DCVMN Pharmacovigilance WG 2022 Key Learnings & Activities

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DCVMN
Developing Countries Vaccine Manufacturers Network

DCVMN Commitment to Pharmacovigilance

- The DCVMN Pharmacovigilance WG goal is to increase and strengthen pharmacovigilance (PV) capacities and to enhance vaccine safety monitoring to implement a mature “fit for purpose” PV System.
- The pharmacovigilance WG ensures the DCVMN members are equipped with up-to date knowledge to implement best practices and training aligned with WHO and relevant national regulatory requirements.

DCVMN Pharmacovigilance Working Group

- Discuss the evolving Pharmacovigilance landscape to identify the needs of DCVMN members and share successful case studies.
- Provide access to external expertise (webinars, workshops, trainings).
- Create ad hoc projects or relevant projects which could benefit from DCVMN participation.

10 companies from

- Brazil
- China
- India
- Indonesia
- South Africa
- Vietnam

DCVMN Pharmacovigilance WG Areas of Focus 2022

- Finalization of the Risk Management Plan project
- Continuation of PV post-licensure training with PATH
- Pre-licensure period: Clinical Safety Management
- Active Vaccine Safety Surveillance
- Electronic Safety Data Management

Risk Management Plan Project

Completed!

- Aimed to strengthen the capacity of DCVMs for the development of risk management plans (RMPs) for vaccine registration and PQ submissions to meet the ICH Guidelines.
- **9 DCVMN member companies** took part in online workshops and active Risk Management Plan preparation exercise.
- Submitted Risk Management Plans were evaluated by DCVMN consultants with 1-1 feedback.
- Culmination of project was a final webinar and publication of DCVMN Risk Management Plan guidance document (RMP project - General Comments (dcvmn.net))

Continuation of post-licensure training with PATH

Completed!

- Held 3 online workshop trainings presented by PATH consultant to pharmacovigilance WG on MedDRA Coding Best practices, Data retrieval and Presentation (Training workshop materials – DCVMN)

	Session 1	Session 2	Session 3
Title	Medical Coding Term Selection Best Practices – Part 1	Medical Coding Term Selection Best Practices – Part 2	Data Retrieval and Presentation – Best Practices
Objectives	To introduce MedDRA® TERM SELECTION: POINTS TO CONSIDER document and cover important aspects related to: 1. General term selection procedures 2. Important term selection points	Continue presentation on the important term selection points	To introduce MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER document and cover important aspects from this guideline

Clinical Development & Medical Affairs WG Collaboration

Ongoing!

- Joint Face-to-Face Workshop held in June 2022 to discuss the role of Pharmacovigilance activities in clinical aspects of vaccines in pre-and post-licensure:
  - Stakeholders in Clinical Trial Safety Management
  - Systematic approach to patient safety
  - Pharmacovigilance Clinical Trials Guidelines
  - Safety assessments in Clinical Trials
  - Signal and Benefit-Risk Management

- From this meeting the Pharmacovigilance WG published a Pharmacovigilance specific SOP Master List with Explanatory Notes for the Pharmacovigilance activities in the pre- and post-licensure period

Active Vaccine Safety Surveillance

Ongoing!

- **Goal:** Strengthen active vaccine safety surveillance activities and capacities, and to support implementation.
- 2 day online training to support the creation of own AVSS plans.
- DCVMN Participant plans will be reviewed by DCVMN expert consultants with feedback.
- Training and outcomes will also be published on DCVMN moodle for future members.

Electronic Safety Data Management Systems

Ongoing

- **Goal:** Outline electronic safety data management systems and support adoption and implementation of such systems.
- Submit for publication a paper providing a holistic view on the requirements for adoption and implementation of an electronic safety data management system
- Distribute a DCVMN electronic safety data management systems acquisition tool and RfP template to assist members in acquiring system best suited to member needs.

Pharmacovigilance WG Key Learnings

- Trainings and direct experience through direct access to expertise and promote adoption of new approaches to pharmacovigilance.
- Pharmacovigilance activities are increasing for DCVMN members and extend throughout entire life-cycle of products including pre-clinical safety aspects relevant to humans.
- Internal collaboration and shared experience facilitate engagement and planning.