# 2018 Multi-Regional Clinical Trial (MRCT) Workshop:

# Challenges and Opportunities

**Date： MAY 9 – 10, 2018**

**Venue：CHANG YUNG-FA FOUNDATION International Convention Center Rm801**

Interpreter: English-Chinese interpreter (TBD)

| **Day 1 Wednesday, May 9** | | |
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| **Time** | **Topics** | **Speaker** |
| 08:30-09:00 | 報到 Registration | |
| 09:00-09:10 | 貴賓致詞 Opening Remarks | • 王兆儀組長 (Taiwan FDA) |
| 09:10-09:20 | 團體合照 Memorial photo taking | |
| **Keynote Speech**<br>• **Moderator: 賴瓊慧 主任 (長庚紀念醫院)** | | |
| 09:20-09:50 | • 台灣 MRCT 執行經驗 Experience sharing on MRCT in Taiwan | • 楊志新 醫師 (臺大醫院) |
| 09:50-10:20 | • 中國加入 ICH 後之醫藥法規改革 | • 蘇岭 所長 (瀋陽藥科大學藥品監管科技研究所) |
| 10:20-10:40 | 休息 Coffee Break | |
| **Session 1: Implementation of ICH E17: Regulatory Perspectives**<br>• **Moderator: 王兆儀組長 (Taiwan FDA) 及 Naoyuki Yasuda (Office Director, Office of International Programs, PMDA** | | |
| 10:40-11:10 | • Introduction of ICH E17 Guideline | • 賴怡君 醫師 (財團法人醫藥品查驗中心) |
| 11:10-11:40 | • Point to Consider for MRCT Results Evaluation and the Impact of ICH E17 Implementation in Japan | • Shuji Kamada (Reviewer, Office of New Drug V, PMDA) |
| 11:40-12:10 | Q & A | |
| 12:10-13:30 | 午餐 Lunch | |

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| **Session 2: Implementation of ICH E17: Industry Perspectives**<br>• **Moderator: 康照洲 院長(國立陽明大學)** | | |
| 13:30-14:00 | • Impact of ICH E17 to New Drug Development and the Design of Global Clinical Trials | • 劉瑞芬<br>(羅氏大藥廠) |
| 14:00-14:30 | • Experience Sharing on Planning and Design a MRCT: Asia-Pacific Regional (TBD) | •Marcin Ernst<br>(VP Clinical Development, Synoes) |
| 14:30-15:00 | Q&A | |
| 15:00-15:20 | Coffee Break | |
| **Session 3: Implementation of ICH E17: Clinical Center Perspectives**<br>• **Moderator: 陳建煒 主任(臺大醫院)** | | |
| 15:20-15:50 | • 台灣臨床試驗能量提升策略<br>Strategies for Strengthening the Clinical Trial Environment in Taiwan | • 陳筱筠 醫師<br>(財團法人醫藥品查驗中心) |
| 15:50-16:20 | • 臨床試驗中心簡介與經驗分享(TBD) | • 林永昌 副主任<br>(長庚紀念醫院臨床試驗中心) |
| 16:20-16:50 | • 臨床試驗中心簡介與經驗分享(TBD) | • 邱昭華 主任<br>(台北榮總醫院臨床試驗中心) |
| 16:50-17:20 | Q&A | |

| **Day 2**<br>**Thursday, May 10** | | |
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| **Time** | **Topics** | **Speaker** |
| 08:30-09:00 | Registration | |
| 09:00-09:10 | Opening Remarks | • 康照洲 院長<br>(國立陽明大學) |
| **Session 4: Implementation of MRCT : Challenges and Opportunities (TBD)**<br>• **Moderator: 康照洲 院長 (國立陽明大學)** | | |
| 09:10-09:40 | • Impact of ICH E17 to New Drug Development and the Design of Global Clinical Trials" | • 張薰文博士<br>(美國安進生物公司亞洲政策及中國法規負責人) |
| 09:40-10:10 | • Implementation of Multi-Regional Clinical Trial- Challenge of PMDA-ATC | • Dr. Junko Sato<br>(Director for Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA) ) |
| 10:10-10:30 | • 休息 Coffee Break | |
| 10:30-11:00 | • Implementation and the experience sharing on MRCT (TBD) | • 陳怡安醫師<br>(台大臨床研究受試者保護中心 執行秘書) |
| 11:00-11:30 | • Potential challenges to effective implementation of ICH E17: A Training Center's perspective | • James Leong<br>(Head of Pharmaceutical Regulatory Science Programme (CoRE) Duke-NUS Medical) |
| 11:30-12:00 | Panel Discussion | |
| 12:00-12:10 | Closing Remarks | • 王兆儀組長<br>(TFDA) |