



DIA 2012 48th Annual Meeting: Collaborate to Innovate
6/24/2012 8:30:00 AM
Pennsylvania Convention Center
1101 Arch Street
Philadelphia, PA 19107

Track:

SIAC Showcase (Track 19)

Day & Time:

June 26, 3:30PM - 4:30PM

Level:

Intermediate

Type:

Siac

Title:

Hot Topics in Clinical Trial Disclosure (CTD)

Chair(s):

Robert Paarlberg, MS

Principal

Paarlberg & Associates LLC, United States

Description:

This showcase will discuss the ever changing clinical trial disclosure (CTD) landscape, the impact on industry, and how companies change their processes to maximize efficiencies to meet the increasing demands of global CTD requirements. Emerging CTD requirements in selected countries will be highlighted. The showcase will also focus on results disclosure in the EU as well as discuss the challenges and complexities companies face in meeting global CTD requirements. An update will be provided on the status of NLM's Notice of Proposed Rulemaking. In addition, the audience will be encouraged to share their organizations' perspectives on these issues and how they are meeting the challenges of clinical trial disclosure. Benefits of participating in the SIAC will also be discussed.

Developed by the Clinical Trial Disclosure (CTD) SIAC.

Objective:

Describe the most recent disclosure developments in the EU, US and other countries/regions;
Discuss results disclosure in the EU and challenges for companies; Explain the benefits of participating in the CTD SIAC.

Presentation(s) & Speaker(s):

Significant Disclosure Developments in Selected Countries

John C. McKenney

President

SEC Associates, Inc., United States

The EU Clinical Trials Register: Practical Hurdles from a Company Perspective

Merete Joergensen, MBA, MSc

Director, Global Clinical Registry

Novo Nordisk A/S, Denmark