

Mini-Sentinel Distributed Query Tool Investigator Manual

Powered by PopMedNetTM

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CONTACTS:

Jeffrey Brown, PhD

Harvard Pilgrim Health Care Institute

Jeff brown@hphc.org

The **PopMedNet**TM application was developed under 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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Document History

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Table 1: Document History

Version	Author(s)	Date	Description
3.1	Lincoln Peak Partners	11/15/2012	Created.
3.2	Jeff Brown, Elizabeth Balaconis, Megan Mazza, Melanie Davies	5/13/2013	New Build. This new documentation represents a new release of the PMN software. Prior Mini-Sentinel query tool documentation was based on release 2.3.24 and this documentation is based on PMN 3.2.0. New features include User Registration, Plug-in Architecture, Security Group Access Control, and Projects.



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 returned to requestors, and the individuals who are permitted to submit queries.

This Mini-Sentinel <u>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 software is comprised of two separate applications, the webbased **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) 8 or later. Earlier versions of IE may not display the user interface properly. Although IE8 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 developed by LPP that is installed locally on an Administrator's desktop. Note the DataMart Client requires Microsoft .NET 4 to be installed on the user's desktop. The free download for Microsoft.NET4 is available at the following link: http://www.microsoft.com/enus/download/details.aspx?id=17851. All communications between the DataMart Client application and the Portal use HTTP/SSL/TLS 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 accessing the Mini-Sentinel Distributed Query Tool
- Submit a query to the available DataMarts
- Monitor status of a query
- Review results of a query

Investigator Security Groups



Security Groups determine the rights that individual users have when using the Portal. There are three Investigator security groups that are available within the system. FDA and the Mini-Sentinel Operations Center will determine the roles network users are assigned. 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 requests to DataMarts that have given them or their organization permission to submit queries and view only <u>aggregated</u> request results. *This role could be assigned to some FDA staff as determined by the FDA Mini-Sentinel team.*

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

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

A user may be a member of one or more Security Groups thereby inheriting the rights of all the security groups.

Related Documents

For more information about the Mini-Sentinel Distributed Query Tool, see one of the following documents below. These documents are available on Resources page of the web Portal. For a Quick Reference Guide describing Investigator tasks see Appendix A.

Mini-Sentinel Distributed Query Tool Sample 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 Overview and Administrator's Guide

The *Overview and Administrator's Guide* 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.



Figure 1: Logon Page

Use these steps to login to the portal:

- Navigate to the Mini-Sentinel custom website login page: https://querytool3.mini-sentinel.org/
- 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, you will not be prompted on subsequent logins.
- 4) Click the Login button to enter the Portal.



Once you have logged in, the portal displays the home page shown below. From the home page, you can view your notifications, view existing requests, and create a new request. This section tells you how to create a request, view its status and results.



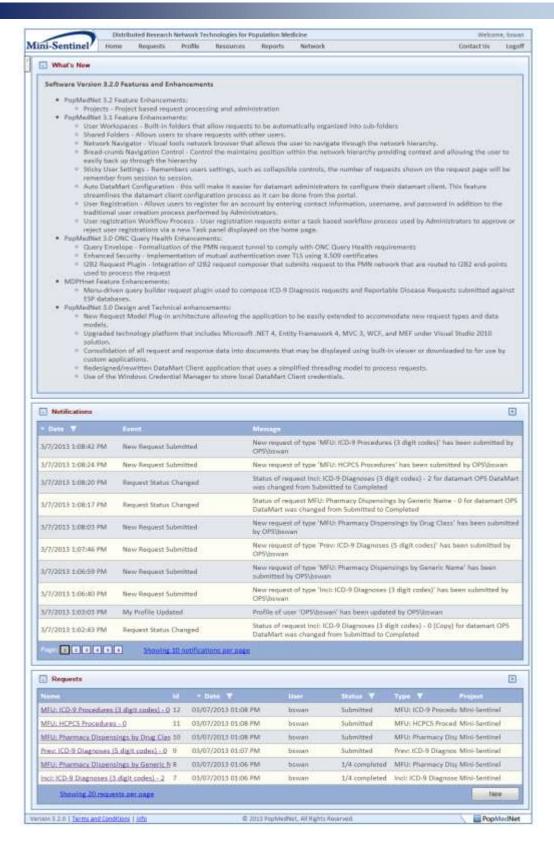


Figure 2: Home Page



The home page is a landing page that contains a set of controls that provide the user with recent information that is relevant to his daily tasks.

The following controls are available on the home page:

- ✓ What's New message panel used to communicate system wide information site upgrades, new features and functions
- ✓ Notifications list of recent notifications on requests and responses performed or associated with the user
- ✓ Requests list recent requests that have been initiated by the user or require the user's approval or review

Collapsible content panels are used throughout the user interface that allows the user to collapse, expand, and maximize the content panel within the page. Additionally, for panels that contain grid controls, the user may specify the number of items displayed in the grid, set column sort orders, and column filters. All these settings are preserved across user sessions.

Note: The term "Request" is used interchangeably with "Query". With the introduction of PopMedNet Release 3, the application has the ability to compose and route a variety of queries, commands, and general *requests* to DataMarts through a "plugin" framework that allows the network to be easily extended to introduce new requests types.



4 Project Based Requests

One of the major enhancements in PMN R3.2 is the introduction of Projects. Projects allow networks to group activities within one or more Projects. A project establishes security policies for composing and executing requests for users and DataMarts assigned to the project. Projects are created within an organizational Group. Groups have one or more member organizations whose users and DataMarts may participate within projects owned by the group. Note that the network may have one or more groups, and an organization may be a member of one or more groups.

The following figure shows a Group detail page along with a Group and Organizational structure displayed in the PMN Network Browser control.

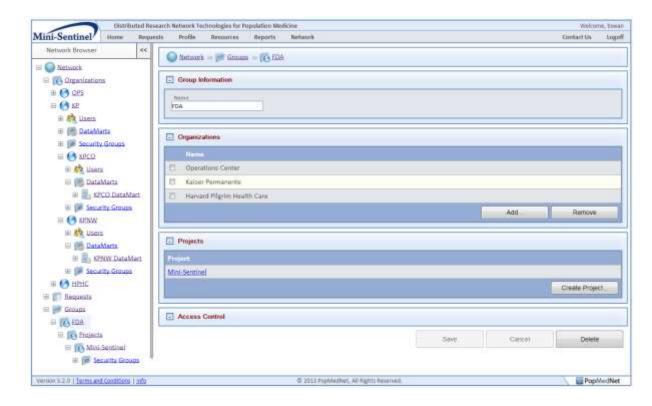


Figure 3: Group Page and Network Browser Control

In this sample network, there is a single Group called FDA that contains three member organizations and a single project called Mini-Sentinel. Only users and DataMarts defined in each of the member organizations, Operations Center, Harvard Pilgrim Health Care, and Kaiser Permanente including its suborganizations, may participate in Mini-Sentinel project owned by the FDA group.

Network administrator or users, such as Group and Project administrators, who have rights to modify and administer the Groups, Organizations, and Projects may grant access to a project and configure its security policies. See the PopMedNet Overview and Administrator's Guide for more information.



Once a group is created and its member organizations are assigned to it, one or more projects may be created. The following figure shows a project detail page used to configure the security policies affecting users and DataMarts assigned to the project.

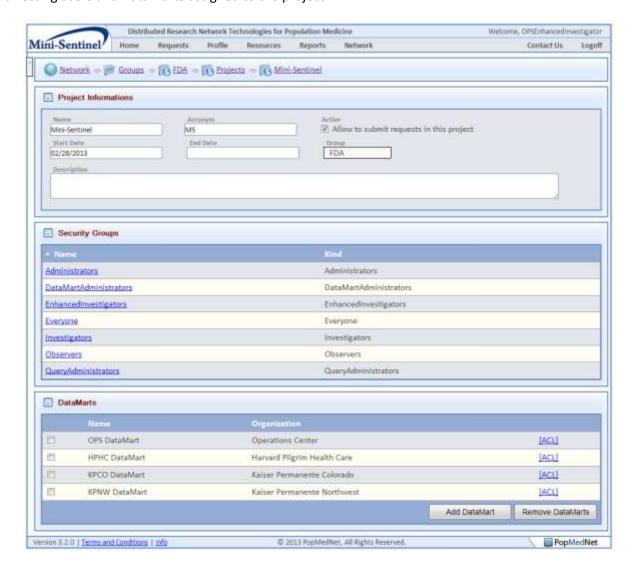


Figure 4: Project Page

The Mini-Sentinel project may be configured to allow requests to be composed by users of the Operations Center, Kaiser Permanente, and its sub-organizations KP Northwest and KP Colorado, and Harvard Pilgrim Health Care. Additionally, review and approval policies may be defined on requests and their execution within the Mini-Sentinel project.



5 Submitting a Request

The Requests panel lists the queries that have been composed by the user. A full page dedicated to requests is available by clicking the Requests menu item at the top of the page. The following figure shows the Requests page with project tabs along the top of the page.

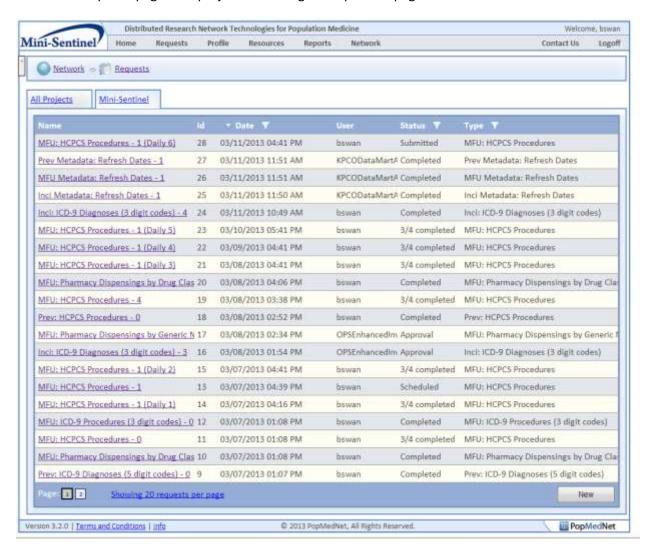


Figure 5: Request Page

The Requests Page allows you to create menu-driven queries within a selected Project. The criteria that you can enter vary for each type. However, the basic steps are the same for all requests. Once you select a query type, the page shows a common header panel that identifies the request, a common footer panel that contains the DataMarts where the request will be routed, and a content panel in the middle that displays controls used to enter criteria settings for the particular request type.

Procedure

Follow these basic steps to submit a request:



- 1) Click the "New" button in the request panel and choose the request category from the drop down menu.
- 2) Choose a request model and type from the drop down menu.
- 3) Enter a unique name for the request in the text box. This name should help you distinguish among your requests. Note that this field only appears after you select the request type.
- 4) Enter a brief description of the request and the reason for submitting this request, for example to assess the utilization of a medical product. This description is distributed along with the request and should be detailed enough to allow data partners to assess the reason for the query. This step also displays your email address. To update your email address, navigate to your **Profile** by clicking the Profile menu item at the top of the page. You must use a business email address, not a personal account.
- 5) Specify the project for the request. Note the project will default to the project selected in the project tab control at the top of the Requests page. If the request was initiated from the home page, the project will need to be assigned manually.
- 6) Specify the request specific criteria and settings for the request type.
- 7) The available DataMarts that you have rights to route the request to will be listed in the DataMart Routing panel at the bottom of the request page. Select one or more of the DataMarts to execute the request.
- 8) Click the Submit button to submit the query. The request goes out to all the DataMarts that you have selected. You may click the Save button to save the request to a Draft status to be reopened later and resume composing the request before submitting it.

5.1 Scheduling Requests

Requests may be scheduled to run in the future rather than immediately when the user clicks Submit by specifying the "Run Mode" on the request detail page.



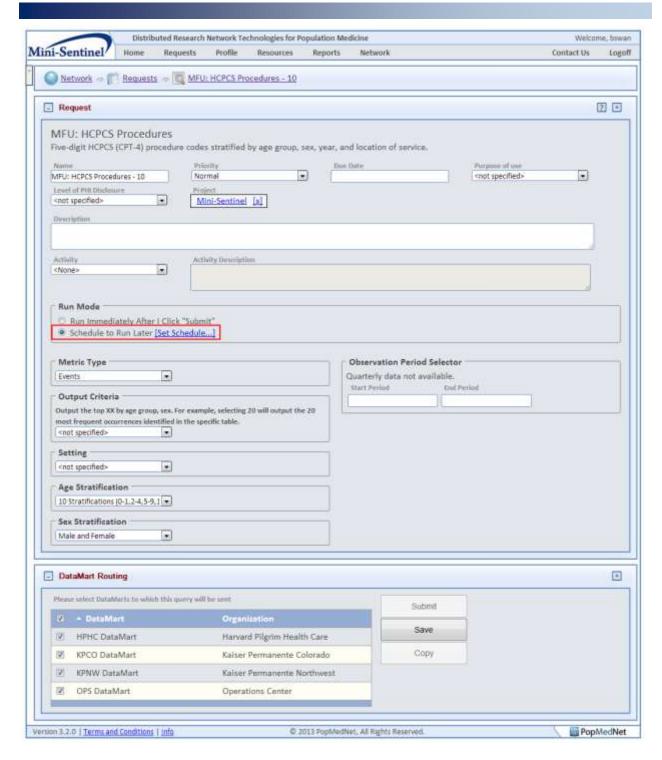


Figure 6: Request Composer Page - Scheduler Function

To schedule a request, click the "Schedule to Run Later" radio button in the Run Mode group on the request detail page. This will display a "Set Schedule" link that will display a popup dialog box that provides in interface to choose a recurrence pattern and date range to run the request.



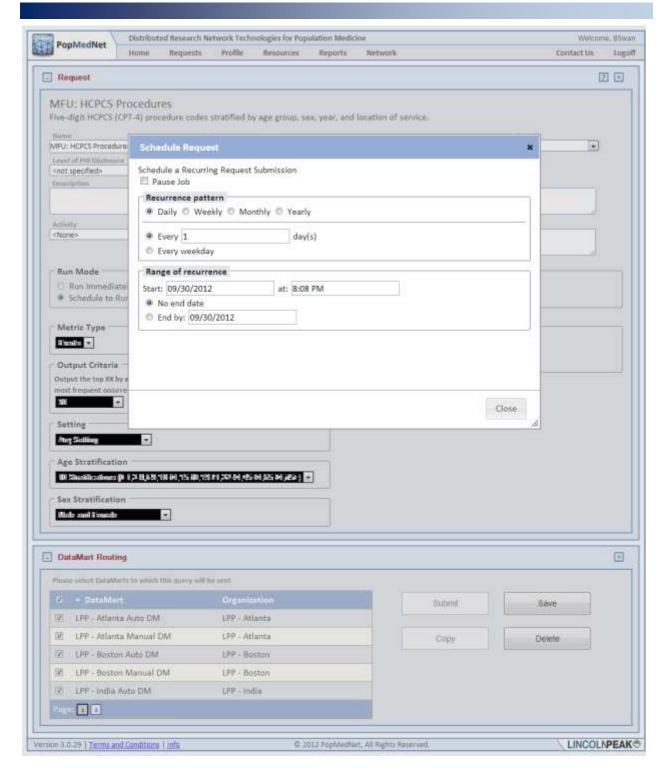


Figure 7: Schedule Request Dialog

Once the schedule is set and the request saved, the request is now scheduled to run based on the settings you've entered. You'll notice that the request status goes to "Scheduled". When the date/time comes to run the request, a copy of the request is made and submitted to the DataMarts that were selected in the base request with its name modified to reflect the scheduled copy (e.g.



BaseRequestName_Weekly_1). Once submitted, the request behaves like any other request that was submitted.

This request's schedule may be adjusted by opening the base request, modifying the request or schedule, and re-saving it. A request can be unscheduled by changing the Run Mode to "Run immediately" and saving the request. This will place the request into a Draft mode.



6 Request Types

The Mini-Sentinel Distributed Query Tool currently supports menu-driven queries that execute against Summary Table databases.

6.1 Summary Queries

The Mini-Sentinel Distributed Querying Tool currently supports querying against summary tables. The structure of the currently supported tables is described in separate documentation. Briefly, these tables provide summary counts of individuals by period, age group, and sex. The summary counts include information on medication use (e.g., number of dispensings, users, and days supplied), diagnoses (e.g., number of individuals with the diagnosis), procedures, and the overall data partner population.

The summary queries are grouped into three request models as follows:

Table 2: Summary Table Request Models and Type

Request Model	Request Type
Prevalence	ICD-9 Diagnosis (3 digit codes)
	ICD-9 Diagnosis (4 digit codes)
	ICD-9 Diagnosis (5 digit codes)
	ICD-9 Procedures (3 digit codes)
	ICD-9 Procedures (4 digit codes)
	Enrollment
	HCPHCS Procedures
	Pharmacy Dispensings by Drug Class
	Pharmacy Dispensings by Generic Name
	Dispensings by National Drug Code
Incidence	ICD-9 Diagnosis (3 digit codes)
	Pharmacy Dispensings by Drug Class
	Pharmacy Dispensings by Generic Name



Request Model	Request Type
Most Frequently Used	HCPCS Procedures
	ICD-9 Diagnosis (3 digit codes)
	ICD-9 Diagnosis (4 digit codes)
	ICD-9 Diagnosis (5 digit codes)
	ICD-9 Procedures (3 digit codes)
	ICD-9 Procedures (4 digit codes)
	Pharmacy Dispensings by Drug Class
	Pharmacy Dispensings by Generic Name
Administrative	Refresh Dates

6.1.1 Prevalence Queries

The Prevalence query types are based on the Prevalence summary tables. The summary tables are created through distributed SAS code written by the Mini-Sentinel Operations Center and executed against the Mini-Sentinel Distributed Database held by each data partner. The Prevalence summary tables represent prevalence counts of diagnoses, procedures, and drug utilization.



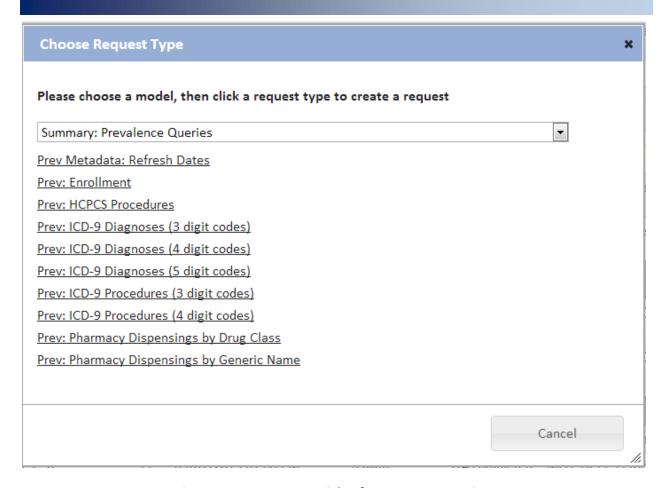


Figure 8: Request Type Dialog for Summary Queries

This will display a request detail page used to enter the criteria for this type of request. The following figure shows a Prevalence Enrollment query.



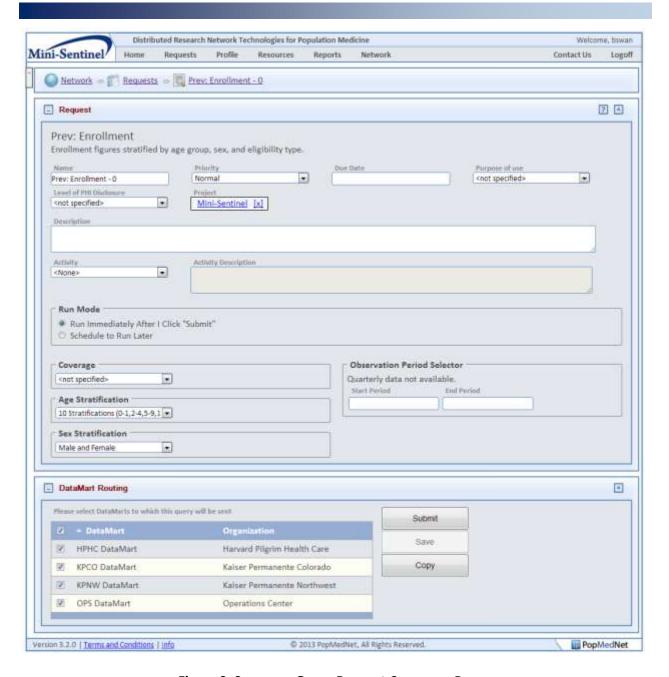


Figure 9: Summary Query Request Composer Page

6.1.1.1 Enrollment Queries

The Enrollment query provides a count of unique individuals who are members/patients during the period. The count is stratified by age group, sex, year, drug coverage status and medical coverage status. The member counts and days covered in the enrollment table can be used as denominators to calculate crude prevalence rates for Prevalence, Incidence, and Most Frequent Utilization query types. See Section 8.1=Calculated Rates Columns for more details.



To compose an Enrollment query, click on the "New" button in the request panel, choose "Summary: Prevalence Queries", and then choose the "Enrollment" request type.

Enter the following criteria for an Enrollment query:

Table 3: Enrollment Query Criteria

Control	Description
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. Enter the start year and ending year for period
	range.
DataMarts	Select the DataMarts to submit your query to. Only the DataMarts for which
	you have rights to route your request to are displayed.

6.1.1.2 Prevalence Diagnosis and Procedure Queries

Enter the following criteria for a given diagnosis (ICD9 3-, 4-, or 5- digit) or procedure (ICD9 3- or 4-digit, or HCPCS) query. The steps in the query are the same for these query types. However, you may not make requests across query types. For example, you may not include codes for ICD9 3-digit and 5-digit diagnosis in the same query.

Enter the following criteria for Diagnosis and Procedures query:



Table 4: Diagnosis and Procedures Query Criteria

Control	Description
Code Selection	You can choose up to 25 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. The code set used for the specifications for HCPCS, ICD-9 Diagnosis (3, 4 and 5 digit) and ICD-9 Procedure (3 and 4 digit) query types are provided by Ingenix, Inc.
Setting	Select the care setting for the query: inpatient, outpatient (ambulatory), emergency department, or any setting
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. Enter the start year and ending year for period range.
DataMarts	Select the DataMarts to submit your query to. Only the DataMarts for which you have rights to route your request to are displayed.

6.1.1.3 Prevalence Drug Queries

Enter the following criteria for a given drug (Pharmacy Dispensings by Drug Category or Generic Name) query. The steps in the query are the same for these query types. However, you may not make requests across query types. For example, you may not include drugs by class and generic name in the same query.

Enter the following criteria for a drug query:



Table 5: Drug Query Criteria

Control	Description
Drug Selection	You can choose up to 25 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 years. Enter the start year and ending year for period range.
DataMarts	Select the DataMarts to submit your query to. Only the DataMarts for which you have rights to route your request to are displayed.

6.1.2 Incidence Queries

Incidence queries are based on the Incidence summary tables. The summary tables are created through distributed SAS code written by the Mini-Sentinel Operations Center and executed against the Mini-Sentinel Distributed Database held by each data partner. These tables represent incidence counts of diagnoses and drug utilization. The new tables can be incorporated into the query tool through a Refresh Dates query with the Incidence query types checked.

Incidence is defined as a member with an encounter with the diagnosis of interest (*i.e.*, the index date), in the care setting of interest, in the year of interest with no evidence of that diagnosis in the 90, 180 and 270 days (*i.e.*, the look back periods) before the index date in <u>any care setting</u>. Both medical and drug coverage are required during the 3 possible look back periods, allowing for eligibility gaps of <=45 days. In addition, the tables also report number of encounters in the care setting of interest with that diagnosis in the 90, 180, 270 days <u>after</u> the index date (including the index event). Only the first incident event/index date within each year is considered.

The Prevalence and Incidence query types follow the same format. For query formats of Incidence Query Types, see the corresponding Prevalence section



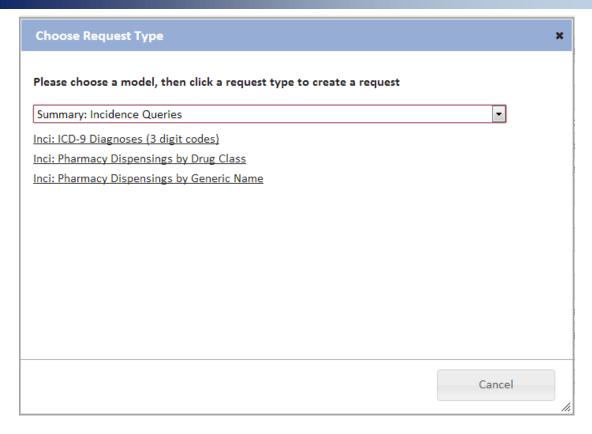


Figure 10: Request Type Dialog for Incidence Queries

6.1.3 Most Frequently Used Queries

The Most Frequent Utilization feature allows investigators to query the top XX events and members within a specified query type (drugs, diagnoses, or procedures) within the prevalence tables.

The counts are stratified by age group, sex, year, code/drug name or class, and for diagnoses and procedures, setting of visit (inpatient, outpatient, emergency department, or any).

To compose a most frequently used query, click on the "New" button in the request panel, choose "Most Frequently Used Queries", and then choose a request type.



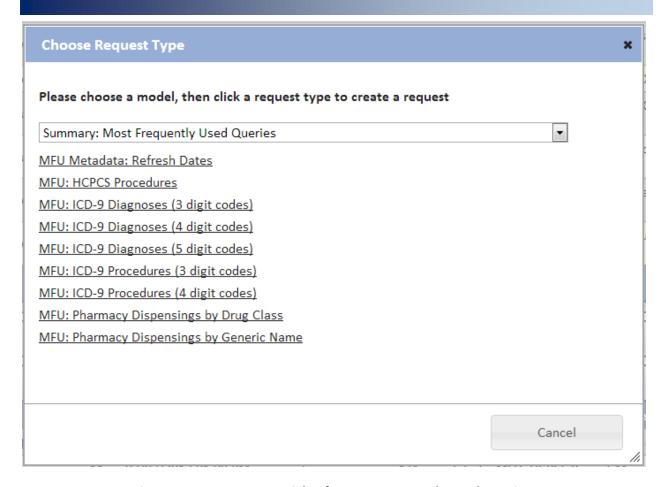


Figure 11: Request Type Dialog for Most Frequently Used Queries

This will display a request detail page used to enter the criteria for this type of request.



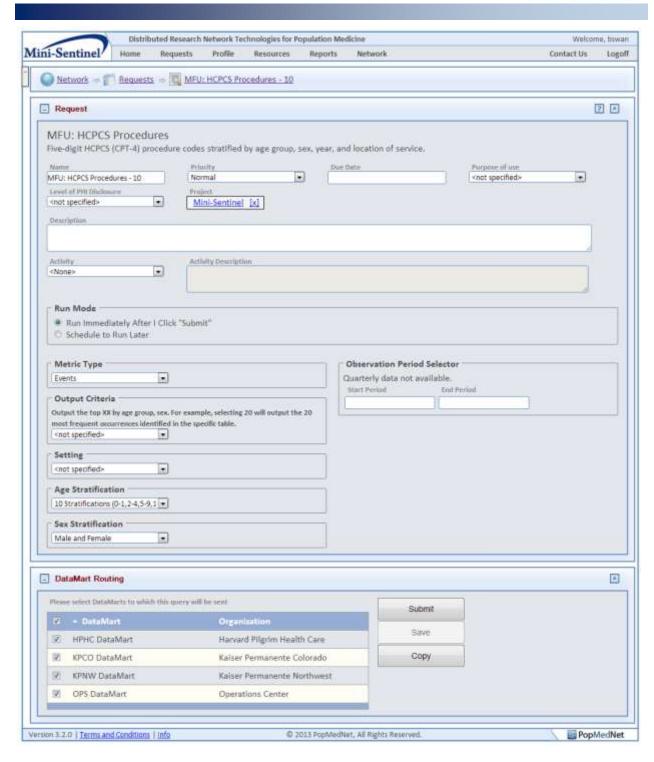


Figure 12: Most Frequently Used Query Request Composer Page

Enter the following criteria for a Most Frequently Used query:



Table 6: Most Frequently Used Query Criteria

Control	Description
Metric Type	Select from one of two metric types: • Events • Users
Output Criteria	Select the criteria ranking value to stratify the output from the list. For example, selecting 20 will output the 20 most frequent occurrences identified in the specific table
Setting	Select the care setting for the query: inpatient, outpatient (ambulatory), emergency department, or any setting.
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 a period.
DataMarts	Select the DataMarts to submit your query to. Only the DataMarts for which you have rights to route your request to are displayed.



7 Checking the Query Status

Once a request is submitted, its status is displayed in the Requests list.

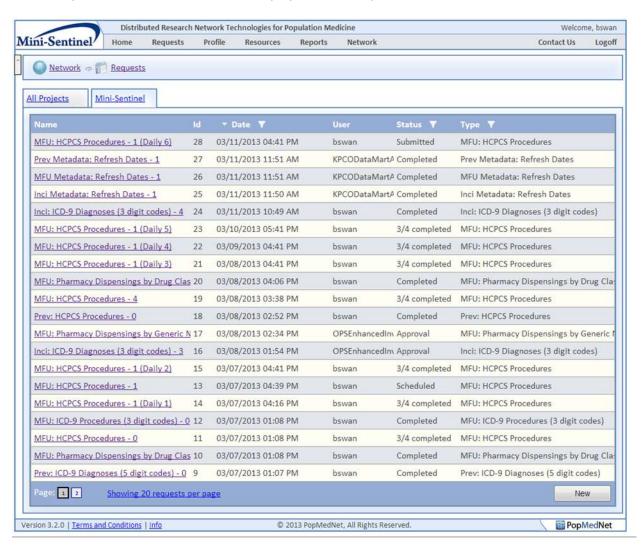


Figure 13: Request Page

You can view the detailed status of a request by clicking on the request name to navigate to the Request Status detail page.



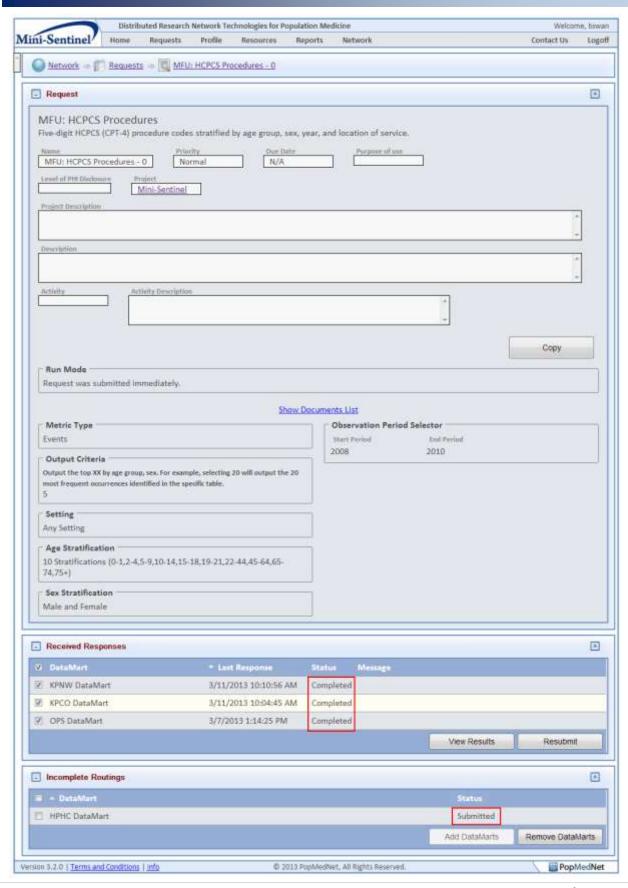




Figure 14: Statuses on Request Detail Page

This displays a list of all the DataMarts to which you submitted the request along with status for each DataMart.



8 Viewing Request Results

You can view the results of a request from the Request Detail page by selecting "View Results."



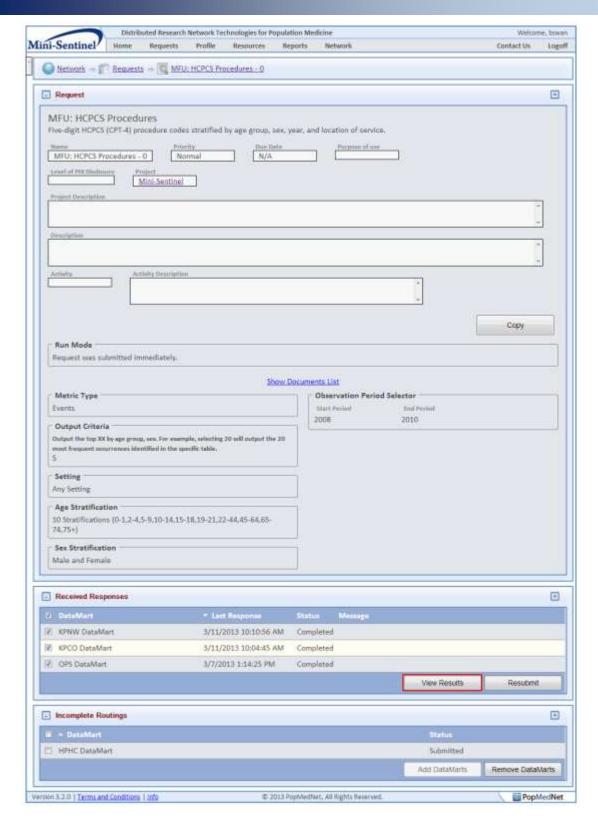


Figure 15: Request Detail Page – View Results Button



A user designated as an Enhanced Investigator will have the right to view site results individually across the organizations within the query. This role will be assigned at the discretion of a Network Administrator and in accordance with the governance of the network.

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.

Selecting "View Results" will display the response based on your query parametrs in a table.



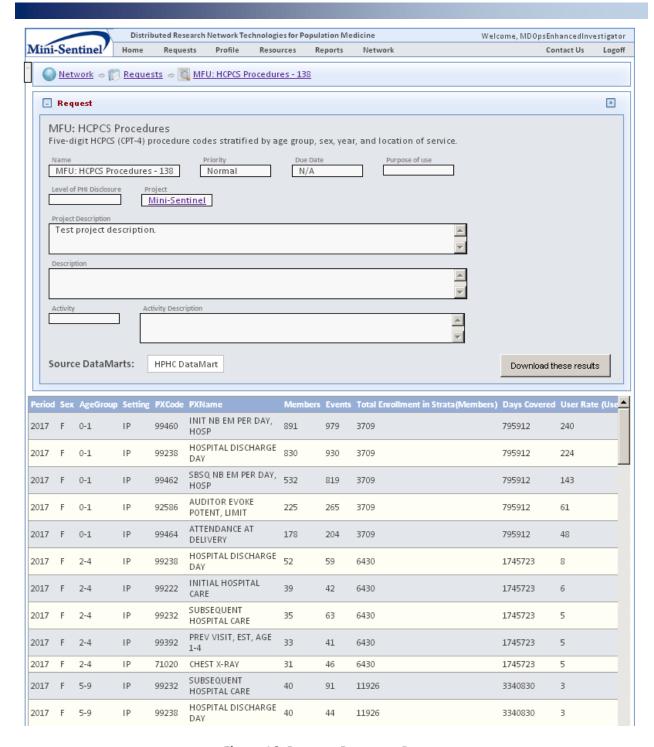


Figure 16: Request Response Page

8.1 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)
- Dispensing Rate (Dispensings per 1000 enrollees)
- Days per Dispensing
- Days per User



9 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:

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



10 Adding or Removing DataMarts from 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.



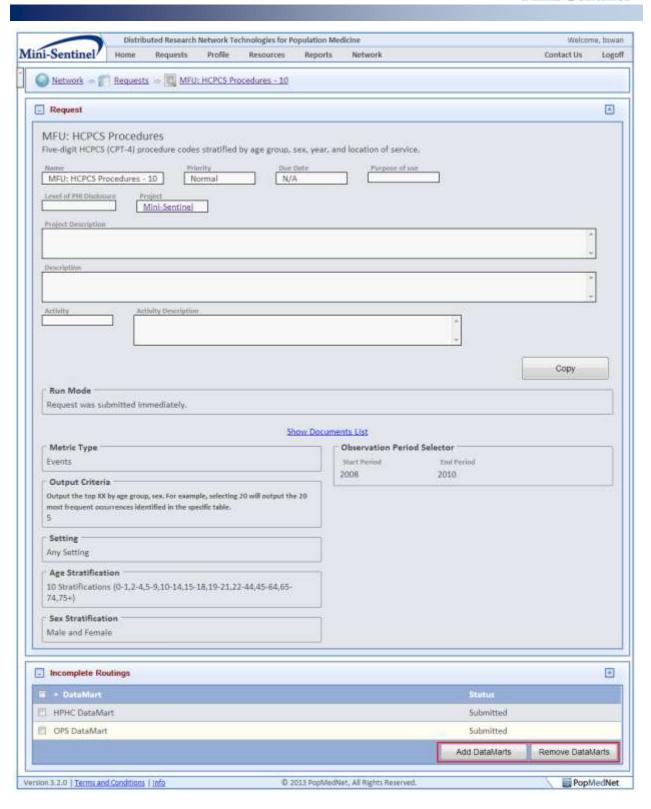


Figure 17: Request Detail Page - DataMart Routing Buttons



To add DataMart from the query, use the "Add DataMarts" button in the Incomplete Routings panel at the bottom of the request status page. This will display a list of available DataMarts you are allowed to route the query.

To Remove a DataMart from the query, first select the DataMart using the checkbox control to next to the DataMart name, then click the "Remove DataMarts" button.



11 Administering your User Profile

You must be logged in to the web portal to administer your user profile. Select "Profile" from the main menu to display your user profile. Use this page to change contact information, password, and notification settings.

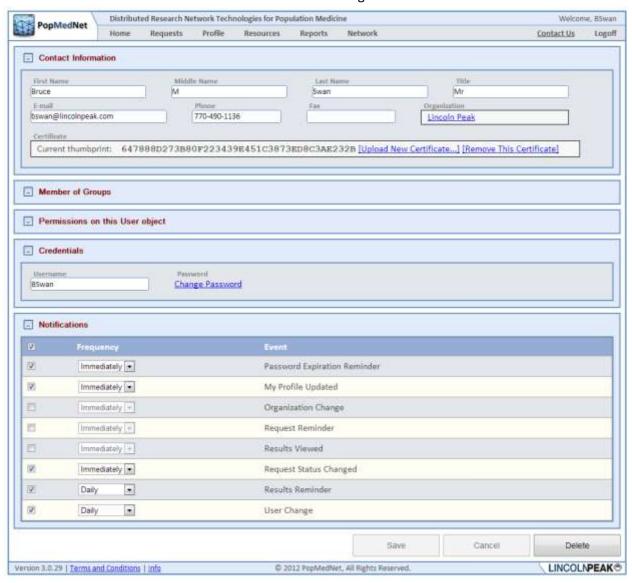


Figure 18: User Profile Page



11.1 How to Reset your Password

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

- Enter the new password in the first Password box.
- Re-enter the new password in the second Password box.
- 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.

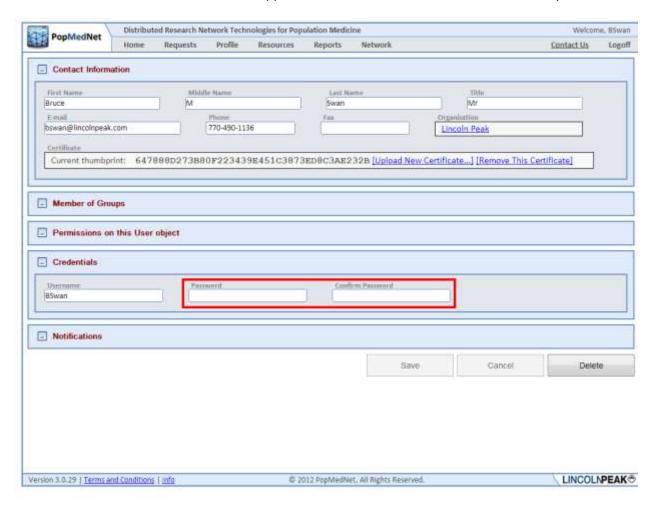


Figure 19: User Profile Page - Password Boxes

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.



11.2 Notifications

Notification options allow the user to manage events that are triggered due to actions performed by the user or related to the user's role, such as a Query Administrator. Users have the option of receiving notifications immediately when they are triggered, daily, weekly, or monthly. When choosing daily, weekly, or monthly, the notifications are batched together with other notifications on the same schedule in a single email.

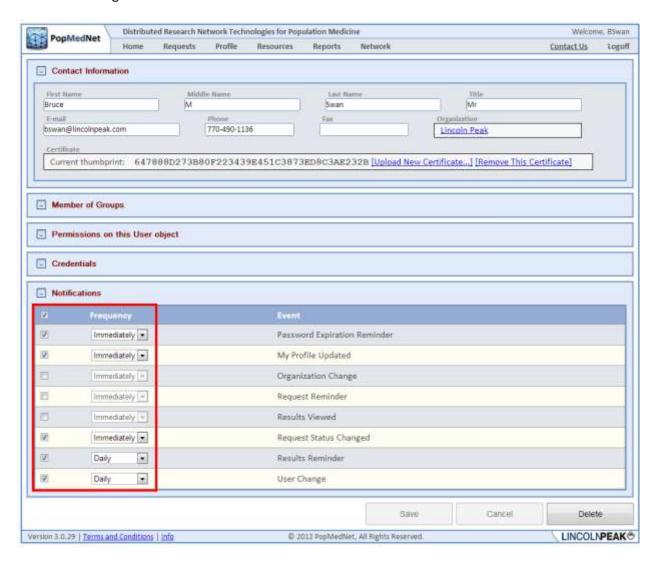


Figure 20: User Profile Page - Notification Options

Note: Once the user has chosen to receive notifications, regardless of the delivery frequency selected; the notifications are displayed in the Notifications panel on the Home page.

The notification options displayed in your profile are dependent on the roles or privileges that have been granted to you. The following is a complete list of notifications.



Table 7: Notifications

Category	Event	Description
User	Password Expiration Reminder	Notifies the user that their password is about to expire.
	My Profile Change	Notifies the user there was an update to their profile.
	User Change	Notifies administrators there was a user added, deleted, or updated.
	New User Registration Submitted	Notifies administrators a new user request has been submitted.
	Registration Change	Notifies administrators there has been a change to a user registration request.
Requests	New Request Submitted	Notifies DataMart administrators that a new request has been submitted.
	Request Status Changed	Notifies investigators and administrators that a change has been made to a request.
	Request Reminder	Reminds DataMart administrators there is a pending request that requires their attention.
	Results Reminder	Reminds administrators and investigators that results have been uploaded for their request.
	Results Viewed	Notifies administrators that a result has been viewed.
Organization	Organization Change	Notifies administrators that an organization has been added, updated, or deleted.



Category	Event	Description
Group	Group Change	Notifies administrators that an group has been added, updated, or deleted.
DataMart	New DataMart Client Version is Available	Notifies DataMart administrators that a new version of the DataMart Client application is available.
	DataMart Change	Notifies administrators that a DataMart has been added, updated, or deleted.



12 Getting Help

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

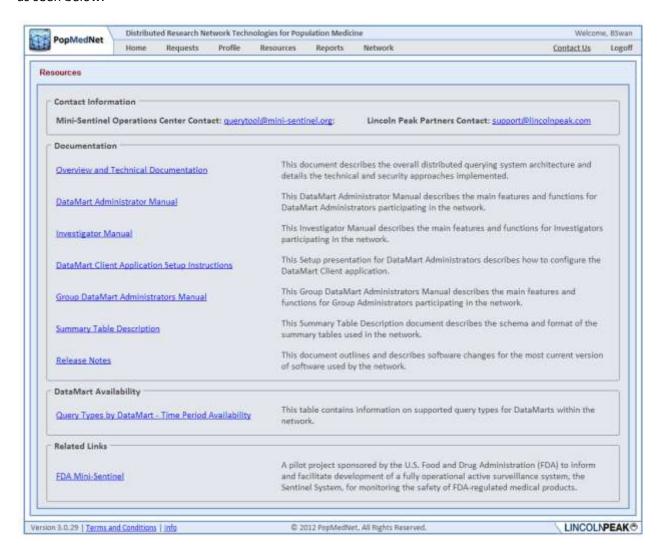


Figure 21: Resources Page

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.



13 Development and Funding Statement

The **PopMedNet™** software application was developed as part of several contracts awarded by the Agency for Healthcare Research and Quality (AHRQ) 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). Additional development was funded by AHRQ under the Scalable PArtnering Network for CER: Across Lifespan, Conditions, and Settings (SPAN) project. Additional support has been provided by The Food and Drug Administration's Mini-Sentinel project (Contract No. HHSF223200910006I) and the US Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) MDPHnet project.

The system was developed by Lincoln Peak Partners under the direction of HPHCI.



14 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. Organizations have
 one or more users and zero, one, or more DataMarts. Users are members of a single
 Organization. Groups are collections of one or more Organizations and an Organization
 may be a member of zero, one, or more Groups. Groups allow management of a
 collection of organizations by a set of administrators.
- What are my rights as a user and how can I change them?
 - Rights can be assigned to individual user accounts for to various security groups for which the user is a member by the Network Administrator or the user's Organization Administrator.
- Where can I get more information on the PopMedNet[™] application?
 - o You may contact the Operations Center for more information:

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

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



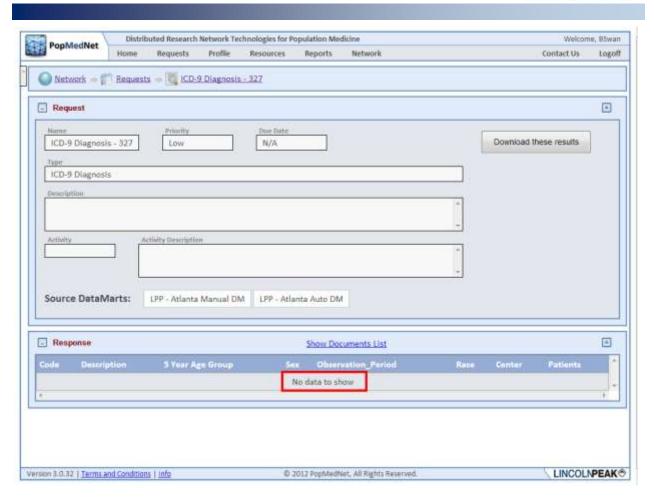


Figure 22: Request Response Page - Empty Results

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: Quick Reference for Investigators

Quick Reference: Investigator

- 1) How to Submit a Query
 - a) Log into the Portal with your credentials.
 - b) Click the New button in the Requests panel and select the Summary Query request model and then choose the type of request from the list.
 - c) Complete the request form by entering a name, brief description of the query, and selecting the relevant parameters.
 - d) Select the DataMarts (Data Partners) who you would like to send the guery.
 - e) Click Submit.

2) How to Distribute a File

- a) Log into the Portal with your credentials.
- b) Click the New button in the Requests panel and select the File Distribution request model and then choose the File Distribution request type.
- c) Complete the File Distribution form by entering a name and a brief description of the file(s) you are sending.
- d) Browse and upload your file(s) you wish to send to DataMarts.
- e) Select the DataMarts (Data Partners) who you would like to send the file(s).
- f) Click Submit button.

3) How to View Results on the Portal

- a) Log into the Portal with your credentials and go to the *Requests* list panel on the home page or click Requests from the top menu.
- b) Find and click on the request name for which you wish to see the results to navigate to the Request Status page.
- c) When all sites have responded, click *View Result*. Enhanced Investigators may view site-specific results by checking a site and clicking *View Selected Results*.
- d) Export result data to Excel/CSV or download returned files for review.



Appendix B: 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 request status is marked as "Approval" as shown in the following figure.

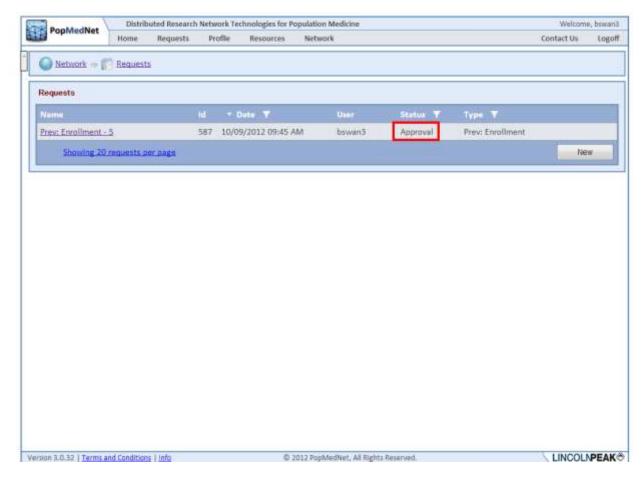


Figure 23: Request Page - Approval Request Status

Clicking on the request name navigates the user to the request status page where they see its status.



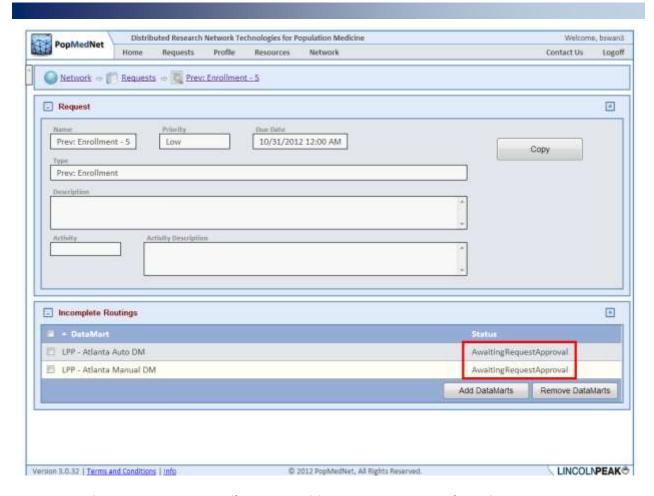


Figure 24: Request Detail Page - Awaiting Response Approval Routing Statuses

The query administrator receives an email notification about a query that is "Awaiting Request Approval". When the Query Administrator then logs in with their login credentials, they will see the new request waiting for approval in their request list.



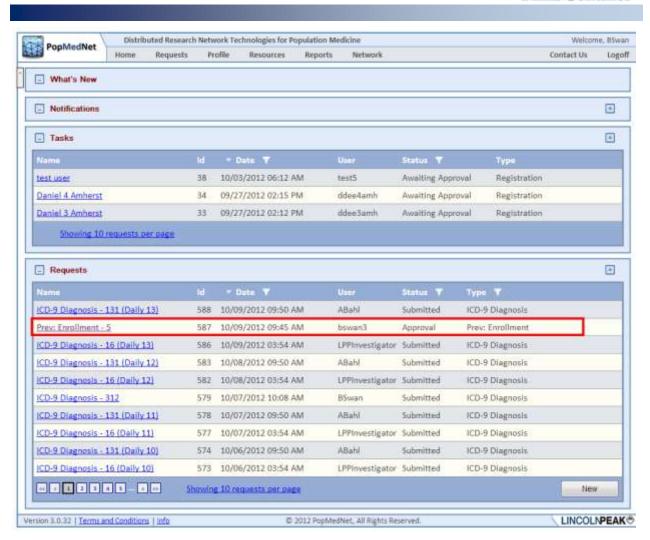


Figure 25: Request Page - Request Awaiting Approval

Clicking request name will navigate the query administrator to the request status page where they can review, approve, or reject the query along with comments.



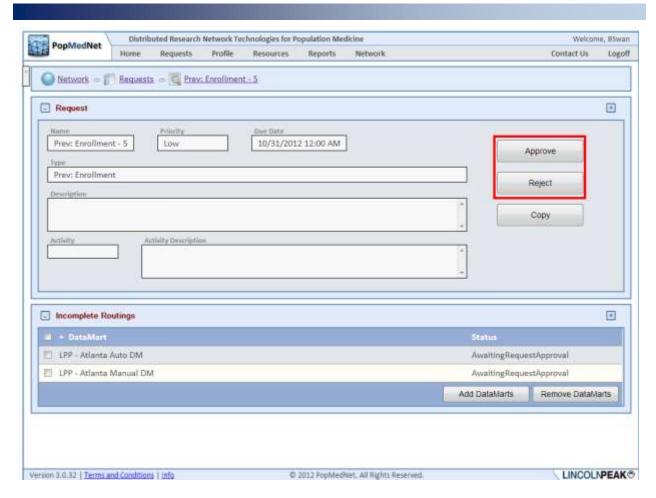


Figure 26: Request Detail Page - Approve and Reject Options

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.