E17：国際共同治験
General principles on planning/designing Multi-Regional Clinical Trials

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E17 PMDA副トピックリーダー
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ICH E17ガイドラインの目的

- 国際共同治験を計画・実施する際の留意点について、国際的なガイドラインを作成する
- 国際共同治験として実施されたデータが、多くの地域で受け入れ可能となるよう、国際的整合化を図ることを目的とする

E17メンバー

Party	Member (New member: underlined)
EU	Kristina Dunder, Armin Koch
EFPIA	Vibeke Bjerregaard, William W.B. Wang
MHLW/PMDA	Yoshiaki Uyama (Rapporteur), Yoko Aoi, Shuji Kamada
JPMA	Osamu Komiyama, Yasuhiko Imai, Hideharu Yamamoto, Masafumi Yokota, Takahiro Araki
FDA	Doug Pratt, Aloka Chakravarty, Lisa M. LaVange
PhRMA	Laurie Letvak, Stuart Green, Rominder Singh
RHI of GCC	Abdullah Hamad Al Hatareshah
DoH Chinese Taipei	Lih-Jiuan Hsu, I-Chun Lai
DRA of Singapore	Foo Yang Tong, Lisa Tan
DRA of Brazil	Ricardo Eccard da Silva, Fernando Casseb Flosi
DRA of Korea	Woo Yong Oh, Tae Gyun Nam

福岡会合前の活動

- The 2nd and 3rd Web-based conference was held in February and March
- Discussion by e-mail after the web-conference
  - ✓Sharing various perspective on discussion points in E17
  - ✓Preparing a working document for discussion in the ICH Fukuoka meeting

福岡会合での活動

Date	Task/Activity
Day 1 (Mon)	■ Discussion about contents of each section on the working document ■ Identifying points need for further discussion
Day 2-3 (Tue/Wed)	■ Continued discussion ■ Revising a draft based on the discussion by the Sub-Team
Day 4	■ Confirming items need to be discussed after this meeting and future work plan

福岡会合の成果

- All important contents were reviewed by all members
- Identifying all points need to be revised in the current E17 draft document
- Discussion with E6 group to confirm effects of revision of E6 guideline currently under consideration to E17
- Initiating to draft a new version of E17 guideline

Basic Concept:
- Encourages to conduct MRCTs in drug development
- Science based-consideration for better planning/designing MRCTs

現時点における目次案

2. General recommendations in planning/designing a MRCT
   - 2.1 Strategy-related points
     - 2.1.1 The value of MRCTs in drug development
     - 2.1.2 The basic requirements and key considerations to conduct a MRCT
     - 2.1.3 Scientific consultation meetings with regulatory agencies
   - 2.2 Clinical trial design and protocol-related points
     - 2.2.1 Pre-consideration of regional variability on efficacy/safety
     - 2.2.2 Preparation for confirmatory trial
     - 2.2.3 Subject selection
     - 2.2.4 Selection of doses for use in confirmatory MRCTs
     - 2.2.5 Choice of endpoint
     - 2.2.6 Estimation of an overall sample size and allocation to each region/country in a MRCT
     - 2.2.7 Collecting and handling efficacy/safety information in MRCTs
     - 2.2.8 Statistical analysis plans that specifically address the features of MRCTs
     - 2.2.9 Selection of comparator
     - 2.2.10 Handling concomitant medications

福岡会合後の予定

- 各項の詳細化
  - By e-mail and the Web-based conference
  - The Web-based conference will be held three times (probably in July, September and November)
- Jacksonvilleでの対面会合を要望

今後のスケジュール

- First face-to-face EWG Meeting in November 2014 in Lisbon
- Discussion by e-mail and web-based conference: 4Q 2014 - 1Q 2015
- Second F2F EWG Meeting in June 2015 in Fukuoka for coordinating opinions of all parties and delivering draft Step 1 document
- Third F2F EWG meeting in 4Q 2015 for adoption of ***Step 2*** document
- Public consultation: 4Q 2015 - 2Q 2016
- Revision of the guideline based on comments: 2Q 2016 - 4Q 2016 (depending on contents of comments received)
- Fourth face-to-face EWG Meeting for adoption of ***Step 4*** document in **4Q 2016 or 2Q 2017**

ご静聴いただきありがとうございました