

AGENDA

ICH Public Meeting

January 21, 2003

10:30AM - 2:00PM

5630 Fishers Lane, Room 1066

- I. Introductory Remarks
- II. ICH General Overview
- III. CTD Implementation Status
 - FDA perspective
 - Other ICH regions Perspective
 - Electronic CTD
- IV. Update on the Preliminary Concept Paper on the Clinical Evaluation of QT Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
- V. Update on the Pharmacovigilance topics
- VI. Update on Gene therapy
- VII. Medical Dictionary for Regulatory Activities (MedDRA)