

FDA Sentinel Network Presentation

EHR Data and Post-market Risk Detection

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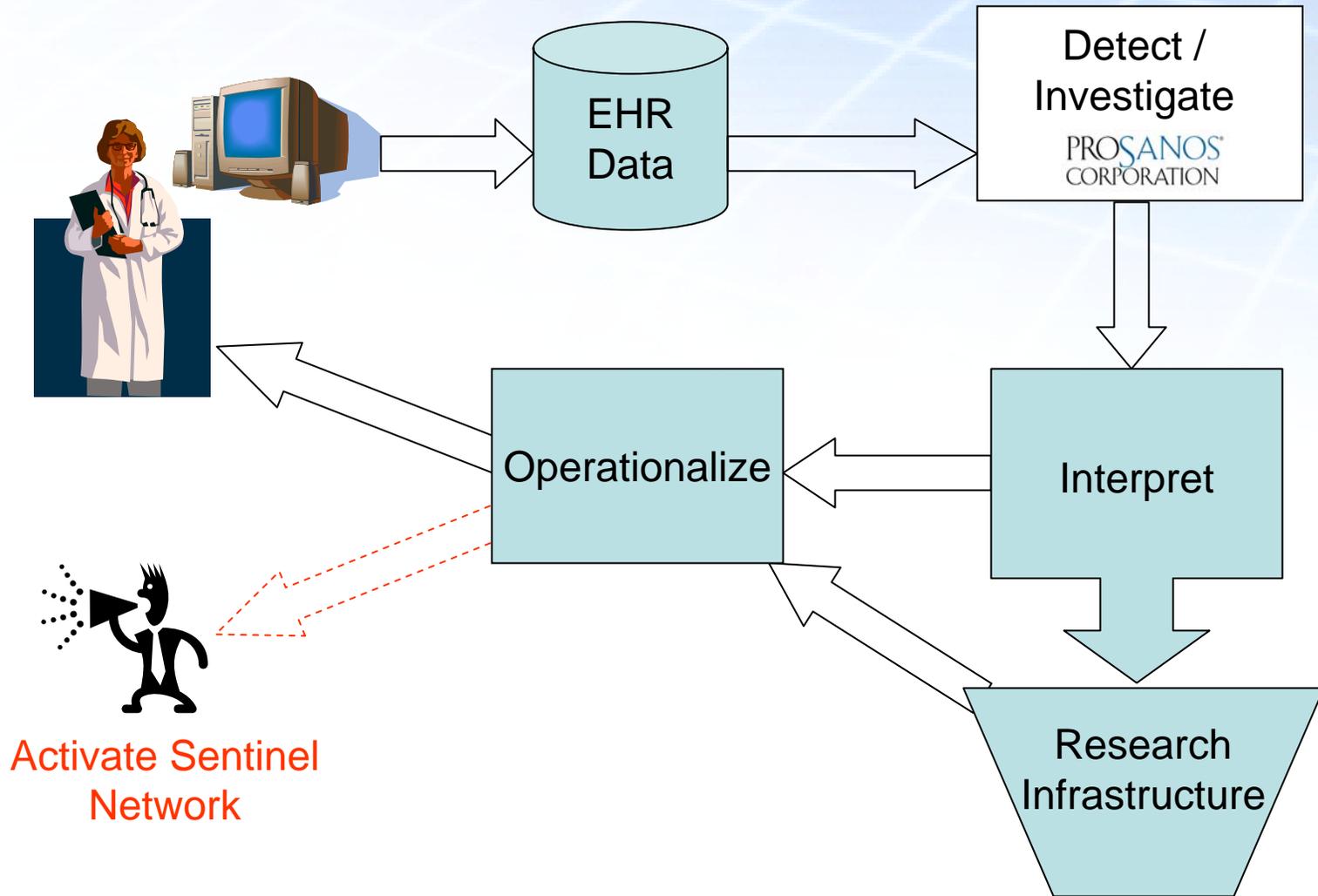
Objectives of Today's Meeting

1. ...
2. ...
3. **Identify opportunities for public-private collaborations for building the data collection and risk identification and analysis components of the network**

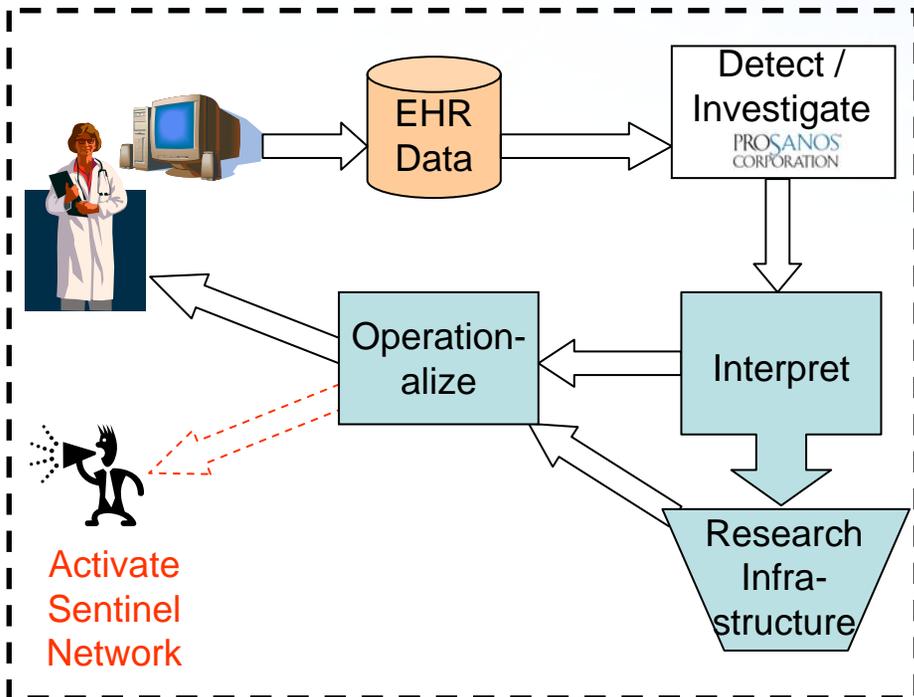
Background

- ◆ **KP system in place with integrated EHR data on >6 million patients**
 - Labs & lab results, diagnoses, radiology, in & out-patient EMR data
- ◆ **ProSanos' tools utilized for member safety screening within KP environment today**
 - Signal detection and signal evaluation on a subset (3 million patients) of de-identified data
 - Vendor agreement in place with Kaiser Pharmacy Analytic Services (PAS)
 - Major commitment to identify known and unknown medication adverse events
 - Program wide responsibility to assure member safety

Vision: Dynamic Surveillance Loop



Dynamic, Robust Data Source



1. Patient events in real time

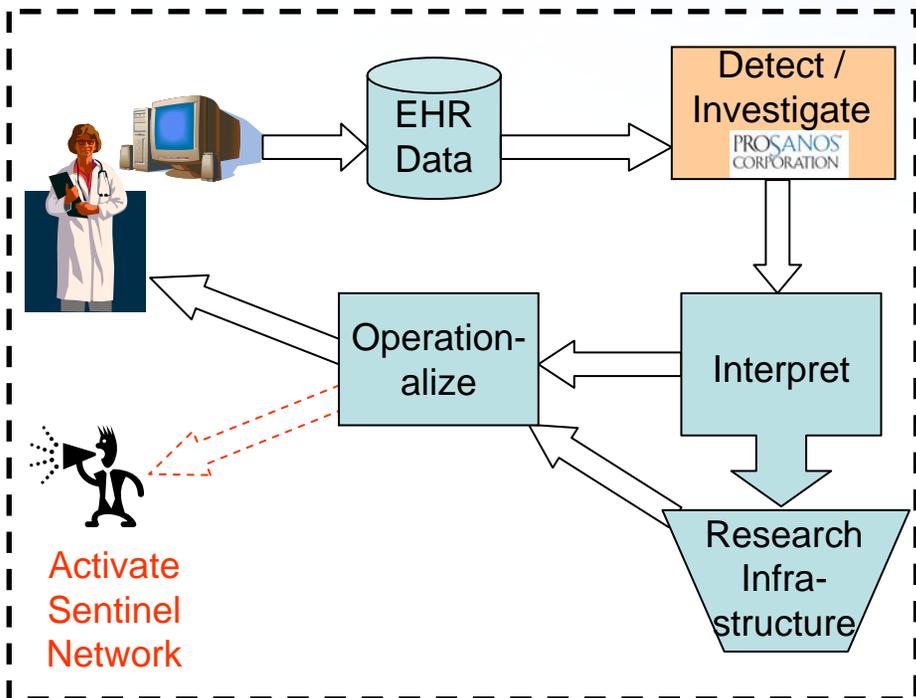
- Continually updated

2. Multi-dimensional data

- Patient focused - diagnoses, test results, exposure level(s), co-administered meds, etc.
- Physician focused - ordering tests, procedures, prescribing medication (practice patterns)
- How do things change over time?

Detect / Investigate “Signals”

Drug exposure → “Something” unexpected happens (*Event*)



1. *Events* in EHR data:

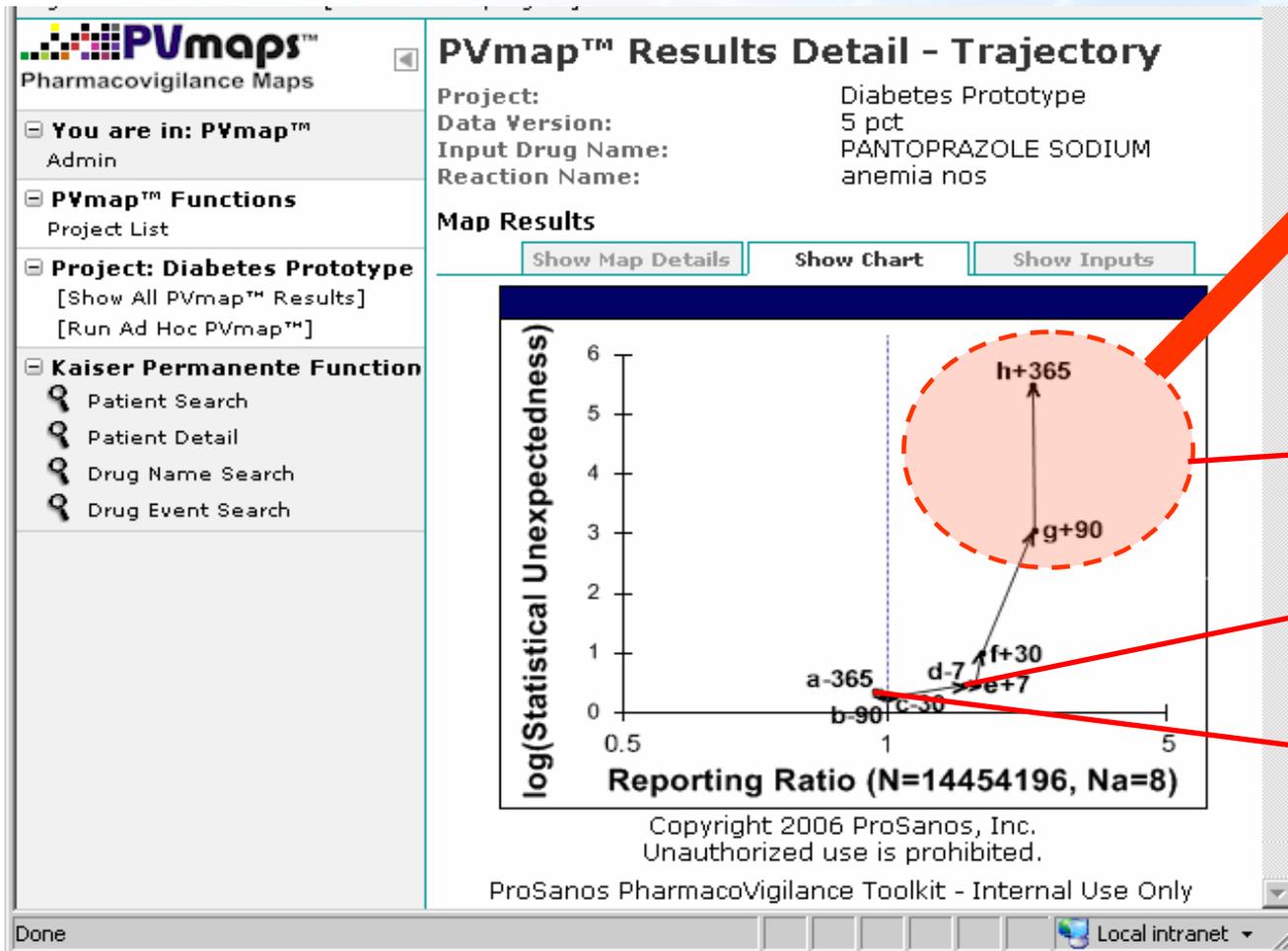
- Test or procedure ordered (physician behavior)
- Office or ER visit (patient behavior)
- Test result, diagnosis, prescription (evidence of event)

2. “Signal Detector” for EHR data:

- Systematic detection of disproportionate occurrences of *Events*
- Exploit temporal nature of data
- Include contextual data (patient characteristics)

Detect / Investigate “Signals”

Example: Pantoprazole & Anemia Diagnosis Code



Strong Signals

Longitudinal View:

- 90-365 days post exposure
- Pantoprazole exposure
- Prior to exposure

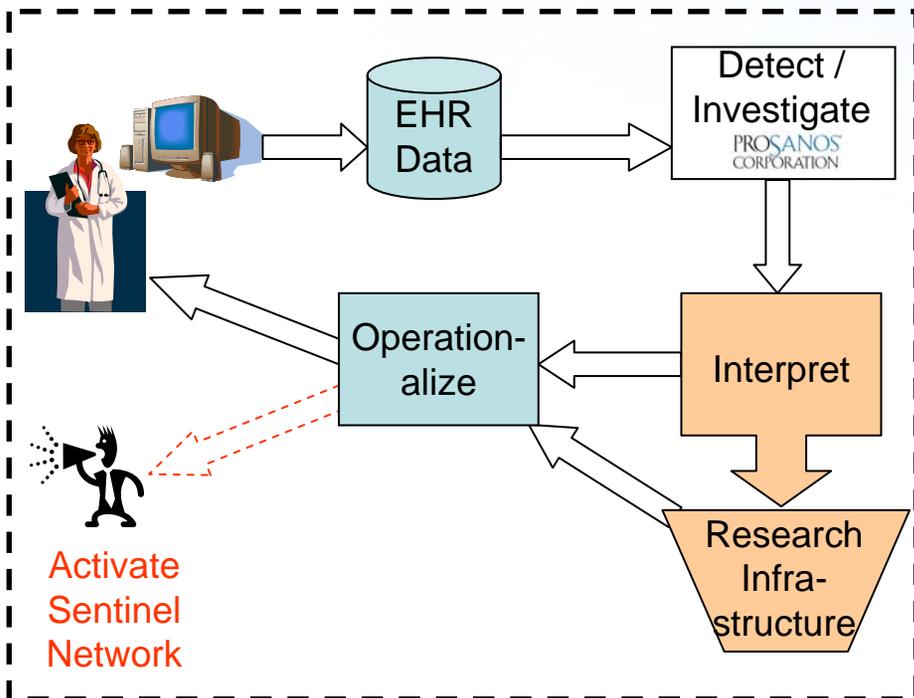
Interpret Results

1. Interpret results:

- Detailed patient / subpopulation characteristics
- Look for evidence that research is necessary to verify or validate signal

2. Focused / further research w/ IRB approval:

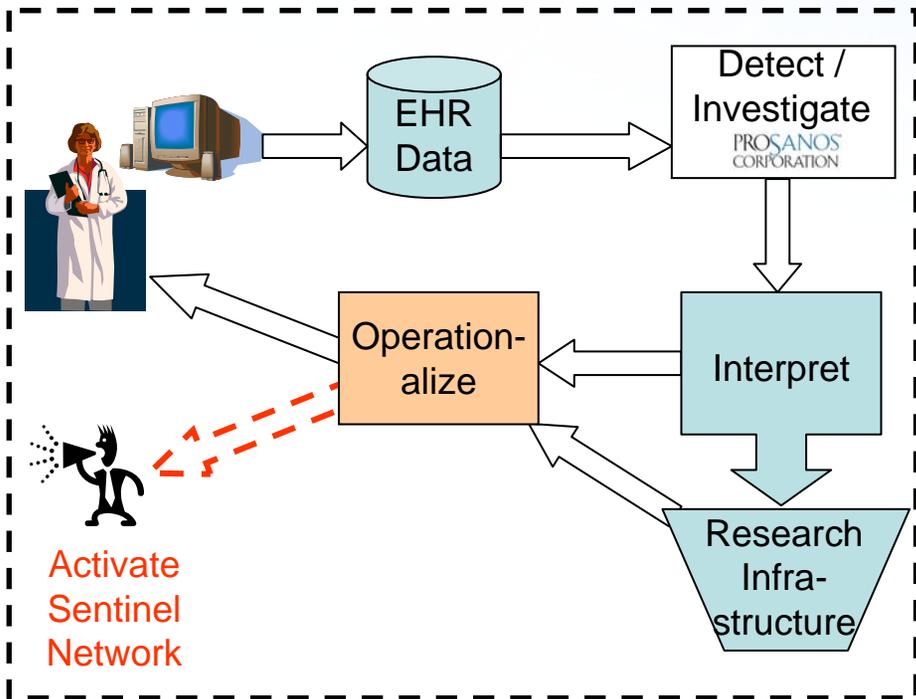
- Comparative populations:
 - Another drug or drug class
 - Non-exposure
- Control for other patient factors (preexisting conditions, demographic characteristics, co-administered meds, etc.)
- Prospective studies to test hypotheses



Operationalize

Current Project → 1. Dynamic decision support and feedback, for example:

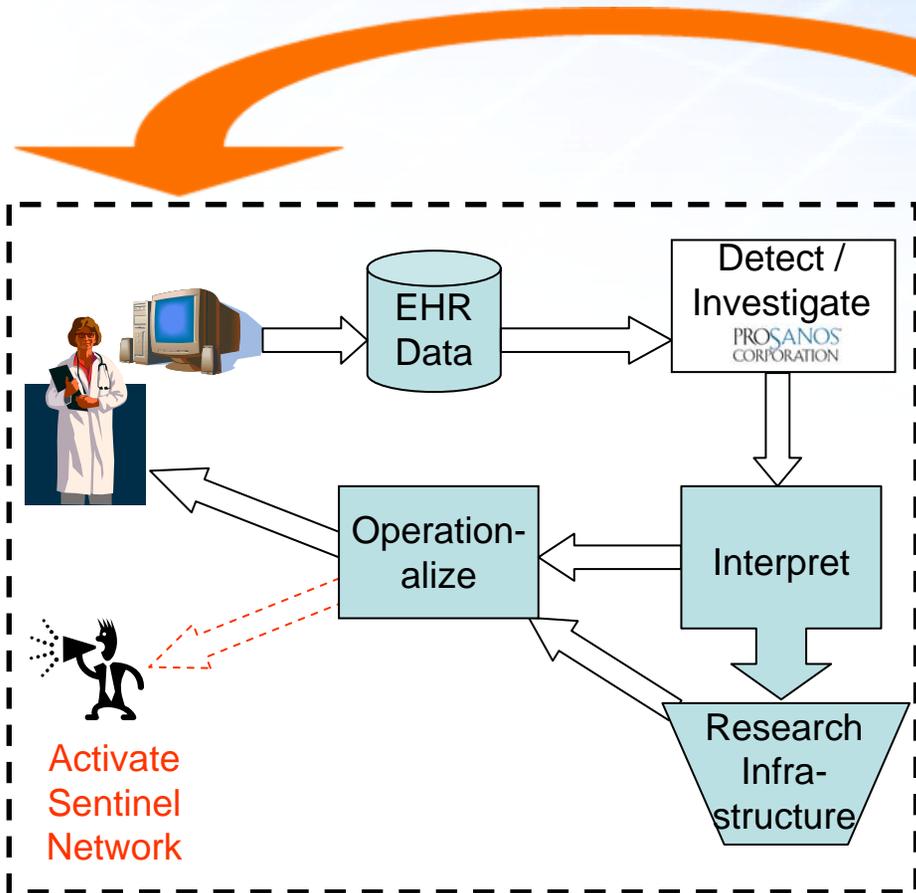
- Notification of new side effects when drug is prescribed
- Automatic reminder to providers to order LFT for newly prescribed medication with hepatotoxic effects
- Electronic system to assure appropriate patient selection and screening.
- Outreach to patients



2. Activate designated “nodes” of sentinel network:

- Vision →
- Communication network predefined, activated when necessary

Implementation Scenarios



1. Case Report or Case Series triggers search of EHR data for safety signal
2. SRS signal triggers search of EHR data for confirmation
3. Scheduled screening (FDA directed)
 - Time-driven (monthly)
 - Investigative
4. Proactive surveillance of new products on market

Conclusions

- ◆ In the near term, the marriage of existing technologies, data, & patient care infrastructures can help to fill gaps in post-approval risk assessment
- ◆ The Kaiser / ProSanos collaboration provides an example of a dynamic surveillance loop that is readily scalable
 - Extending to implement a “Sentinel Network” is of mutual interest
- ◆ Legal framework, input requirements from one or many 3rd parties (FDA), modified operational/business rules, reporting/output needs, extended IRB/security, and appropriate funding are some of the key obstacles to be addressed before fully building out a Sentinel Network