

DCVMN Regulatory Affairs WG Agenda 26th May 2022 13:00-14:30 (CET)

Chair: **Dr Parag Nagarkar**
Co-Chair: Mr Sebastian Comellas
Consultant: Dr Bernadette Hendrickx

Objectives:

The objectives of the meeting are:

- A) Update RAWG of new WG Chair
- B) Provide insight on DCVMN CRP usage and issues
- C) Discuss proposed CRP strategy
- D) Discuss next steps with 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	RAWG WG Meeting Introduction <ul style="list-style-type: none"> - Update and handover of RAWG Chair position - Introduction of Agenda - Member AOB (to be discussed in the final agenda item) 	Dr Nirav Chokshi Dr Parag Nagarkar/ Sebastian Comellas
13:05-13:40 35min	1. Collaborative Registration Procedure <ul style="list-style-type: none"> - High level summary of CRP Survey Distributed to DCVMN members - RAWG CRP Strategy <ul style="list-style-type: none"> o <i>CRP process and procedures Training</i> o <i>Organization Interactions</i> - Member discussion (10-15 min) 	Dr Parag Nagarkar/ Sebastian Comellas Dr Bernadette Hendrickx
13:40-14:05 25 min	2. Development of Regulatory Training <ul style="list-style-type: none"> - Registration dossier development - Clinical and Preclinical Trial data - Post approval change management - Member Discussion and Feedback (15 min) 	Dr Parag Nagarkar/ Sebastian Comellas Dr Bernadette Hendrickx
14:05-14:15 10 min	3. CEPI Update	Dr Bernadette Hendrickx
14:15-14:30 15 min	4. Closing + Actions + AOB	Dr Parag Nagarkar/ Sebastian Comellas