Agenda for DCVMN Workshop Bali 17- 21 July 2016

Agenda	Topic	Speaker
Day1 Sunday 17th July 2016		
13:00- 14:00	Registration	Host
14:30- 15:00	DCVMN introduction	DCVMN
15:00-15:30	Train the trainers initiative	DCVMN
15:30- 16:00	Test 1 Assessment	Participants
16:00- 16:30	Coffee break	
16:30- 17:00	Introduction to Clinical Studies Overview	Dr. S. Viviani
17:00- 17:30	Q&A	Dr. S. Viviani
19:00	Dinner	

Agenda	Topic	Speaker
Day2 Monday 18th July 2016		
8:30-9:00	Introduction	Dr. S. Viviani
9:00- 10:00	Clinical Development Department: - Clinical Quality manual - Clinical SOPs - Clinical Staffresources - Outsourcing	Dr. S. Viviani
10:00-10:30	Coffee break	
10:30- 12:00	Clinical Development plan: - Rationale, regulatory strategy, ethics - Safety and efficacy evaluation - WHO PQ and international requirements	Dr. S. Viviani
12:00- 13:00	Lunch	
13:00- 15:30	How to design a clinical development plan: Case study and practicals in working group	Dr. S. Viviani
15:30- 16:00	Coffee break	
16:00- 17:00	Report from working groups	Participants
17:00- 18:00	From study protocol to study report: introduction to clinical trial management	Dr. S. Viviani
18:00	Adjourn	
19:00	Dinner	

Agenda	Topic	Speaker
Day 3 Tuesday 19th July 2016		
8:30- 9:30	Overview of ICH-GCP, Ethical aspects of a trial, responsibilities of investigator and sponsor	Dr. S. Viviani
9:30- 10:30	Developing the clinical trial protocol	Dr. S. Viviani
10:30- 11:00	Coffee break	
11:00- 11:30	Patient information: Written and oral information, informed	Dr. S. Viviani

	consent, assent	
11:30- 12:00	Case report form (CRF)	Dr. S. Viviani
12:00- 13:00	Lunch	
13:00- 14:00	Organization at trial site, Clinical Trial Team, recruitment of trial participants, Source Data Document, Site SOPs, TMF	Dr. S. Viviani
14:00- 15:00	IHC-GCP: Reporting clinical trial results	Dr. S. Viviani
15:00- 15:30	Coffee break	
15:30- 17:00	Practical in working groups	Participants
17:00- 18:00	Reporting from working groups and Q&A	Participants
19:00	Dinner	

Agenda	**Topic**	**Speaker**
Day 4 Wednesday 20th July		
Introduction to Pharmacoviglance		
8.30- 9.30	Welcome and Introduction - *Questions around WHO Guidance*	Participants
9.30- 10.30	Vaccine development and safety considerations <u>Pharmacovigilance</u> - Why do we need it? - Challenges of implementation - Roles and responsibilities Manufacturer, Distributor, Regulatory Agency, Government (National Immunization Provider)	Dr. Jeff Davies and Mr. Greg Plunkett
10:30-11.00	Coffee Break	Group
Regulation and Post marketing Surveillance		
11.00-12.30	Regulatory Requirements and guidelines: An overview - Europe - ASEAN - ICH - Challenges for Developing Countries ○ *Content based on Comparative*	Dr. Jeff Davies and Mr. Greg Plunkett

	analysis of pharmacovigilance in 5 Asian countries (template document)	
12:30 -13:30	Lunch Break	Group
Post Marketing Surveillance of Vaccines: Systems and the role of manufacturers		
13:30- 14:00	**Aris Global: The importance of technology use in pharmacovigilance**	Dr. Vivek Ahuja
14:00-15:30	**Fundamentals of an Effective Pharmacovigilance System** - Data capture - Data categorization and coding - Follow up on case outcomes - Investigation plans and actions - Analysis of adverse event information	Dr. Jeff Davies and Mr. Greg Plunkett
15:30- 16:00	Coffee break	
16.00-18.00	Interactive session with a case study designed to reinforce learnings	
18:00 adjourn		
19:00	Dinner	

Agenda	Topic	Speaker
Day 5 Thursday 21st July		
	Post Marketing Surveillance	

08.30-10.30	**Signal identification and assessment**
	- Analysis of adverse event database
	  ○ Statistical evaluation of data
	  ○ Signal detection
	- Evaluation of change to Vaccine risk:benefit profile
	- Ongoing review and updates to Core Safety Information
		Dr. Jeff Davies and Mr. Greg Plunkett

10.30-11.00	Coffee Break	Group
11.00-11.30	**Annual or Periodic Safety Update Reports (PSUR)** - What is a PSUR? - What information is required? - How often are they required? - How is the information evaluated and used?	Dr. Jeff Davies and Mr. Greg Plunkett
11.30-12.30	**Risk Management (RMP) and Pharmacovigilance Plans** - What is an RMP - Development of an RMP and implementing risk minimization strategies - Maintaining RMP during product lifecycle	Dr. Jeff Davies and Mr. Greg Plunkett
12.30-13.30	Lunch Break	Group

13:30-14:00	**Test 2 Assessment**	
14.00-16.00	**Gap Analysis Workshop** *(Delegates will be asked to bring summaries of systems currently in place)* - Review existing Pharmacovigilance systems for delegate members companies - Workshop enhancements to systems and processes - General action plan for delegates to address	Dr. Jeff Davies and Mr. Greg Plunkett
16:00-16:30	**Coffee Break**	Group
16:30-17:30	**Review of Assessment, open discussion and Q&A**	Adjourn
19:00	Dinner	