DCVMN TRAINING WORKSHOP

CLINICAL STUDIES MANAGEMENT AND PHARMACOVILANCE STRATEGIES

SUBJECT: Pre-reading and preparation for Pharmacovigilance Workshop July 20, 21 2016

Dear Participants.

Please find attached some pre-reading material for the Pharmacovigilance workshop.

The pre-read includes:

- Pharmacovigilance on Asia. Pipasha Biswas: J Pharmacol Pharmacother. 2013 Dec; 4(Suppl1): S7–S19.
  This article speaks to the need for improved systems in Asia and some of the challenges associated with introducing them. A succinct summary of the challenges faced in Asia
  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3853674/

- WHO; Minimum Requirements for a functional Pharmacovigilance System. A brief summary extract on international and national system requirements.
  http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_2010_2.pdf

- PROCEDURE FOR CONDUCTING PHARMACOVIGILANCE INSPECTIONS ....While European focused this audit inspection procedure is a concise summary of what auditors will look for is assessing your company's PV systems. This is a useful reference in assessing the current status of your company's PV systems.
  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004944.pdf

- ICH HARMONISED TRIPARTITE GUIDELINE : PHARMACOVIGILANCE PLANNING (E2E)
  This is a relatively high level summary of Pharmacovigilance systems.
  http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2E/Step4/E2E_Guideline.pdf

- ICH guideline E2C (R2) on periodic benefit-risk evaluation report (PBRER)
  This document outlines how to prepare a Periodic Safety Update Report. In reading this document think about the systems that need to be in place to generate the information required in a timely manner.
  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/12/WC500136402.pdf

- Adverse Event Estimation in Post Marketing WHITE PAPER Jesna Jose and Dr. A.K. Mathai from Pharm Centre
  This brief paper highlights sample size consideration in Post Marketing Surveillance and provides some simple examples.
  http://www.pharmcentre.com/WhitePapers/adverseevent_est_pms_trials.pdf

- AUSTRALIAN REQUIREMENTS AND RECOMMENDATIONS FOR PHARMACOVIGILANCE RESPONSIBILITIES OF SPONSORS OF MEDICINES

  Australia has relatively well developed pharmacovigilance systems. This is a lengthy document but captures important elements of Pharmacovigilance systems generally and the interface with the WHO. It is a good example of national regulations in place to secure Good Pharmacovigilance Practice

  https://www.tga.gov.au/sites/default/files/australian-pharmacovigilance-sponsors-00-140604.pdf

We are looking forward to meeting and working with you in Bali

Kind Regards

Jeff Davies and Greg Plunkett