## PRISM Forum Special Interest Group on:

# Pharmacovigilance and Risk Management

**BMS, Lawrenceville, NJ**
**Tuesday 21st October and Wednesday 22nd October 2003**

**Membership** – Informaticians supporting Pharmacovigilance

**Expected Outcome** – a Presentation to the PRISM Forum identifying current trends and regulatory requirements in Pharmacoviglance and Risk Management

**Background Reference material for members**

- Guidance for Industry: Providing Regulatory Submissions in Electronic Format — Postmarketing Periodic Adverse Drug Experience Reports – June 2003
- Safety Reporting Requirements for Human Drug and Biological Products [Docket No. OON-14843] March 2003
- Guidance for Industry: E2BM Data Elements for Transmission Of Individual Case Safety Reports - April 2002
- FDA Commissioner Dr. Mark McClellan's Statement on FDA's Commitment to MedDRA DIA Annual Meeting ("Ask the Regulators" Session) San Antonio, TX, - 18 June 2003
- ICH web sites
- Eudravigilance - *http://www.eudravigilance.org/start.htm*
- Volume 9 – The rules governing medicinal products in the European Union
- PDUFA3 Section viii – risk management programs
- Privacy Laws

**The Status Quo and Future**

Systems and Solutions currently in place in Members' organisations
Systems and Solutions planned by Members

**The new Risk Management Approach – topics to be addressed will include:**

Clinical Trials Safety

Post-Marketing Pharmacovigilance

Global Standardization (ICH M1-M3)
Reporting
Electronic Submissions and Transmissions

Standard Coding (MedDRA)

Analysis and Trending
- Data-Mining including FoI DB
- Changing Role of PSURs

Risk Management Solutions
- Education
- Control
- Large Cohort Analysis

**The ideal Risk Mgmt and Pharmacovigilance Landscape**

Brainstorming

**Report to the PRISM members**