Final Business Plan

E17: General principle on planning/designing Multi-Regional Clinical Trials

dated 21 May 2014

Endorsed by the ICH Steering Committee on 5 June 2014

Introduction

A new guideline on general principle on planning/designing Multi-Regional Clinical Trials (MRCTs) is proposed to be published through the ICH process. This guideline mainly focus on practical issues in planning/designing MRCT. This will result in promoting conduct of MRCTs more appropriately and facilitate its' data acceptance by multiple regulatory agencies.

1. The issue and its costs

- *What problem/issue is the proposal expected to tackle?*

Drug development has rapidly been globalized recently and MRCTs for regulatory submission have widely been conducted in non-ICH regions as well as ICH regions. Regulatory agencies currently face challenges in evaluating data from MRCTs for drug approval. However, there is currently no harmonised ICH Guideline on MRCTs, especially focusing on scientific issues in planning/designing MRCTs, although Q&A of ICH E5 Guideline partly covers issue relating to MRCTs. An international guideline will be needed to promote conducting MRCT appropriately. A lack of harmonisation on this topic may cause additional burden for sponsor and difficult situation for conducting MRCTs.

- *What are the costs (social/health and financial) to our stakeholders associated with the current situation or associated with "non action"?*

The conflicting regional requirements on data from MRCT are leading to duplication of unnecessary clinical trials and delaying drug development, which result in inefficiency of drug development and a delay of drug approval.

2. Planning

- *What are the main deliverables?*

A new harmonised guideline on general principle on planning/designing MRCTs that will provide points to consider in planning/designing MRCTs for regulatory submission.

- *What resources (financial and human) would be required?*

Formation of an Expert Working Group (two or three experts nominated by EU, EFPIA, FDA, PhRMA, MHLW, JPMA, Health Canada and Swissmedic). One member can also be nominated by WHO Observer, RHIs and DRAs/DoH (if requested).

- *What are the time-frame and key milestones of the project?*

The request will be discussed in the ICH Steering Committee (SC) in Minneapolis in June 2014 with the expectation of the EWG meeting face-to-face in November 2014. It is anticipated that a *Step 2b* Guideline will be completed by 4Q 2015 and that *Step 5* will be reached by 2017.

3. The impacts of the project

- *What are the likely benefits (social, health and financial) to our key stakeholders of the fulfillment of the objective?*

The proposed guideline will promote conduct of MRCTs more appropriately, increase an efficiency of drug development, resulting in avoiding duplicative works in drug development and a better regulatory decision. The guideline will provide a harmonised approach in planning/designing of MRCTs to minimize conflicting opinions from regulatory bodies. It will facilitate further utilisation and acceptance of data from MRCTs in multiple regions.

- *What are the regulatory implications of the proposed work – is the topic feasible (implementable) from a regulatory standpoint?*

The proposal is consistent with current laws and regulations of the ICH regions. Regulatory authorities will need to agree globally on points to consider in planning/designing MRCTs. This guideline may have impacts for revising or superseding regional guidelines. An overall effect on regulatory resources cannot be established at this time.

4. Post-hoc evaluation

- *How and when will the results of the work be evaluated?*
  Not applicable.