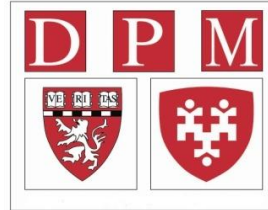


# Cohort Identification within FDA's Mini-Sentinel Program

October 31, 2013

# Mini-Sentinel partner organizations

Lead – HPHC Institute



Data and scientific partners



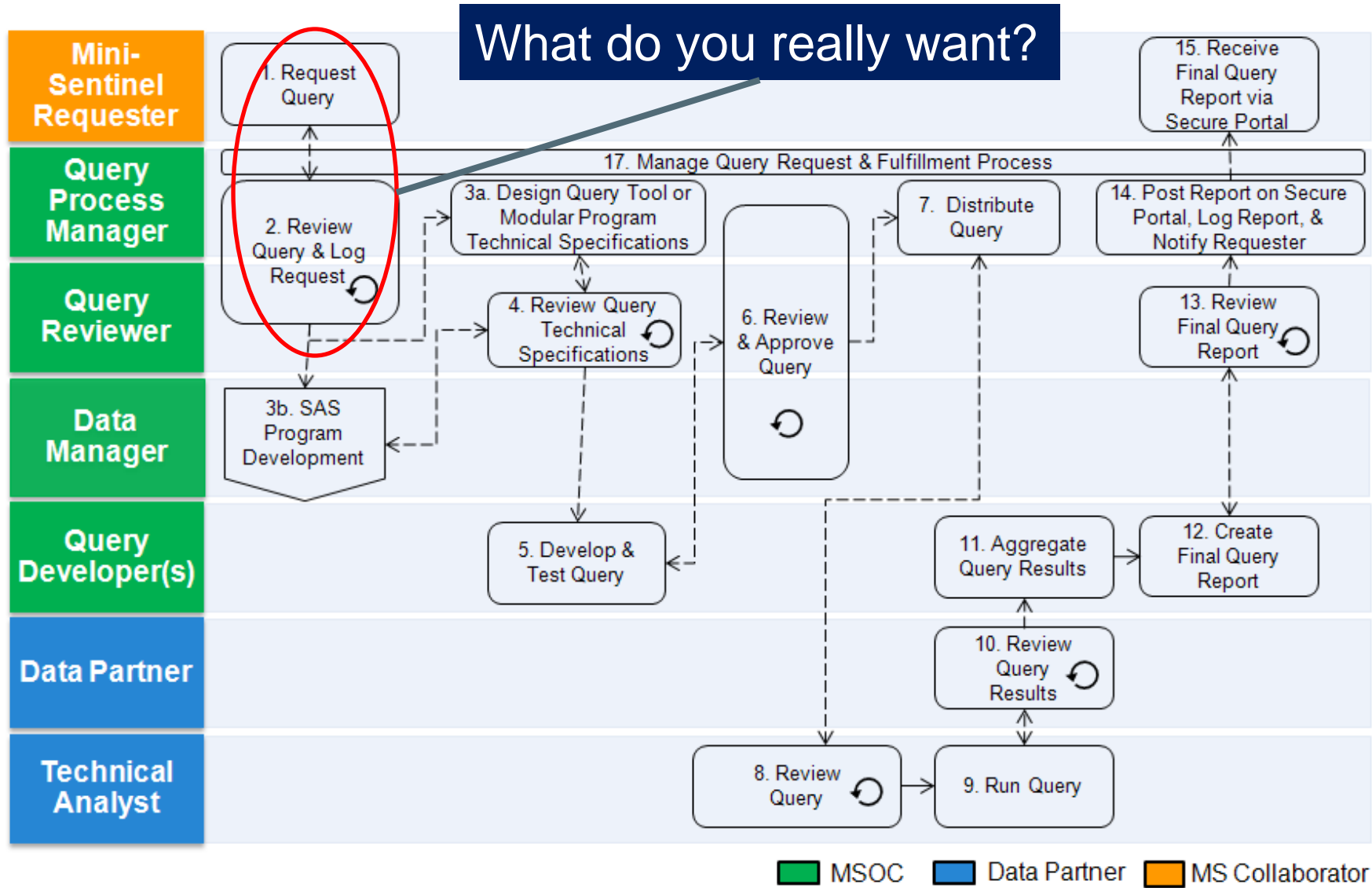
Scientific partners



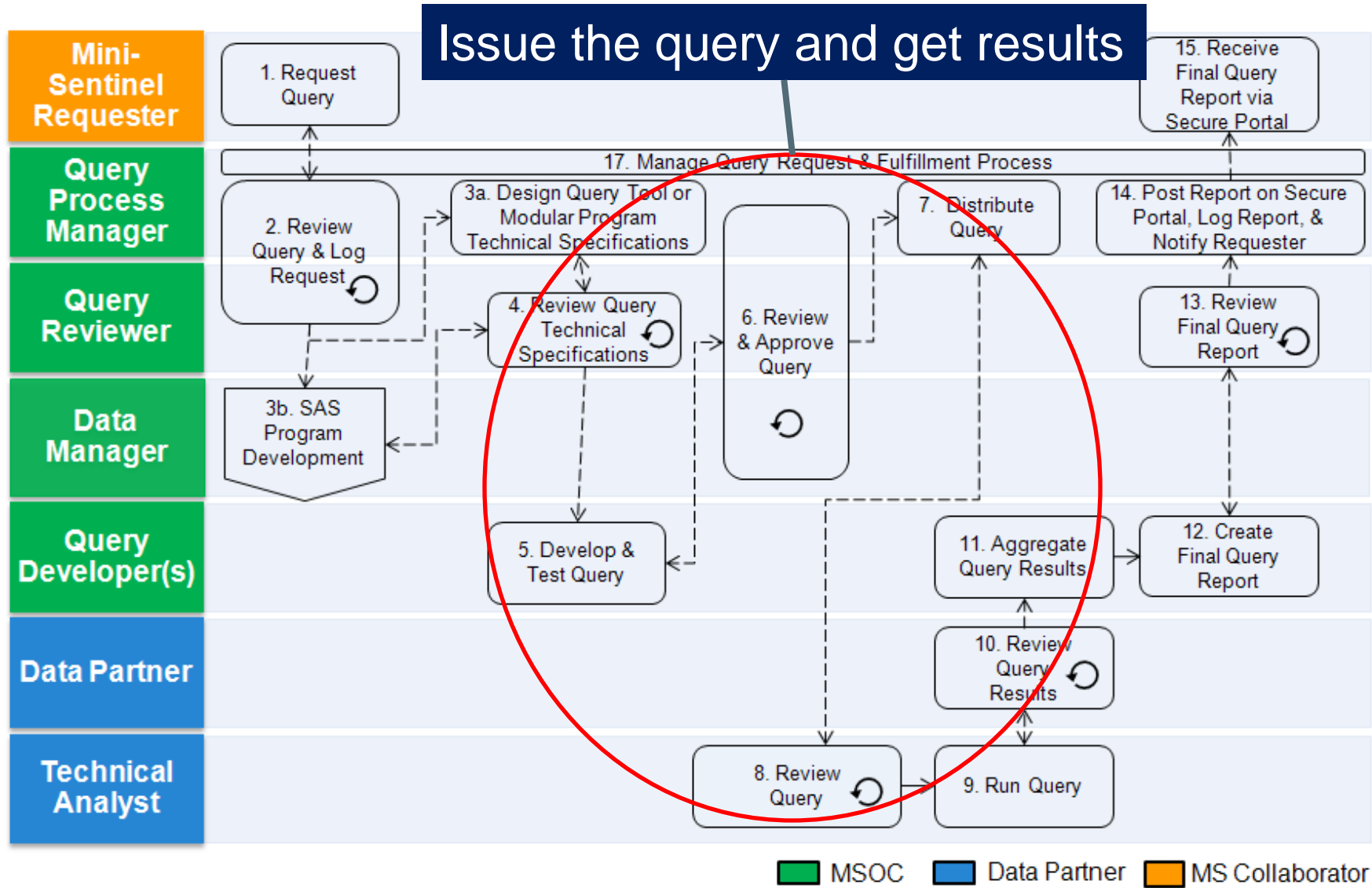
# Cohort identification within Mini-Sentinel

- ❑ Summary table queries
- ❑ Modular programs
- ❑ De novo programming

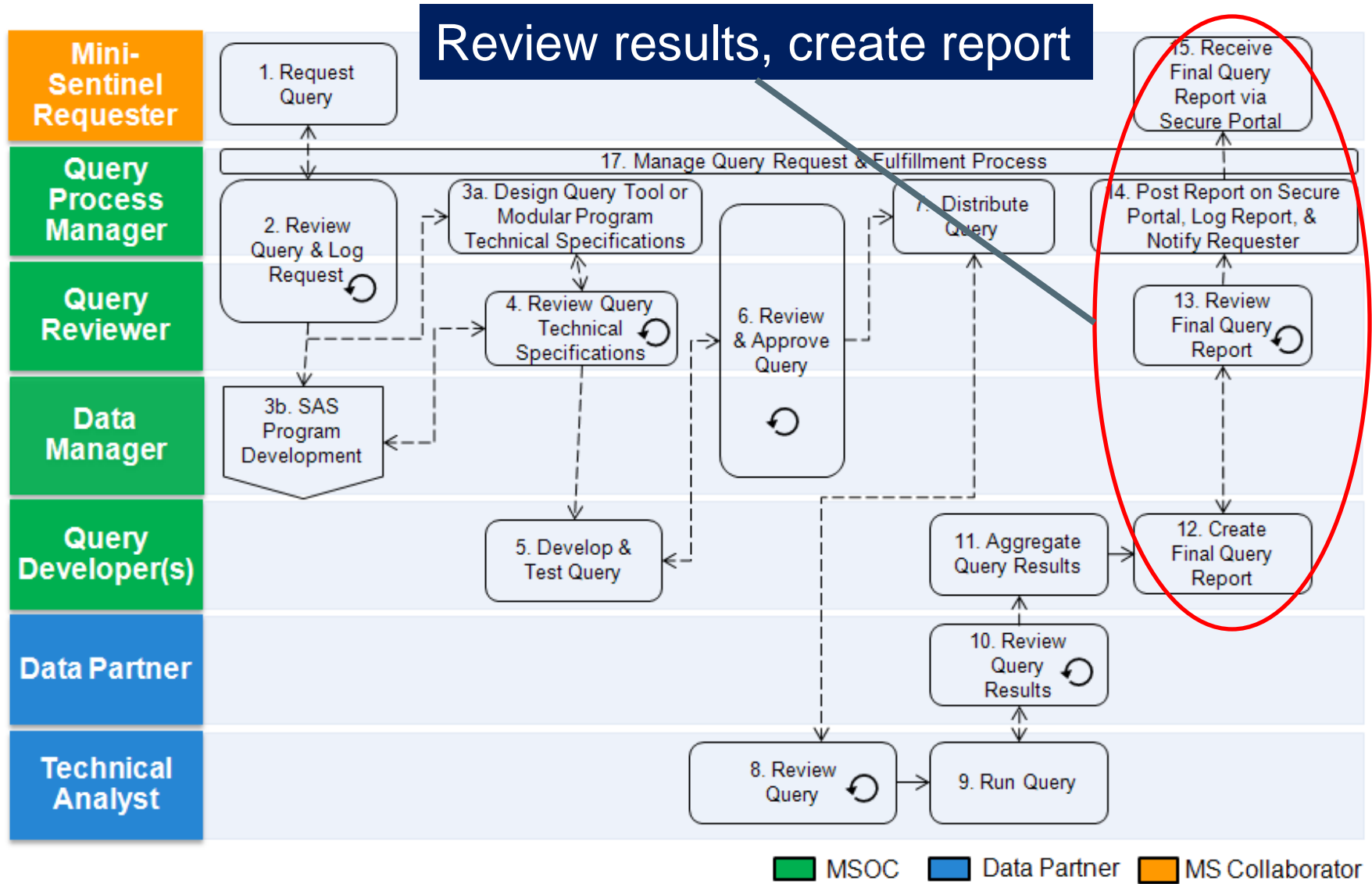
# Query fulfillment process



# Query fulfillment process

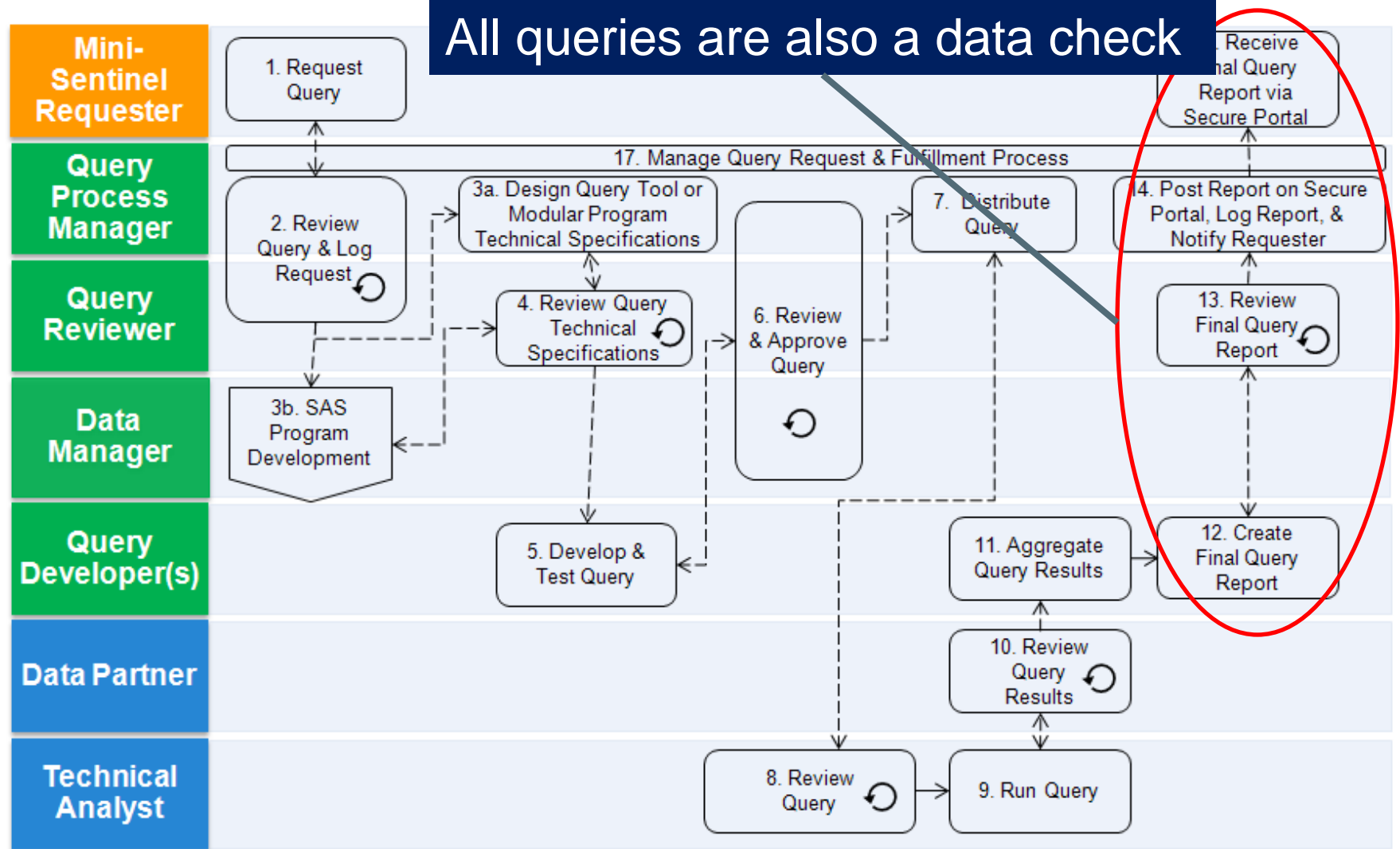


# Query fulfillment process



# Query fulfillment process

All queries are also a data check



MSOC Data Partner MS Collaborator

# Questions

- How many people use lindane?
- How many people are overweight?
- How many patients had an acute myocardial infarction?
- How many patients underwent revascularization procedures?
- How many patients use antidepressants and proton pump inhibitors concomitantly? For how long?
- What is the background rate of Guillain-Barre syndrome by age, sex, and year?
- How many patients receive a statin within 60 days of a stroke?
- How many warfarin patients had a new bleeding event within 30 days of treatment initiation?



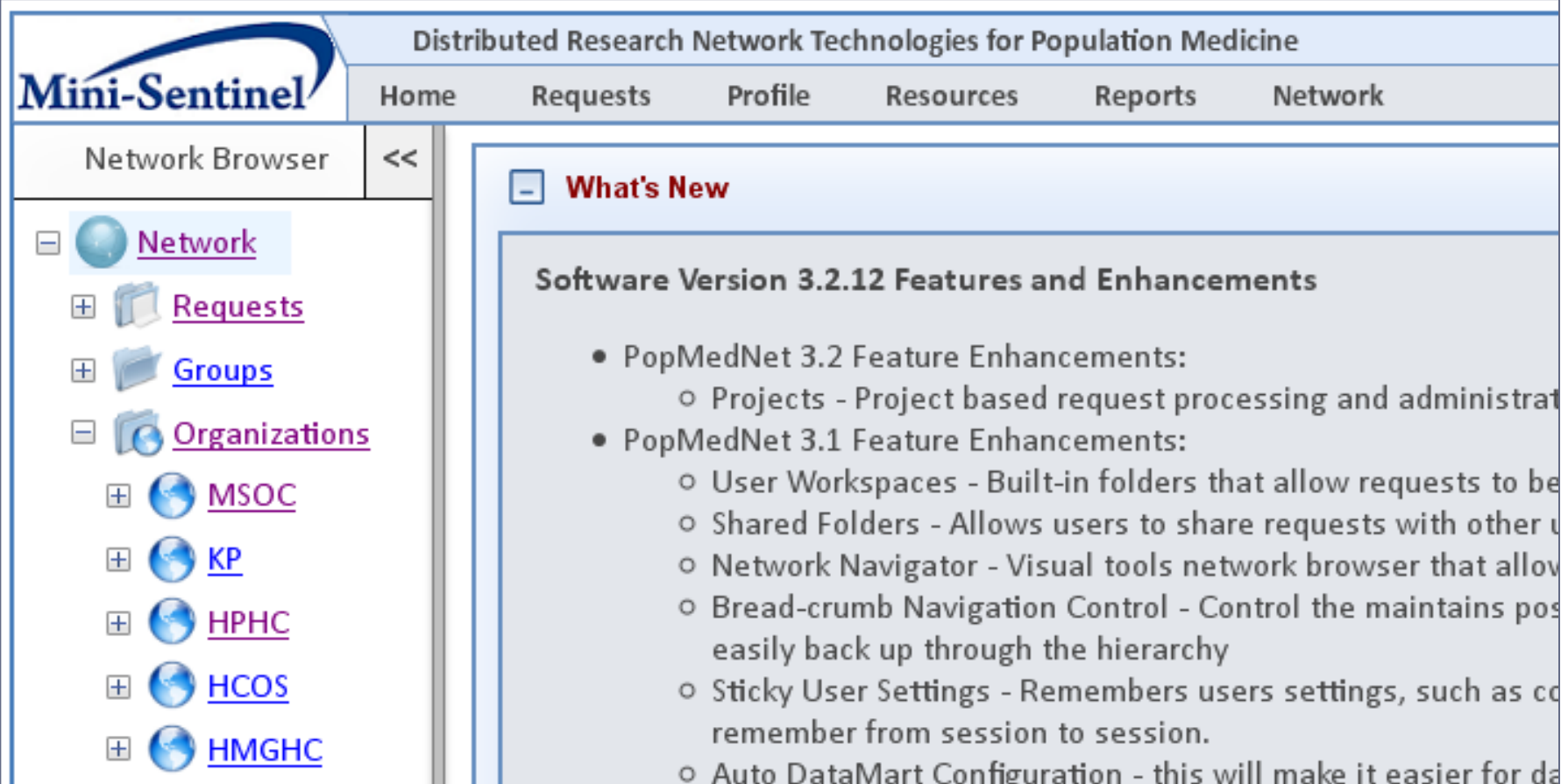
# Summary tables

- ❑ Counts of medical utilization , dispensings, and enrollment
  - Stratified by age group, sex, and year
- ❑ Created via distributed programs run against Mini-Sentinel Common Data Model
- ❑ Aggregate data held by the Data Partners
- ❑ Use PopMedNet™ to securely send queries and responses
  - Point-and-click interface to generate and send query
  - Data partners execute query and respond using the software
  - Query tracking and auditing
  - No technical expertise needed

# Summary tables

- ❑ Standard output for dispensing queries
  - Total users (incident/prevalent), dispensings and days supplied
  - Days per user
  - Dispensings per user
  - Days per dispensing
  - Prevalence and incidence rates
  
- ❑ Standard output for medical utilization queries
  - Patients and count of encounters
  - Count by care setting (ambulatory, ER, inpatient, any)
  - Visits per person

# Mini-Sentinel distributed query tool



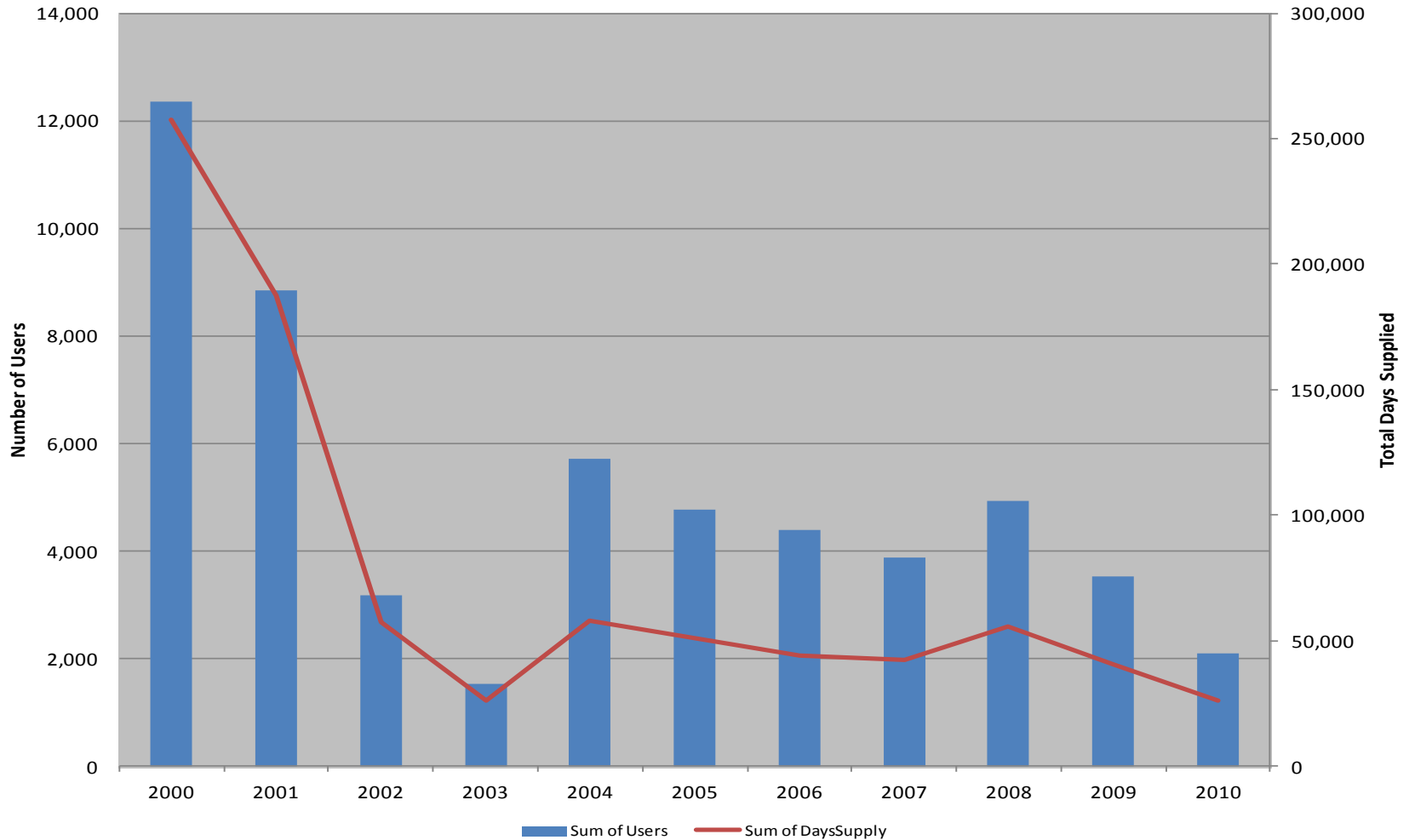
The screenshot displays the Mini-Sentinel web application interface. At the top, the Mini-Sentinel logo is on the left, and the title "Distributed Research Network Technologies for Population Medicine" is centered. Below the title is a navigation menu with links for Home, Requests, Profile, Resources, Reports, and Network. On the left side, there is a "Network Browser" sidebar with a tree view containing: Network (expanded), Requests, Groups, Organizations (expanded), MSOC, KP, HPHC, HCOS, and HMGHC. The main content area features a "What's New" section with a minus sign icon, titled "Software Version 3.2.12 Features and Enhancements". This section lists two categories of enhancements: PopMedNet 3.2 and PopMedNet 3.1, each with several sub-points.

**What's New**

**Software Version 3.2.12 Features and Enhancements**

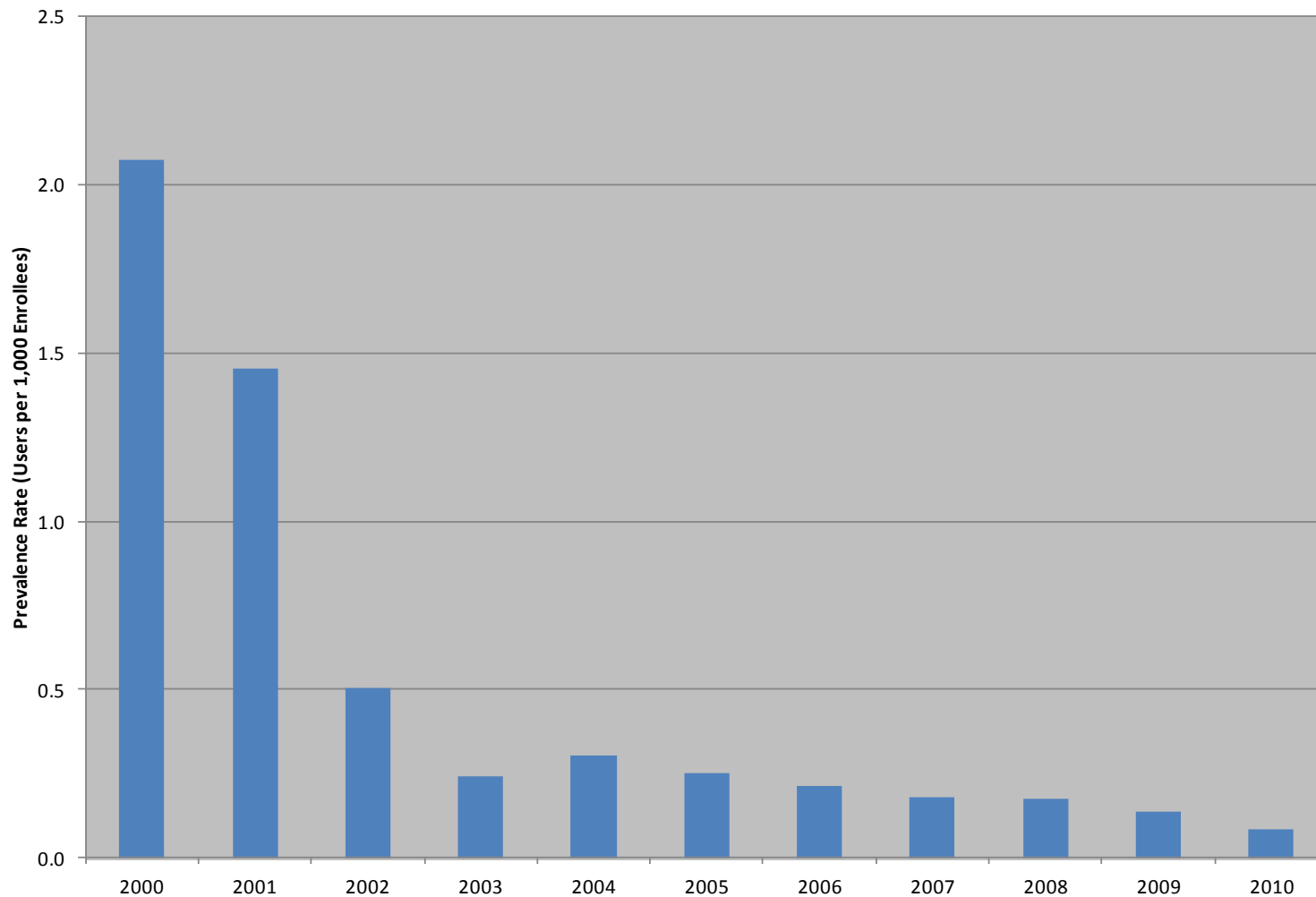
- PopMedNet 3.2 Feature Enhancements:
  - Projects - Project based request processing and administration
- PopMedNet 3.1 Feature Enhancements:
  - User Workspaces - Built-in folders that allow requests to be organized
  - Shared Folders - Allows users to share requests with other users
  - Network Navigator - Visual tools network browser that allow users to navigate the network
  - Bread-crumbs Navigation Control - Control the maintains position and allows users to easily back up through the hierarchy
  - Sticky User Settings - Remembers users settings, such as column preferences, to remember from session to session.
  - Auto DataMart Configuration - this will make it easier for data integration

# Lindane users and days supplied by year



[http://www.mini-sentinel.org/assessments/medical\\_products/details.aspx?ID=141](http://www.mini-sentinel.org/assessments/medical_products/details.aspx?ID=141)

# Lindane prevalence rate by year



# Prevalent acute myocardial infarction patients by year, sex, and age group: Inpatient diagnoses

**Table 1. Number of Acute Myocardial Infarction Patients in the Inpatient Setting by Year, Sex, and Age Group**

Sum of Patients			
Year	Sex	Age	Patients
2000			
2001			15,143
2002			15,237
2003			15,172
2004			65,721
2005			64,632
2006			64,174
2007			74,515
2008			83,669
2009			81,608
2010	F		26,948
	M	0-1	6
		2-4	1
		5-9	1
		10-14	2
		15-18	23
		19-21	35
		22-44	1,973
		45-64	15,056
		65-74	9,260
75+	12,499		

About 65k to 80k hospitalized AMIs in most recent years

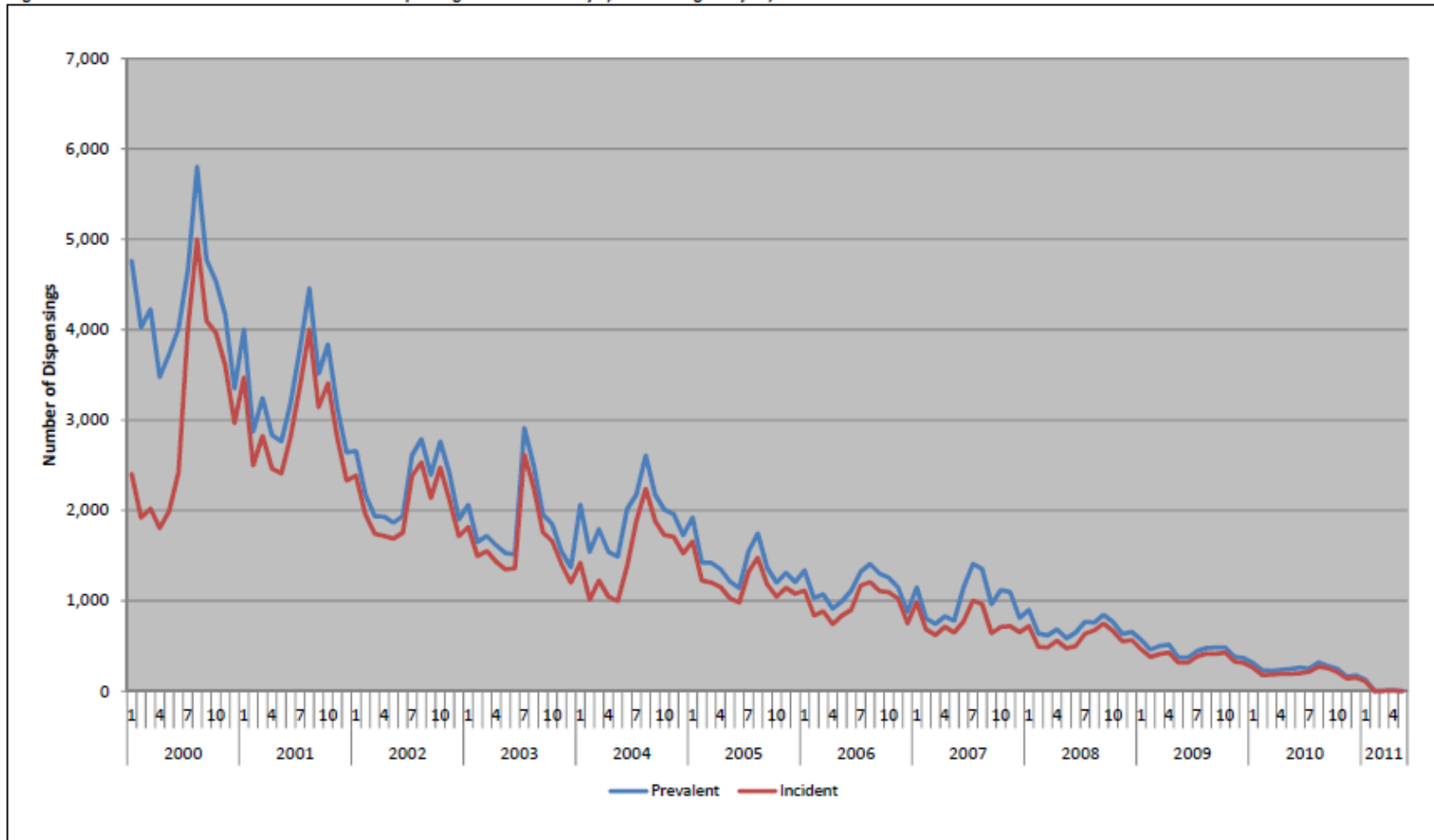
Report stratified by year, sex, and age group

# Modular programs

- ❑ Parameterized SAS programs
- ❑ Based on the Mini-Sentinel Common Data Model
- ❑ Input forms for each program
- ❑ Each program focused on a common question
- ❑ Flexible parameters to determine treatment exposure, inclusion/exclusion criteria, outcomes, etc
- ❑ Output (incident/prevalent)
  - Users, dispensings/visits, days supplied, dispensings per user, days per user, days per dispensing

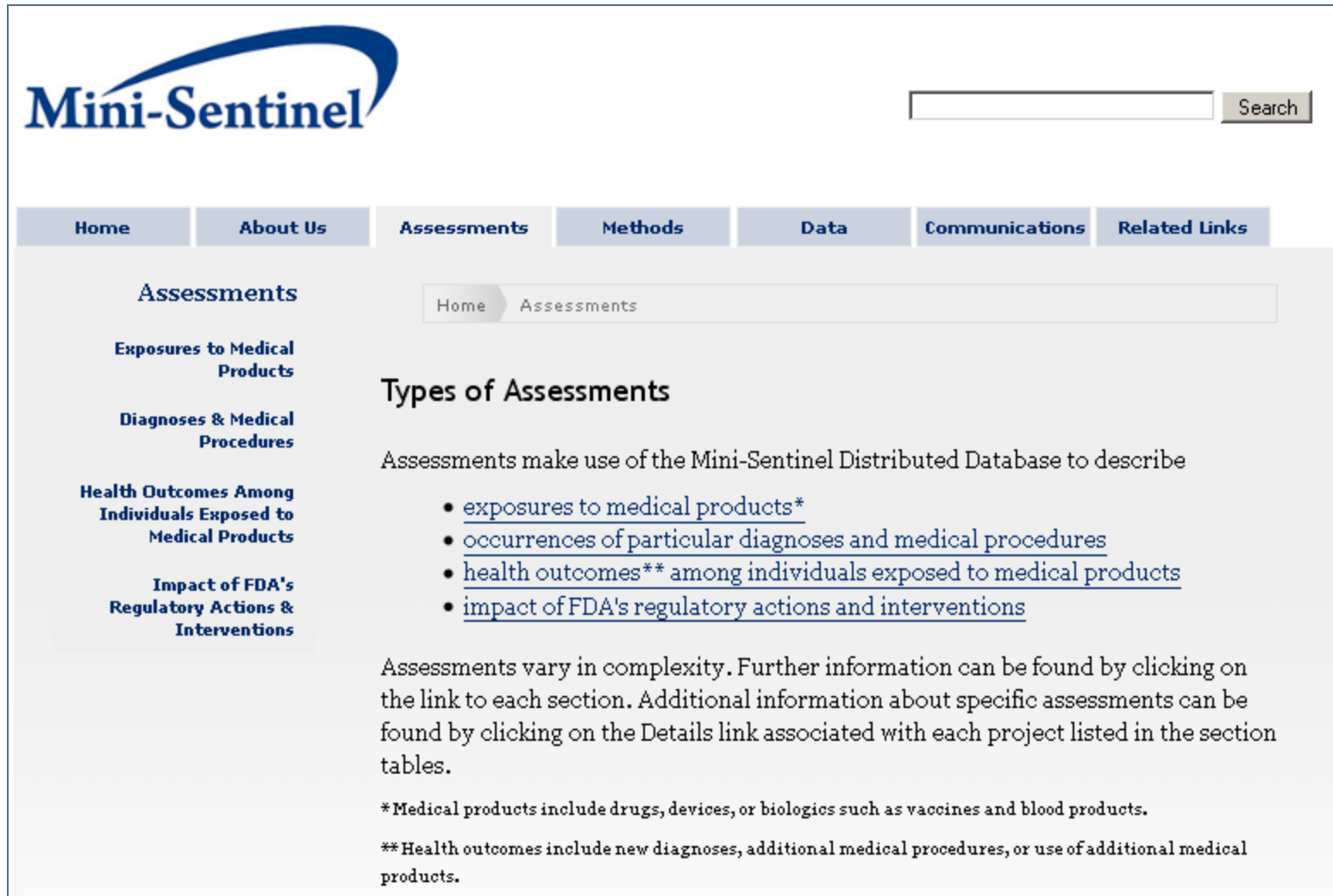
# Lindane use: Prevalent and incident counts

Figure 1. Number of Prevalent and Incident Lindane Dispensings between January 1, 2000 through May 31, 2011





# Reports posted online



The screenshot shows the Mini-Sentinel website interface. At the top left is the Mini-Sentinel logo. To its right is a search bar with a 'Search' button. Below the logo is a navigation menu with tabs for Home, About Us, Assessments, Methods, Data, Communications, and Related Links. The 'Assessments' tab is selected. On the left side, there is a sidebar with links to 'Exposures to Medical Products', 'Diagnoses & Medical Procedures', 'Health Outcomes Among Individuals Exposed to Medical Products', and 'Impact of FDA's Regulatory Actions & Interventions'. The main content area has a breadcrumb trail 'Home > Assessments' and a heading 'Types of Assessments'. Below the heading, it states that assessments use the Mini-Sentinel Distributed Database to describe:

- [exposures to medical products\\*](#)
- [occurrences of particular diagnoses and medical procedures](#)
- [health outcomes\\*\\* among individuals exposed to medical products](#)
- [impact of FDA's regulatory actions and interventions](#)

Assessments vary in complexity. Further information can be found by clicking on the link to each section. Additional information about specific assessments can be found by clicking on the Details link associated with each project listed in the section tables.

\*Medical products include drugs, devices, or biologics such as vaccines and blood products.

\*\*Health outcomes include new diagnoses, additional medical procedures, or use of additional medical products.

<http://www.mini-sentinel.org/assessments/default.aspx>

# Cohort Identification within FDA's Mini-Sentinel Program

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