Regulatory and PV Working Groups Workshop

16th-17th Feb 2026- Andaz, New Delhi, India

Participants from DCVMN: Rajinder Suri (RS), Kumar Gaurav (KG), Manish Mahajan (MM),, Viska Indriani (VI), Ashna Pema (AP), Bruno Antonio De Oliveira (BO), Chetanraj Bhamare (CB), Devang Patel (DP), Devi Prasad Sahoo (DPS), Karunakaramaiah Jangam (KJ), Mandar Kshirsagar (MK), Pradip Das (PD), Reza Bosman (RB), Rini Mulia (RM), Sravan Kumar (SrK), Subhodeep Chakraborty (SCh), Yamini Bhatt (YB), Katharina Harmann (KH), Malika Almansouri (MA), Sonia Villaseñor (SV), Prerna Kumar (PK). Beatriz Luchesi (BL)-**VIRTUAL**

Signal Management, Risk Management, Benefit-Risk Management: An Integrated Framework

KH gave the group a presentation on the conceptual framework focusing on the main important points:

- PV is a continuous lifecycle (input-decision-action-re-assessment) loop: Signal Management → Risk Management → Benefit-Risk Management.
- **Signal Management**: The "engine" that triggers the loop through the question: Is this a risk? Signal management process: activities to determine if, based on the information retrieved, there are new risks associated with the product. Regulatory frameworks define how signals must be detected, assessed, and communicated by MAHs and authorities.
  - Detection -> Triage -> Validation -> Signal Evaluation -> Prioritization
  - *Signal Management Methods*
    - Qualitative (Case-by-Case) for small datasets (e.g., <100 cases) and systematic review for patterns, clusters, and trends in a specific time period.
      Requires the involvement of expert judgement and medical assessment with the support of epidemiology and consideration of background rates.
    - Quantitative Disproportionality Analysis is a method to detect statistical signals of disproportionate reporting in large databases (e.g., VigiBase, Vaers). The Observed vs. Expected quantitative analysis detects signals of disproportionate risk rates based on known exposure rates and background rates in the exposed population. Extension of the Observed to expected Analysis. Rapid Cycle Analysis (RCA). Is a near real-time method to compare observed vs. expected rates of pre-specified adverse events after exposure.
    - Machine Learning (ML) is at an emerging research stage.
- **Risk Management**: Operationalizes the benefit-risk assessment.
  - Identify the risk-> Assess the Risk -> control the risk -> Review controls and Risk communication.
  - Risk Identification: Confirmed signals become identified risks.
  - RMP: A prospective, proactive plan to manage risks. Make sure the RMP is aligned to the CTD and vice versa.
- **Benefit-Risk Management**: The core assessment that drives RMP and PSUR content. The assessment of safety is always the assessment of the Benefit-Risk Balance.
  - Assessment: A qualitative judgment weighing benefits against risks, highly dependent on therapeutic context (e.g., disease burden). Needs cross-functional teams.
  - Documentation: The PBRER/PSUR provides a retrospective, cumulative review. The RMP is a prospective and proactive risk management document.
  - Challenges related to: data quality, methodology, regulatory and compliance, operational and resources, stakeholder and decision-making as well as technological and

analytical challenges.

Manufacturer Perspectives & Challenges in Signal Management, Risk Management and Benefit-Risk assessment

Participants shared their perspectives and challenges on this topic, having the presentation from BL for Butantan, VI for Bio Farma, RB for Biovac, DPS for Indian Immunologicals, DP for Zydus and YB for Panacea.

Each company has their own processes, mostly similar, and their own specific challenges, but some common challenges were identified:

- Underreporting: Caused by HCP lack of awareness, fear of negative consequences, low quality of reported data, and time constraints.
- Regulatory Diversity: Inconsistent requirements across NRAs, including non-PV queries on RMPs.
- Data Gaps: Lack of local background rates and detailed clinical information in spontaneous reports.
- Need for developing CMC based risk assessment.
- Need for more extensive trainings on B-R assessments.
- India specific challenges:
    - To increase the timeline for submitting PSURs and RMPs from 30 days to 60 days.

To share proper product specific AE data instead of incomplete data.

Defining objectives and project structure

MA provided guidance on structuring the group's SMART objectives and projects, including defining goals, scope, resources, roles/responsibilities (through RACI matrices), methodology, and project roadmap. The group discussed applying this structure to the CRP project as an example and will be applied to each of the objectives set by the Regulatory WG. SCh presented the background information on the summary process and benefits of the CRP.

Regulatory working group objectives

The group reviewed RA objectives for 2026 and following the guidance of RS, they focused on 3 objectives to carry on for the year.

The projects/objectives need to be staffed, and valid roadmap developed. The RWG needs to inform and enroll participants, it needs as well to consolidate the team to work more smoothly and efficiently. MA took the action to coordinate the RWG consolidation and to support the different projects.

Pharmacovigilance working group objectives

VI as Co-chair presented the three key objectives for the pharmacovigilance working group: 1) Strengthening signal management capacity, 2) Revising the RMP process, and 3) Developing a PSMF template. The group outlined the activities, timelines, and responsibilities for each objective.

Reliance and work sharing in Pharmacovigilance

KH shared that reliance in PV started during the COVID-19 pandemic. A new WHO strategy builds on pandemic learnings to create a global, collaborative PV system, aiming to:

1. Strengthen global patient safety and modernize PV.

2. Reduce duplicative PV activities across countries.
3. Enable regulators to leverage assessments and decisions from trusted authorities.
4. Support resource limited countries in making faster, evidence based decisions.

Scope: All medicinal products — vaccines, biologics, devices, combination therapies, etc. Covers pre-authorization, clinical trials, post authorization, and emergency use.

The core principles of the strategy include Public Health Focus, Trust & Transparency, Proportionality & Efficiency, and Equity & Solidarity.
The strategic pillars of this strategy are: Smart Data & systems, Smart collaboration, Smart Decision Making and Smart Capacity Building, and prioritization will be made based on risk
Reliance implementation tied to WHO's regulatory maturity levels:

Level 1 – Basic

- Mostly standalone national AEFI reporting
- Possibly preliminary participation in global databases

Level 2 – Foundational

- Active participation in VigiBase
- Some access to global signal assessments

Level 3 – Functional

- Joint signal detection and assessment
- Trust from WHO in regulatory capacity
- Ability to use background rates

Level 4 – Advanced

- Shared safety conclusions & risk management decisions
- Emergency response capacity
- Routine reliance on WHO or trusted NRAs

Level 5 –Proactive Leadership

- Advanced surveillance and analytics
- Active work-sharing
- Contextualized regulatory action at national level

Challenges for Manufacturers

KH noted these **longstanding pain points**, which may not yet be fully solved by the WHO strategy:

- Fragmented and inconsistent national PV requirements
- Duplicated submissions
- Different formats and expectations across countries
- Varied emphasis on data cutoffs, assessment depth, timelines
- Limited transparency on decisions
- Resource constraints in manufacturers and regulatory bodies

Announcements

RS announced that the PAC learning module has been uploaded on DCVMN Website

RS announced that there will be a meeting from IFPMA for which DCVMN is nominating the head of Regulatory Biovac for this meeting. He suggested the team to take forward this thread and bring back this information to the group so that the relation topic moves forward immediately without having to wait.

There will also be a workshop from WHO on CRP, for which DCVMN will nominate SCh.

As part of pre-work for upcoming SEARO workshops, a group activity has been conducted wherein the group divided into sub-groups to work on: Reliance request template, Checklist for the critical documents, and WHO vs EMA Risk Management Plan comparison.
The group has also finalized their action plan for WHO SEARO.

Notes taken by SV

17th Feb 2026

Rajinder Suri
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