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## Webinar: Clinical Trials: Moving Stem Cell based Therapies to the Clinic



Regenerative  
Medicine  
Consortium

### WEBINAR

Clinical Trials: Moving Stem Cell based

Therapies to the Clinic

**Presentations from FDA and Leading Experts**

**This webinar was held on April 15th at 10:00 am PT**

**You can watch the introduction here and the speaker's presentations here.**

#### Moderator

Ellen Feigal, M.D., Senior Vice President of Research and Development, CIRM

#### Speakers

- John Hyde, M.D., Ph.D, Medical Officer, Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT), Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA) - First-in-Human Trials of Cellular Therapies Slides
- Eduardo Marbán, M.D., Ph.D., Founder and Chairman of Scientific Advisory Board, Capricor, Inc. and Director, Cedars-Sinai Heart Institute, Mark S. Siegel Family Professor - Lessons learned from Phase 1 trial of heart-derived stem cells as we move into Phase 2 Slides
- Jonathan D. Glass, M.D., Professor, Neurology and Pathology, Emory University School of Medicine - A Phase 1 trial of spinal cord transplantation of neural progenitor cells in ALS (Neuralstem) Slides

#### Topics

The focus of this webinar is on the Lessons Learned from IND/Phase I trials including overcoming the challenges, and addressing the regulatory issues, as stem cell based therapies move towards the clinic.

- Presentation by FDA - Considerations for Early Phase Clinical Trial Design in Cellular Therapies- issues the FDA considers in evaluating the risks vs. benefits of early phase trial proposals
- Lumbar Intraspinal Injection of Neural Stem Cells in Patients with ALS: Results of a Phase I Trial in 12 Patients
- Lessons learned from Phase I trial of autologous cardiosphere-derived stem cell product for myocardial infarction and comparison to new allogeneic trial with the same indication
- Questions and Answers

#### Background Information

- Fifteen Cell Therapies/Stem Cell Therapies in Phase III Clinical Trials (Cell Culture Dish by Brandy Sargent) - *Cell Culture Dish* by Brandy Sargent [pdf]

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