Siddhartha Chowdhury, J Clin Trials 2018, Volume 8
DOI: 10.4172/2167-0870-C3-028

7th International Conference on CLINICAL TRIALS
&
12TH WORLD CADD & DRUG DELIVERY SUMMIT
September 24-26, 2018 | Chicago, USA

Siddhartha Chowdhury

Northeastern University, USA

Planning and submitting clinical trial applications to ex US countries

There is a lot of preparation and planning that goes into submitting Clinical Trial Applications (CTA) to Ex-US countries. Alkermes has performed CTA submissions to countries such as Italy, Spain, Germany, the UK, Ireland, Austria, Israel, Poland, Bulgaria, Ukraine, and Serbia recently for Phase III schizophrenia studies. A pharmaceutical sponsor company such as Alkermes can't do this alone and therefore, CRO support is critical in this regard. Both the Sponsor Company and CRO need to understand the regulatory landscape, patient population, study design and treatment type, study drug etc. to plan for submissions and weigh in risks. The CRO plays a key role in being the in-country expert, shares intelligence on in-country submission requirements and dates for competent authority and ethics submissions and tentative approvals. Internally, it is key to delegate roles and responsibility for documents needed for CTA submission based on cross-functional expertise. A rapid response team for queries and aligning internally on expectations, roles, and deliverables during CTA submission will prevent additional delays when the regulators share queries or concerns on your study protocol. This presentation or workshop will allow for alkermes representative to discuss case studies on challenges faced during Ex-US submissions and ways to overcome them.

Biography

Sid Chowdhury has completed his Bachelors in Pharmacy at the age of 22 years from Mumbai University, Mumbai and Masters of Science (MS) from Northeastern University, College of Professional Studies, Boston, MA. He is the Study Start-Up lead for Alkermes, a premier pharmaceutical company based out of the Boston metro area. He has been managing Study Start-Up for global Phase III CNS studies for more than 3 years and has been serving as a Clinical Trial Manager, Global Clinical Services.

Notes: