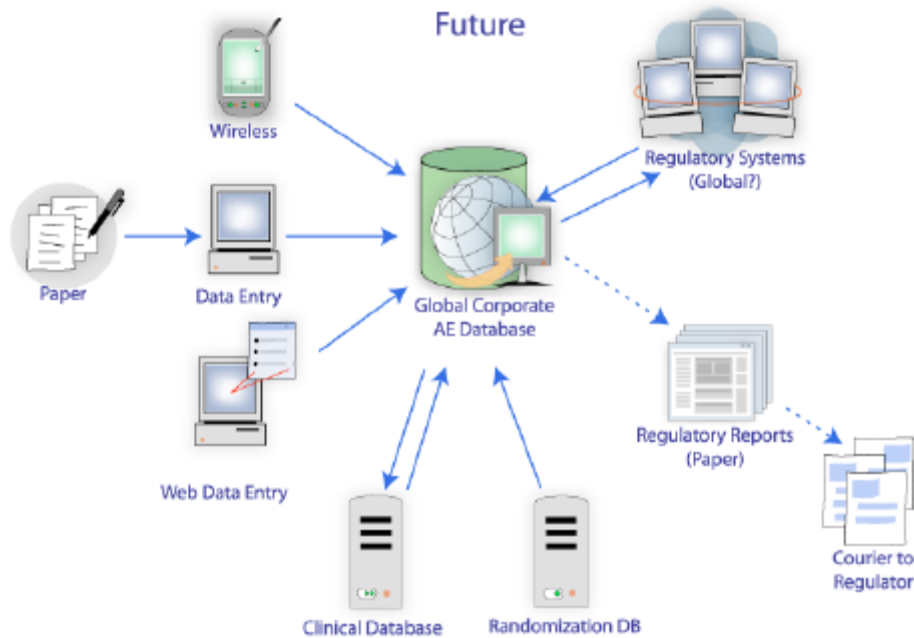


Public and regulators set higher standards

Pharmaceutical companies today face consumers who know and care more about drug safety, and regulators who are increasingly vigilant about it. The prospect of a post-approval drug withdrawal is an industry nightmare. Although recalls are rare, the direct cost to a pharmaceutical company of such an event can exceed one hundred million dollars. Potential legal costs and the negative impact on company image can drive total costs far higher. And the number of recalls is increasing — while there were 15 recalls in the last ten years, there were 10 FDA recalls in the last four years alone.

Regulators are setting the bar higher in drug safety, requiring electronic submission of drug safety reports by 2003. Globalization is driving a need for real-time safety reporting, while ICH, CIOMS and other efforts to harmonize international safety data and Adverse Events (AE) reporting require companies to increase reporting standardization. Failure to effectively manage drug safety data and pharmacovigilance processes can affect patient well-being, jeopardize a company's reputation, and create a regulatory disaster area.

Safety Data Processing:



Management of Safety Data: Condition Critical

At the same time that pharmacovigilance pressures are increasing, companies are running as fast as they can to stand still in managing safety data. AE data volume is being driven skyward by the growth in trials per regulatory submission, greater numbers of approved drugs that must be tracked, and regulators who are setting tighter standards for events reporting. Gearing up for the mandatory implementation of MedDRA further complicates safety data management. The use of contract staff to handle volume results in high costs and employee turnover and creates human resources issues around long-term contractors.



Poor integration between AE systems and other data systems also drives costs up. Manual processing makes it hard to obtain the data to correct errors occurring at the source. Processes for ensuring data consistency between databases in different countries are poor to non-existent. Reconciliation with the Clinical Database Management System is usually manual and time consuming, as is breaking randomization blinding when required. There are no good tools to automatically update labeling as AE data change.

Needed: Data Agility

Pharmaceutical companies need to show both regulators and consumers that they are doing everything possible to assure drug safety, while finding more effective approaches to managing drug safety data. This requires "data agility" — the ability to pull and analyze data from adverse event reporting systems in conjunction with other internal company data or external data sources. And data agility requires an integrated approach to AE data systems and pharmacovigilance, along with appropriate business processes.

Intrasphere: Making it Happen Through Data Integration

Intrasphere can give your company the agility it needs to manage pharmacovigilance and drug safety data for maximum benefit. We see a fully integrated corporate AE system where:

- Paper-based regulatory reporting is augmented or replaced by electronic submission
- The Safety and Clinical Database Management Systems are linked to manage discrepancies online
- Links between the Treatment Randomization and Safety Systems allow the blind to be broken when necessary, with appropriate security
- Wireless or web-based data capture takes the place of paper data entry
- All data are stored only once in the corporate AE System and accessed by sites worldwide
- Integrated tools allow immediate notification of required updates to the product label based on changes in adverse event frequency

Our tools will let you detect signals and trends in adverse events data by:

- Integrating data from your Adverse Events database with other denominator data, allowing for early identification of sub-populations at risk — or those more likely to benefit from a drug
- Providing web-based tools that let you produce scheduled reports and graphs on key data (e.g. AE trends in a compound or drug class vs. historical or published norms) and drill down into those data using ad hoc reporting capabilities
- Reconciling data from AE and clinical data sources and creating an update interface that keeps the data consistent
- Providing an AE Internet portal that alerts staff and external investigators to new, serious AE's for a given product or therapeutic group, via an always-on monitor display. The portal also facilitates communication with regulators, preventing blindsiding and decreasing the time for problem resolution

**Intrasphere -- Working with
You to Create Information
That Works for You**

We achieve this by integrating your Safety Reporting and Safety Analysis Systems, either virtually or physically, with the Clinical Database Management System and Clinical Trial Management Systems. We create custom tools to meet your specific requirements. Where required, we evaluate vendors, select and implement the commercial AE systems. These may include web-based AE data collection tools that eliminate redundant data entry and reduce transcription errors.

You achieve better relationships and interactions with regulators, investigators, clinicians and consumers through pre-emptive handling of AE problems based on earlier detection of signals and trends. Costs are reduced while data quality and analytical capability improve. Time to submission and to market is accelerated by controlled and validated reconciliation of data, while the risk of regulatory scrutiny is reduced. And of course, you greatly minimize financial exposure by preventing the possibility of a post-approval drug withdrawal.

**Experience in
Pharmaceuticals and
Technology**

Implementing a truly integrated AE system is a challenging and complex task. Just how difficult it can be is suggested by our research: recently replaced AE systems often fail to meet expectations, and exceed projected costs and timeframes.

Intrasphere has the expertise in both technology and in drug safety and pharmacovigilance to help you surmount the barriers to successful implementation. We've worked with the mainstream commercial AE applications. Our principals have managed and implemented safety systems for large pharmaceutical corporations. Intrasphere has the business skills to manage the process of system implementation.

We know that building consensus around system requirements with your stakeholders can be as important to implementing an AE project as software functionality. Those system requirements shape the specific criteria for vendor assessment, a process that addresses over 40 factors relating to the business profile, financial, technical, and support capabilities of candidate firms.

Our technology skills enable us to develop the plumbing for modular integration of safety systems within an overall clinical and regulatory infrastructure facilitating maintenance, upgrades and components replacement. We make certain you have the tools, training and support that you need for frictionless phase-in of your new system. Our understanding of data systems throughout the pharmaceutical enterprise means we can bridge the information silos to create new value for you from existing data resources.



Linking the silos and putting integrated information to work for pharmaceutical and biotechnology companies is the heart of our business.

For more information, please email us at safety@intrasphere.com or visit us on the web at www.intrasphere.com

Copyright © 2001 Intrasphere Technologies, Inc.