Final Business Plan
E18: Genomic Sampling and Management of Genomic Data
dated 17 September 2015
Endorsed by the ICH Management Committee on 5 October 2015

Introduction

There is growing awareness and interest in the significance of genomic data in evaluating efficacy and safety of drugs, in all phases of drug development. This includes early clinical trials as well as post marketing assessment. Success of genomic research is dependent on systematic collection and analysis of genomic samples, ideally, from all subjects. The samples may be used for a variety of analyses that may or may not be pre-specified in the clinical study objectives at the time of collection. This guideline defines non-pre-specified use as "future use". Sample retention is essential for furthering any subsequent evaluation and research using methodologies that preserve data integrity, sample quality and tracking. The main objective of this document is to provide a harmonized guideline for the general principles of genomic sampling and use of such samples to generate genomic data in both pre-specified and future use contexts.

1. The issue and its costs

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

  Genomic data have become important to evaluate efficacy and safety of a drug for regulatory approval. As a result, genomic information has been increasingly included in drug labels as relevant for the benefit/risk evaluation of a drug. To accumulate such data during drug development and throughout the product life cycle, genomic samples from clinical trials should be collected, used and stored as per specific guiding principles.
  It has been reported that collection rate of genomic samples is low in many ICH regions (ref. Clin Pharmacol Ther 89: 529, 2011). All ICH regulatory agencies (EMA, FDA and MHLW/PMDA) have independently published guidelines encouraging genomic sample collection. There is currently no harmonised ICH Guideline on genomic sample collection in clinical trials or other studies. Harmonisation across regions on this topic will maximize the information gathered from the studies for e.g., sample collection and analysis (including ethical considerations) and facilitate implementation of pharmacogenomics for the benefit of all stakeholders.

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

  The lack of consistency of guiding principles for genomic sampling and genomic data likely contributes to the low prevalence of genomic data generated in drug development programs. This represents a lost opportunity in drug development and healthcare delivery and consequently with negative impact on the ***development programmes, public heath programmes and delivery of stratified or personalized medicine***.

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2. Planning

- *What are the main deliverables?*

  Harmonized guidance on genomic sampling and data generationwill clarify points to consider in collecting genomic samples in clinical trials and other studies and when using those samples to generate genomic research data during the development of new drugs. Storage of genomic samples and data in clinical studies may be subject to national laws, policies and regulations. This guideline focuses on aspects relating to collection, handling and storage of genomic samples for both pre-specified and future use and supports methodology as well as considerations for sponsors, investigators and ethical committees.

  The following are the main issues identified from past experiences and will be addressed in this guideline.
  - Situations, value and importance of appropriate planning for genomic sample collection for both pre-specified and future use.
    - To enable retrospective analysis when new scientific evidence emerges or when additional analysis of genomic samples becomes necessary
    - To enable analysis/evaluation using sufficient number of samples obtained from multiple clinical trials
  - Recommendations for genomic sampling in clinical trials and other studies.
    - Genomic sample collection and coding: (1) Samples should be obtained without selection bias, (2) Appropriate use of coded samples and anonymized/anonymous samples in accordance with ICH E15 guideline.
    - Genomic sample storage, i.e. it is important to process and store samples (blood, DNA, RNA, etc) under optimal conditions, and in consideration of target analytes.

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

  Total of twenty persons: Two (Four only in Japan) persons from each of the six ICH parties and one observer each from the ICH observers (Canada, Brazil, Korea and Singapore). Four meetings of the Expert Working Group will be necessary to reach step 4 of the ICH process.

- *What is the time frame of the project?*

  Two and a half years

- *What will be the key milestones?*

  STEP 2: December 2015
  STEP 4: 2Q 2017

3. The impacts of the project

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

  The anticipated benefit of this work includes further encouragement for sponsors to collecti genomic samples in a standardized way and facilitate the use of pharmacogenomic data in drug development, resulting in promotion of a considered regulatory decision making to the benefit of the better public health delivery.

In addition, the new guideline will integrate the experiences of both regulatory authorities and pharmaceutical industries. This guideline will provide recommendations through this process of harmonization and intends to establish harmonised guiding principles genomic sampling for pre-specified and future use , so as to enable more efficient global drug development.

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

  The gulideline and the topic are of specific interest to the regulatory agencies and provides opportunity for harmonization of data collection across the regions. However, no major impact on existing regulatory framework or a need for new regualtions in the ICH regions is anticipated.

4. Post-hoc evaluation

- *How and when will the results of the work be evaluated?*

  If harmonization is successful, implementation of genomic sampling and genomic research by sponsor companies will increase without delay. A questionnaire based assessment could be performed evaluating the clarity, use and interpretation of genomic guiding principles described in this guideline by relevant bodies such as regulatory authorities and sponsor companies.
  An assessment will be made documenting the impact of the guideline in supporting the implementation of genomic sampling and researchat a global level, the resource required to review the applications and the time taken to provide that review: a survey of the experience gathered will be reported to the ICH SC within three years from the formal implementation of the planned ICH Guideline.