



AGENDA



Fundamental GCP Training

Ramathibodi Hospital, Faculty of Medicine, Mahidol University

Day 1: 18 February 2016

Time	Topics	Speakers
08.00-08.15	Registration	
08.15-08.30	Pre-Test	
08.30-08.40	Opening	Prof. Boonsong Ongphiphadhanakul
08.40-08.50	Direction of Clinical Research Participation	Prof. Boonsong Ongphiphadhanakul
08.50-09.15	Role of Clinical Research Unit, Rama CRC	Prapatson Rattanapan
09.15-10.15	Principle Introduction of ICH GCP	Dr.Panuwat Lertsithichai
10.15-10.30	Break	
10.30-11.30	Role & Responsibility of Ethics Committee	Dr.Panuwat Lertsithichai
11.30-12.00	Informed Consent	Dr.Panuwat Lertsithichai
12.00-13.00	Lunch	
13.00-14.00	Role & Responsibility of Investigator	Dr.Thanyanan Reungwetwattana
14.00-15.30	Essential documents and document management	Dr.Thanyanan Reungwetwattana Somthawin Lukerak
15.30-16.30	Q&A	



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Fundamental GCP Training

Ramathibodi Hospital, Faculty of Medicine, Mahidol University

Day 2: 19 February 2016

Time	Topics	Speakers
08.00-08.30	Registration	
08.30-09.15	Research Protocol & Protocol Compliance	Pichet Kamolrungsantisuk
09.15-10.15	Quality Assurance (Audit & Inspection)	Pichet Kamolrungsantisuk
10.15-10.30	Break	
10.30-11.15	Subject recruitment, subject retention, and subject compliance	Dr. Pravich Tanyasittisuntorn
11.15-12.00	Data Collection and Data Management	Dr.Pravich Tanyasittisuntorn
12.00-13.00	Lunch	
13.00-14.00	Monitoring	Dr.Pravich Tanyasittisuntorn
14.00-14.15	Break	
14.15-15.15	Safety Report (AE, SAE & SUSAR)	Nitaya Jeanpan
15.15-16.00	Investigational drug handling	Nitaya Jeanpan
16.00-16.15	Post-Test	
16.15-16.30	Closing remark	