

Mini-Sentinel Distributed Query Tool Investigator Manual

Based on release 2.2

May 11, 2011

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PopMedNetTM application was developed under from the Agency for Healthcare Research and Quality, US Department of Health and Human Services as part of the Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) program, awarded to the DEcIDE centers at the HMO Research Network Center for Education and Research on Therapeutics (HMORN CERT) and the University of Pennsylvania. The Food and Drug Administration's Mini-Sentinel project provided additional support.

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1 Introduction

The Mini-Sentinel Distributed Query Tool is based on the PopMedNet[™] software application that enables simple, efficient creation and use of distributed data networks, through a set of tools and webbased services. It is optimized to facilitate distributed analyses of medical product safety, comparative effectiveness, quality, medical resource utilization, cost-effectiveness, and related studies. The system provides secure, customized private portals, query tools, and file transfer capabilities. It supports both menu driven queries and distributed analyses using complex, single use or multi-use programs designed to execute against a local data resource.

Data partners exercise full control over the files they make available for querying, the results are returned to requestors, and the individuals who are permitted to submit queries.

This <u>Mini-Sentinel Investigator Manual</u> describes the main features and functions for Investigators participating in the network. Investigators will primarily interact with the network through a secure web-based Portal as described below.

The Department of Population Medicine at the Harvard Pilgrim Health Care Institute (HPHCI) led development of the system in collaboration with Lincoln Peak Partners (LPP). Lincoln Peak Partners provides support services and secure hosting for current system users, and leads development of system enhancements.

2 System Overview

The Mini-Sentinel Distributed Query Tool is comprised of two separate applications, the web-based **Portal** and the **DataMart Client**. There is one Portal in the network and each data partner has one or more "DataMarts". The Portal is the starting point for all information requests and controls all system communications, security, and governance policies. Data Partners receive queries, process them, and securely return them to the Portal via their locally installed DataMart Client software application. Each Mini-Sentinel Data Partner will have at least one DataMart; multiple DataMarts per Data Partner are possible. Each DataMart can contain different types of data and DataMarts can have different query processing settings. All query requests and communications within the network are securely routed from the Portal to the DataMarts and then back to the Portal.

Note: The term **DataMart** is used in an information technology context referring to the place where the data are held for querying. Use of this term does not imply that data partner information is being sold or being made broadly available; Data Partners maintain control of all their data and all uses.

Browser Requirements

The Portal is designed to work with Internet Explorer (IE) 7 or later. Earlier versions of IE may not display the user interface properly. Although IE7 is the only officially supported browser, other browsers such as Firefox and Chrome may also work; Firefox has been used extensively in testing.

The DataMart Client Application

The DataMart Client application allows the DataMart Administrator to view queries distributed to the DataMart, execute queries locally, review the results, and upload the results to the portal. The DataMart Client is a .NET/C# Windows desktop application that is installed locally on one or more data partner computers. All communications between the DataMart Client application and the Portal use HTTP/SSL connections to securely transfer queries and results between the application and the Portal. The application uses ODBC connections to the local DataMart databases used to process queries and generate results.

Audience

This manual is intended for Mini-Sentinel Investigators who want to:

- Get started using the Mini-Sentinel Distributed Query Tool
- Submit a guery to the available DataMarts
- Monitor status of a query
- Review results of a query

Investigator Roles

Roles determine the rights that individual users have when using the Portal. There are three Investigator roles available within the system. FDA and the Mini-Sentinel Operations Center will determine which network users are assigned which roles. Only FDA and selected Mini-Sentinel Operations Center staff will be given permission to send queries to the Mini-Sentinel data partners.

<u>Investigator</u>: can submit queries to DataMarts that have given them or their organization permission to submit queries and view only <u>aggregated</u> query results. *This role could be assigned to some FDA staff as determined by the FDA Mini-Sentinel team.*

<u>Enhanced Investigator</u>: can submit queries to DataMarts that have given them or their organization permission to submit queries and review their query results. This role has the additional right to view <u>disaggregated</u> (site-specific) results. Authorized FDA and selected Mini-Sentinel Operations Center staff will be given this role to enable cross-site comparisons.

<u>Query Administrator</u>: can approve queries before they are sent to DataMarts. This user has the rights of an Enhanced Investigator for sending and reviewing queries. *This role will be assigned to selected FDA staff to assist with monitoring FDA use of the network.*

Related Documents

For more information about the Mini-Sentinel Distributed Query Tool, see one of the following documents available on the Mini-Sentinel Distributed Query Tool portal:

Mini-Sentinel Distributed Query Tool DataMart Administrator Manual

The *DataMart Administrator Manual* describes the tasks and activities required to install and manage a DataMart. This includes:

- Setting up and configuring the physical environment -- consisting of Internet connectivity/desktop computer requirements, and system software
- Installing and performing initial administrative setup of a DataMart Client
- Managing the DataMart setting in the Portal

Mini-Sentinel Distributed Query Tool Group DataMart Administrator Manual

The *Group DataMart Administrator Manual* describes the tasks and activities required to manage results of a group. This includes:

- Viewing group results
- Approving group results

Mini-Sentinel Distributed Query Tool Network Administrator Manual

The *Network Administrator Manual* describes the tasks and activities required to install and manage the Portal. This includes:

- Installing an instance of a Portal and an associated database
- Performing the initial administrative setup
- Performing typical Network Administrator functions such as adding new users and DataMarts, creating new roles, and deleting users and DataMarts

Mini-Sentinel Distributed Query Tool Overview and Technical Documentation

The *Overview and Technical Documentation* describes the overall network system architecture, key querying features, and hosting and security details. This includes:

- System overview and workflow
- Policies and features
- Technical architecture and security

3 How to Login to the Web Portal

Before you can login to the Mini-Sentinel Distributed Query Tool portal, you need a username and password assigned by the Mini-Sentinel Operations Center support staff. Once you have your Login Credentials, follow the steps below.



Use these steps to login to the portal:

1. Navigate to the Mini-Sentinel custom website login page:

[Secure URL distributed by Mini-Sentinel Operations Center]

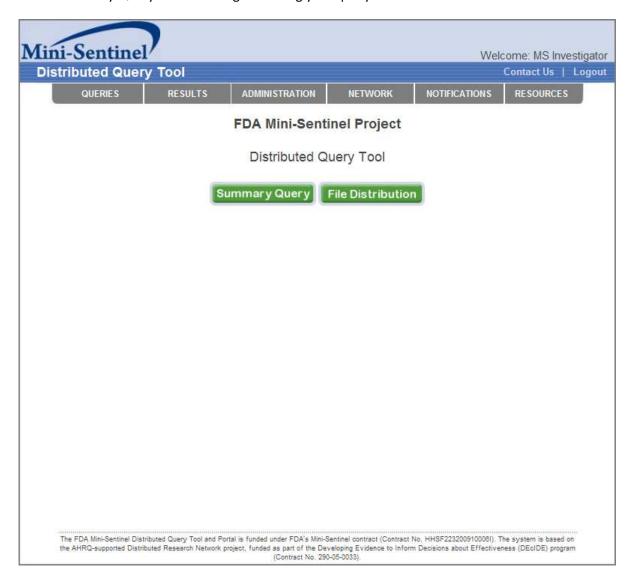
- 2. Enter your Username and Password in the boxes.
- 3. If this is your first login, you will be prompted to read and acknowledge your agreement to the Terms and Conditions of use. If you have cookies enabled on your web browser, you will not be prompted on subsequent logins.
- 4. Click the Login button to enter the Portal.

4 Submitting a Query, Viewing Query Status, and Viewing Results

Once you have logged in, the Portal displays the home page shown below. From the home page, you can create a Summary Query. This section tells you how to create a Summary Query, view the status of a query, and view the results. File Distribution is not featured in the Mini-Sentinel Network.

4.1 Getting Started

Click the Summary Query button to begin creating your query.



4.2 Submitting a Query

The Queries page allows you to create menu-driven queries. There are nine query types. The criteria that you can enter vary for each type. However, the basic steps are the same for all queries. Once you select a query type, the page shows numbered steps that lead you through the required input fields.

Procedure

Follow these basic steps to submit a query:

- 1. Choose the query category from the drop down menu. (Note: In version 2.2 of the query tool only Prevalence query types are available for querying.)
- 2. Choose a query type from the drop down menu.
- 3. Enter a unique name for the query in the text box. This name should help you distinguish among your queries. Note that this field only appears after you select the query type.
- 4. Enter a brief description of the query and the reason for submitting this query, for example to assess the utilization of a medical product. This description is distributed along with the query and should be detailed enough to allow data partners to assess the reason for the query.

Note: This step also displays your email address. To update your email address, please contact the Network Administrator. You must use a business email address, not a personal account.

- 5. Follow the numbered steps on the screen to enter criteria for each query type.
- 6. The available DataMarts will not appear until after at least one year is selected; once the year is selected, click on the Display DataMarts button to identify DataMarts available for querying.
- 7. Click the Start This Query button to submit the query. The query goes out to all the DataMarts that you have selected.

4.3 Query Types

The sections that follow describe the information to enter for each of the currently available query types. Detailed information regarding the data available through the queries is provided on the Portal and is available in separate documentation available from the Mini-Sentinel Operations Center support staff.

The currently available query types are:

1. Prevalence: Enrollment

2. Prevalence: HCPCS Procedures

3. Prevalence: ICD-9 Diagnoses (3 Digit Codes)

4. Prevalence: ICD-9 Diagnoses (4 Digit Codes)

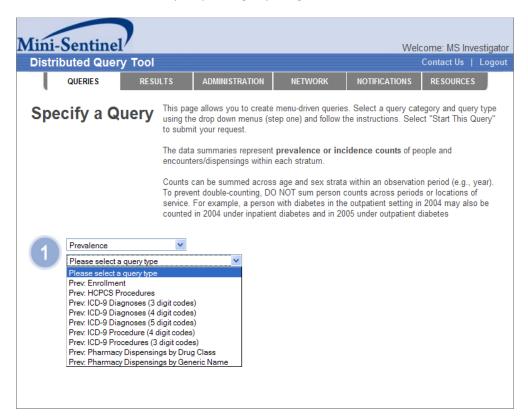
5. Prevalence: ICD-9 Diagnoses (5 Digit Codes)

6. Prevalence: ICD-9 Procedures (3 Digit Codes)

7. Prevalence: ICD-9 Procedures (4 Digit Codes)

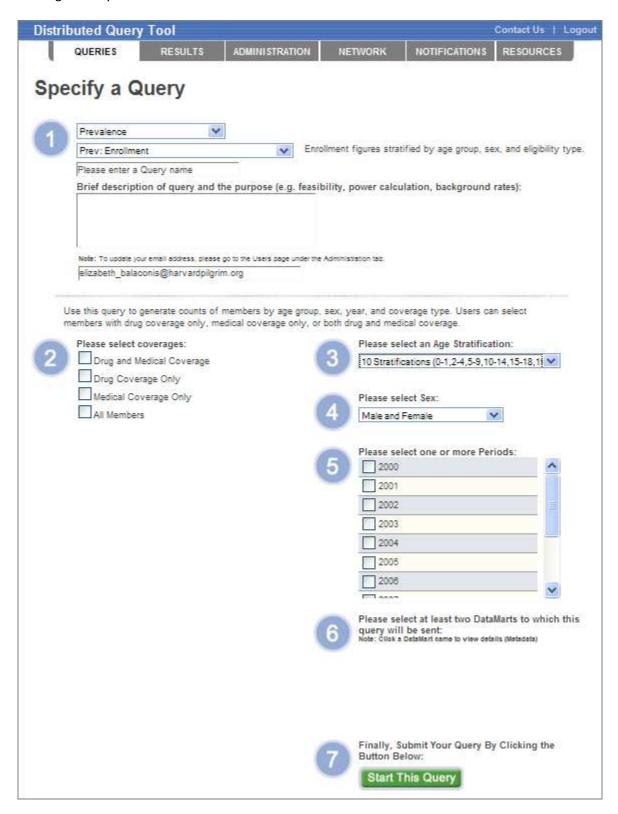
8. Prevalence: Pharmacy Dispensings by Generic Name

9. Prevalence: Pharmacy Dispensings by Drug Class



4.2.1 Enrollment

When you select Prevalence Enrollment from the query type menu in step 1, the screen displays the criteria you need to enter for this type of query. Step 1 is common to all types of queries. See Submitting a Query above.



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Enter the following criteria for an Enrollment query:

Coverage Select one of the coverage types that this query is based upon:

Drug and Medical Coverage

Drug Coverage Only

Medical Coverage Only

All Members (which represents a the union of previous 3 coverage

types)

Age Stratification Select the required age stratification from the drop down menu.

Sex Stratification Select a sex grouping from the drop down menu to specify the sex

stratification for your results (female only, male only, male and female, or

male and female aggregated).

Period Select one or more years. Check the box next to the year to include it in your

query.

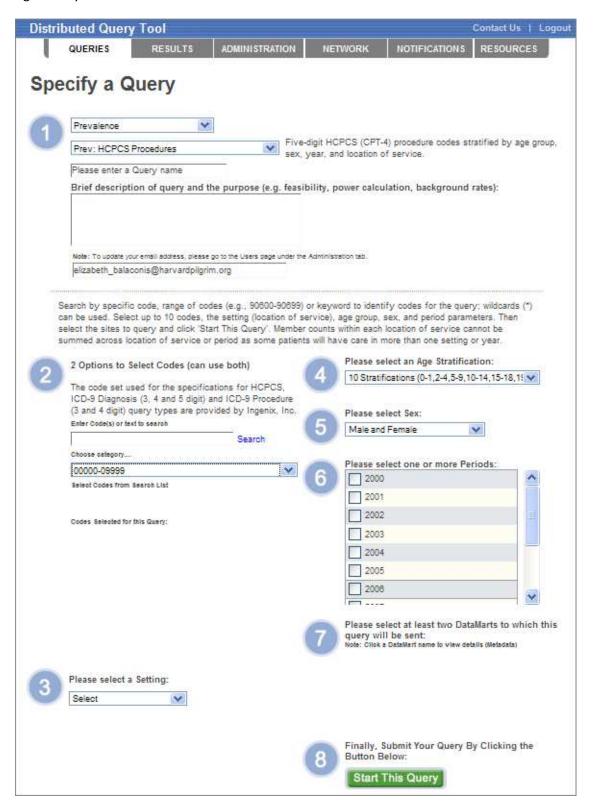
DataMarts Select the DataMarts to submit your query to. Only the DataMarts that have

data for the given Period are displayed.

Note: These counts are used to calculate prevalence rates as seen in Section 4.4.1.

4.2.2 HCPCS Procedures (Healthcare Common Procedure Coding System)

When you select Prevalence HCPCS Procedures from the query type menu in step 1, the screen displays the criteria you need to enter for this type of query. Step 1 is common to all types of queries. See Submitting a Query above.



Enter the following criteria for HCPCS Procedures query:

Code Selection You can choose up to 10 HCPCS (CPT-4) procedure codes to view in one

query.

There are two ways to select the codes:

• Search by text string or code; search using wildcards "*" is available.

• Choose a category and select from a list. The list shows code and name. Click on the column header to sort by code or by name.

Click on Add Codes to add the selected codes to the list and display the list.

Setting Select the care setting for the query: inpatient, outpatient (ambulatory), or

emergency department.

Age Stratification Select the required age stratification from the drop down menu.

Sex Stratification Select a sex grouping from the drop down menu to specify the sex

stratification for your results (female only, male only, male and female, or

male and female aggregated).

Period Select one or more years. Check the box next to the year to include it in your

query.

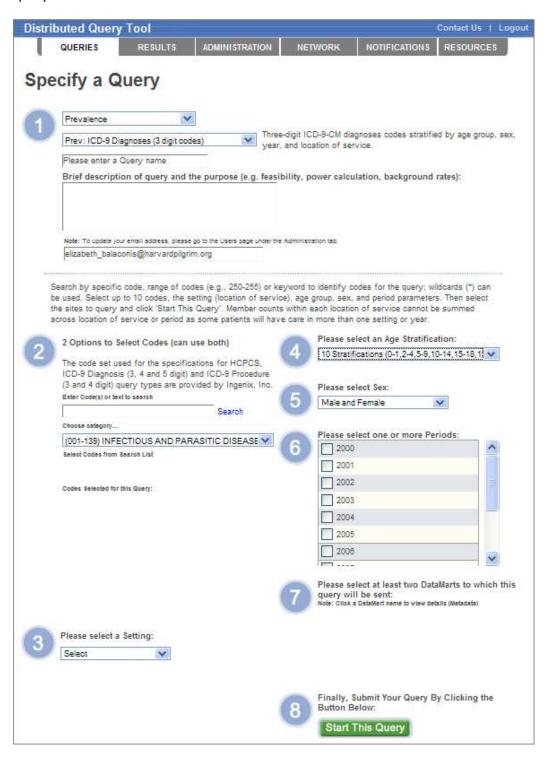
DataMarts Select the DataMarts to submit your query to. Only the DataMarts that have

data for the given Period are displayed.

4.2.3 ICD-9 Diagnoses (3, 4 and 5 Digit Codes)

When you select Prevalence: ICD-9 Diagnoses (3, 4, or 5 Digit Codes) from the query type menu in step 1, the screen displays the criteria you need to enter for this type of query. Step 1 is common to all types of queries. See Submitting a Query above.

Note: Each different digit code represents a separate query. You may not combine different digit codes into one query.



Enter the following criteria for an ICD-9 Diagnoses query:

Code Selection You can choose up to 10 ICD-9 diagnoses codes per query.

There are two ways to select the codes:

• Search by text string or code; search using wildcards "*" is available.

• Choose a category and select from a list. The list shows code and name. Click on the column header to sort by code or by name.

Click on Add Codes to add the selected codes to the list and display the list.

Age Stratification Select the required age stratification from the drop down menu.

Sex Stratification Select a sex grouping from the drop down menu to specify the sex

stratification for your results (female only, male only, male and female, or

male and female aggregated).

Setting Select the care setting for the query: outpatient, emergency department, or

inpatient.

Period Select one or more years to include in your query. Check the box next to

each year to add it to your query.

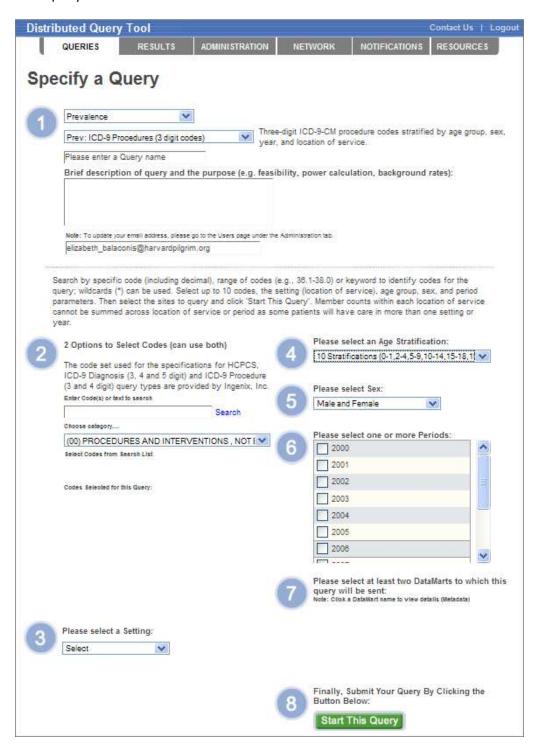
DataMarts Select the DataMarts to submit your query to. Only the DataMarts that have

data for the given Period are displayed.

4.2.4 ICD-9 Procedures (3 and 4 Digit Codes)

When you select Prevalence: ICD-9 Procedures (3 or 4 Digit Codes) from the query type menu in step 1, the screen displays the criteria you need to enter for this type of query. Step 1 is common to all types of queries. See Submitting a Query above.

Note: Each different digit code represents a separate query type. You may not combine different digit codes into one query.



Enter the following criteria for an ICD-9 Procedures query:

Code Selection You can choose up to 10 ICD-9 procedure codes to view in one query.

There are two ways to select the codes:

• Search by text string or code; search using wildcards "*" is available.

• Choose a category and select from a list. The list shows code and name. Click on the column header to sort by code or by name.

Click on Add Codes to add the selected codes to the list and display the list.

Setting Select the care setting for the query: inpatient, outpatient (ambulatory), or

emergency department.

Age Stratification Select the required age stratification from the drop down menu.

Sex Stratification Select a sex grouping from the drop down menu to specify the sex

stratification for your results (female only, male only, male and female, or

male and female aggregated).

Period Select one or more years. Check the box next to the year to include it in your

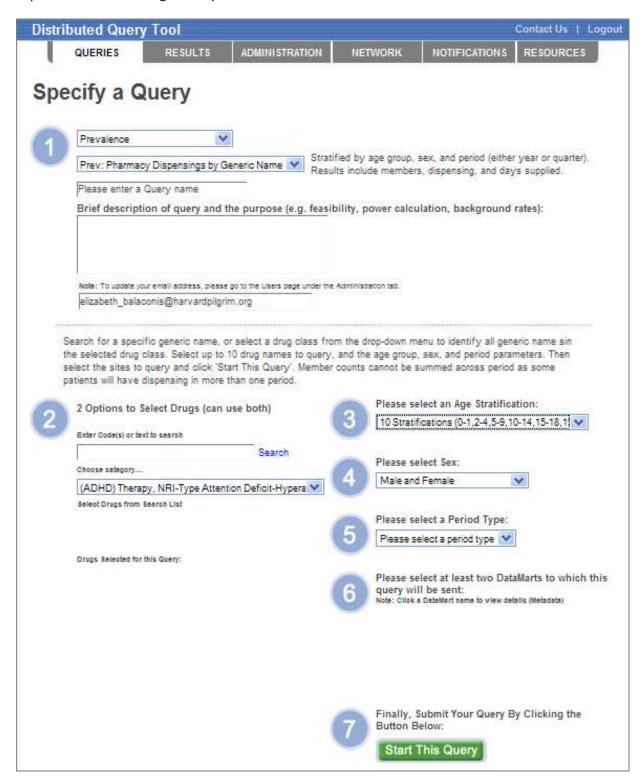
query.

DataMarts Select the DataMarts to submit your query to. Only the DataMarts that have

data for the given Period are displayed.

4.2.5 Pharmacy Dispensings by Generic Name

When you select Prevalence: Pharmacy Dispensings by Generic Name from the query type menu in step 1, the screen displays the criteria you need to enter for this type of query. Step 1 is common to all types of queries. See Submitting a Query above.



Enter the following criteria for a Pharmacy Dispensings by Generic Name query:

Drug Selection

You can choose up to 10 drugs per query. Note: First DataBank was used to map National Drug Codes to the Generic Name list.

There are two ways to select the drugs:

• Search by text string or code; search using wildcards "*" is available.

• Choose a category and select from a list.

Click on **Add Codes** to add the selected drugs to the list and display the list.

Age Stratification

Select the required age stratification from the drop down menu.

Sex Stratification

Select a sex grouping from the drop down menu to specify the sex stratification for your results (female only, male only, male and female, or male and female aggregated).

Period Type

Select the period type: Quarterly or Yearly.

Period

Select one or more periods. Check the box next to the period to include it in

your query.

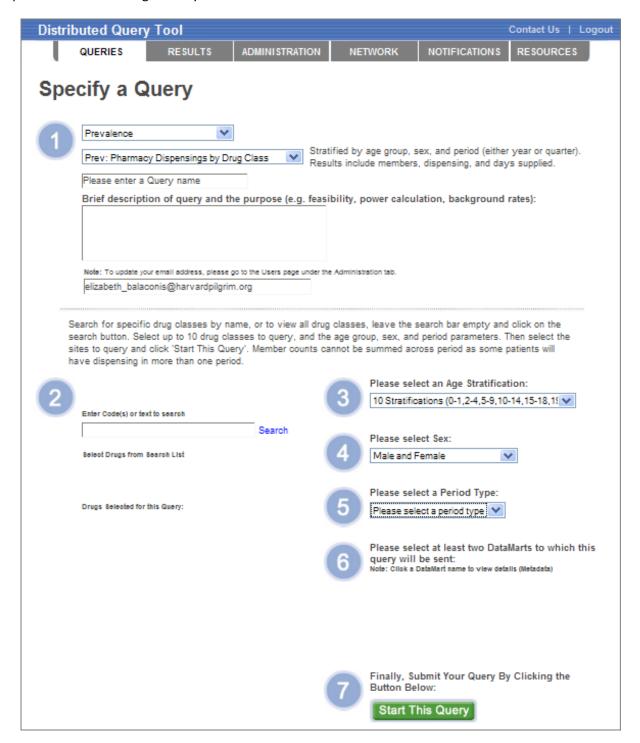
DataMarts

Select the DataMarts to submit your query to. Only the DataMarts that have

data for the given Period are displayed.

4.2.6 Pharmacy Dispensing by Drug Class

When you select Prevalence: Pharmacy Dispensings by Drug Class from the query type menu in step 1, the screen displays the criteria you need to enter for this type of query. Step 1 is common to all types of queries. See Submitting a Query above.



Enter the following criteria for a Pharmacy Dispensings by Drug Class query:

Drug Class Selection

You can choose up to 10 drugs per query. Note: First DataBank was used to map National Drug Codes to the Drug Class list.

There are two ways to select the drugs:

• Search by text string or code; search using wildcards "*" is available.

Select from a list of drug classes.
 Leave the text box blank and click Search to display the list of drug classes available for this query. Check the box next to each drug class to include in your query.

Click on **Add Codes** to add the selected drug classes to the list and display the list.

Age Stratification Select the required age stratification from the drop down menu.

Sex Stratification Select a sex grouping from the drop down menu to specify the sex

stratification for your results (female only, male only, male and female, or

male and female aggregated).

Period Type Select the period type: Quarterly or Yearly.

Period Select one or more periods. Check the box next to the period to include it in

your query.

DataMarts Select the DataMarts to submit your query to. Only the DataMarts that have

data for the given Period are displayed.

4.3 Checking the Query Status

You can view the status of a query using the Results tab. You must be logged in to view query status.



Use these steps to view the status of a query:

- 1. At the top of the home page, click Results. The page displays a list of your queries. The Status column shows whether your query is completed, partially completed, or submitted.
- 2. Click on the column name to sort the queries. For example, if you want to view queries by date they were submitted, click Submitted On.
- 3. To see status for a specific query type, choose the query type from the drop down menu on the right. To filter the query results by date, select the range in the top left and click Filter.
- 4. Click on View Details to see query status by DataMart as shown on the View a Query screen in section 4.4 Viewing Query Results below. This displays a list of all the DataMarts to which you submitted the query along with status for each DataMart.

4.4 Viewing Query Results

You can view the results of a query on the View a Query screen, after clicking on View Details for the query of interest on the Query Status page as described in section 4.3 above.

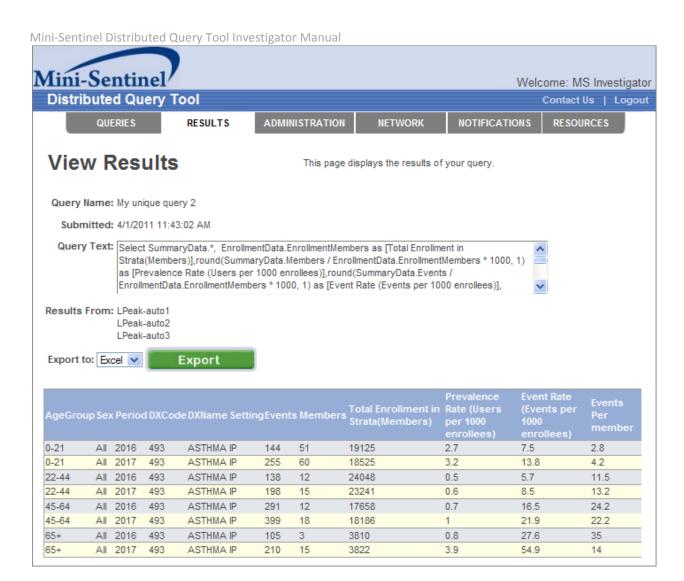
A user designated as an Enhanced Investigator will have the right to view site results individually across the organizations within the query by selecting View Selected Results. This role will be assigned at the discretion of a System Administrator and in accordance with the governance of the system.

Note: Be sure to check the status of a query before you view the results. If you select View Result before all DataMarts have uploaded their results, you will cancel queries which have not yet been responded to (i.e., you will not be able to see any results from the DataMarts that did not respond to that query). If you want information from those DataMarts, you must submit a new query.



Use these steps to view query results:

- 1. Complete the steps described in the Checking Query Status section to navigate to the View a Query page.
- 2. Check the status column to verify that all results have been uploaded.
- 3. Click on the View Result button.
- 4. View the guery results on the View Results screen as shown in the screen shot below.



4.4.1 Calculated Rates Columns

The calculated columns are included to give supporting information for the codes of interest. The Enrollment summary tables for each category are used with the corresponding selected query type to calculate the rates.

Medical Queries: HCPCS Procedures, ICD-9 Diagnoses and Procedures

- Total Enrollment in Strata (Members)-Total count includes members with both medical and drug coverage plus those with medical coverage only.
- Prevalence Rates (Users per 1000 enrollees)
- Event Rate (Events per 1000 enrollees)
- Events per Member

Drug Queries: Pharmacy Dispensings by Generic Name and Drug Class

- Total Enrollment in Strata (Members)- Total count includes members with both medical and drug coverage plus those with drug coverage only.
- Prevalence Rates (Users per 1000 enrollees)

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- Dispensing Rate (Dispensings per 1000 enrollees)
- Days per Dispensing
- Days per User

4.5 Exporting Result Data

You can export the result data to a CSV File or to Excel from the View Results screen.

Use these steps to export data:

- 1. Choose CSV or Excel from the "Export to:" drop down box.
- 2. Click the Export button.

The file name for your exported data is made up of: the query name up to the first space in the name. For example: if your query name is "NamingScheme_SummaryQuery for Query Tool," the name of the file will be "NamingScheme SummaryQuery.xls."

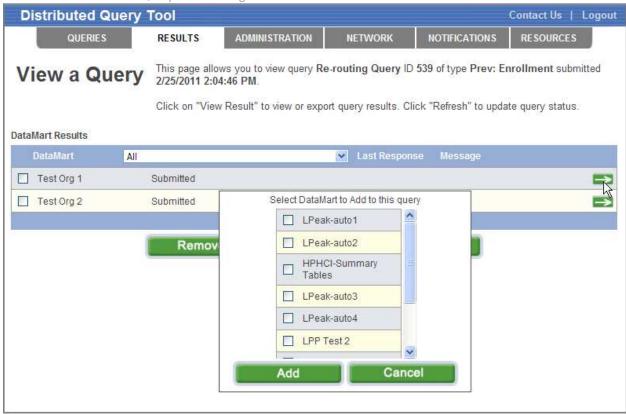
4.6 Rerouting Submitted Queries

Before viewing your query result, you can add DataMarts to or remove them from a query. Note: You cannot remove a particular DataMart after it has uploaded results to the query.

Use these steps to re-route a query:

- 1. Click the arrow on the far right of the DataMart you would like to remove from the query.
- 2. Select a different DataMart to send the query to.
- 3. An email will be sent to the removed DataMart to cancel the request, while a new query email will be sent to the added DataMart.

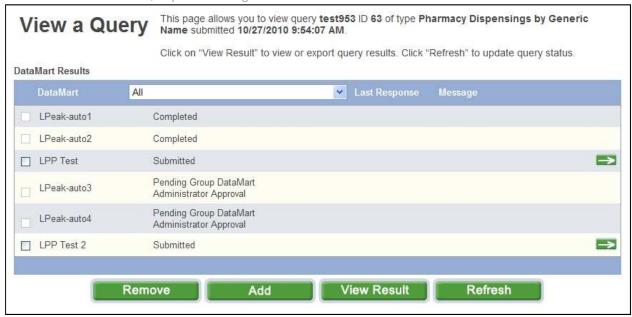
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4.6.1 Removing a DataMart from a Query

Use these steps to remove a DataMart from a query:

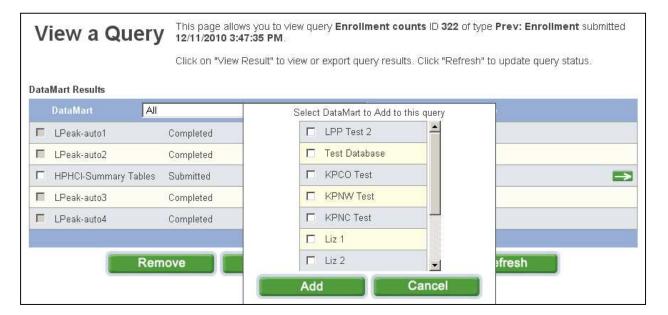
- 1. On the View a Query page, check the box beside the DataMart(s) you would like to remove from the query.
- 2. Click the Remove button.
- 3. An email will be sent to the removed DataMart(s) cancelling your query request.



4.6.2 Adding a DataMart to a Query

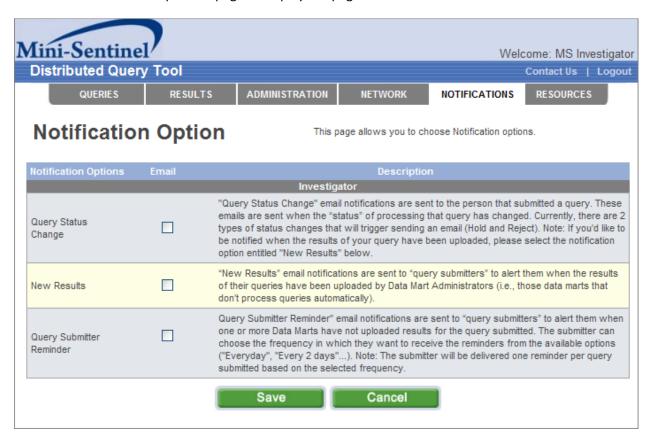
Use these steps to add a DataMart to a query:

- 1. On the View a Query page, click the Add button to display a list of possible DataMarts.
- 2. Check box for each of the DataMarts that you would like to send the guery to.
- 3. Click the Add button.
- 4. The query request will be sent to the newly added DataMart(s).



5 Notification E-mails

This section describes how to set up notifications to be e-mailed to your email address. You must be logged in to the web portal to change your notification settings. Click Notification Options on the Notifications tab at the top of the page to display the page shown below.



The notification options for the Investigator role are:

Query Status Change Notifies you when your submitted query has been on placed on hold or rejected by the DataMart administrator that you submitted the query to.

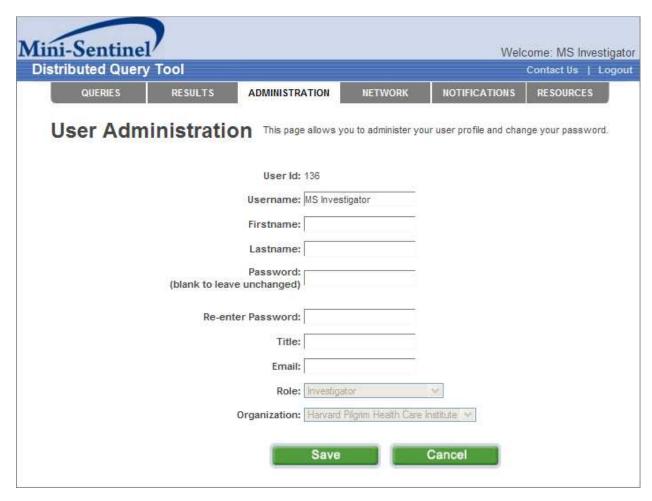
New Results Notifies you when the DataMart administrator has accepted your query and

the query results have been uploaded.

Query Submitter Notifies you when one or more DataMarts have not uploaded results for the **Reminder** query submitted.

6 Administering your User Profile

This section describes how to administer your user profile. You must be logged in to the web portal to administer your user profile. Click Users on the Administration tab located at the top of the screen. The screen displays your user profile.



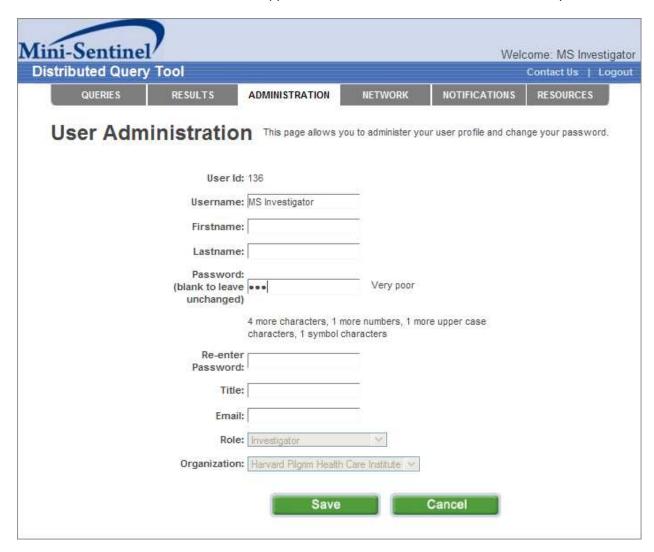
6.1 How to Reset your Password

Your user profile has two boxes for passwords. To change your password:

- 1. Enter the new password in the first Password box.
- 2. Re-enter the new password in the second Password box.
- 3. Click the Save button.

Note: All passwords must meet the following complexity standard:

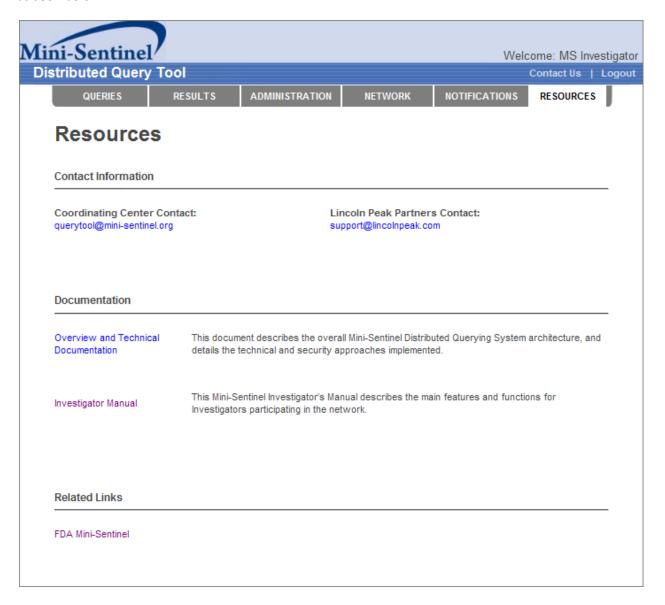
- Length must be at least 7 characters
- Password must include at least 1 upper case letter, 1 lower case, 1 number, and 1 symbol.



Once you initially get your login credentials from the system administrator, it is highly advised that you change your password from the default password given to you.

7 Getting Help

Once logged in, the Resource Tab offers helpful contact information, documentation, and related links, as seen below.



If you have trouble accessing the Web Portal or your user account, click on the Contact Us link and describe your issue to request help from the Mini-Sentinel Operations Center support staff.

8 Development and Funding Statement

The **PopMedNet™** software application was developed as part of several contracts awarded by the Agency for Healthcare Research and Quality to the HMO Research Network (HMORN) Center for Education and Research on Therapeutics (CERT) DEcIDE Center housed in the Department of Population Medicine at the Harvard Pilgrim Health Care Institute (HPHCI). The software application has been enhanced using additional funding via the FDA Mini-Sentinel contract with Harvard Pilgrim Health Care. The system was developed by Lincoln Peak Partners under the direction of HPHCI.

9 Frequently Asked Questions

This section lists some of the most frequently asked questions.

What is the difference between Groups, Organizations, and Users?

Users are individuals with various roles and associated rights within the system such as Investigator, DataMart Administrator, and System Administrator. Individual users may be part of a Group or Organization.

What are my rights as a user and how can I change them?

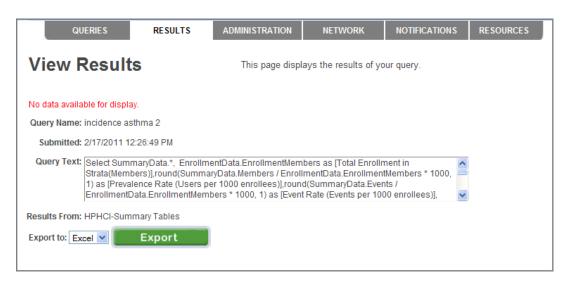
Rights can only be assigned to various roles by the Network Administrator. The Network Administrator can also assign rights to multiple users by giving that right to an Organization or Group.

Where can I get more information on the PopMedNet[™] application?

You may contact the Operations Center for more information:

Jeffrey Brown, PhD Harvard Pilgrim Health Care Institute Jeff_brown@hphc.org

When I viewed my results, I got the error message "No data available for display." What does this mean?

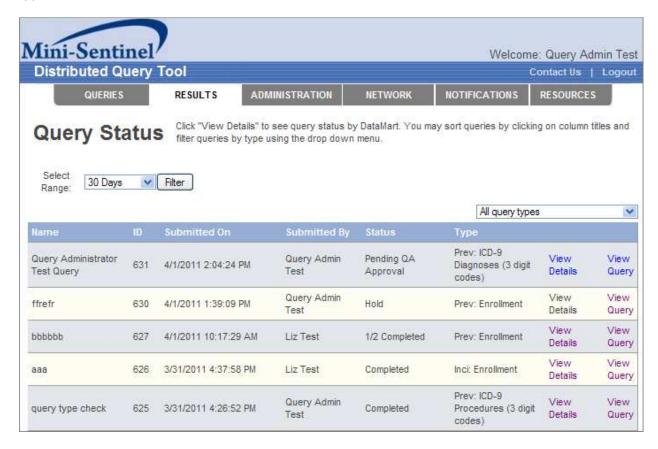


This means that the sites queried had no data in their database that matched your query specifications so an empty set was returned to the portal

Appendix A: Query Administrator Role

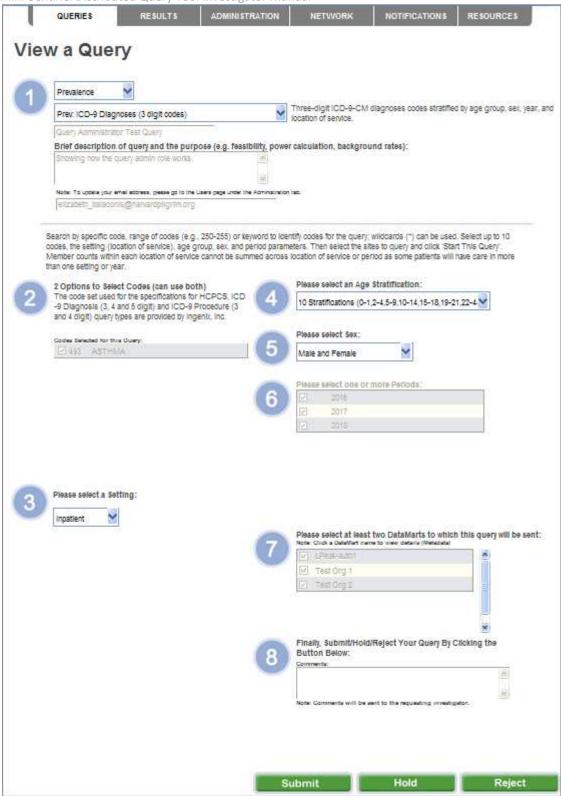
The Query Administrator acts as a gatekeeper for all the queries coming out of an organization. Given budgeting for queries, this role can monitor query submission so that only the most relevant queries are distributed to the sites in the network.

Once an investigator within the organization submits a query, the query administrator receives an email notification about a query that is 'Pending QA Approval.' The Query Administrator then logs in with his/her login credentials. The Query Status page includes an extra column specifically for query approval.



By clicking 'View Query,' the query administrator views the parameters of the query. Queries may be submitted, held, or rejected by the query administrator, who can provide comments to the investigator about the query.

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As results are uploaded to the query, the Query Administrator can view individual site results, just like an Enhanced Investigator. Query Administrators can also submit queries.

The Query Administrator has an additional query notification for pending queries than investigators.

