

Training on “International Conference on Harmonisation Good Clinical Practice (ICH GCP)”

**Venue** – Advanced Molecular Research Center, Department of Medical Research

**Time** – 13-14 February 2020

**Training Workshop Schedule**

Day 1			
1	8:30-9:00	<b>Registration</b>	
2	9:00-9:15	<b>Opening remark</b>	<b>Prof. Zaw Than Htun DG, DMR</b>
3	9:15-9:30	<b>Introduction of participants</b>	<b>All participants</b>
4	9:30-10:15	<b>Introduction to ICH GCP</b> Historical Background, 13 Key Principles of ICH E6 (R2) GCP Guideline	<b>Dr. Win Aung</b>
5	10:15-10:45	Tea Break	
6	10:45-11:30	<b>Introduction to Good Clinical Practice</b> Drug Regulations, Investigators’ responsibilities	<b>Dr. Myo Khin</b>
7	11:30-12:15	<b>Principles of Research Ethics in Good Clinical Practice</b>	<b>Prof. Hla Hla Win</b>
8	12:15-1:00	Lunch break	
9	1:00-1:45	<b>Basic Statistical Concepts and Study Design</b> Defining the research question	<b>Dr. Khin Thet Wai Dr. Kyaw Lwin Show</b>
10	1:45-2:30	<b>Research protocol in clinical trials</b> How would you improve the clinical trial protocols?	<b>Dr. Han Win</b>
11	2:30-3:00	Tea Break	
12	3:00-3:45	<b>Case Report Form and Data Management</b> From Case Report Forms to Final Analysis	<b>Dr. Myat Phone Kyaw</b>
13	3:45-4:30	<b>Documentation and Archiving</b> Essential Documents, Trial Master File, Retention	<b>Dr. Myint Oo Dr. Nyein Su Aye</b>
Day 2			
1	9:00-10:00	<b>Research Misconduct and Fraud</b> Definition and Consequences; Case Examples	<b>Dr. Hlaing Myat Thu</b>
2	10:00-10:30	Tea break	
3	10:30-11:30	<b>Quality Management of Clinical Trials</b> SOPs, Training, Auditing	<b>Dr. Ye Htut</b>
4	11:30-12:30	<b>Recruitment, Informed Consent and Safety Reporting</b>	<b>Dr. Yin Thet Nu Oo</b>
5	12:30-1:15	Lunch	
6	1:15-2:00	<b>Risk-based Monitoring in Clinical Trials</b>	<b>Dr. Theingi Thwin</b>
7	2:00-2:45	<b>Review of clinical trials, Ethics Committee Submission Processes, MHRR registration</b>	<b>Dr. Min Wun Dr. Khin Hnin Pwint</b>
8	2:45-3:15	Tea break	
9	3:15-4:00	<b>Summary and Q &amp; A</b>	<b>Chaired by Prof. Zaw Than Htun and Dr. Myo Khin</b>
10	4:00-4:30	<b>Evaluation and Certificate Awarding</b>	