

Responding to Signals of Prescription Opioid Abuse

Breakout Group I
Signal Management
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Program in Opioid Risk Management
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Signal Management

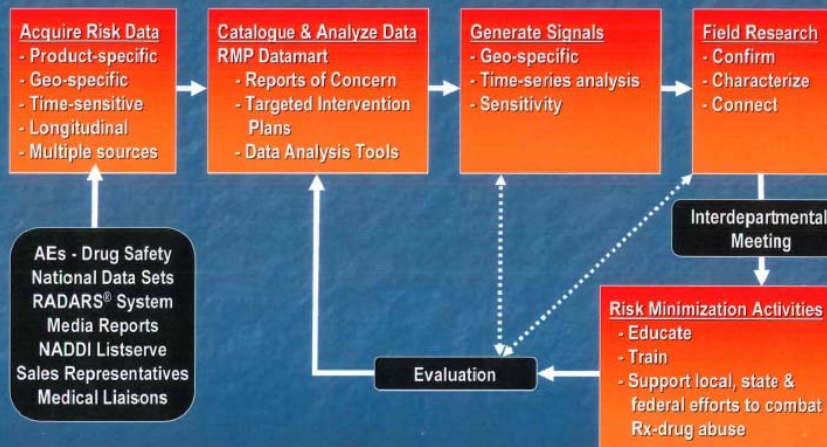
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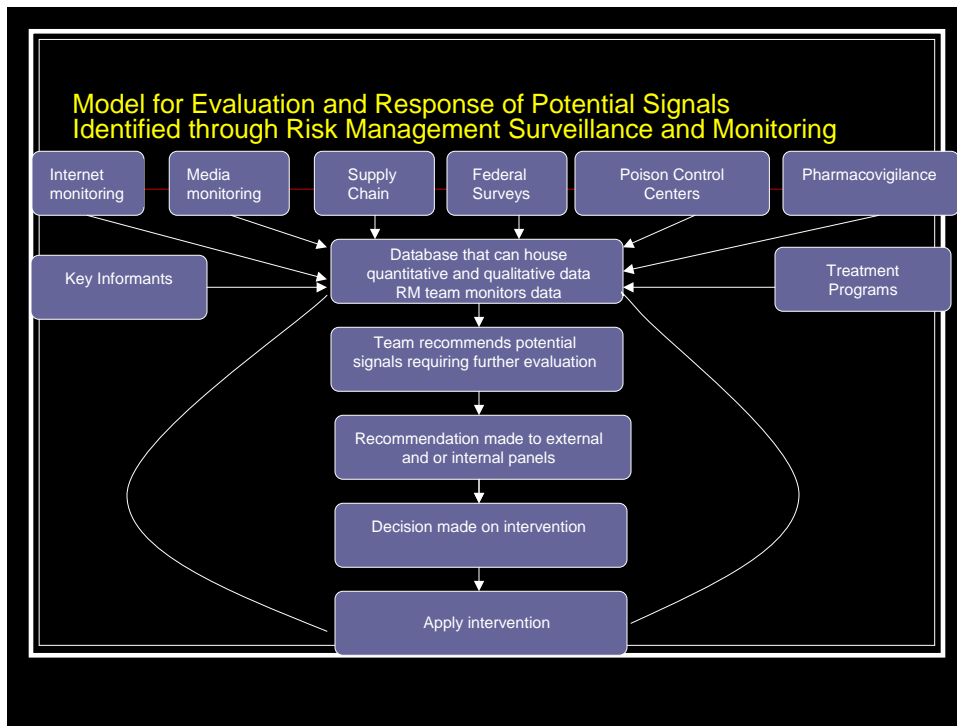
Deliverable: Model flow diagram for signal management for a pharma company

Tasks

- Classification system for the types of information received
- Verification of accuracy and veracity of information
- When information should be directed to other agencies
- When investigation is warranted
- Results expected from investigations
- Actions to be taken on completion of investigations

Integrated Risk Management Approach





- ## Classification System for Source Data
- Is Source X...
- Formal or Informal?
 - Qualitative?
 - Quantitative?
 - Verifiable?
 - Passive or Active?
 - Timely?
 - Sensitive?
 - Specific?

Classification System for Source Data

Source	Formal vs informal	qualitative	quantitative	verifiable	Passive or active	Timely (3 months)	Sensitive/specific
Internet	informal	+	+/-	-	active	+	sensitive
Key informants	informal	+	+/-	+	active	+	sensitive
Media monitoring	informal	+	+/-	+	active	+	sensitive
Supply Chain	formal		+	+	active	+/-	specific
National surveys	formal		+	+	active	-	sensitive +/-
Poison Control	formal	+/-	+	+	passive	+	both
Pharmaco-vigilance	formal	+	+	+/-	passive	+/-	neither

Classification System for Source Data

Source	formal vs informal	qualitative	quantitative	verifiable	passive or active	timely	sensitive/specific
Treatment centers	formal		+	+	active	+	both
Company reps	informal	+	-	+	active	+	neither
Company survey	formal		+	+	active	+	sensitive specific +/-
Law enforcement	informal	+	-	+	active	+	specific

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