conferenceseries.com

2nd International Conference on

Clinical Trials and Therapeutic Drug Monitoring

August 22-24, 2016 Philadelphia, USA

Michael Bernstein, J Clin Trials 2016, 6:4(Suppl)
http://dx.doi.org/10.4172/2167-0870.C1.010

Regulatory and compliance considerations for Direct-To-Patient (DTP) distribution of clinical trial material

Michael Bernstein
Clinical Supplies Management, Inc., USA

FDA's "Paving the Way for Personalized Medicine" reports along with the funding of the Precision Medicine Initiative are changing the clinical drug development landscape in the United States. Drug development stratification has resulted in numerous drugs being developed for small geographically dispersed patient populations with fewer clinical investigators participating in the clinical studies. This creates a challenge for patients who cannot travel long distances to obtain their clinical medication. DtP shipment of clinical trial material is a potential solution that addresses various challenges introduced by the Precision Medicine Initiative. The objective of this paper is to provide guidance and best practices for study sponsors and clinical investigators wanting to utilize the DtP distribution model for their clinical studies. The author reviewed various regulations, guidance documents and case studies pertaining to DtP distribution of clinical trial material and identifies regulatory and compliance considerations when using the DtP distribution model. There are multiple regulations and guidance documents pertaining to clinical studies but none specifically address the DtP distribution model. Sponsors wanting to utilize DtP distribution in their clinical trial must ensure they get proper buy-in from key stakeholders including Principal Investigators, IRB's, CRO's and the patients. Sponsors must develop a clear concise investigation plan incorporating DtP distribution language in their regulatory documents. They must have early transparent dialog with regulators and ensure their plan addresses any concerns the regulators may have.

Biography

Michael Bernstein is Vice President of Global Compliance and Risk Management at Clinical Supplies Management, Inc. He is responsible for the oversight of CSM's global compliance, risk management, process excellence and quality programs. He has over 28 years of Compliance experience in the pharmaceutical industry. Prior to joining CSM, he held various R&D, Manufacturing and Global Compliance positions during his 26-years at Merck & Co. Inc.

mbernstein@csmOnDemand.com

Notes: