

# COVID-19 Vaccine Safety Interest Group (CVSIG) Meeting Minutes

Date and Time:

Thursday, June 3<sup>rd</sup>, 2021

7 am – 8 am EDT

## Attendees

Present	Country/ Organization	Name		Present	Country/ Organization	Name
x	Brazil	Mario Rosa Borges		x	Saudi Arabia	Hind Almodaimegh
x	Canada	David U		x	Singapore	Augustine Tee
x	Canada	Dorothy Tscheng			Singapore	Alvin Lee
	Canada	Gary Lee		x	Singapore	Adelina Young (MOH)
x	Canada	Sarah Finlayson		x	Spain	Maria Jose Otero
x	Colombia	Ismael Basto			Uppsala Monitoring Centre (UMC)	Alem Zekarias
	Colombia	Juan Pablo Osorio		x	USA	Christina Michalek
	European Medicines Agency (EMA)	Alexios Skarlatos		x	USA	Jill Paslier
x	France	Etienne Schmitt		x	USA	Merissa Andersen
x	France	Marie-Blanche Rabier		x	USA	Mike Cohen
x	Germany	Birgit Vogt		x	USA	Rita Jew
	Germany	Torsten Hoppe-Tichy		x	USA	Ahreum Yoo
x	Health Canada	Jhona Rose		x	USA	Matthew Fried
x	Health Canada	Sally Pepper			USA	David Yoon
	Hong Kong	Benjamin Lee		x	US Food and Drug Administration (FDA)	Lubna Merchant
	International Society of Pharmacovigilance (ISoP)	Angela Caro		x	US Food and Drug Administration (FDA)	Karen Farizo
x	International Society of Pharmacovigilance (ISoP)	Brian Edwards			US Food and Drug Administration (FDA)	Craig Zinderman
	Ireland	Muriel Pate			United Arab Emirates (UAE)	Sohail Fiteh
x	Ireland	Niamh O’Hanlon			Vaccine Dynamics USA	John Grabenstein
	Medicines and Healthcare products Regulatory Agency (MHRA) UK	Mitul Jadeja		x	World Health Organization (WHO)	Ayako Fukushima
x	Morocco	Ghita Benabdallah		x	World Health Organization (WHO)	Raffaella Balocco
	Morocco	Houda Sefiani		x		P Nguyen
	National Health Service (NHS) UK	Jennie Hall				
x	Netherlands	Jacob (Jaap) Dik				
	Netherlands	Rob Essink				
	New Zealand	Michael Tatley				
	Norway	Sigurd Hortemo				

Topic	Presenter	Discussion	Action Items
Welcome and follow up	Chris Michalek	Any questions about the Morocco COVID-19 Presentation? - None	
Member Presentations- Saudi Arabia	Dr. Hind Almodaimegh Chairperson Saudi Medication Safety Center	<ul style="list-style-type: none"> <li>• Vaccines available: Pfizer and AstraZeneca</li> <li>• Vaccines offered to everyone living in Saudi Arabia</li> <li>• Government restrictions: face masks, social distancing, avoid mass gatherings, curfew <ul style="list-style-type: none"> <li>○ Still limiting gatherings: 20 people for a wedding, 5-15 people in a store</li> <li>○ Was distance learning until now</li> </ul> </li> <li>• Vaccination plan <ul style="list-style-type: none"> <li>○ First stage: citizens and residents &gt;65 years, BMI &gt;40, immunocompromised, 2+ chronic conditions, high risk occupations</li> <li>○ Second stage: citizens and residents &gt;50 years, other HCP, 1+ chronic conditions, BMI 30-40</li> <li>○ Third stage: all citizens and residents</li> </ul> </li> <li>• Vaccine side effects: blood clots with AZ, benefits outweigh risks. Treatment guidelines now available</li> <li>• Considerations for mandated vaccine</li> </ul>	
International Nonproprietary Names (INN)	Dr Raffaella Balocco Mattavelli, Unit Head, International Nonproprietary Names Programme and Classification of Medical Products, World Health Organization	Defining names for vaccines Name the substance vs the product Add short 3 letter prefix to INN <a href="https://www.who.int/publications/i/item/inn-21-520">https://www.who.int/publications/i/item/inn-21-520</a>	
Begin ranking of recommendations for global implementation of Safe COVID-19 Immunization Practices	Chris Michalek	Main categories presented <ul style="list-style-type: none"> <li>- Procurement</li> <li>- Storage</li> <li>- Preparation</li> <li>- Administration</li> <li>- Follow up</li> <li>- Monitoring</li> </ul> Comments <ul style="list-style-type: none"> <li>- Vaccination hesitancy</li> <li>- Scheduling</li> <li>- Standardized identification of COVID-19 vaccines</li> <li>- Adverse event management- people need to report (training for staff to encourage reporting)</li> <li>- Training</li> <li>- Add patient screening or segregate it from administration</li> <li>- Information and advice (include with administration)</li> <li>- Planning (in procurement)</li> <li>- Rollout definitions, clear guidance to prevent queue jumping</li> <li>- Guidance around allergic reactions (should they get second dose)</li> <li>- About monitoring, communication towards patients and HCP is also important to improve data on AESI after 1st and after second dose</li> <li>- Under Admin - wrong dose with diff volume 0.3ml vs 0.5ml</li> </ul>	
Next Steps	Chris Michalek	Next Meeting <ul style="list-style-type: none"> <li>- Plan to discuss recommendations in next meeting</li> </ul>	

Respectfully submitted, Jill Paslier, PharmD, CSP, ISMP International Medication Safety Management Fellow