

Mini-Sentinel Distributed Query Tool

Group DataMart Administrator Manual

Based on release 2.2

May 10, 2011

CONTACTS:

Jeffrey Brown, PhD

Harvard Pilgrim Health Care Institute

Jeff_brown@hphc.org

The **PopMedNet**[™] 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 web-based 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 Distributed Query Tool Group DataMart Administrator Manual describes the main features and functions for Group DataMart Administrators responsible for query response through the Mini-Sentinel Distributed Query Tool. Group DataMart Administrators differ from DataMart Administrators in that the Group DataMart Administrators are responsible for query response for a group of Mini-Sentinel partners. Group DataMart Administrators will interact with the Mini-Sentinel network through a secure web-based Portal and through the desktop DataMart Client as described below. This document is based on the FDA Mini-Sentinel Network's implementation of the PopMedNet™ system, including the query types available for Mini-Sentinel.

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 during 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 an Administrator's desktop. 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 Distributed Query Tool** Group DataMart Administrators who want to:

- View group results
- Approve group results

Related Documents

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

Mini-Sentinel Distributed Query Tool Investigator Manual

The *Investigator Manual* describes the tasks and activities required for Mini-Sentinel Investigators to:

- Submit a query to the available DataMarts
- Monitor status of a query
- Review results of a query

The Investigator Manual also describes the types of queries and the criteria required for submission of each query type.

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 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 System 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* described 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

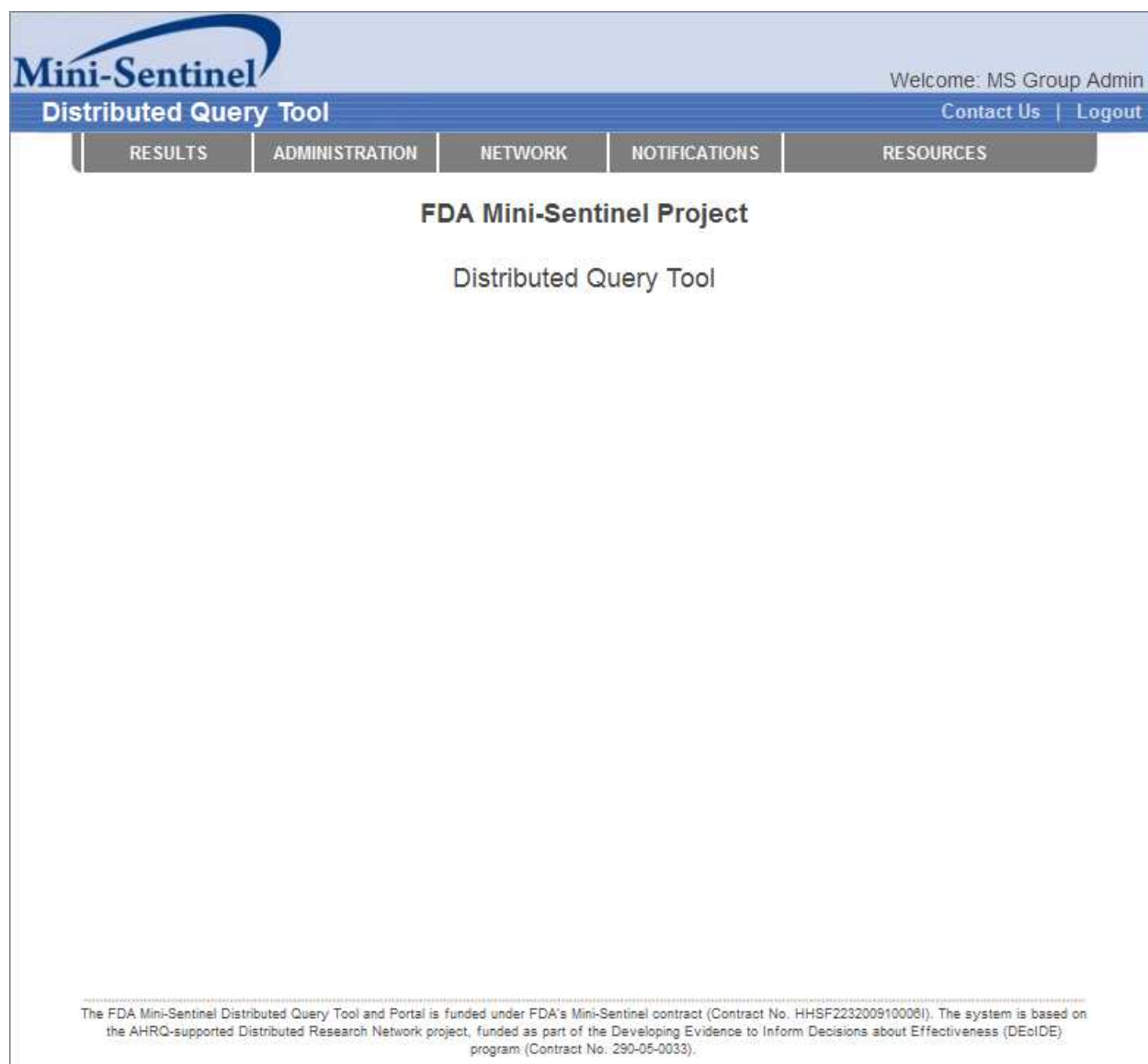
Before you can login to your Mini-Sentinel Distributed Query Tool network Website Portal, you need a username and password assigned by your Network Administrators at the Mini-Sentinel Operations Center. Once you have your Login Credentials, follow the steps below.



The screenshot shows the login interface for the FDA Mini-Sentinel Project Distributed Query Tool. At the top, there is a blue header with the Mini-Sentinel logo on the left and a 'Contact Us' link on the right. Below the header, the page title 'FDA Mini-Sentinel Project' is centered, followed by 'Distributed Query Tool' and 'Version: 2.2.1'. A section of instructions reads: 'INSTRUCTIONS: Please complete the form below and read the Terms and Conditions before using the Query Tool.' The login form includes a 'Username:' label with a text input field, a 'Password:' label with a password input field, and a blue link for 'Forgot Password?'. Below the password field is a checkbox labeled 'I agree to the Terms and Conditions of use.' At the bottom of the form is a green 'Login' button.

1. Navigate to the Mini-Sentinel custom website login page:
[Secure URL distributed by Mini-Sentinel Operations Center].
2. Enter your assigned 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. Check the check box to agree to the Terms and Conditions of use (Initial Login only)
5. Click the Login button to enter the Mini-Sentinel website portal.

Upon logging into the query tool portal, you will be directed to this screen. Unlike other users, Group DataMart Administrators do not have access to the Query tab because they do not have the right to submit queries.



4 Viewing and Releasing Results

4.1 Checking the Query Status

You must be logged in to view query status. You can see the statuses for all queries submitted to your group. You may choose to receive notifications when results are uploaded and ready for approval. 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 below. This displays a list of all the DataMarts that the query was sent within your group.

The screenshot shows the 'Query Status' page of the Mini-Sentinel Distributed Query Tool. The page has a header with the Mini-Sentinel logo, 'Welcome: MS Group Admin', and links for 'Contact Us' and 'Logout'. Below the header is a navigation bar with tabs: RESULTS, ADMINISTRATION, NETWORK, NOTIFICATIONS, and RESOURCES. The 'RESULTS' tab is selected. The main content area is titled 'Query Status' and includes a sub-header: 'Click "View Details" to see query status by DataMart. You may sort queries by clicking on column titles and filter queries by type using the drop down menu.' Below this, there is a 'Select Range:' dropdown set to '30 Days' and a 'Filter' button. To the right is a dropdown for 'All query types'. A table lists three queries:

Name	ID	Submitted On	Submitted By	Status	Type	
3 Dig ICD9 Diagnosis	713	5/9/2011 9:28:08 AM	MS Investigator	2/5 Completed	Prev: ICD-9 Diagnoses (3 digit codes)	View Details
Refresh date request	712	5/9/2011 9:21:40 AM	HPHC-System Admin 2	Completed	Refresh Dates	View Details
Refresh date request	711	5/6/2011 1:51:36 PM	Test Org 1-DM	Completed	Refresh Dates	View Details

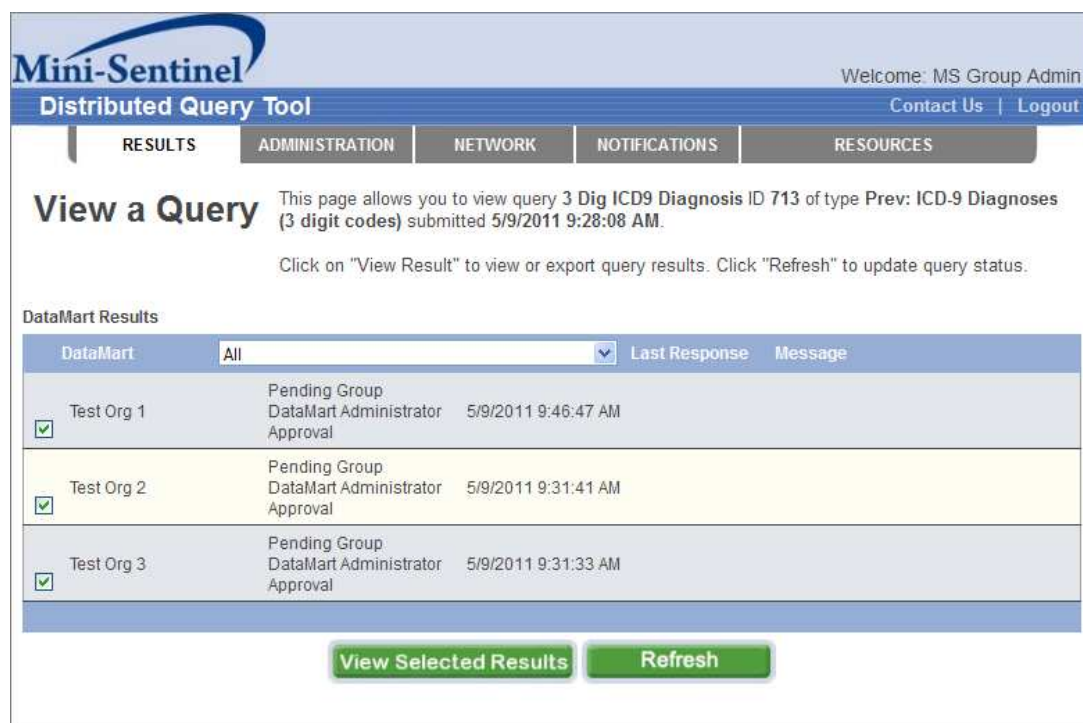
When a query is newly submitted, the DataMarts will show up with a status of Submitted.

The screenshot shows the 'View a Query' page of the Mini-Sentinel Distributed Query Tool. The page has the same header and navigation bar as the previous screenshot. The 'RESULTS' tab is selected. The main content area is titled 'View a Query' and includes a sub-header: 'This page allows you to view query 3 Dig ICD9 Diagnosis ID 713 of type Prev: ICD-9 Diagnoses (3 digit codes) submitted 5/9/2011 9:28:08 AM.' Below this, there is a sub-header: 'Click on "View Result" to view or export query results. Click "Refresh" to update query status.' Below the sub-header is a section titled 'DataMart Results' with a dropdown for 'DataMart' set to 'All' and a 'Last Response' column. A table lists three DataMarts:

DataMart	Last Response	Message
<input type="checkbox"/> Test Org 1	Submitted	
<input type="checkbox"/> Test Org 2	Submitted	
<input type="checkbox"/> Test Org 3	Submitted	

Below the table is a green 'Refresh' button.

Once results have been uploaded by the DataMart Administrator, you will receive an email notification (see Section 5 for Email Notification Options) and the status shifts to Pending Group DataMart Administrator Approval



Check all of the sites that you would like to view results for and click View Selected Results.

Note: If you do not select a site, it will not be included in the release of results to the query submitter. You can still release the results at a later date, however, if you prefer to group the results, the late site will not be included in the previous grouping.

4.2 Approving Results

For all sites selected, the results will be stacked based on its DataMart ID. You can see what sites are included in this view by the Results From list.

Mini-Sentinel
Distributed Query Tool

Welcome: MS Group Admin
Contact Us | Logout

RESULTS ADMINISTRATION NETWORK NOTIFICATIONS RESOURCES

View Results

This page displays the results of your query.

Query Name: 3 Dig ICD9 Diagnosis
Submitted: 5/9/2011 9:28:08 AM

Query Text: `Select SummaryData.*, EnrollmentData.EnrollmentMembers as [Total Enrollment in Strata(Members)],round(SummaryData.Members / EnrollmentData.EnrollmentMembers * 1000, 1) as [Prevalence Rate (Users per 1000 enrollees)],round(SummaryData.Events / EnrollmentData.EnrollmentMembers * 1000, 1) as [Event Rate (Events per 1000 enrollees)],`

Results From: Test Org 3
Test Org 2
Test Org 1

Export to:
Enter a Prefix for Group Name:

Member ID	Age	Sex	Year	Events	Diagnosis	AV	Members	Rate	Rate	Rate	Rate	
102	65+	All	2016	250	DIABETES MELLITUS	AV	4061	2	1270	1.6	3197.6	2030.5
102	65+	All	2017	250	DIABETES MELLITUS	AV	6105	7	1274	5.5	4792	872.1
102	65+	All	2018	250	DIABETES MELLITUS	AV	3281	4	1285	3.1	2553.3	820.2
103	0-21	All	2016	250	DIABETES MELLITUS	AV	144	13	6375	2	22.6	11.1
103	0-21	All	2017	250	DIABETES MELLITUS	AV	205	20	6175	3.2	33.2	10.2
103	0-21	All	2018	250	DIABETES MELLITUS	AV	179	14	6114	2.3	29.3	12.8

Results Options

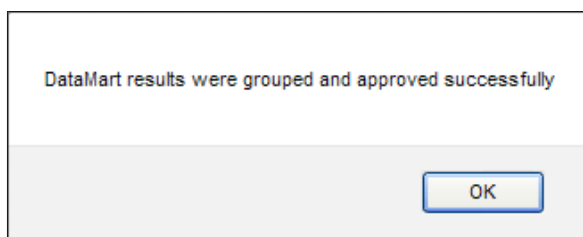
Export Export the results in CSV or Excel format. The file name for your exported data is made up of the query name up to the first space in the name.
For example: if your query name is “NamingScheme_SummaryQuery for Query Tool,” the name of the file will be “NamingScheme_SummaryQuery.xls.”
You may export results at any time.

Approve Results This button releases the results to the query submitter as individual site results. If the submitter is an Enhanced Investigator (MSOC and special FDA users), that user will be able to see the separate results for Test Org 1, 2, and 3.

Individual DataMart results approved successfully

**Group &
Approve
Result**

This button aggregates any of the results that are currently being viewed (if a site was not checked on the View a Query screen, it will not be included in the grouped results). By entering a prefix for the group name, you can denote what results are submitted. For example, by typing 'All Group' the results will appear as 'All Group [Group DataMart Administrator's Organization]'. If you do not include a prefix, the site will appear as the Group DataMart Administrator's organization name plus the number of times the results are grouped- for this query it would be Test Org 1 1, since the Group DataMart Administrator is from Test Org 1 and it is the first grouping of sites' data. If there were more organizations in the group that were aggregated later, they would show up as Test Org 1 2. Grouped results will also receive a new DataMart ID.



Once grouped, the results cannot be disaggregated, even if a user is an Enhanced Investigator.

Approve Results: Shown below is how individual site results appear for the query submitter.

Mini-Sentinel
Distributed Query Tool

Welcome: MS Investigator
Contact Us | Logout

View a Query This page allows you to view query **Drug class query ID 714** of type **Prev: Pharmacy Dispensings by Drug Class** submitted **5/9/2011 10:04:22 AM**.
Click on "View Result" to view or export query results. Click "Refresh" to update query status.

DataMart Results

DataMart	All	Last Response	Message
<input type="checkbox"/> LPeak-auto1	Completed		
<input type="checkbox"/> LPeak-auto2	Completed		
<input type="checkbox"/> Test Org 1	Completed	5/9/2011 10:16:33 AM	
<input type="checkbox"/> Test Org 2	Completed	5/9/2011 10:16:34 AM	
<input type="checkbox"/> Test Org 3	Completed	5/9/2011 10:48:04 AM	

Add View Selected Results View Result Refresh

Group & Approve Result: Shown below is how the grouped results appear for the query submitter.

Mini-Sentinel
Distributed Query Tool

Welcome: MS Investigator
Contact Us | Logout

View a Query This page allows you to view query 3 Dig ICD9 Diagnosis ID 713 of type Prev: ICD-9 Diagnoses (3 digit codes) submitted 5/9/2011 9:28:08 AM.

Click on "View Result" to view or export query results. Click "Refresh" to update query status.

DataMart Results

DataMart	All	Last Response	Message
<input type="checkbox"/> LPeak-auto1	Completed		
<input type="checkbox"/> LPeak-auto2	Completed		
<input type="checkbox"/> All Group_Test Org 1 1	Completed	5/9/2011 9:50:11 AM	

Add View Result Refresh

4.3 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

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.

Mini-Sentinel
Distributed Query Tool

Welcome: MS Investigator
Contact Us | Logout

QUERIES RESULTS ADMINISTRATION NETWORK **NOTIFICATIONS** RESOURCES

Notification Option

This page allows you to choose Notification options.

Notification Options	Email	Description
Investigator		
Query Status Change	<input type="checkbox"/>	"Query Status Change" email notifications are sent to the person that submitted a query. These emails are sent when the "status" of processing that query has changed. Currently, there are 2 types of status changes that will trigger sending an email (Hold and Reject). Note: If you'd like to be notified when the results of your query have been uploaded, please select the notification option entitled "New Results" below.
New Results	<input type="checkbox"/>	"New Results" email notifications are sent to "query submitters" to alert them when the results of their queries have been uploaded by Data Mart Administrators (i.e., those data marts that don't process queries automatically).
Query Submitter Reminder	<input type="checkbox"/>	Query Submitter Reminder" email notifications are sent to "query submitters" to alert them when one or more Data Marts have not uploaded results for the query submitted. The submitter can choose the frequency in which they want to receive the reminders from the available options ("Everyday", "Every 2 days"...). Note: The submitter will be delivered one reminder per query submitted based on the selected frequency.

Save **Cancel**

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 uploaded results to the portal that are ready for your approval. |
| Query Submitter Reminder | Notifies you when one or more DataMarts have not uploaded results for the 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.

Mini-Sentinel
Distributed Query Tool

Welcome: MS Investigator
Contact Us | Logout

QUERIES RESULTS **ADMINISTRATION** NETWORK NOTIFICATIONS RESOURCES

User Administration

This page allows you to administer your user profile and change your password.

User Id: 136

Username: MS Investigator

Firstname:

Lastname:

Password:
(blank to leave unchanged)

Re-enter Password:

Title:

Email:

Role:

Organization:

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.

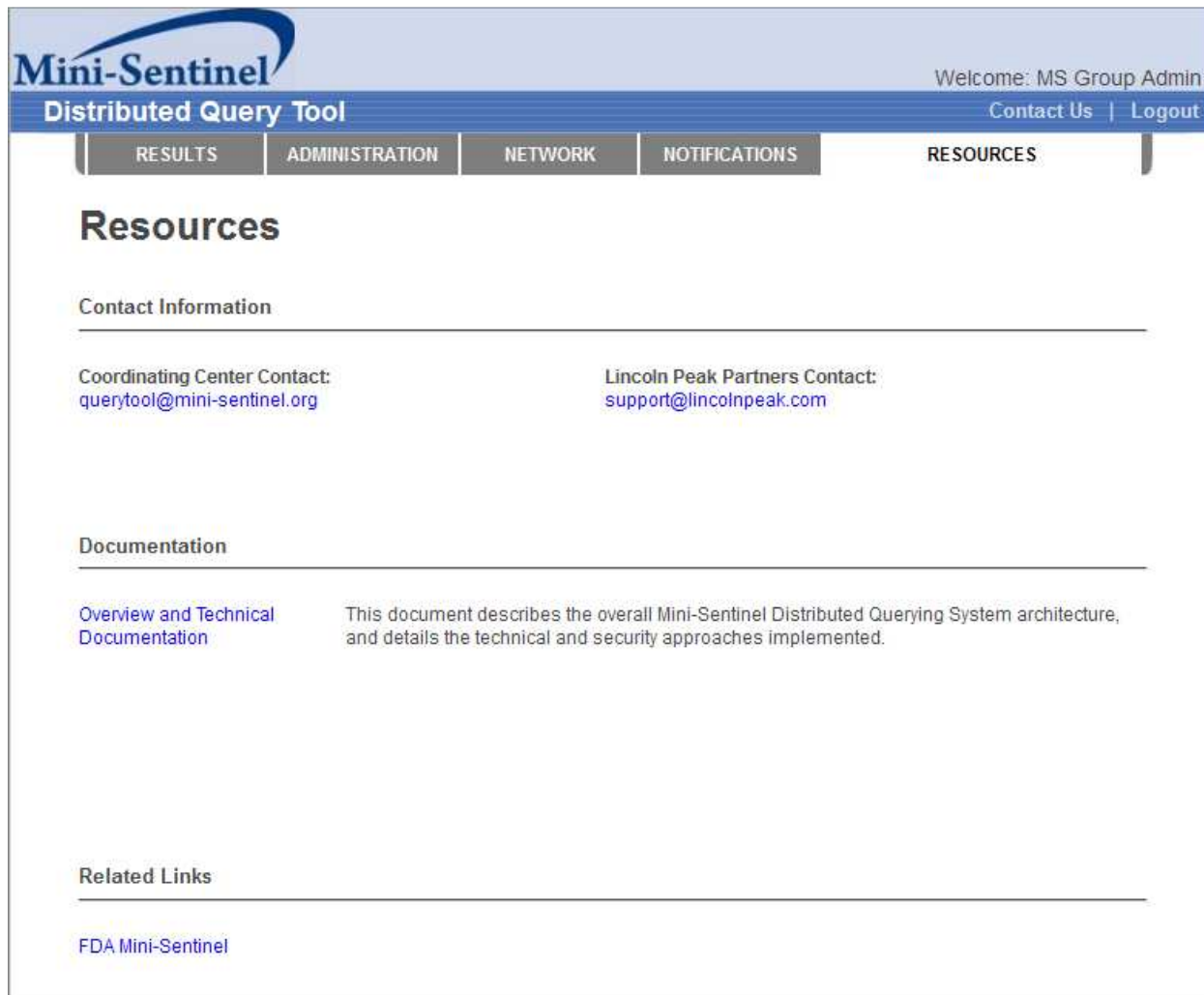
The screenshot shows the 'User Administration' page of the Mini-Sentinel Distributed Query Tool. The page has a blue header with the Mini-Sentinel logo and the text 'Distributed Query Tool'. On the right side of the header, it says 'Welcome: MS Investigator' and 'Contact Us | Logout'. Below the header is a navigation bar with tabs: 'QUERIES', 'RESULTS', 'ADMINISTRATION' (which is selected), 'NETWORK', 'NOTIFICATIONS', and 'RESOURCES'. The main content area is titled 'User Administration' and includes a sub-header: 'This page allows you to administer your user profile and change your password.' The form contains the following fields and options:

- User Id: 136
- Username: MS Investigator
- Firstname: [text input]
- Lastname: [text input]
- Password: [password input] (blank to leave unchanged) Very poor
- 4 more characters, 1 more numbers, 1 more upper case characters, 1 symbol characters
- Re-enter Password: [text input]
- Title: [text input]
- Email: [text input]
- Role: Investigator (dropdown menu)
- Organization: Harvard Pilgrim Health Care Institute (dropdown menu)
- Save button
- Cancel button

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.



The screenshot displays the 'Resources' section of the Mini-Sentinel Distributed Query Tool interface. At the top, the Mini-Sentinel logo and 'Distributed Query Tool' title are visible. A navigation bar includes tabs for RESULTS, ADMINISTRATION, NETWORK, NOTIFICATIONS, and RESOURCES (which is active). The 'Resources' section is titled 'Resources' and contains three sub-sections: 'Contact Information', 'Documentation', and 'Related Links'. Under 'Contact Information', there are two contact points: 'Coordinating Center Contact: querytool@mini-sentinel.org' and 'Lincoln Peak Partners Contact: support@lincolnpeak.com'. Under 'Documentation', there is a link 'Overview and Technical Documentation' and a description: 'This document describes the overall Mini-Sentinel Distributed Querying System architecture, and details the technical and security approaches implemented.' Under 'Related Links', there is a link 'FDA Mini-Sentinel'.

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