



Leading with Science to Optimize  
Safety and Mitigate Risk

# Safety & Risk Management



PRA International

# Safety and Risk Management

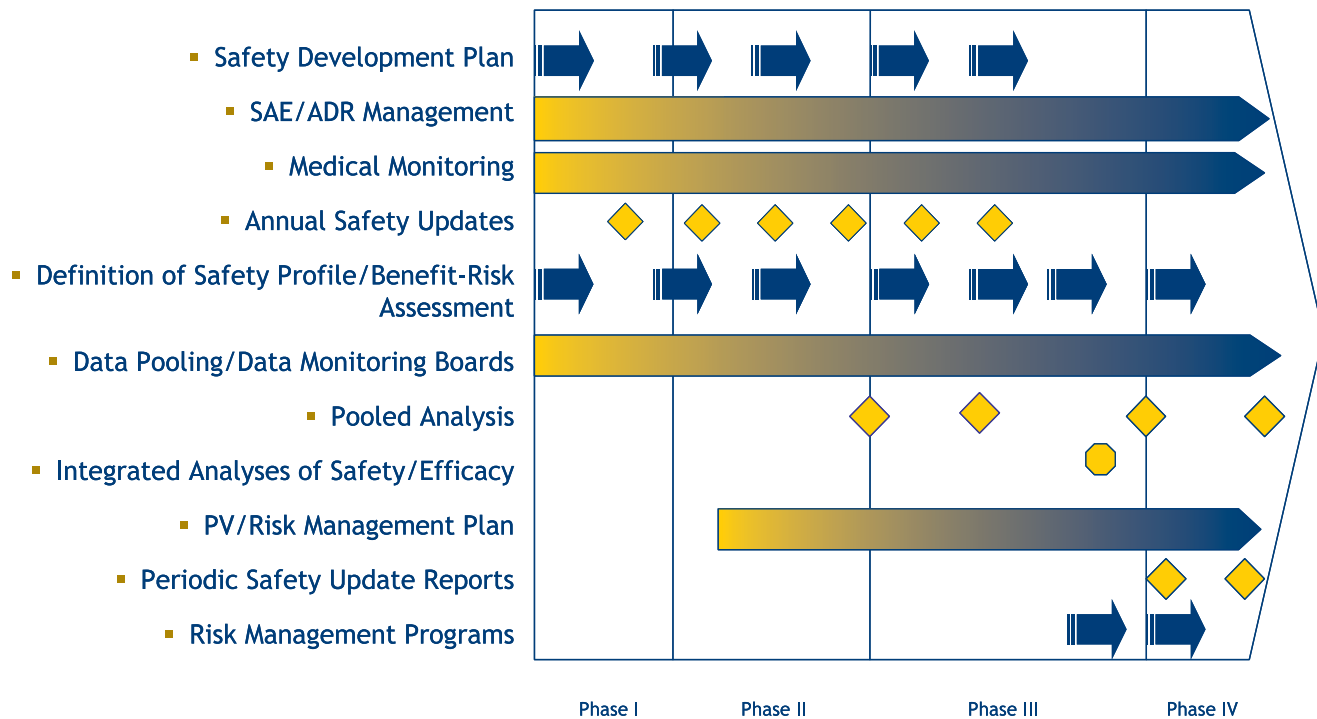
In response to an internationally recognized need for increased safety and risk management vigilance in drug development, the FDA, EMEA and ICH have created and posted guidance documents for the development of risk minimization plans.

An effective risk management strategy must be integrated throughout the entire product lifecycle. The continuous flow of actionable information generated by an ongoing risk evaluation and mitigation strategy allows you to make informed, intelligent decisions about product development. PRA International's Safety and Risk Management team has the skills and the experience to help you plan, develop and execute a total safety plan for your products.

## The Right Tools, The Right Talent

With so much at stake, and so many steps to take before you reach your goal, you need the right partner. PRA has the tools and talent to plan and implement the proper safety procedures throughout your product's lifecycle. Combining the skills of in-house experts within our Safety and Risk Management department and external consultants, PRA's world-leading team has the knowledge, expertise and experience to deliver the following services:

Safety and Risk Management Throughout the Product Lifecycle



# Highlights of Achievements in 2007

- 15,800 expedited safety reports
- 2,100 SAEs reconciled
- 5,900 protocol clarifications processed
- 9 data integration and pooled analysis projects
- 4 client audits of pharmacovigilance organizations conducted
- 23 pharmacovigilance client audits and 3 regulatory agency inspections successfully completed



## Additional Specialty Services

- Pharmacovigilance System Audits
- Pharmacovigilance Mock Regulatory Inspections
- Set-up/redesign of Drug Safety Departments
- Standard Operating Procedure (SOP) review and generation
- Evaluation and implementation of safety databases, including data migration services
- MedDRA training
- Risk management consultancy

## Expert Committee Support

- Independent Data Monitoring Committees (DMC)
- Endpoint/Event Adjudication Committees (EAC)
- Scientific Advisory Board (SAB)

## Safety Management Success Stories

### Expedited Safety Reporting:

**Initially:** PRA contracted to perform expedited safety reporting of 2 clinical trials

**Now:** Responsible for expedited reporting for all clinical trials conducted by sponsor

- 20 ongoing clinical trials
- 7 compounds
- 6 continents, 50 countries

### Includes:

- Notification to sponsor of changes in reporting requirements
- Expedited paper reporting to non-EU regulatory authorities and central IRB/ECs
- Distribution of safety reports to > 800 sites

### Post-marketing Adverse Event Case Processing:

**Includes:** Receipt and processing of post-marketing Adverse Event case reports (including consumer reports, observational study, study-literature, partner-sponsored clinical trials, investigator-sponsored clinical trials)

**Coverage:** Currently 2 compounds (others to be added)

**Results:** Processing metrics for Q3/4 2007:

- 1,500 cases received and processed
- 650 of these cases considered serious and processed in less than 3 business days (each version)

PRA International is one of the world's leading clinical development organizations, with over 3,600 employees working from offices in North America, Europe, South America, Asia, Africa and Australia.

© Copyright 2008 PRA International. All Rights Reserved

[WWW.PRAINTERNATIONAL.COM](http://WWW.PRAINTERNATIONAL.COM)



*PRA International*

**World Headquarters**

4141 ParkLake Avenue, Suite 530

Raleigh, North Carolina 27612 USA

Tel: +1 919 786-8200 ■ Fax: +1 919 786-8201

Email: [endpoints@praintl.com](mailto:endpoints@praintl.com)