Introduction

ClinicalTrials.gov

US FDAAA (2007 and amendments)

- **on September 27, 2007, result posting mandates**
  - Post results within 1 year of Primary Completion Date (PCD)
  - Trials meeting all of the criteria
    - Product approved in any country
    - Controlled trial (placebo or active comparator)
    - Initiated or ongoing as of 27-Sep-2007, and completed after/on 26-Dec-2007
    - Phase 2 to 4
  - If new approval
    - 30 days to report results for completed trials > 1 year from PCD

- **on January 18, 2017, the Final Rule of result posting**
  - For all applicable trials including for non-licensed products
  - Disclose the full protocol, SAP and all amendments as redacted
  - Data fields have changed and new AE tables will have to be disclosed
    - Baseline Characteristics
    - Adverse Events
    - Outcome Measures

Introduction

EudraCT

European Medicines Agency (EMA)

- **on July 21, 2014, result posting mandates**
  - **Post result within :**
    - **1 year after Last Patient Last Visit (LPLV) for Adult trials**
    - **6month after Last Patient Last Visit (LPLV) for Pediatric trials**
  - **Trials meeting all of the criteria**
    - **Approved & Unapproved**
    - **All interventional trials**
    - **Completed after 1May2004**
    - **Phase 1 to 4**

Janssen Automation of Result Disclosure Working Group

- **Denis Michel**

  Statistical Programming, USA
- **Sherry Meeh**

  Statistical Programming, USA
- **Sivasankara Arikala**

  Statistical Programming, USA
- **Ilse Augustyns**

  Statistical Programming, EU
- **Yeming He**

  Statistical Programming, USA
- **Diye Kang**

  Statistical Programming, EU
- **James Li**

  Statistical Programming, USA
- **Layfong Lim**

  Statistical Programming, USA
- **Kenneth Yan**

  Statistical Programming, China
- **Christina Zackiewicz**

  Clinical Registry , EU
- **Erica Schirmer**

  Clinical Registry , USA
- **Min Fu**

  Biostatistics, USA

Presenter Contact information:
Sherry Meeh, smeeh@its.jnj.com