



Sentinel Network Workshop

UMD Shady Grove Center

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➔ To enable the discovery, management, and conveyance of risk associated with drugs, biologics, devices, and medical products in a way that is scientifically sound, credible and compliant

Sentinel Network for Post Approval Medical Product Safety



- ➔ **Gaps**
- ➔ **Obstacles**
- ➔ **Issues (Forks in the Road)**



➔ Most if not all gaps on post approval MP safety surveillance involve issues of data quality

- Data Relevance
- Data Quantity (i.e. power)
- Data Consistency
 - *Data Definitions (Data Standards)*
- Comprehensive Data

➔ Obstacles

- The Sentinel Networks shares the obstacles to EHR deployments
- Privacy and Workflow issues are **not** (technical)_obstacles to EHR deployments or the Sentinel network
- Dependence on healthcare providers for drug safety data is not realistic

➔ Obstacles

- Do we know what we mean by “drug safety”
 - *Recognize a looming disaster?*
 - *Is Risk Management part of drug safety?*
 - *Learning more about risk benefit ratio*
 - Virtual registries
 - Virtual clinical trial
- Regulatory Barriers.....
 - *GCP for sentinel networks???*
- What will be the communication and conveyance role
 - *Labeling*

➔ Obstacles

- What do you want this system to do?
 - *Pull and cull data from point of care systems?*
 - *Clean, map and aggregate data?*
 - *Apply data mining algorithms for signal” detection*
 - *Then what?*
 - Industry rebuttal?
 - Comparative product safety?
 - Communication to providers?

What is the Vision?



➔ Linking

■ Linking What?

- *Elemental Data or aggregate data?*
- *All data or subsets?*
- *EMR only (? Research databases, Registries)*
- *Reports based on standardized queries?*
- *Tools?*
- *Methods, algorithms?*
- *Computational processing power?*



➔ Obstacles

- AERs Culture
 - *“Best we have” mentality*
 - *Regulatory semantic*
 - “Serious skin rash” and “non serious breast cancer”
 - MedDRA is not an acceptable medical terminology
- AERs or (AERsII) should not be allowed to lessen the vision of the Sentinel Network



- ➔ **Some existing systems sufficiently mature for proof of concept or demonstration**
 - Not all may be able or willing
- ➔ **Ability to answer questions depends on “metadata” and data standards**
 - Leverage other efforts (Biosurveillance)
 - Think high level first!



➔ Must identify mutually beneficial partnership role with all stakeholders

- Will require a brokering and governance layer and agreement of all to abide

“Few men have sufficient virtue to withstand the highest bidder”

George Washington

First president of US (1732 - 1799)

A Metadata Model for Pharmacovigilance System

