Timothy R Cote, J Genet Syndr Gene Ther 2016, 7:5 (Suppl)
http://dx.doi.org/10.4172/2157-7412.C1.008

Timothy R Cote

Cote Orphan LLC, USA

Inside track to an orphan designation

All too often, creators of new therapies for people with rare diseases will expend vast resources on drug discovery, manufacturing, clinical key opinion leaders and of course raising money but ignore regulatory affairs, assuming that will just itself somehow work out. In this presentation, Dr. Cote, previous Director of the FDA orphan drug office, will discuss the intricacies of the orphan drug designation in the US and in Europe, preparing for a winning pre-IND meeting, crafting clinical trials that make sense to regulators, special incentives like breakthrough therapy designation, the pediatric rare disease designation and the PRIME program will also be demystified.

Biography

Timothy R Cote is a leading national Regulatory Expert in orphan drug development with 23 years of Federal Service at the FDA, NIH and CDC. He has recently served as the Director of the FDA Office of Orphan Products Development (OOPD) from 2007-2011. As an Anatomic Pathologist and Medical Epidemiologist, he has published 80 peer-reviewed articles on areas as diverse as HIV/AIDS-related malignancies, typhoid fever epidemics and the impact of bicycle helmet laws on injury statistics. He is the Founder and CEO of Cote Orphan; where he directs and trains staff to create compelling regulatory submissions that are finely tuned to each client's business strategy and to the unwritten rules within the FDA. He has received his Bachelor's degree from Syracuse University, Medical Doctorate from the Howard University College of Medicine and a Master's degree in Public Health from Harvard School of Public Health.

tim@coteorphan.com

Notes: