

DCVMN Regulatory Affairs WG Agenda 24th March 2022 13:00-14:30 (CET)

Chair: Nirav Chokshi
Co-Chair: Sebastian Comellas
Consultant: Bernadette Hendrickx

Objectives:

The objectives of the meeting are:

- A) Align on ways of working of the working group.
- B) Determine strategy for CRP and donor deliverable expectations.
- C) Discuss and decide future training opportunities within DCVMN.
- D) Provide update on Regulatory strategy at CEPI.

Participant's profile:

DCVMN secretariat and project management.
One volunteer representative from DCVMN membership.

Technical Support and meeting minutes: **Sivashen Cunden**

Time	Topic	Speaker
13:00-13:05	Introduction of all new participants & agenda	Nirav Chokshi
13:05-13:15	1. Regulatory Affairs WG 2022 - Ways of working (Member participation)	Nirav Chokshi
13:15-13:45	2. Collaborative Registration Procedure - Voluntary submission of 3 CRP by September 2022 - Summary of regional feedback on CRP procedure from RAWG 1-1 sessions - Member discussion (15 min)	Nirav Chokshi All
13:45-14:15	3. Development of Regulatory Training - CRP process and procedures - Registration dossier development - Clinical and Preclinical Trial data - Post approval change management - Member Discussion and Feedback (15 min)	Nirav Chokshi All
14:15-14:20	4. CEPI update	Bernadette Hendrickx
14:20-14:30	5. Member Updates and Closing remarks - IFPMA strategic engagement on PACs for targeted countries	All