



## THE INTERNATIONAL MEETING ON RESPIRATORY CARE INDONESIA

### SECRETARIAT

Apartment Menteng Square  
3<sup>rd</sup> Floor BO 55-56  
Jl. Matraman 30E, Central Jakarta  
INDONESIA

### PHONE

+62-21-2961 4273 ; 2961 4274  
+62-813 8200 8877  
+62-857 1933 5220

### FAX

+62-21-2961 4274

### EMAIL

info.respina@yahoo.com  
or  
info.respina.indonesia@gmail.com

### HOME PAGE

<http://www.respina.org>

### 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)



## WORKSHOP – 1:

### GOOD CLINICAL PRACTICE (GCP)

Wednesday – Thursday, 24 – 25 July 2019

Auditorium RSPI Prof. Dr. Sulianti Saroso, Jakarta

### Supported by:

Ministry of Health Indonesian Republic and National Agency of Food and  
Drugs Control (BPOM) and Balitbangkes

### Objectives :

1. To provide the basis of clinical research and how to submit the application
2. To be aware of the issue of ethics, medicolegal associated with clinical research
3. To understand how to handle investigational products
4. At the end of the workshop, the participants will be able to conduct research according to GCP guidelines

### TENTATIVE Schedule

#### DAY 1, 24 July 2019

- 08.00 – 09.00 Registration
- 09.00 – 09.15 Welcome address
- 09.15 – 09.30 Key Note Speech
- 09.30 – 09.45 Coffee Break
- 09.45 – 11.00 Good Clinical Practice (GCP) and GCP Principle
- 11.00 – 12.00 Material Transfer Agreement
- 12.00 – 13.00 Lunch
- 13.00 – 14.00 Regulatory Framework for GCP in Indonesia
- 14.00 – 15.00 Roles of Ethics Committee
- 15.00 – 15.15 Coffee Break
- 15.15 – 16.15 Roles of Clinical Trial Players

#### DAY 2, 25 July 2019

- 08.30 – 09.30 Facilities
- 09.30 – 09.45 Coffee Break
- 09.45 – 11.15 Clinical Trial Documents  
Management in Clinical Trial
- 11.15 – 11.45 a. Subject Recruitment
- 11.45 – 12.15 b. Safety Reporting
- 12.15 – 13.15 Lunch
- 13.15 – 13.45 c. Drug Handling
- 13.45 – 14.45 Informed Consent
- 14.45 – 15.15 Questionnaire
- 15.15 – 15.30 Coffee Break
- 15.30 – 15.45 Evaluation of The Course

