

Communication Paper

**Gene Therapy Discussion Group Meeting
Tallinn, Estonia, June 6, 2010**

Status Report:

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

- sharing regional updates and monitoring regional emerging issues,
- discussing a detailed outline of an ICH Considerations document on General Principles to Address in Preparation for First-in-Human Gene Therapy Studies, and
- making plans for future activities.

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

Future activities:

The GTDG agreed that productivity would be enhanced by meeting face-to-face. At the next meeting the group will exchange regional information and continue to work on ICH Considerations documents.

The GTDG will review a 1st draft proposal of an ICH Considerations document on General Principles to Address in Preparation for First-in-Human Gene Therapy Studies.

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The next formal meeting of the ICH GTDG will take place in parallel with the ICH SC and EWG meetings in November 2010.