COVAX is the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator

Covid-19 Vaccines Risk Management Planning: Stakeholders Experiences and Perspectives

A COVAX Vaccine Safety Working Group Webinar

Date	Time	Location
04/28/2021	EDT (Washington DC): 9 am GMT (London): 2 pm CET (Berlin): 3 pm IST (New Delhi): 6:30 pm CST (Beijing): 9:00 pm	Zoom Webinar

Background

The WHO Safety Surveillance Manual encourages developers in the Module "Engaging with the pharmaceutical industry for COVID-19 vaccine safety surveillance" to adopt existing formats of risk management strategies such as the EU risk management plan (RMP). All national regulatory authorities (NRAs) are encouraged to follow ICH guidelines and to provide clear guidance and directives to vaccine developers on the respective requirements to vaccine manufacturers. Recently, EMA has provided guidance on core requirements for RMPs of COVID-19 vaccines (coreRMP19).

Developers with broad licensure experience will provide core RMPs that meet the requirements summarized in the WHO Safety Surveillance Manual. These RMPs will contain a Pharmacovigilance Plan consisting of "routine pharmacovigilance" and, where applicable, a list of global commitments on additional PV activities, including enhanced safety surveillance, post-marketing safety and effectiveness.

With this workshop, we would like to discuss expectation and requirements related to pharmacovigilance strategies and corresponding RMPs.

Objectives

- To inform Covid-19 vaccine developers and Marketing Authorization Holders (MAHs) about the expectations of Regulatory Agencies from different countries concerning Pharmacovigilance Planning, and to share their experience in assessing Covid-19 vaccine files and post approval safety surveillance as well as their challenges with routine/expected pharmacovigilance activities.

- To share Covid-19 vaccine developers/MAHs' experience in getting their RMP approved in different countries and their post-approval challenges in implementation.
- To develop consensus on how to bridge expectations and "real world experience", and how to improve efficiency and effectiveness of pharmacovigilance activities in the context of a pandemic.

Intended Audience

Pharmacovigilance and regulatory professional from Covid-19 vaccine developers/MAHs, country-specific NRAs, EMA, WHO, and COVAX

Draft Agenda

Time (PDT)	Session	Speaker
(2:30 pm CET)	*Tech check*	
(2:50 pm CET)	Attendees start to arrive	
(2:50 pm CET)	Platform and webinar dynamics slide & instructions	
3:00 pm CET	Workshop welcome	Katharina Hartmann Daniel Brasseur
3:00 pm CET	Introduction	Rogério Gaspar (WHO) Jakob Cramer (COVAX)
3:10 pm CET	**Regulators' Experience and Expectations**	
	Presenters: • Petra Doerr (WHO) • Emil Cochino (EMA) • Suzie Marie Teixeira Gomes (Brazil) • Juan Roldan (Chile) • Christianah Adeyeye Mojisola (Nigeria) Joint Q&A	Moderator: Daniel Brasseur Q&A curator: Gabrielle Breugelmans
3:40 pm CET	**Industry Experience & Perspective**	
	Presenters: • Sarah Frise (AstraZeneca) • Jamie Wilkins (Pfizer) • Marc Ceuppens (J&J) • Polina Dombure (Gamelaya, Inpharmatis) • Jiayi Wang (Sinovac)	Moderator: Katharina Hartmann Q&A curator: Gabrielle Breugelmans
4:10 pm CET	**Round table**	
	Panelists: • Shanthi Pal (WHO) • WHO PQ, • Emil Cochino (EMA), • Suzie Marie Teixeira Gomes (Brazil)	Moderator: Katharina Hartmann Q&A curator: Gabrielle Breugelmans

Time (PDT)	Session	Speaker
	• Juan Roldan (Chile) • Christianah Adeyeye Mojisola (Nigeria) • Corinne Jouquelet-Royer (IFPMA) • Alexander Precioso (DCVMN)	
4:50 pm CET	Summary and Closure	Shanti Pal (WHO) Jakob Cramer (COVAX)
5:00 pm CET	**End of meeting**	