

Agenda

Joint Working Group Workshop

The Lalit, New Delhi

February 15th – 16th, 2024

Objectives:

1. To strengthen the relationship amongst the PV, Clinical Development and Regulatory areas and to provide a holistic understanding of the product's life cycle with the interlinkages between the three Departments.
2. To build on the areas identified collectively by the teams at the Joint DCVMN CDMA / PV Working Group Meeting June 2022, including the gaps, responsibilities of each area and mitigation activities covering the whole vaccine product life cycle (ie. pre licensure /clinical development) and post-licensure activities).
3. To build on best practice concepts for preparing regulatory documents (i.e. the Common Technical Document CTD and WHO PQ Dossier, Post-approval changes, safety processes and documents, a.o. as appropriate)

Deliverables:

1. Roadmap of interdepartmental workflows, SOPs and essential documents.
2. A common harmonized action plan of the problems identified (i.e. implementation of Collaborative registration procedure (CRP), harmonized PAC guidance, and a first draft on action plan for regulatory reliance among NRAs for faster evaluation of post-approval changes).
3. Create a "Wishlist" for regulators to accelerate licensure (pre and post) filing / submission time as well as for CRP and PAC for subsequent publication.

Day 1, 15th February, 2024

Time	Topic	Presenter
900–915	Welcome	Rajinder Suri
915–1030	Roundtable: Workshop expectations of each WG Major topics are discussed and analyzed in the dynamic workshop session	All: (CDMA, REG, PV)
1030–1100	<i>Coffee Break</i>	
1100–1230	Clinical / Medical Affairs activities during the whole vaccine life cycle, what works well, gaps and limitations	CD & MA

1230–1330	<i>Lunch</i>	
1330–1500	Regulatory activities during the whole vaccine life cycle, what works well, gaps and limitations	REG
1500–1530	<i>Coffee Break</i>	
1530–1700	Safety monitoring during the whole vaccine life-cycle (development and post-marketing), what works well, gaps and limitations AVSS project	PV
1900 onwards	Dinner	Venue:

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Day 2, 16th February, 2024

Time	Topic	Presenter
900–905	Opening of day 2	Rajinder Suri
905–1030	Breakout session of the 3 WG (PV – Reg – CDMA) to consolidate the deliverables	3 WG (PV – Reg – CDMA)
1030–1100	<i>Coffee Break</i>	
1100–1230	Presentation of the breakout sessions	3 WG (PV – Reg – CDMA)
1230–1400	<i>Lunch</i>	
1400–1420	Presentation from Jean Michel Dogné	Jean Michel Dogné (tbc)
1420-1515	<i>Action Plan / Deliverables</i>	
1515–1545	<i>Coffee Break</i>	
1545–1700	Finalization of the Action Plan Conclusions and action plan on next steps	All
1730–1745	Wrap-up of the workshop	Rajinder Suri