Final Business Plan
S9: Pre-Clinical Guideline on Oncology Therapeutic Development
30 April 2007
Endorsed by the ICH Steering Committee on 10 May 2007

1. The issue and its cost

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

  The approaches to the preclinical development of oncology drug products have been and continue to be independently discussed and developed in Europe, the USA and Japan. The preclinical approaches are not agreed on across product classes, between small molecules of different molecular mechanisms and across product classes such as biologics and drugs. The available disharmonized guidance has resulted in inefficient use of animal resources, and ineffective drug development in a critical area of human health.

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

  Each of the Regulatory Authorities is developing guidances independently that are focused on pre-clinical issues in oncology drug development. Harmonization is necessary to avoid the emergence of variations across regulatory jurisdictions that will have great impact on public health and resource implications.

2. Planning

- *What are the main deliverables?*

  It is proposed that ICH develop a guideline on the pre-clinical development of oncology therapeutics This ICH guidance would focus on preclinical recommendations to support the development and marketing of cancer therapeutic agents for the treatment of cancer. It is expected to:

  1) address the current state of disharmony noted above,
  2) facilitate development of agents considered as a global critical public health need,
  3) result in refinement and reduction in the use of animals in an area of extensive pharmaceutical research and development, and
  4) address the gaps in preclinical development guidance that have arisen from the new therapeutic classes of targets identified from the human genome project, and recent advances in cancer biology.

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

  An Expert Working Group should be established. The EWG would include one or two experts from each of the ICH Parties and Observers, in addition, a representative from one of the major biotechnology associations should be invited. EWG members' sponsoring organizations would need to provide financial resources for periodic face-to-face meetings (at least twice/year).

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

  May 2007 through 2009.

  Work will be conducted via teleconferences and email; face-to-face meetings are contemplated twice per year from October 2007 through October 2009. A 12-month interval is anticipated between the Step 2 and Step 4 documents to allow for the usual consultation.

- *What will be the key milestones?*

  The established ICH processes and procedures should be followed. It is expected that the work of the EWG will be completed within this general schedule:

  Step 2 guideline: October 2008
  Step 4 guideline: Early 2010

3. The impacts of the project

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

  Currently separate guidances are in effect and/or planned in the three ICH regions. The generation of the proposed guidance will be valuable in the production of a single global guidance and prevent the unnecessary duplication of non-clinical safety studies to satisfy the requirements in each region. An ICH consensus effort would result in the harmonization of disparate global recommendations and avoid any adverse impact to the global development of needed cancer therapies. This guidance would facilitate the global development and access to needed medicines for patients and avoid wasteful use of valuable resources (including animals). By addressing the specific needs for diverse classes of cancer therapeutics it should contribute to establishing the safety of patients exposed to such drugs.

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

  Applicable regulations and guidelines in the various regions would be enhanced and clarified by a guidance in this area.

4. Post-hoc evaluation

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

  The results will be evaluated by:

  - Implementation of local requirements in line with this final Guidance
  - A comparison of resources required under current guidance's versus those needed under the new guidance.