IVD VIGILANCE

AMDM Annual Meeting

Elliot P. Cowan, PhD

April 10, 2019

Partners in Diagnostics, LLC
Regulatory Consulting to Advance Global Health
13817 Congress Drive • Rockville, Maryland 20853-2632 USA • Tel: +1 301-233-0897 • Email: elliot.cowan@partnersindiagnostics.com

The Agenda

is IVD vigilance?

should you care?

you can help.

WHAT …

is IVD vigilance?

WHY…

should you care?

HOW…

you can help.

IVD Vigilance

- Pharmacovigilance
  - The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
  - Key target is substandard and falsified (SF) products [formerly referred to as substandard, spurious, falsely labeled, and counterfeit (SSFFC) medical products]
  - Worldwide effort to address
- IVD vigilance
  - Same concept but for IVDs

What's the problem?

- Despite the critical role IVDs play, they tend to be the least regulated of all medical products globally.
- Lack of regulatory oversight provides fertile ground for the introduction of substandard and falsified IVDs.
- Problems that arise with medicines are far more likely to be reported in the medical and scientific literature compared to IVDs

Tropical Medicine and International Health doi:10.1111/j.1365-3156.2011.02852.x

VOLUME 16 NO 11 PP 1439–1449 NOVEMBER 2011

Quality of medical devices and *in vitro* diagnostics in resource-limited settings

Marcella Mori[1,4], Raffaella Ravinetto[2] and Jan Jacobs[1,3]

1 *Unit of Tropical Laboratory Medicine, Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium*
2 *Clinical Trials Unit, Prince Leopold Institute of Tropical Medicine, Antwerp, Belgium*
3 *Department of Medical Microbiology, Faculty of Health, Medicine and Life Sciences, Maastricht, The Netherlands*
4 *Operational Unit Genito-pathology, Operational Directorate Bacterial Diseases, Veterinary and Agrochemical Research Center, Brussel*

Little evidence of problems with IVDs.

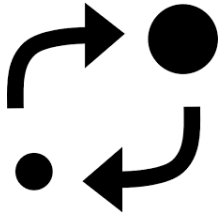
Scarcity of information on IVD issues likely not due to the fact that substandard and falsified IVDs do not exist, but rather they are either underreported or not recognized.

The extent of the problem is simply not known.

Examples of Substandard and Falsified IVDs

Changed Expiration Date

Unaddressed Quality Issues



Regulatory Versions

Misleading Information

Counterfeit Product

WHAT …

is IVD vigilance?

WHY…

should you care?

HOW…

you can help.

Impact

Human

Financial

Reputation

WHAT …

is IVD vigilance?

WHY…

should you care?

HOW…

you can help.

Council for
International
Organizations of
Medical
Sciences

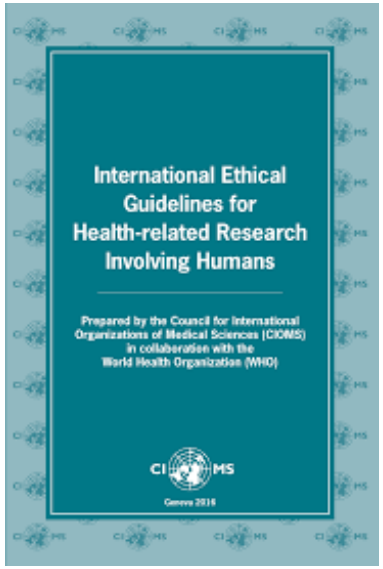
https://cioms.ch/

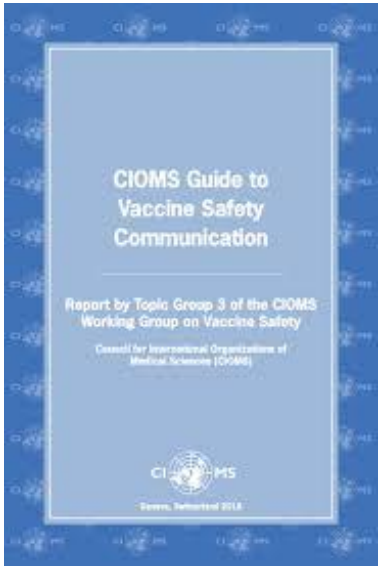
What is CIOMS?

- An international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949.
- CIOMS represents a substantial proportion of the biomedical scientific community through its member organizations, which include many of the biomedical disciplines, national academies of science and medical research councils.
- Mission: *To advance public health through guidance on health research including ethics, medical product development and safety.*

Programs, Activities

TECHNICAL WORKING GROUPS

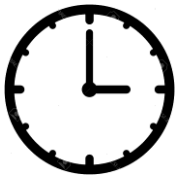




See https://cioms.ch/ for list of TWGs and their meeting minutes.

CIOMS guidelines have served as the basis for several ICH pharmacovigilance guidelines.

CIOMS Technical Working Groups

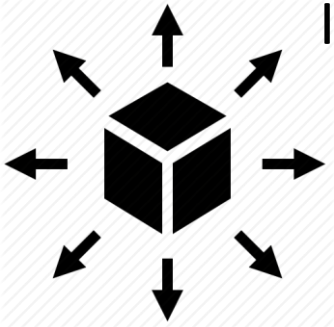


Run-time

- Typically 2-4 years
- 2 in-person meetings/year in Geneva

Product

- Public report with recommendations



Impact

- Legally not binding, yet significant influence on healthcare community (including decision makers and other organizations with impact)
- Can be transformed to be legally binding when embodied in regional/national legislation

TWG Composition

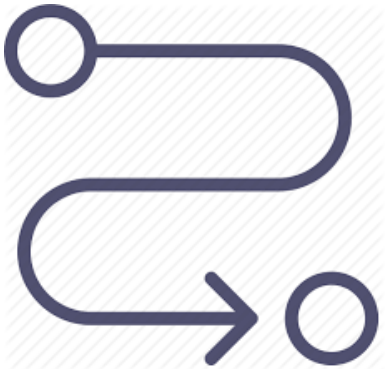
- International experts from different countries and regions
- Usually composed of all important stakeholders (20-30)
  - Regulators (from IMDRF countries)
  - Academia
  - Industry (6-8)
    - CIOMS has a history of collaboration with global industry associations for medicines and vaccines
  - WHO (as member/observer of the TWG)
  - Others
- Also, participation by representatives from CIOMS member organizations and other organizations interested in the topic

Where We Are

Approval received from CIOMS to form a TWG for IVD Vigilance

Beginning to assemble the TWG

Where this is headed



- Goal
  - Create a framework for IVD vigilance, similar to pharmacovigilance
- Strategy
  - Define substandard and falsified IVDs.
  - Determine the current extent of substandard and falsified IVDs.
  - Raise awareness of the threat posed by substandard and falsified IVDs, from both a health and economic perspective, including through publications.
  - Develop a plan/framework for IVD vigilance, modeled after pharmacovigilance.

For more details on how your company can be a part of this important effort:

elliot.cowan@partnersindiagnostics.com

301-233-0897