

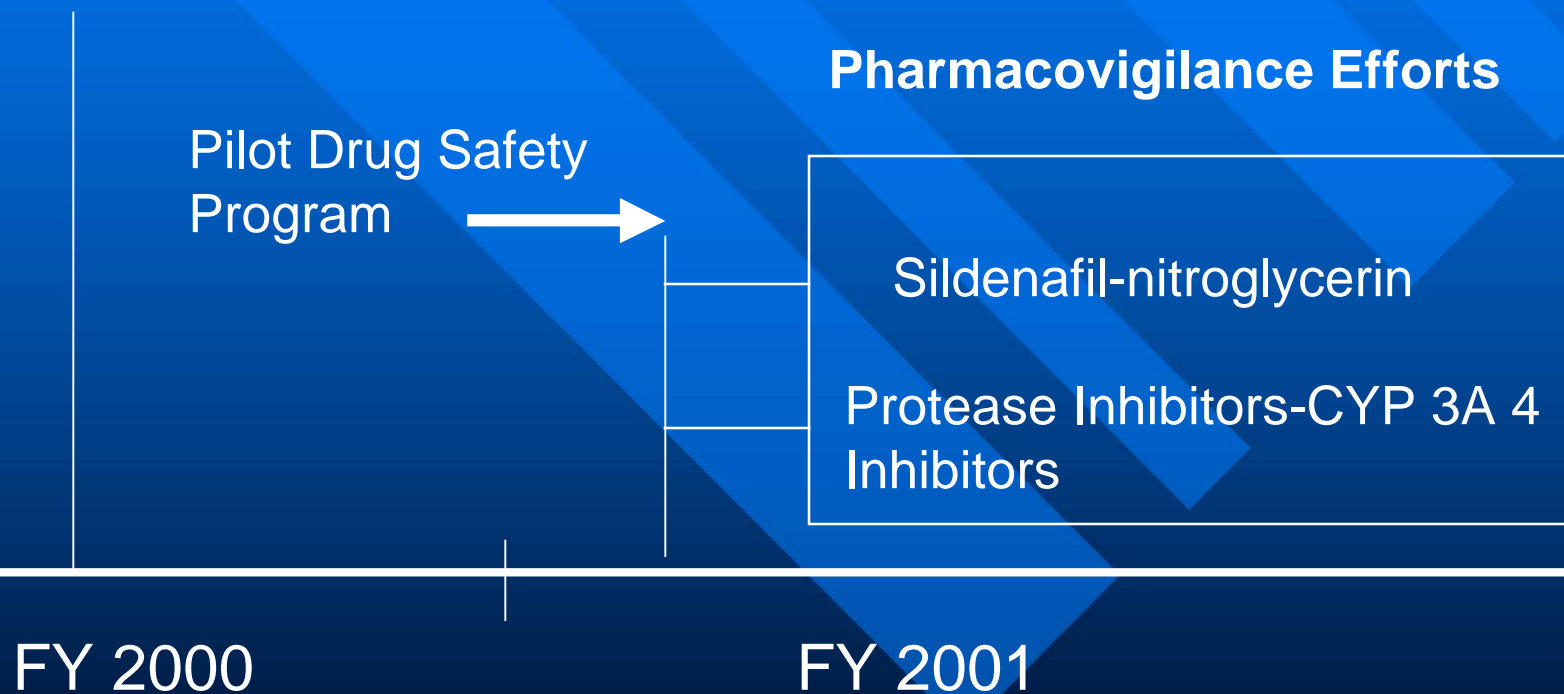
**VAMedSAFE: Focus on Pharmacovigilance & VA Databases**



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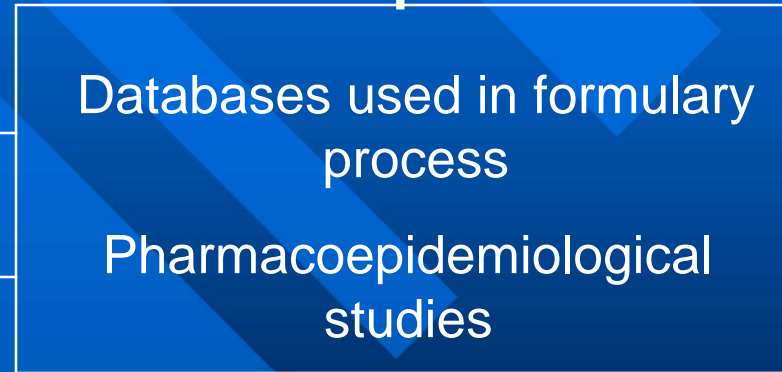
# Overview of Pharmacovigilance in the VA

Develop and optimize National Prescription database for Quality and Research initiatives



# Overview of Pharmacovigilance in the VA

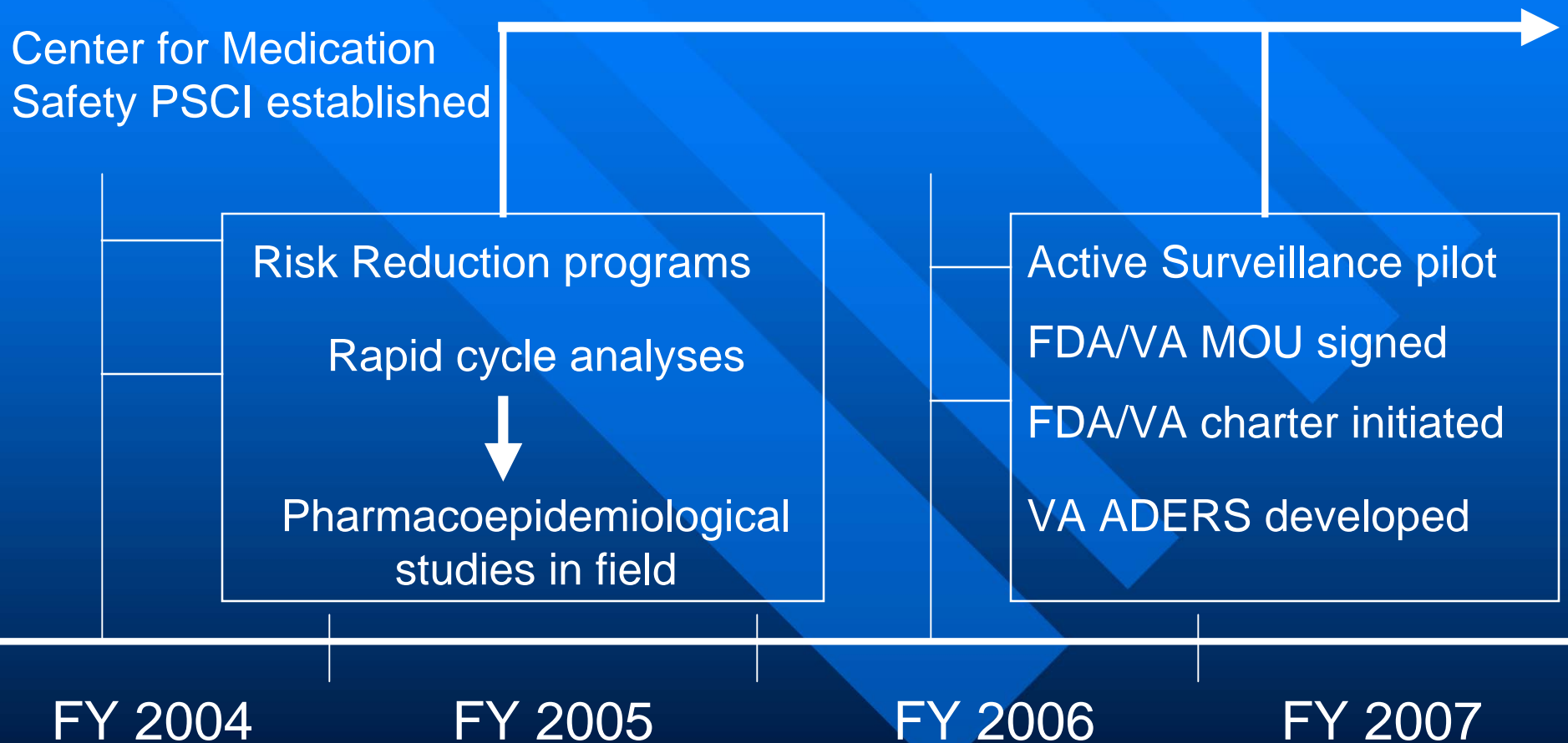
Integrated databases utilized to track ADEs by National PBM



FY 2002

FY 2003

# Overview of Pharmacovigilance in the VA



# VAMedSAFE GOALS

- Pharmacovigilance/Postmarketing Surveillance
  - Identify and Verify (ADEs)
    - Known and proven ADE signals
    - Preliminary or unconfirmed ADE signals
    - *Unknown signals*
- Track ADEs and effect of intervention
- Enhance education and communication of ADEs and potential ADEs on a national level
- Institute and promote risk reduction efforts
- Promote medication safety research in VA

# **Adverse Drug Events in VA**

## ***Reporting, Tracking, Monitoring***

- **Adverse Drug Event Database (VA ADERS)**
  - Spontaneous Reporting
  - FDA MedWatch Form 3500 and mod/mild rxns
- **Adverse Reaction Tracking Package (ART Package)**
  - CPRS – Electronic Medical Record
  - Every VA Facility
- **Adverse Drug Event Tracking and Evaluation Using VA Integrated Databases**
  - Prescription Database
  - Inpatient/Outpatient Files
  - Mortality Database
  - Chart Validation

# **SPONTANEOUS DATABASE EXAMPLES**

# **VA ADERS National Database**

- **Standardization**
- **Centralization**
- **MedWatch Reports**
- **Surveillance & Benchmarking**



# Available Reports

## ■ Quarterly Reports

- Top 10 primary suspected agents
- Top 10 symptoms by primary agents
- Benchmarking
  - » VISNs
  - » Facilities
- Preventable ADEs

## ■ VA ADERS Cube

- Dynamic views for drill down analyses

# Applications of VA ADERS

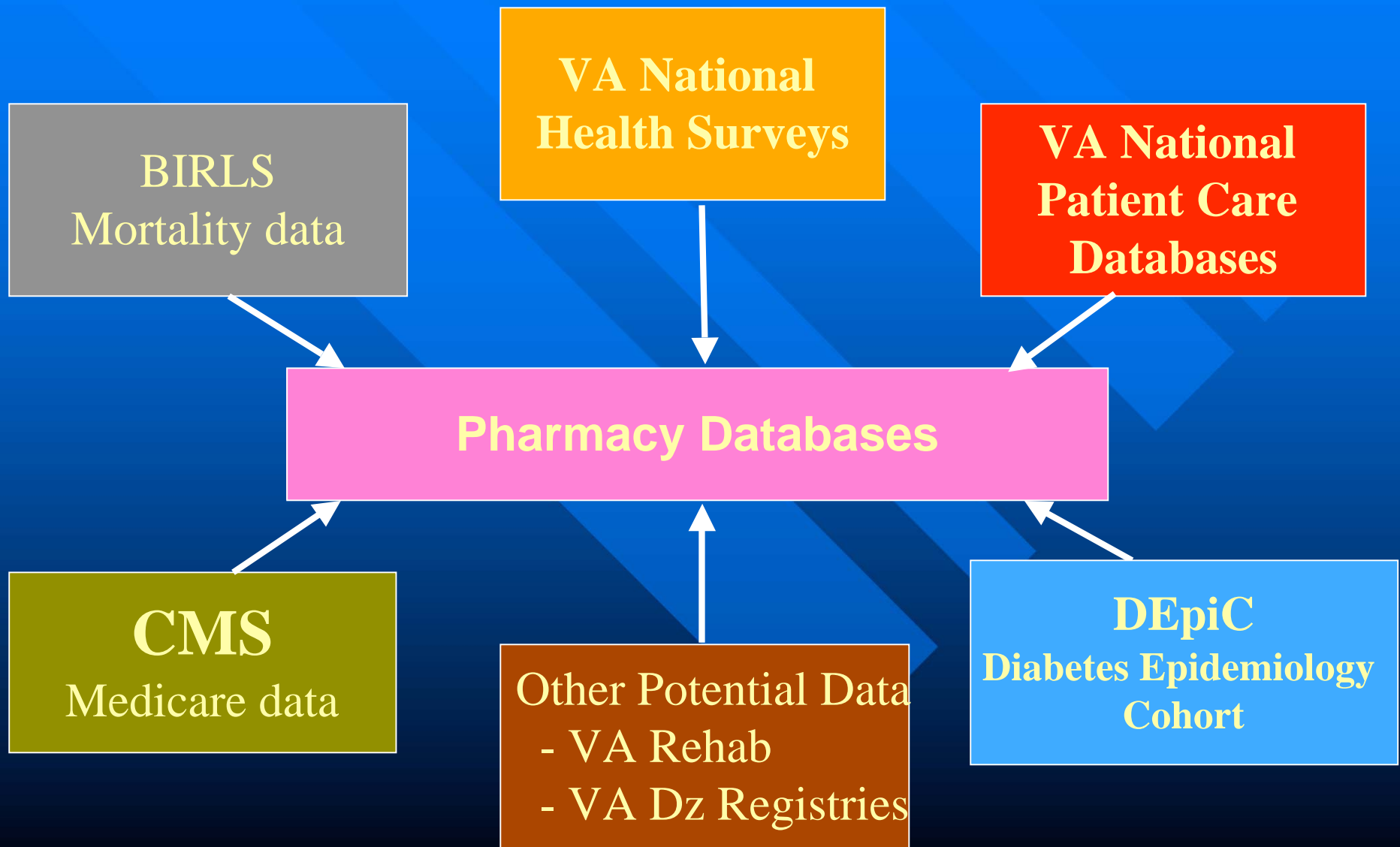
- **Data aggregation for national surveillance projects**
  - » Varenicline
  - » Heparin
  - » Tiotropium/Ipratropium
  - » Atypicals/SSRIs
- **Cross-reference symptoms reported independently from reported suspect drugs**
  - Tiotropium
- **Process and system improvements**
  - Topical Steroids

# EXAMPLES

# **INTEGRATED DATABASES**

# VA Integrated Databases

## Linkages with Pharmacy Data



# VA National Prescription Databases

- Includes data from October 1998 to present
- Provides every individual Rx filled in the VA
- Provides prescription days supply
- Data is specific to outpatient divisions
- Patient identifier is included for every Rx
- Provides cost per unit for every prescription
- NDC number is provided
- Provides dosing instructions for each prescription

# Data available

- **Demographic**
- **Diagnoses: medical and psychiatric**
- **All visits**
  - **Costs**
- **All treatments**
- **Laboratory data**
- **All medications**
  - **Dose, frequency, duration**
  - **Cost**
  - **Provider**

# VA Databases as a Tool

- **VA databases provide the mechanism for**
  - Medication safety projects and initiatives
  - Clinical decisions
  - Research
  
- **An effective tool in VA**
  - Monitoring exposure rate and ADRs
    - » High risk agents
    - » New agents
    - » Agents with newly identified safety information



# Select Example of VA Pharmacovigilance/Drug Surveillance Projects - FY 2006-2008

- Fluoroquinolones
- High Dose Statins
- Rosuvastatin
- Etodolac
- Leflunamide
- Bevacizumab
- Varenicline
- Deferasirox
- Pegylated Interferons
- Bisphosphonates
- Antipsychotics
- Ezetimibe
- PPIs
- Thiazolidinediones
- AEDs

# **Postmarketing Surveillance Examples**

# Risk Reduction Projects

- Risk Reduction Pilot Program was initiated to:
  - identify patients receiving medications with a true contraindication for a given disease state.
  - Success of that project led to the conduct of more of these risk reduction efforts to prevent potential ADR's.

# Risk Reduction Projects

- *Nifedipine (short Acting) – Prototype*
- High Dose Vitamin E
- Cilostazol
- Drug-Drug Interactions
- Alpha Blocker Monotherapy
- TZDs in HF
- LABA Monotherapy
- Ketoconazole/Simvastatin
- Glyburide Use in RI
- High Dose Vitamin D
- High Dose Statins and Fibrates
- High Dose Zolpidem IR

# RISK EDUCATION EFFORTS

- Goal is to provide background material, literature, and programs for communication to the field in order to improve the environment of medication safety. This is done via website programs as well as disseminating warnings and alerts on new medication safety issues.
- <http://www.pbm.va.gov/VACenterForMedicationSafety-AdverseEventTrackingTools.aspx>
- <http://www.pbm.va.gov/VACenterForMedicationSafety-DrugSafetyFeatures.aspx>

# National PBM/VAMedSAFE Safety Bulletins (FY 2007-08)

- Allergic Reactions to Heparin Sodium– February 19, 2008
- Antiepileptic Drugs and Suicidality - February 11, 2008
- *Varenicline Safety Update-National Bulletin – January 2008*
- Varenicline (marketed as Chantix) and Suicidal Thoughts and Aggressive or Erratic Behavior – November 20, 2007
- Aprotinin (Trasylol®) and Increased Risk of Death and Other Serious Adverse Events – Temporary Suspension in Marketing – November 6, 2007
- Codeine Use in Breast-Feeding Women – October 9, 2007
- Ceftriaxone (Rocephin®) and Incompatibility with Calcium Products UPDATE - September 11, 2007

# **National PBM/VAMedSAFE Safety Bulletins (FY 2007-08)**

- **Rosiglitazone (Avandia®) and Cardiovascular Events – May 21, 2007**
- **Tegaserod –Removal from Market – April 2007**
- **Pergolide (Permax®) and Heart Valve Damage – March 29, 2007**
- **Erythropoiesis Stimulating Agents (ESAs) –**
- **Omalizumab (Xolair®) and Anaphylactic Reactions – February 2007**
- **Bevacizumab –Safety Concerns for Intravitreal Administration**

# Questions