

Communication Paper

**Gene Therapy Discussion Group Meeting
Chicago, 7-9 November 2005**

Status Report:

The scope of the ICH GT Discussion Group (GTDG) meeting included:

- holding a one day workshop on oncolytic viruses,
- discussing the information from the Oncolytic Viruses Workshop
- discussing and further working on the draft ICH Considerations for Minimization of the Risk of Germline Transmission, and
- sharing regional updates.

Representatives from the three ICH regions (including experts from regulatory authorities and industry), EFTA, and Health Canada participated.

The GTDG agreed on the following points:

ICH Workshop on Oncolytic Viruses

The GTDG held the 1-day meeting on Oncolytic Viruses, including: adenovirus, herpes simplex virus, reovirus, Newcastle disease virus, vaccinia, measles virus, and Sendai virus. The GTDG wrote a summary of the meeting for the SC [Addendum 1].

ICH Considerations for Minimization of the Risk of Germline Transmission

The GTDG completed and discussed draft 2 of the ICH Considerations for Minimization of the Risk of Germline Transmission of gene therapy vectors. Comments for incorporation into draft 3 are due in January 2006 to the Japanese rapporteur.

Future activities

In addition the group agreed that there are two main lines of outcomes possible following discussions:

- ICH Considerations will be proposed for topics for which the science is still rapidly evolving.
- ICH Guidelines may be prepared for topics for which sufficient experience has been accrued in the Regions.

The next formal meeting will take place in parallel with the ICH SC EWG meeting in June 2006.