INVITATION!

PRISM Forum Special Interest Group: Pharmacovigilance and Risk Management

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

The PRISM Forum invites you to a Pharmacovigilance workshop to be held at Bristol Myers Squibb, in Lawrenceville, New Jersey. The aim of the meeting is to bring together informaticians supporting Pharmacovigilance to discuss the informational issues within the industry and the future challenges of this important discipline. By enabling discussion, The PRISM Forum aims to increase the understanding of the future needs of the Pharmacovigilance function within the biopharmaceutical industry and inform the industry's planning cycle.

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

Workshop Topics for Discussion

Over the course of a the workshop, delegates will discuss:

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

- Clinical Trials Safety
- Post-Marketing Pharmacovigilance
- Global Standardization (ICH M1-M3)
    - Reporting
- Electronic Submissions and Transmissions
    - Standard Coding (MedDRA)

The New Risk Management Approach (continued)

- 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

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

About the PRISM Forum

The PRISM Forum has an international membership drawn from a number of biopharmaceutical organizations, including Novartis, Roche, AstraZenenca, Syngenta, Aventis, American Home Products, Pfizer, Abbott, Johnson & Johnson, Bristol Myers Squibb, GlaxoSmithKline and a number of smaller biotech organizations. The Forum meets twice a year, once in Europe and once in USA. The Forum meets to exchange pre-competitive information and to consider the application of emerging IT technologies within the Biopharmaceutical research process.

The forum also organizes Special Interest Group meetings that overlap with the main Forum meetings. The SIGs provide a focused activity in a key area enabling members to invite special expertise from their organizations to participate within the framework of the Forum.

Reply

If you would like to attend this meeting, please email Rowan Gardner at: rowan@biolauncher.com