DCVMN BioNet Asia Workshop: Vaccine Clinical Studies Management
17-21 July 2017, Pullman King Power Bangkok, Thailand

| DAY1, Monday 17 July- Welcome and Vaccine Trial Overview<br>Location: Infinity 1- G Floor | | |
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| Time | Topic | Speaker |
| 8:30-9:00 | Welcome and introduction by BioNet Asia | BioNet Asia |
| 9:00-9:30 | DCVMN Introduction | DCVMN |
| 9:30-10:30 | Vaccine Clinical Trials Overview | Dr. Jo White |
| 10:30-11:00 | Coffee Break | |
| 11:00-12:00 | Rationale and Contents of a Clinical Development Plan | Dr. Jo White |
| 12:00-12:30 | Tools for Epidemiological Studies | Dr. Jo White |
| 12:30-13:30 | Lunch | |
| 13:30-14:00 | Test 1 | |
| 14:00-15:00 | Practical in Working Groups | Participants |
| 15:00-15:30 | Coffee Break | |
| 15:30-16:30 | Practical in Working Groups | Participants |
| 16:30-17:30 | Reports from working groups. Q&A. | Dr. Jo White |
| 17:30 | Adjourn | |
| 18:00 | Welcome reception | BioNet Asia |

| DAY2, Tuesday 18 July- GCP and Vaccines Protocols<br>Location: Infinity 1- G Floor | | |
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| Time | Topic | Speaker |
| 8:30-9:30 | Overview of Good Clinical Practices | Dr. Jo White |
| 9:30-10:30 | Protocol Considerations for Infant Vaccines | Dr. Jo White |
| 10:30-11:00 | Coffee Break | |
| 11:00-12:30 | Protocol Considerations for Adult and Elderly Vaccines | Dr. Jo White |
| 12:30-13:30 | Lunch | |
| 13:30-14:30 | Innovative Cell culture and purification approaches applied to cost-effective manufacturing of viral vaccines | Benjamin Damien, Univercells |
| 15:00-15:30 | Practical in Working Groups | Participants |
| 15:00-15:30 | Coffee Break | |
| 15:30-16:30 | Practical in Working Groups | Participants |
| 16:30-17:30 | Reports from working groups. Q&A. | Dr. Jo White |
| 17:30 | Adjourn | |

| DAY3, Wednesday 19 July- Clinical Trials Operations<br>Location: Eternity - G Floor | | |
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| Time | Topic | Speaker |
| 8:30-10:30 | • With the clinical development plan already done, you are going to start the process of planning the actual clinical trials. These steps are:<br>  ○ Hiring your own clinical research team or to outsource to CROs? | Prof. Teoh Yee Leong, CEO Singapore Clinical Research Institute |

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| | ○ How to select the right CROs<br>○ Defining the roles of sponsor vs CROs in managing the trial<br>○ How to select and engage site investigators (site feasibility assessment)<br>○ How to prepare a budget for clinical trials (cost involved in a trial and its breakdown)?<br>○ Clinical trial agreement<br>○ Issues with trial sponsorship (who should be the trial sponsor)<br>○ Regulatory and IRB approval<br>Site initiation meeting | |
| 10:30-11:00 | Coffee Break | |
| 11:00-12:30 | • Case study on CRO selection<br>• Project management of a CRO vendor, what must you look out for? | Prof. Teoh Yee Leong, CEO Singapore Clinical Research Institute |
| 12:30-13:30 | Lunch | |
| 13:30-15:30 | • Now that the trial has started, what do you need to manage:<br>○ Timelines in starting a trial<br>○ Cold chain management of investigational product<br>○ Dealing with delays (mitigation plans)<br>○ Issues of deaths or serious adverse events in clinical trials<br>○ Interim analysis and data safety monitoring board<br>○ Study report<br>○ Regulatory submission after study completion<br>○ Post marketing surveillance<br>○ Publication issues (who should be in the authorship)<br>Engagement of Investigators to be speaker | Prof. Teoh Yee Leong, CEO Singapore Clinical Research Institute |
| 15:30-16:00 | Coffee Break | |

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| 16:00-17:30 | • Case study of a large scale Phase 3 Rotavirus trial in Asia<br>• What do you need to do to manage the site investigators? | Prof. Teoh Yee Leong, CEO Singapore Clinical Research Institute |
| 17:30 | Adjourn | |

| DAY4, Thursday 20 July<br>Location: Sigma 1&2- 6th Floor | | |
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| Time | Topic | Speaker |
| 8:30-9:30 | How to write a Clinical Study Report | Dr. Jo White |
| 9:30-10:30 | Regulatory Considerations for Licensure | Dr. Jo White |
| 10:30-11:00 | Coffee Break | |
| 11:00-12:00 | Publications and Marketing Support | Dr. Jo White |
| 12:30-13:30 | Lunch | |
| 13:30-15:00 | Practical in Working Groups | Participants |
| 15:00-15:30 | Coffee Break | |
| 15:30-16:30 | Practical in Working Groups | Participants |
| 16:30-17:30 | Reports from working groups. Q&A. | Dr. Jo White |
| 17:30 | Adjourn | |

| DAY5, Friday 21 July- Optional visit | | |
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| Time | Topic | Speaker |
| 8:30- 17:00 | Optional Visit to GPO's Flu Facility | GPO |

Dr. Jo White has 28 years of clinical development, medical affairs and pharmacovigilance experience in the pharmaceutical industry. Her experience has been focused in vaccine development, primarily in the areas of infectious diseases. She has had experience negotiating with regulatory agencies worldwide for licensure and for updating package inserts post-marketing following signal detection activities. She has had senior management positions at

Merck, Aviron (now MedImmune/AstraZeneca), North American Vaccine (now Baxter), Wyeth (now Pfizer), and VGX Pharmaceuticals (now Inovio Biomedical). She has served on the affiliate staff of the University of Pennsylvania Infectious Diseases Department and has cared for patients with HIV in the Philadelphia VA Medical Center.

Prof Teoh Yee Leong is the Chief Executive Officer at SCRI. He is a Public Health Physician with more than 20 years experience in public health and clinical research. Prof Teoh has in-depth experience in the development of vaccines and immunotherapeutic products. He was the Director of Clinical Research and Medical Affairs at, and he conducted one of the largest Phase III vaccine clinical trials in Singapore involving more than 6,000 subjects for a Rotavirus vaccine. Prof Teoh is also an Adjunct Associate Professor at the Saw Swee Hock School of Public Health, National University Singapore.