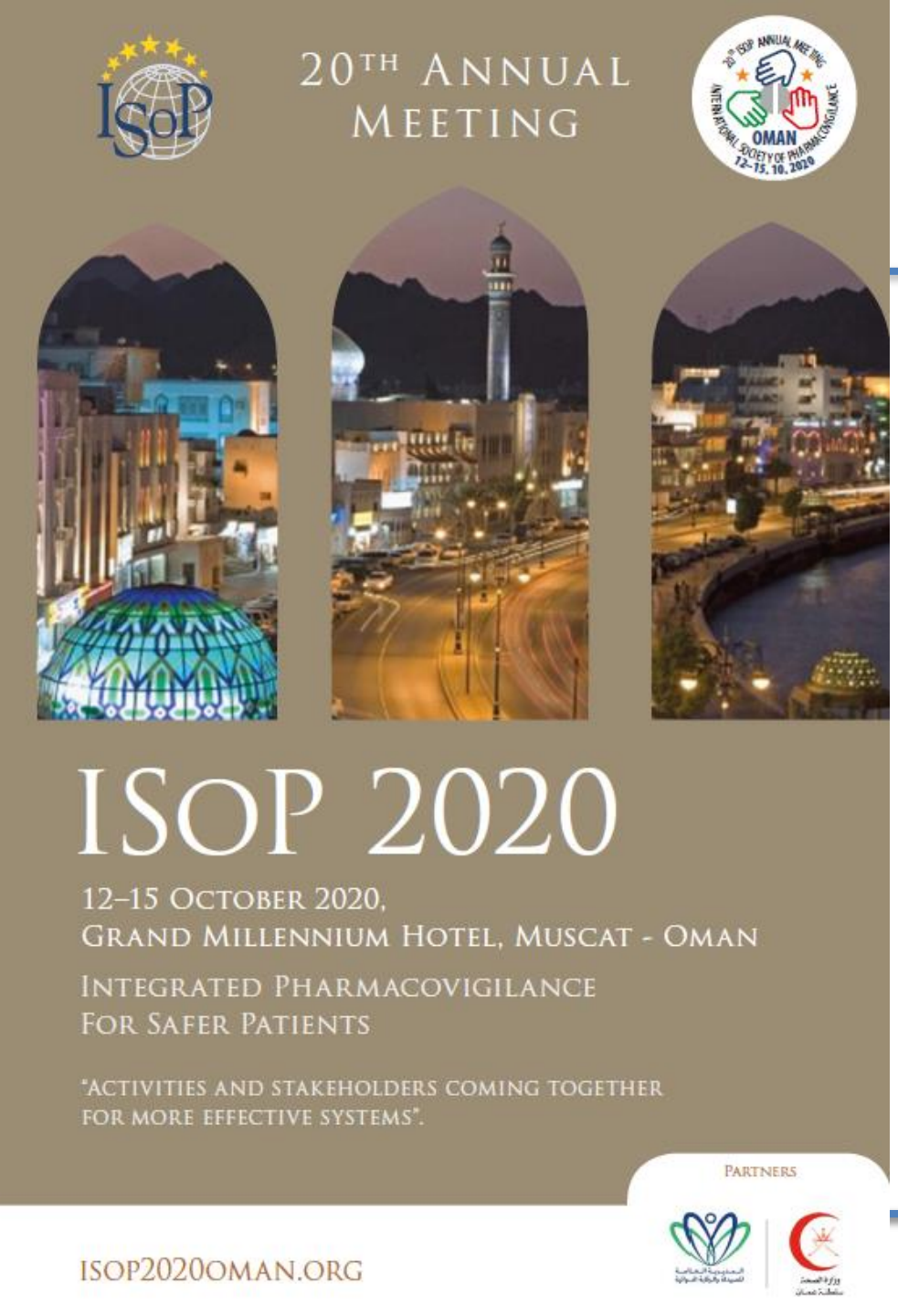
An integrated national pharmacovigilance system



An integrated global PV system



ISoP Annual Meeting 2020



- ☐ This ISoP event will be organised in Moscow in collaboration with Roszdravnadzor.
- ☐ Faculty from the EAEU region as well as Experts from ISoP and other international institutions will be involved as presenters and panellists.
- ☐ This event will include a one-day symposium followed by a two-day training course.
- ☐ Registration will be starting at 08:30 on the Symposium day. Sessions will be starting at 09:00 and ending at 17:30.
- ☐ The venue will be announced later on the ISoP website: www.isoponline.org.
- ☐ Practical information, programme and registration forms will be available from the ISoP Secretariat Ltd. based in the UK:

- 140 Emmanuel Road, London SW12 0HS
- Phone and Telefax: +44 (0)20 3256 0027
- E-mail: administration@isoponline.org
- Website: www.isoponline.org.

Moving Pharmacovigilance Forward in the Eurasian Economic Union (EAEU)

ISoP Symposium & Training Course

Moscow April 2020

First Announcement

Thank you for your attention

Acknowledgements:
Shanthi Pal, WHO
Helena Sköld, Anna Hegerius, UMC

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