Data Analytics in Pharmacovigilance

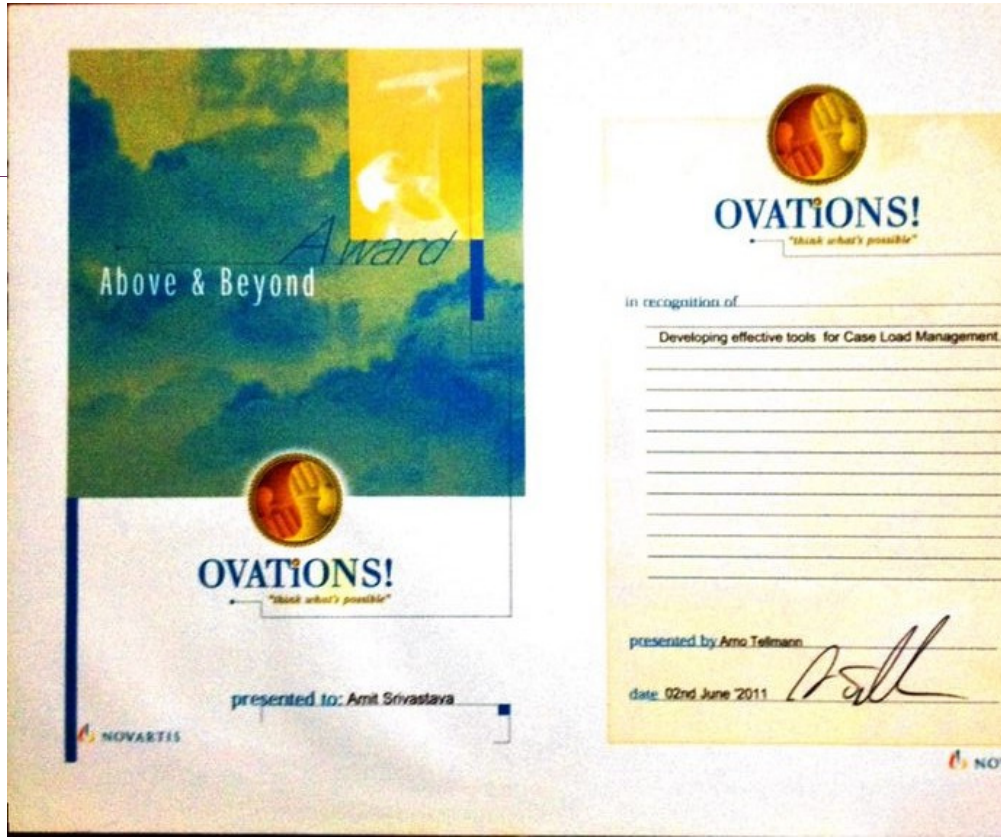
- Amit Srivastav
- Founder & Director, Infocorp Software Solution

Executive Program in Business Analytics – IIM Lucknow - 2014 - 1

How I Saved 7 Hours Per Day of a PV Org!

How I Saved 7 Hours Per Day of a PV Org!

- Dashboard using EXCEL & VBA Macros
- Refers two base excel files and operates on two transactional excel files
- Completes all transactions in less than five minutes which was earlier completed in 6-7 hours.



Scope

- Signal Detection
- Trends and other Analytics on case data
- PV Organization's Operational Efficiency

The specific aims of pharmacovigilance:

- The specific aims of pharmacovigilance are:
- the identification of previously unrecognized Adverse Drug Reactions (ADRs, novel by
- virtue of nature, frequency and/or severity);
- the identification of subgroups of patients at particular risk of adverse reactions;
- the continued surveillance of a product throughout the duration of its use, to ensure
- that the balance of its benefits and harms are and remain acceptable;
- the description of the comparative adverse reactions profile of products within the same
- therapeutic class;
- the detection of inappropriate prescription and administration;
- the further elucidation of a product's pharmacological and toxicological properties and
- the mechanism(s) by which it produces adverse effects;

The specific aims of Pharmacovigilance: (contd.)

- the detection of clinically important drug–drug, drug–herb/herbal medicine, drug–food, and drug–device interactions;
- the communication of appropriate information to health-care professionals;
- the confirmation or refutation of false-positive signals that arise, whether in the professional or lay media, or from spontaneous reports (see below for definition of a “signal”)

Signal Detection

- “Signal detection is the act of looking for and/or identifying signals using event data from any source".
- Spontaneous Reporting Systems (SRSs) constitute the dominant source of signals.
- Prominent SRSs are the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS1) of US, EudraVigilance maintained by the European Medicines Agency and VigiBase3 maintained by the Uppsala Monitoring Center of the World Health Organization (WHO-UMC).
- Other Sources:
  - Electronic medical records
  - Claim databases

Analytics With FAERS - Data

- FAERS Data Sets available at →

- Steps to work on →
- Download.
- Import in Excel
- Following Tables:
- Demo, Drug, Indication, Outcome, Reaction, Report Source, Therapy

Analytics with Social Media Data

- Problems:
  - Availability
  - Accuracy
  - Sentiments
  - Community Bias

Things I've learned working at client locations (Pharma Companies)

- Almost always struggling to cope up with the incoming flood of cases for triage in their safety systems
- Dealing with fines in one or the other part of the world – due to various reasons
- Always on toes for Regulatory Audits and Inspections

What is a PV Org?

Operational Efficiency

- Case Processing
- Identification of issues in Case Workflow
- CRO Management
- Case Processor Management
- Others

Dashboards for Operational Efficiency

- Case Workflow Tracking & Management
- Case Processors' Tracking & Management
- CRO Tracking & Management

- Look Out for Data
- Initiatives for Data Capturing
- Top down approach

Tools for Analytics in Pharmacovigilance

- Basic Excel Utilities
- VBA Macros
- R
- SAS JMP
- Empirica Signal
- Tableau, Spotfire etc.

Problems in Data Analytics for PV

- Huge Data
- Data present in different formats / structures
- Dynamism
- Interpretation
- Public Data –
- Why only FDA AERS is public? Why not others?
- Canada Vigilance Adverse Reaction Online Database

Thank You!

- Amit Srivastava
- Amit.Srivastava@InfocorpSolutions.Net
- +91-9453937447