

Designing Clinical Studies and Navigating the FDA Approval Process in the United States

Carlos Peña, PhD, MS, Chief Regulatory Officer and Chief Quality Officer, Jacobs Institute - Buffalo, USA

The United States (US) Food and Drug Administration (FDA) objective is to bring patients and physicians safe and effective neurological, cardiovascular, and related medical devices to market.

The FDA's Center for Devices and Radiological Health reviews innovative and emerging medical technologies, including devices that interface with the nervous system and the brain.

This presentation will introduce and present the FDA's regulatory authorities and oversight, share with attendees the best practices in the design of clinical studies and first in human investigations, navigate FDA review and approval submission pathways, and how best to successfully bring medical devices to patients in the US and abroad.