

Day Two (Friday 22nd September 06)

Session III : Data management

09.00 – 09.40	Monitoring a clinical trial <input type="checkbox"/> <i>Preparation : source data, patient file , time , place staff</i> <input type="checkbox"/> <i>Collaboration with CRA : correction , data validation</i>	Dr. Anita Limaye
09.40 – 10.10	Group discussion/Workshop (6 participants/group)	
10.10 – 10.30	Break	
10.30 – 11.10	Appropriate use of investigational products <input type="checkbox"/> <i>drug request and receiving</i> <input type="checkbox"/> <i>drug storage and dispensing</i> <input type="checkbox"/> <i>drug destruction</i>	Mrs. Suwan Sriviriyakul
11.10 – 11.40	Group discussion/Workshop (6 participants/group)	
11.40 – 12.00	Summary of Session III (Monitoring & Investigational Product & Clinical Study Report) <ul style="list-style-type: none">• Question and Answer	Dr. Anita Limaye Mrs. Suwan Sriviriyakul
12.00 – 13.00	LUNCH	

Session IV : Adverse event reporting and Quality Assurance

13.00 – 13.40	Adverse events & Serious Adverse Event <input type="checkbox"/> <i>Collecting information</i> <input type="checkbox"/> <i>Reporting adverse events</i>	Dr. Esmond Yeoh
13.40 – 14.10	Group discussion/Workshop (6 participants/group)	
14.10 – 14.30	Break	
14.30 – 15.10	Quality Assurance <input type="checkbox"/> <i>Preparation for internal audit</i> <input type="checkbox"/> <i>Preparation for FDA/HA inspection</i> <input type="checkbox"/> <i>How important is it?</i>	Dr. Anita Limaye
15.10 – 15.40	Group discussion/Workshop (6 participants/group)	
15.40 – 16.00	Summary of Session IV (AE/SAE & Quality Assurance) <ul style="list-style-type: none">• Question and Answer CONCLUSION	Dr. Anita Limaye Dr. Anita Limaye

Speaker and Trainer (International level)

Dr. Michael Goldbrunner	<i>Clinical Research Manager, Ph.D. Exploratory Clinical Development Oncology Novartis Pharma AG, Basel, Switzerland</i>
Dr. Anita Limaye	<i>Quintiles Research (India) Pvt. Ltd. Mumbai, India</i>
Dr. Esmond Yeoh	<i>Quintiles Research . Ltd.</i>
Mrs. Suwan Sriviriyakul	<i>Quintiles Research (Thailand) Pvt. Ltd. Bangkok, Thailand</i>

Training days	2 days
Course	Lecture + small group discussion
Program	<u>All sessions are</u> in English.
Trainer	International clinical trial training agency: Quintiles, Novartis
Time	21-22 September 06
Number of delegates	24 – 30 doctors, nurses and oncology clinical research specialists
Specification	Medical oncologist, Surgical oncologist, Radiation oncologist, Gynecologic oncologist, Hematologist
Place	Chulabhorn Research Institute Convention Center Chulabhorn Research Institute Vipavadee Rd. Bangkok, THAILAND
Secretariat	CCC Research and Academic Affairs Tel: 0-2984-8654, Fax: 0-2984-8655