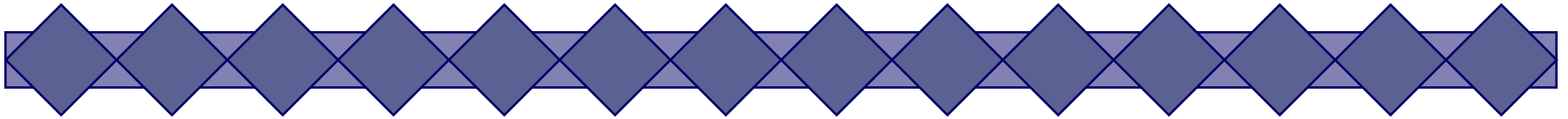




Building Blocks for a Post-Market Surveillance System




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There is Currently No “System”

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- ❑ Pharmaceutical industry captures observations of AE's and are mandated to follow up and report to FDA
 - ❑ No look at misuse, overuse, off label use
 - ❑ Much is learned from studies – randomized, case-control or observational that are performed post market

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- ❑ This was acceptable in 1970 but not now – given scope and magnitude of pharmaceutical use
 - ❑ Need to rapidly understand impact of introduction of new drug into system

Opportunity

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- ❑ New Opportunities – unprecedented
 - ❑ Basic science
 - ❑ E-HR and automation in healthcare

 - ❑ Important that new system not be just problem count → learning, improvement, understanding root cause (misprescribing, inherent risk, individual risk, over Rx, etc.)

What Should We Ask of New System



- Capacity

- Rapid signal detection

- Capacity for confirmatory studies

- Scope

- Broad population coverage – diversity in population and settings

- Broad range of products and interventions

What Should We Ask of New System




Science Based

- Capacity for research; strong links to academia
- Research component for continuous improvement
- Link to basic science → mechanistic studies


Operation

- Transparent and public
- Consensus methods for detection and analysis
- Broad stakeholder input and oversight

What Should We Ask of with New System

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- Communication and Implementation
 - Findings broadly disseminated
 - Collaboration of health plans, medical journals and outreach method

Organizational Design

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- Convenor hub (non- or quasi- governmental), ability to engage in PPP
 - Oversight board
 - Data Management organization (contract)
 - Research group
 - Communication group
 - Methodologic group—consensus methods and analyses
 - Possible DMB-type structures to oversee analyses

Is This Possible?















