

# Signal Detection and Data Mining



October 22-24, 2013  
Beijing, China

This training course will review approaches to the implementation of signal detection and data mining as part of your pharmacovigilance operations. The requirement for companies to perform signal detection is mandatory in Europe and highly recommended in the US. Many simple techniques can be applied to the generation and review of potential signals, which can also be augmented by the application of sophisticated data mining algorithms.

## SESSION TOPICS

- ▶ Signal assessment process
- ▶ Pharmacovigilance overview
- ▶ FDA & EU regulatory requirements
- ▶ Data mining methodologies
- ▶ Signaling and risk assessment
- ▶ Series of interactive case studies

## LEARNING OBJECTIVES

At the end of the training course, participants will be able to:

- ▶ Understand regulatory requirements for drug safety and pharmacovigilance practice
- ▶ Learn how to collect, assess, report and analyze adverse event
- ▶ Understand the basic concepts and principles of signal detection for accumulating clinical data
- ▶ Describe how to apply these techniques within the company
- ▶ Apply data mining techniques to analyze large volumes of adverse event report data
- ▶ Conduct signaling analyses on real-life data

## WHO SHOULD ATTEND

Professionals with background in the following areas:

- ▶ Clinical Research
- ▶ Clinical Safety/Pharmacovigilance
- ▶ Public Policy/Law/Compliance
- ▶ Regulatory Affairs
- ▶ Research & Development
- ▶ Risk Management

### PROGRAM COMMITTEE

#### **Xiaojun GUO, PhD**

Head of Clinical Safety and Pharmacovigilance, R&D China GlaxoSmith-Kline, China

#### **Vera LIANG, MD**

Director and Global Safety Risk Lead, Safety Surveillance and Risk Management, Pfizer (China) R&D Co. Ltd., China

#### **Daniel LIU, PhD**

Director, China Development Medidata Solutions Worldwide, China

#### **Xiaoyao(Conny) MO**

Director, Head of Pharmacovigilance and Product Information (PPI), China R&D and Scientific Affairs, Janssen, Johnson&Johnson, China

#### **Xue TANG, PhD**

Country Safety Lead for China, Global Pharmacovigilance Office, WSRO, Pfizer, China

#### **Tracy ZENG, PhD**

Senior Manager of Patient Safety AstraZeneca, China

### SPEAKER

#### **Steve JOLLEY**

Principal  
SJ Pharma Consulting, USA

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