

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Cellular, Tissue and Gene Therapies Advisory Committee  
Meeting #36  
March 4, 2005

Update Retroviral Vector-Mediated Insertional Mutagenesis

Bibliography

Kelly, P. F., et.al., *Prolonged multilineage clonal hematopoiesis in a rhesus recipient of CD34 positive cells marked with a RD114 pseudotyped oncoretroviral vector*. Blood Cells, Molecules and Diseases, 2003. **30**: p. 132-143.

Hacein-Bey-Abina, S., et.al., *LM02-associated clonal T cell proliferation in two patients after gene therapy for SCID-X1*. Science, 2003. **302**: p. 415-419.

Hacein-Bey-Abina, S., et.al., *Sustained correction of X-linked severe combined immunodeficiency by ex vivo gene therapy*. N Engl J Med, 2002. **346**(16): p. 1185-1193.

Dave, U.P., Jenkins, N.A., Copeland, N.G., *Gene therapy insertional mutagenesis insights*. Science, 2004. **303**: p. 333.

Aiuti, A, et.al., *Correction of ADA-SCID by stem cell gene therapy combined with nonmyeloablative conditioning*. Science, 2002. **296**: p. 2410-2413.

Gaspar, H.B., et.al., *Gene therapy of x-linked severe combined immunodeficiency by use of a pseudotyped gammaretroviral vector*. The Lancet, 2004. **364**: p. 2181-2187.

Modlich, U., et.al., *Leukemias following retroviral transfer of multidrug resistance 1 (MDR1) are driven by combinatorial insertional mutagenesis*. Blood First Edition Paper, prepublished online February 15, 2005.