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Safety and PV Issues and Approaches

Track IV

Instituting a Truly Global Compliance Program

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Contents

Introduction to WCI

- WCI have worked with many companies globally in patient safety for over 15 years
  - Anticipating and responding to future regulations
  - Identifying & addressing gaps in compliance and product risk
  - Developing Safety strategy, transforming operations

- WCI manage pvnet Forums for sharing practices and developing the future of Safety
  - 50 member companies: Pharma, Biotech, Consumer, Devices

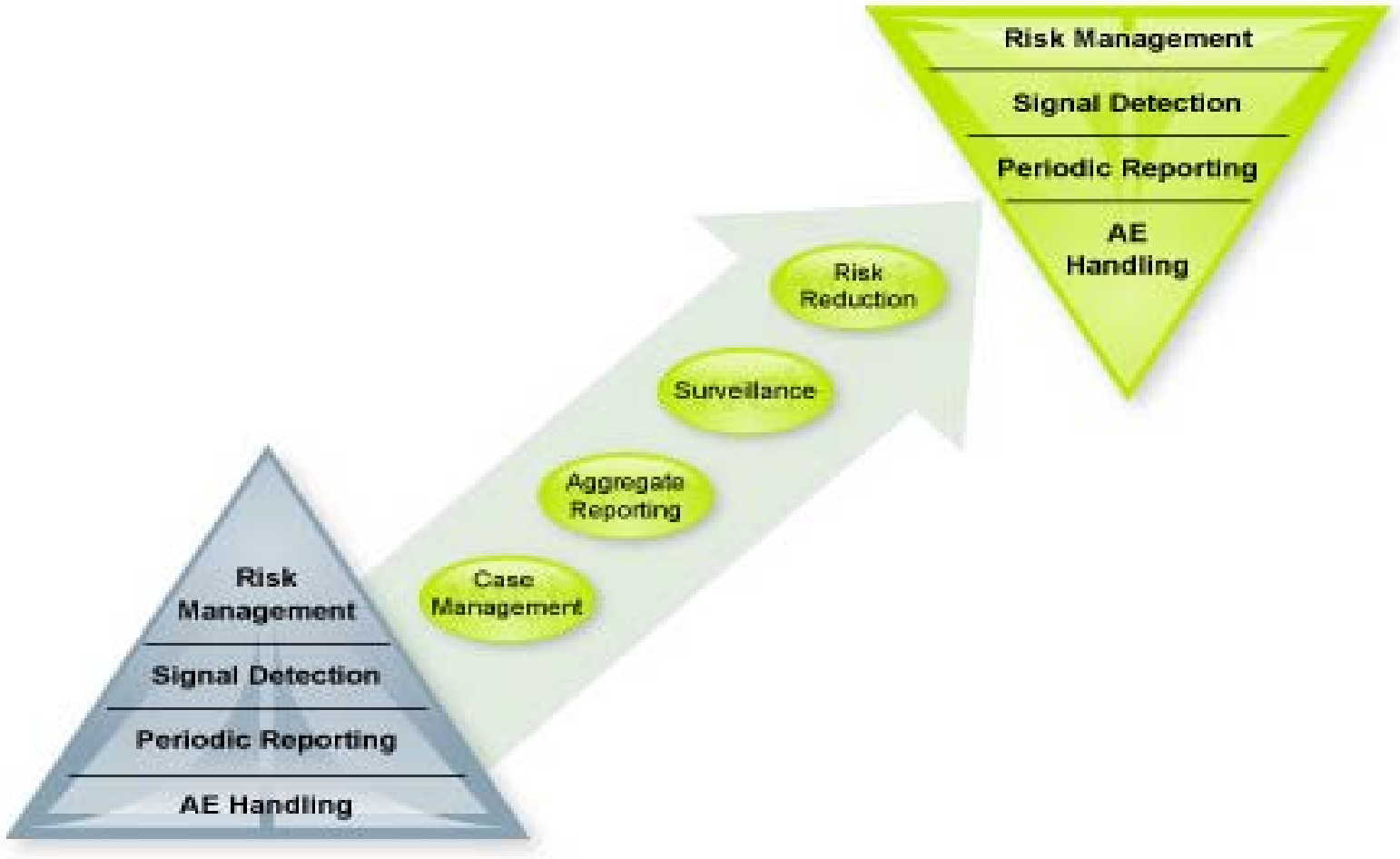
Executive Summary

- Regulatory emphasis shifting towards proactive saftey
- Need for well defined Signal Detection and Safety Risk Management processes & governance
- pvnet members working together to ensure safety activities are integrated
- Many companies redesigning their operating model to account for strategic drivers
- Need for alternative Sourcing methods, enhanced Skills and Competencies
- Integrated cross functional, collaborative approach to patient safety risk, closed loop approach is critical

Key drivers for change

- Move beyond compliance to proactive, medically driven safety risk management
- Increased interest in drug safety by a growing number of stakeholders
- Changing case profile: Increase in caseload accompanied by increase in proportion of serious cases
- Constantly evolving regulatory environment with increased enforcement
  - Redesign of EU Pharmacovigilance system
  - Volume 9A: Guidelines on Pharmacovigilance
  - New REMS regulations
- FDA shift toward more proactive PV and mirroring EMEA focus on risk management
  - Draft REMS Guidance recently released for U.S.
  - CDRH considering REMS-like powers for devices
- FDA focusing on social media and relationship to PV
  - Emphasizes need for scalable model, efficient and effective processes and likely data mining solution
- Increasing global focus on what and how to present information to consumers
  - Proposed Volume 9A revisions clarify ways in which MAH performa outreach to consumers, maintains ban on DTC advertising
  - FDA issued draft guidance on proprietary naming submissions and is also evaluating role of effectiveness information in print advertising for prescription drugs

Changing focus of safety – from reactive to proactive



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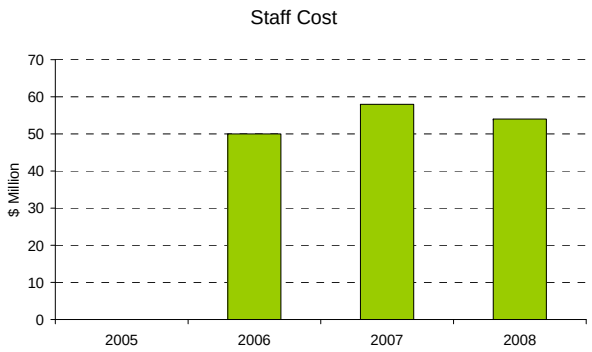
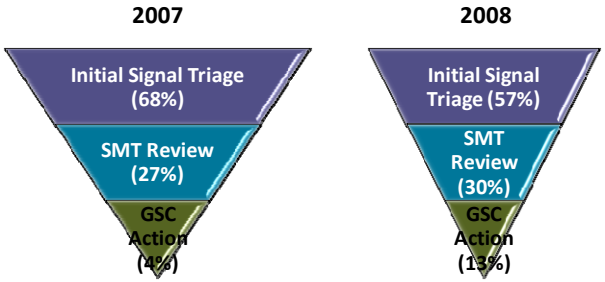
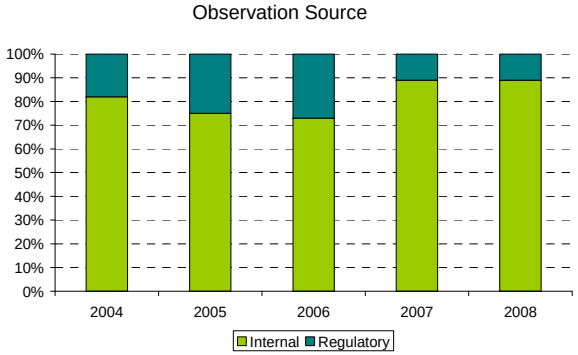
Signal detection is becoming a key focus area for PVNet members



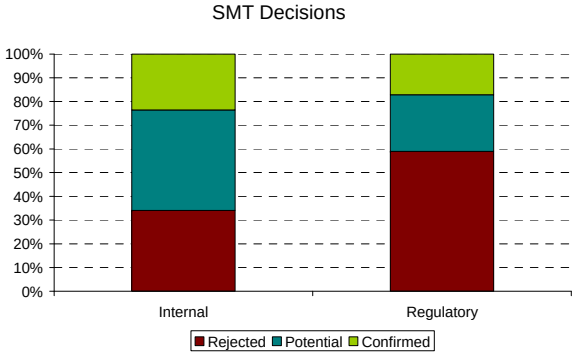
Investment in signal detection has grown over the past four years



Process refinement is resulting in more specific outcomes



The ratio of internal to regulatory signals is increasing



Internal signals are of a higher quality

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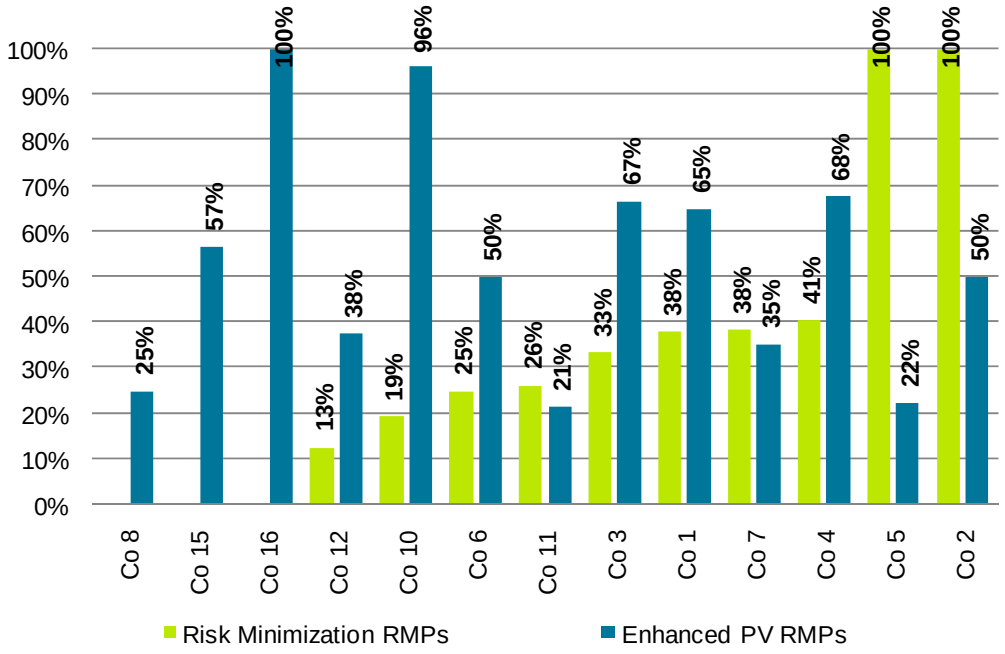
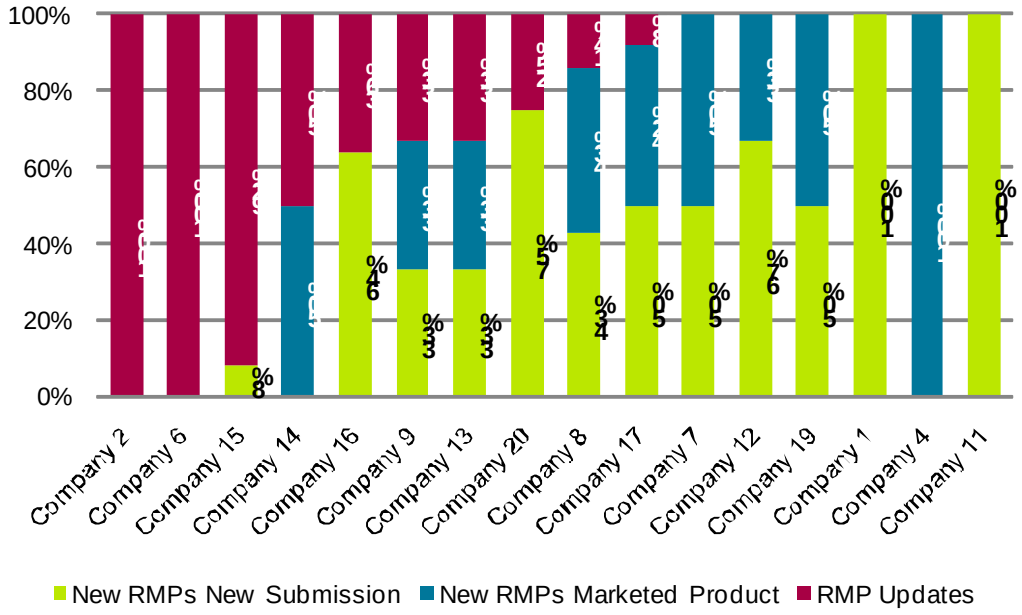
Members are relying upon routine PV as defined in their PV Systems, more often than Enhanced PV or Risk Minimisation RMPs

- On average 46% of RMPs included Enhanced PV (e.g. PASS studies, sentinel sites, AE of special interest)
- On average 26% of RMPs included Risk Minimization (e.g. patient registries, influencing behaviour on appropriate use, and patient education programs)

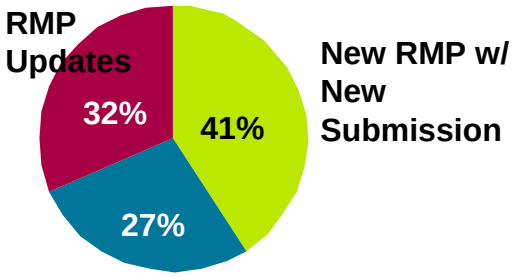


For pvconnect members, less than half of RMP activity relates to new submissions

- Companies which submitted MAAs before the EU RMP template was released are putting effort into updating their RMPs to meet the new expectations
- Regulators are requesting RMPs for established products
- RMPs are being updated to reflect new understanding of product's benefit -risk profile



pvconnect



For pvnet members, less than a quarter of RMP activity was for new submissions

Safety Risk Management – new requirements (pvnet 2008 view)

- Establish Safety Mgt Teams across the product lifecycle from FIH
- Develop SOPs covering the processes of how safety risk information & document development will be managed
- Ensure Safety has access to all relevant data and oversight of all local additions/updates to approved RMPs
- Define clear accountability for ensuring RMP commitments are undertaken in a timely and effective manner
- Develop qualitative and quantitative tools to assess the effectiveness of risk minimization activity
- Develop mechanisms to feedback the effectiveness of RMPs and their associated risk intervention actions

WCI's Good Risk Management Practices model is central to the Safety Risk Management approach

Many companies are beginning the transition to Patient Safety “Good Risk Management Practice”

Integrated programs are required to ensure patient safety and compliance

Life Cycle Safety Risk Management

- Formalised and consistent safety RM process throughout product lifecycle
- Safety Management Teams manage the process
- Proactive auditable signal detection process which consideres relevant internal and external sources

Governance & Quality Mgt System

- Develop Governance & Quality Management Systems to integrate and transparently control PV processes and decisions

Enabling organisation

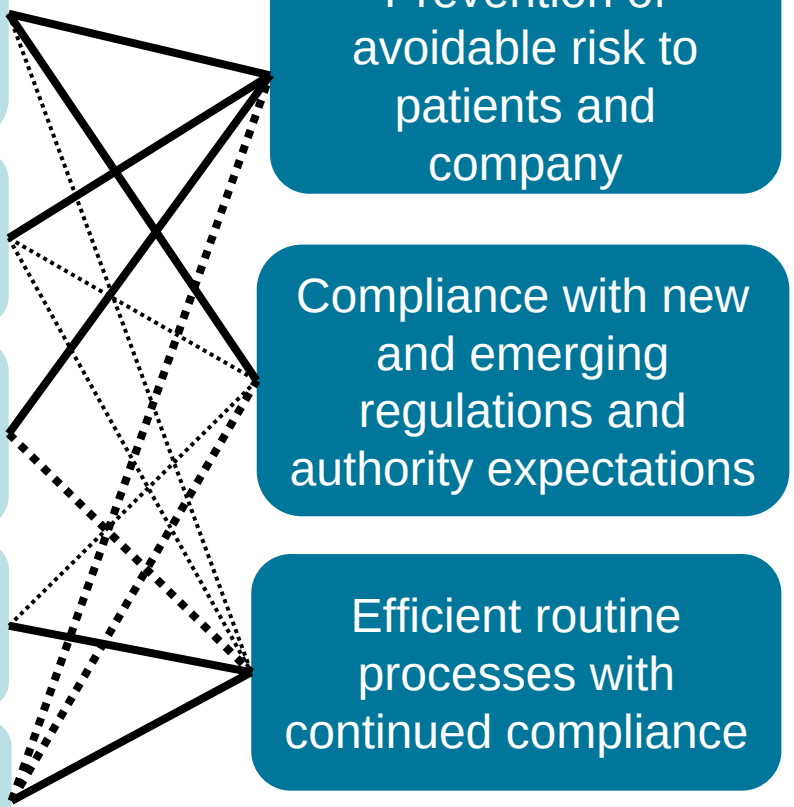
- Align Global organisation to enable proactive engagement of drug safety professionals
- Increase risk management capabilities and alignment with partner functions

Routine PV processes

- Automation to replace manual processes
- PV Sourcing via Capabilities in new markets
- Dynamic workload balancing across Global PV

Supporting Technology

- Technology to support efficient processing of data and provides advanced support for signal detection and risk management



Prevention of avoidable risk to patients and company

Compliance with new and emerging regulations and authority expectations

Efficient routine processes with continued compliance

Conclusions

- No need to re-invent the wheel on basic PV processes
- Industry collective is working together with WCI to develop and implement efficient responses to new regulatory requirements
- Early adopters of SD and RM will see benefit – not only in reducing safety risk, but in enhancing reputation in the eyes of the regulators
- Well proven models for process, organisation, technology for companies of all sizes and varying volume of safety activity
  - Key is knowing which is right and implementing and operating effectively