REMS – Compliance Implications for Drug Safety

Track II

Washington DC, November 2009

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Introduction to WCI

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

- WCI manage pvnet™ forums for sharing practices and developing the future of drug safety
  - 50 member companies: Pharmaceutical, Biotechnology, Consumer Health, and Medical Devices

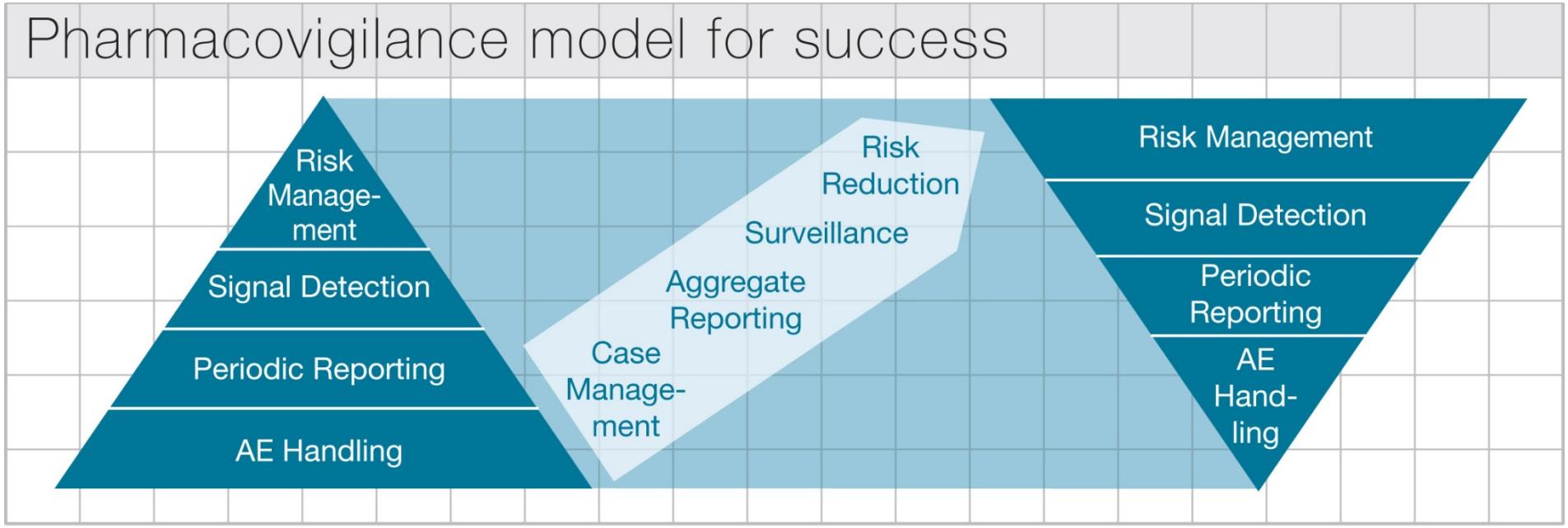
Significant changes are occurring in the Drug Safety arena

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

Key drivers for change

- Move beyond reactive reporting to proactive, medically driven, Safety Risk Management
- Increased interest in drug safety by a growing number of stakeholders
- Constantly evolving regulatory environment with increased enforcement
- FDA focusing on social media and relationship to PV
- Increasing global focus on what and how to present information to consumers
- Focus on cost reduction / avoidance
- FDA shift toward more proactive PV and mirroring EMEA focus on Risk Management

Changing focus of safety – from reactive to proactive



Safety Risk Management – new requirements (pvnet™ 2008 view)

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

Some further considerations....

- REMS are a key component of the shift from reactive to proactive Drug Safety
  - Clearly work in progress
    - New guidance the next iteration
    - Use of class wide REMS e.g. Long acting Opioids
    - Clarity required around areas such as “Foreign experiences”
- They are only one element of holistic approach to RM
- Effective governance, follow up and review critical
- This full life cycle approach has significant compliance implications
- Future alignment of regulations (FDA / EMEA)