



ON
RESPIRATORY
CARE
INDONESIA

SECRETARIAT
PERSAHABATAN HOSPITAL

Asthma Building, 2nd Floor
Persahabatan Raya, Jakarta 13230
INDONESIA

PHONE
+62 - 21 4786 4646

FAX
+62 - 21 4786 6543

HOME PAGE
<http://www.respina.org>
email: info-respina@cbn.net

STEERING COMMITTEE

Head Dept. of Pulmonology Fac. of Medicine
Univ. of Indonesia

APSR - Representative for Indonesia

Governor of ACCP - Chapter Indonesia

Chairman of PERBRONKI
(Indonesian Society of Bronchoscopy)

Chairman of PDPI
(Indonesian Association of Pulmologist)



GOOD CLINICAL PRACTICE WORKSHOP

3-4 December 2009, Borobudur Hotel—Jakarta.



These are exciting and challenging times for both researchers and drug companies, as more and more compounds are being tested here in Asia.

With more human subject involvement, it is no surprise that the clinical trials are scrutinized under the watchful eyes of regulatory authorities, the ethics committee and the public in general. With these reasons in mind, we have specially designed a program to ensure that you will understand and apply the most important fundamental of Clinical Research, the Good Clinical Practice.

The Good Clinical Practice (GCP) represents the operational standards in Clinical Drug Development and ensures that clinical trials meet ethical and scientific standards.

In this 2-day GCP workshop, you will be exposed to the theoretical and operational aspects of core Clinical Trials Management activities. Participants will get a step by step understanding of the clinical trial management process, from drug discovery to the conduct of a clinical trial. Ethical issues involved and potential problems faced in clinical trials will be covered through mind-stimulating and interactive discussion based on examples and exercises. We believe that it is important that participants will put what they are learning to use, and they will be evaluated on their knowledge through a GCP Test. Participants who pass the test will receive a certificate exclusively issued by GleneaglesCRC Pte. Ltd, endorsed by Murdoch University, Western Australia.

Who should attend?

- ✓ Clinical research professionals in the pharmaceutical and biopharmaceutical industry, clinical research organizations, and research institutions.
- ✓ Clinical Research Associates
- ✓ Clinical Research Coordinators
- ✓ Clinical Research Managers
- ✓ Medical Directors
- ✓ Project Team Leaders/ Coordinators
- ✓ Investigators
- ✓ Clinicians, nurses and pharmacists, who are currently engaged or interested in the conduct of clinical trials
- ✓ Experienced research personnel, and Business Development Executives who are interested in networking with other clinical research professionals
- ✓ Statisticians and Database Managers.





SECRETARIAT
PERSAHABATAN HOSPITAL
Asthma Building, 2nd Floor
Persahabatan Raya, Jakarta 13230
INDONESIA

PHONE
+62 - 21 4786 4646

FAX
+62 - 21 4786 6543

HOME PAGE
<http://www.respina.org>
email: info-respina@cbri.net

STEERING COMMITTEE

Head Dept. of Pulmonology Fac. of Medicine
Univ. of Indonesia

APSR - Representative for Indonesia

Governor of ACCP - Chapter Indonesia

Chairman of PERBRONKI
(Indonesian Society of Bronchoscopy)

Chairman of PDPI
(Indonesian Association of Pulmologist)



GOOD CLINICAL PRACTICE WORKSHOP (AGENDA)

Day 1 (Thursday, 3 December 2009)

- 0800 - 0830 Registration
- 0830 - 0845 Welcome address by Dr. Yap Kok Wei,
CEO, GleneaglesCRC Group,
Group VP Research, ParkwayHealth, Singapore
- 0845 - 0915 Overview of Drug Development & Clinical Research
Dr. Yap Kok Wei, CEO, GleneaglesCRC Group,
Group VP Research, ParkwayHealth, Singapore
- 0915 - 0945 Overview of ICH-GCP Guidelines
Ms. Azizah Mohamed, IRB Member
Parkway Independent Ethics Committee, Singapore
- 0945 - 1015 Exercise 1: ICH-GCP Guidelines
GCRC
- 1015 - 1045 Morning refreshments
- 1045 - 1115 Indonesia GCP Guidelines – Salient Points
Dra. Ratna Irawati, MKes, Head of Sub-Directorate of Evaluation
National Agency of Drug & Food Control (BPOM), Indonesia.
- 1115 - 1200 Regulatory Requirements of Clinical Trials in Indonesia
Dra. Ratna Irawati, MKes, Head of Sub-Directorate of Evaluation
National Agency of Drug & Food Control (BPOM), Indonesia.
- 1200 - 1300 Networking luncheon
- 1300 - 1330 Ethics in Clinical Research and Role of Ethics Committee
Ms. Azizah Mohamed, IRB Member
Parkway Independent Ethics Committee, Singapore
- 1330 - 1400 Informed Consent Process
Ms. Angeline Lim, Senior Clinical Research Manager
Gleneagles CRC Pte. Ltd
- 1400 - 1500 Exercise 2: Informed Consent
GCRC
- 1500 - 1530 Handling and Accountability of Clinical Trial Material
Ms. Fabiola C. R. Hutabarat, Senior Clinical Research Associate
Gleneagles CRC Pte. Ltd
- 1530 - 1600 Good Documentation and Archiving
Ms. Fabiola C. R. Hutabarat, Senior Clinical Research Associate
Gleneagles CRC Pte. Ltd
- 1600 - 1630 Q & A
- 1630 - 1630 Tea and End of Session.

Gleneagles
CRC





SECRETARIAT
PERSAHABATAN HOSPITAL
 Asthma Building, 2nd Floor
 Persahabatan Raya, Jakarta 13230
 INDONESIA

PHONE
 +62 - 21 4786 4646

FAX
 +62 - 21 4786 6543

HOME PAGE
<http://www.respina.org>
 email: info-respina@cbri.net

STEERING COMMITTEE

Head Dept. of Pulmonology Fac. of Medicine
 Univ. of Indonesia

APSR - Representative for Indonesia

Governor of ACCP - Chapter Indonesia

Chairman of PERBRONKI
 (Indonesian Society of Bronchoscopy)

Chairman of PDPI
 (Indonesian Association of Pulmologist)



GOOD CLINICAL PRACTICE WORKSHOP (AGENDA)



Day 2 (Friday, 4 December 2009)

- 0815 - 0830 Registration
 - 0830 - 0915 Clinical Research in Indonesia
 Dr. Lina Ratulangie, Medical Director
 PT. Taisho Pharmaceutical Indonesia (formerly BMS-Indonesia)
 - 0915 - 1000 Role and Responsibilities of the Sponsor
 Dr. Lina Ratulangie, Medical Director
 PT. Taisho Pharmaceutical Indonesia (formerly BMS-Indonesia)
 - 1000 - 1030 Role and Responsibilities of the Investigator
 Ms. Angeline Lim, Senior Clinical Research Manager
 Gleneagles CRC Pte. Ltd
 - 1030 -1100 Morning Refreshments
 - 1100 -1130 Role and Responsibilities of the Study Site Coordinator
 Mr. Rodmar Pulido, Country Manager
 Gleneagles CRC Pte. Ltd
 - 1130 -1300 Networking luncheon & Friday Praying
 - 1300 -1330 Role and Responsibilities of the Site Study Monitor
 Mr. Rodmar Pulido, Country Manager
 Gleneagles Clinical Research International Pte. Ltd, Philippines
 - 1330 -1400 Safety Monitoring and Reporting
 Ms. Angeline Lim, Senior Clinical Research Manager
 Gleneagles Clinical Research International Pte Ltd, Philippines
 - 1400 -1430 Quality Assurance in Clinical Trials: Fraud and Misconduct
 Mr. Rodmar Pulido, Country Manager
 Gleneagles Clinical Research International Pte Ltd, Philippines
 - 1430 -1500 Exercise 3: Case Studies on Fraud and Misconduct in Clinical Trials
 GCRC
 - 1500 -1530 Q & A
 - 1530 -1545 Closing Remarks by Dr. Yap Kok Wei,
 CEO, GleneaglesCRC Group,
 Group VP Research, ParkwayHealth, Singapore
 - 1545 -1630 Multiple choice question examination for certification
 - 1630 -1700 Participants Evaluation & Farewell Tea
- End of Session.



