



“Drug Safety and FDA Risk Evaluation and Mitigation Strategies (REMS): Advancing Regulatory Science with Implementation Science”

The Food and Drug Administration Amendments Act of 2007 gave FDA authority to require REMS from manufacturers to ensure that the benefits of a drug or biologic outweigh its risks when used in real-world settings. This talk will discuss the evolution of REMS Guidance to Industry over the past decade, pragmatic approaches from implementation science for advancing REMS design and evaluation, and implications for drug development.

Dr. Morrato's health services research focuses on accelerating the translation of health innovation into practice, with an emphasis on drug warnings. Her experience launching new drugs and indications while an R&D manager in Procter & Gamble's global healthcare division informs her research and practice. She is currently on sabbatical with the FDA in the Office of Surveillance and Epidemiology.

**March 21, 2018
4:00 – 5:00 p.m.
DRUG Lobby Conference Room**



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