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.

Contents

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

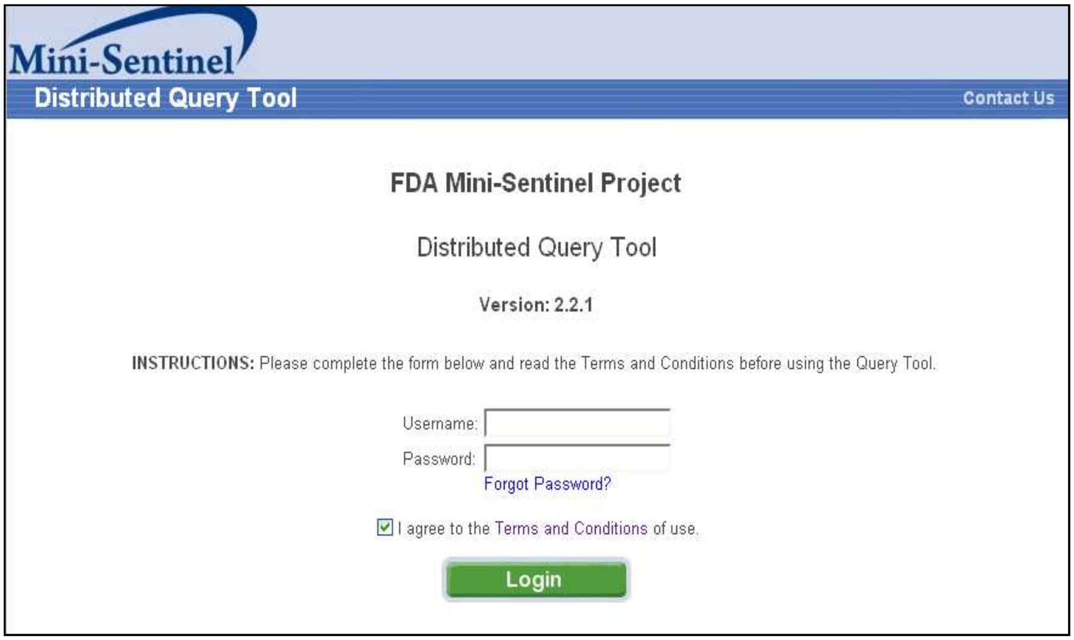
Mini-Sentinel Distributed Query Tool Overview and Technical Documentation

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.

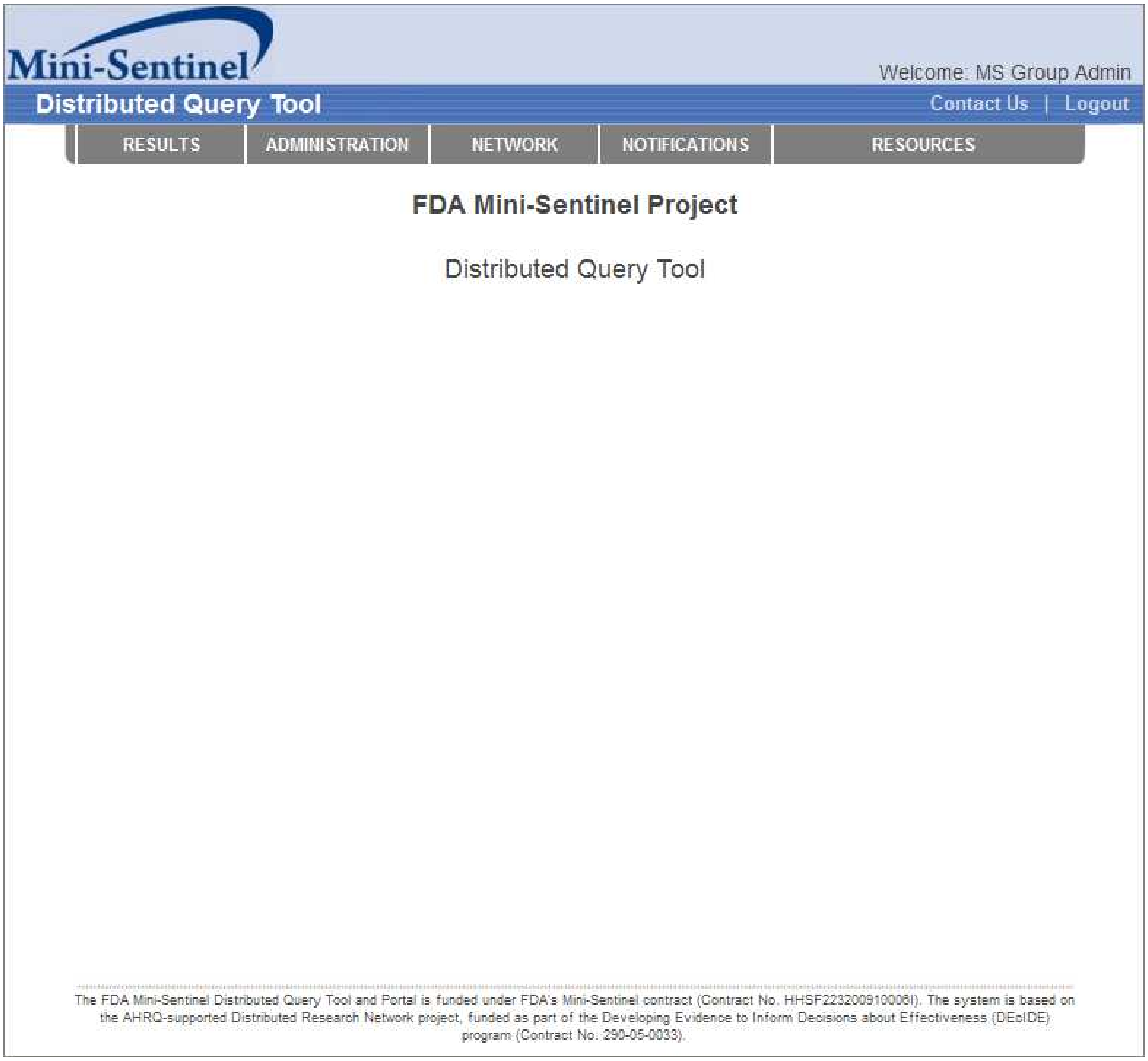


1. Navigate to the Mini-Sentinel custom website login page:

[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

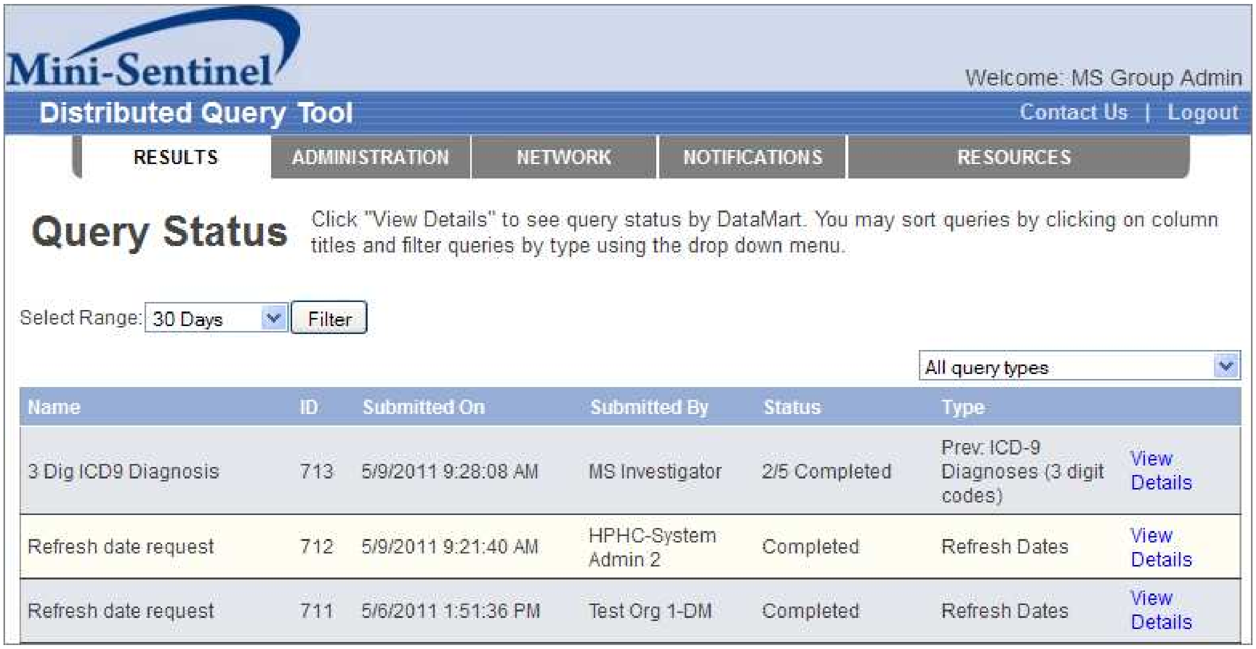
You must be logged in to view query status. You can see the statuses for all queries submitted to your group. You may choose to receive notifications when results are uploaded and ready for approval. Use these steps to view the status of a query:

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.

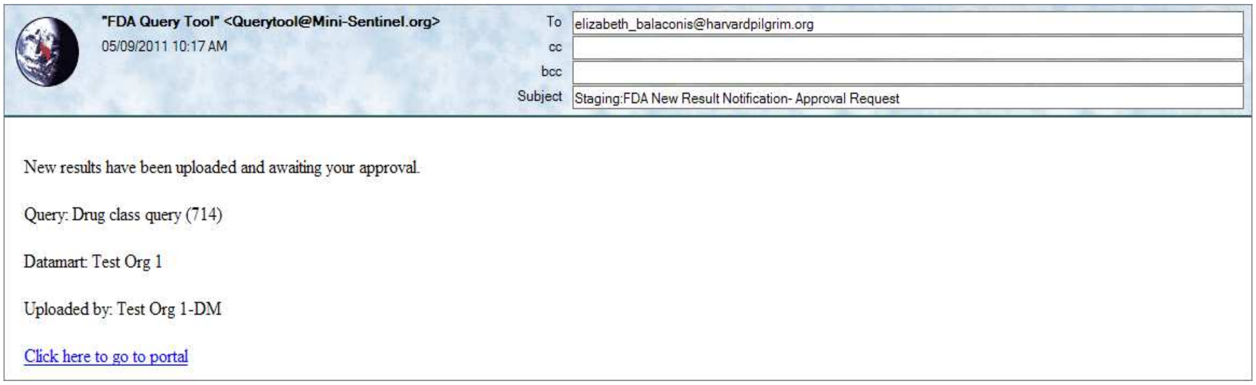
3. To see status for a specific query type, choose the query type from the drop down menu on the right. To filter the query results by date, select the range in the top left and click Filter.

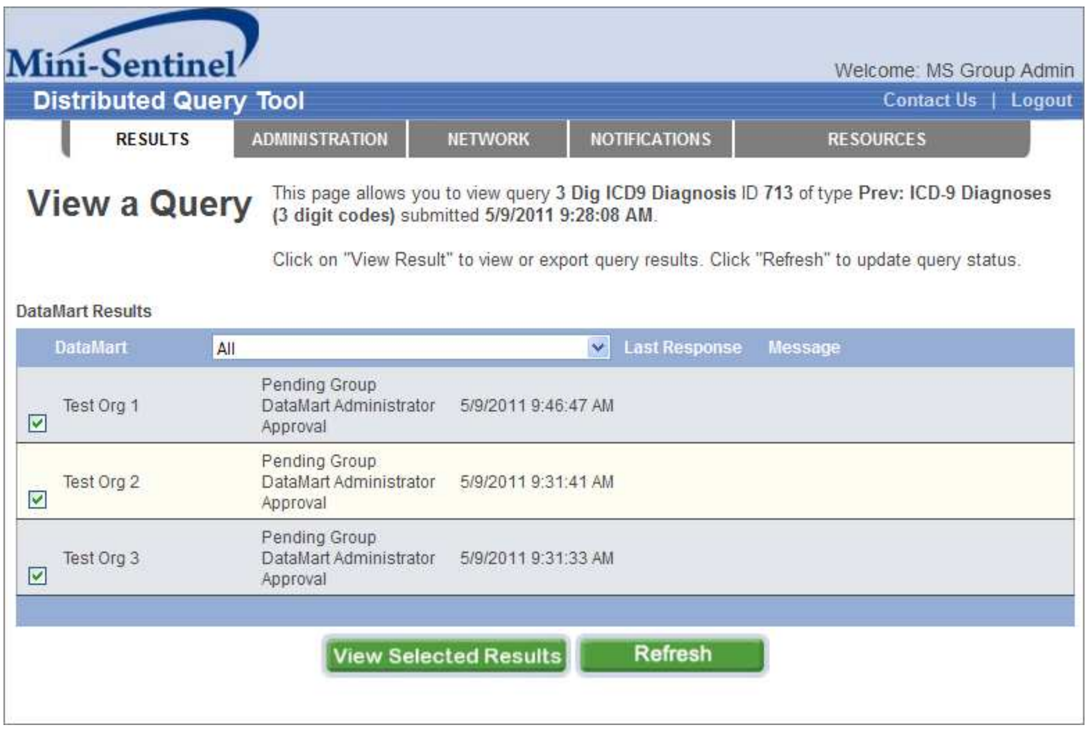
4. Click on View Details to see query status by DataMart as shown on the View a Query screen below. This displays a list of all the DataMarts that the query was sent within your group.



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

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



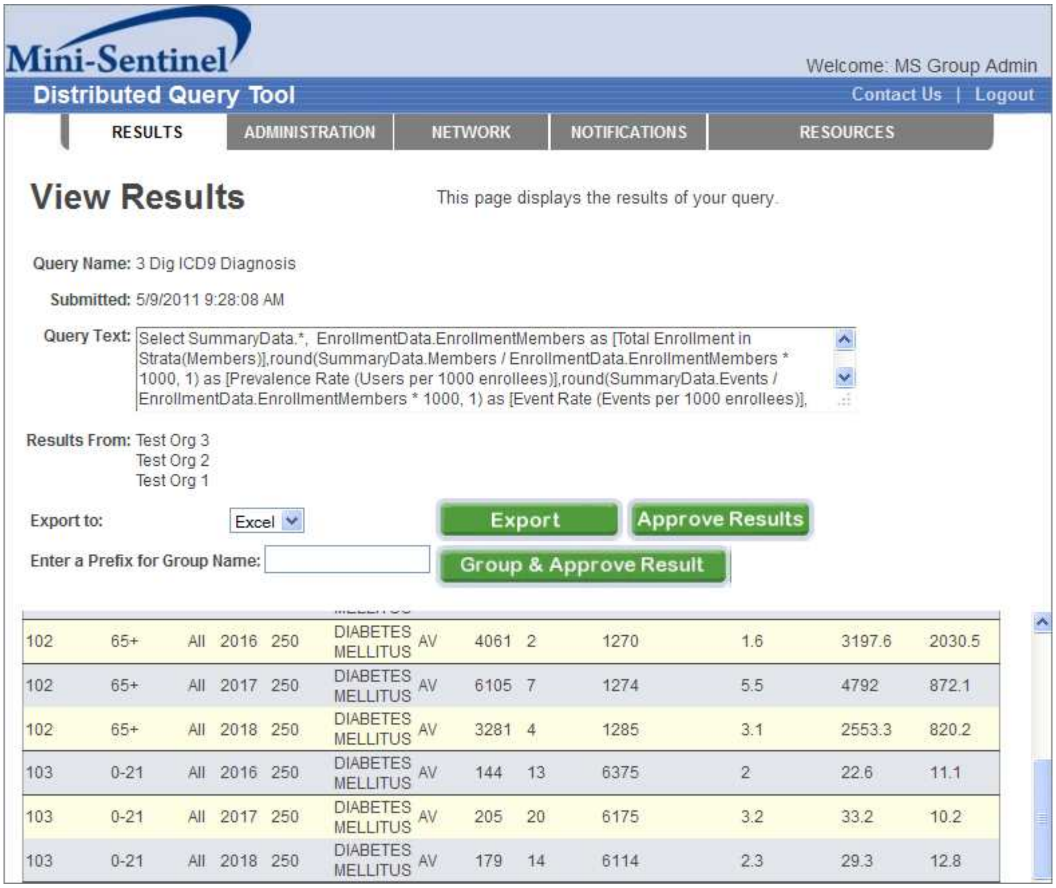


Check all of the sites that you would like to view results for and click View Selected Results.

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

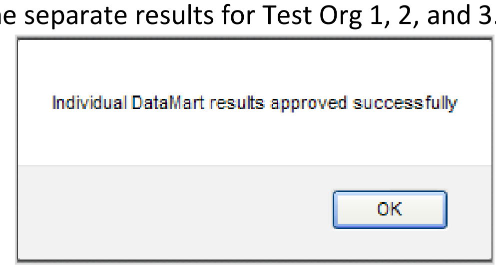
For all sites selected, the results will be stacked based on its DataMart ID. You can see what sites are included in this view by the Results From list.



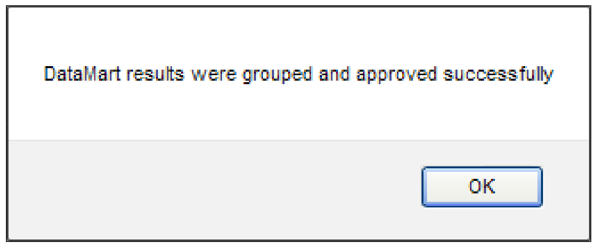
Results Options

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.

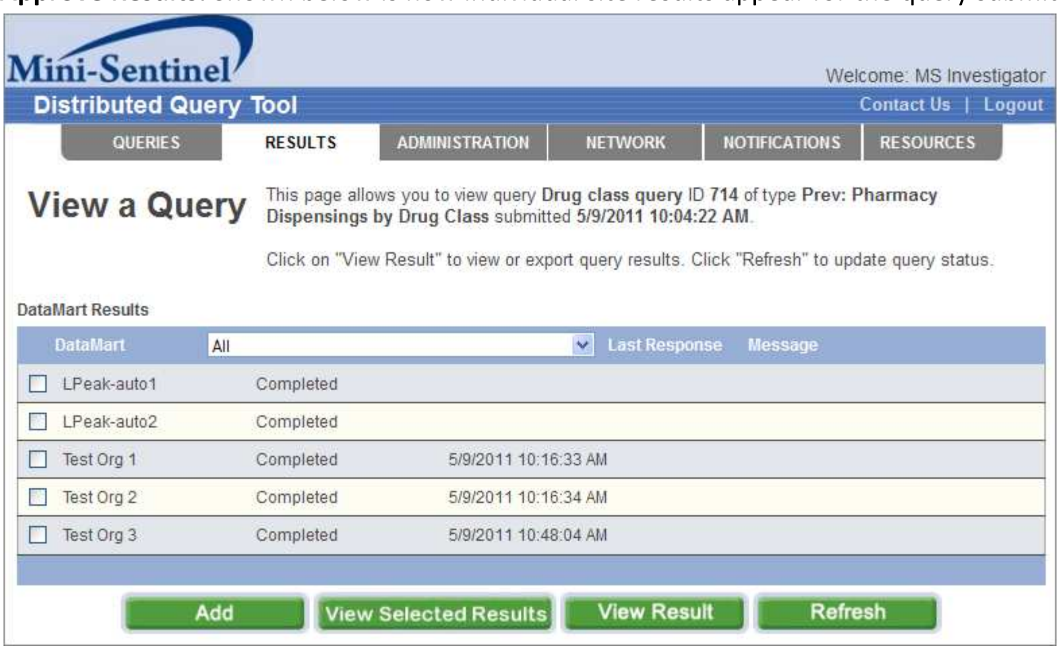


Group & Approve Result	This button aggregates any of the results that are currently being viewed (if a site was not checked on the View a Query screen, it will not be included in the grouped results). By entering a prefix for the group name, you can denote what results are submitted. For example, by 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.



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

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

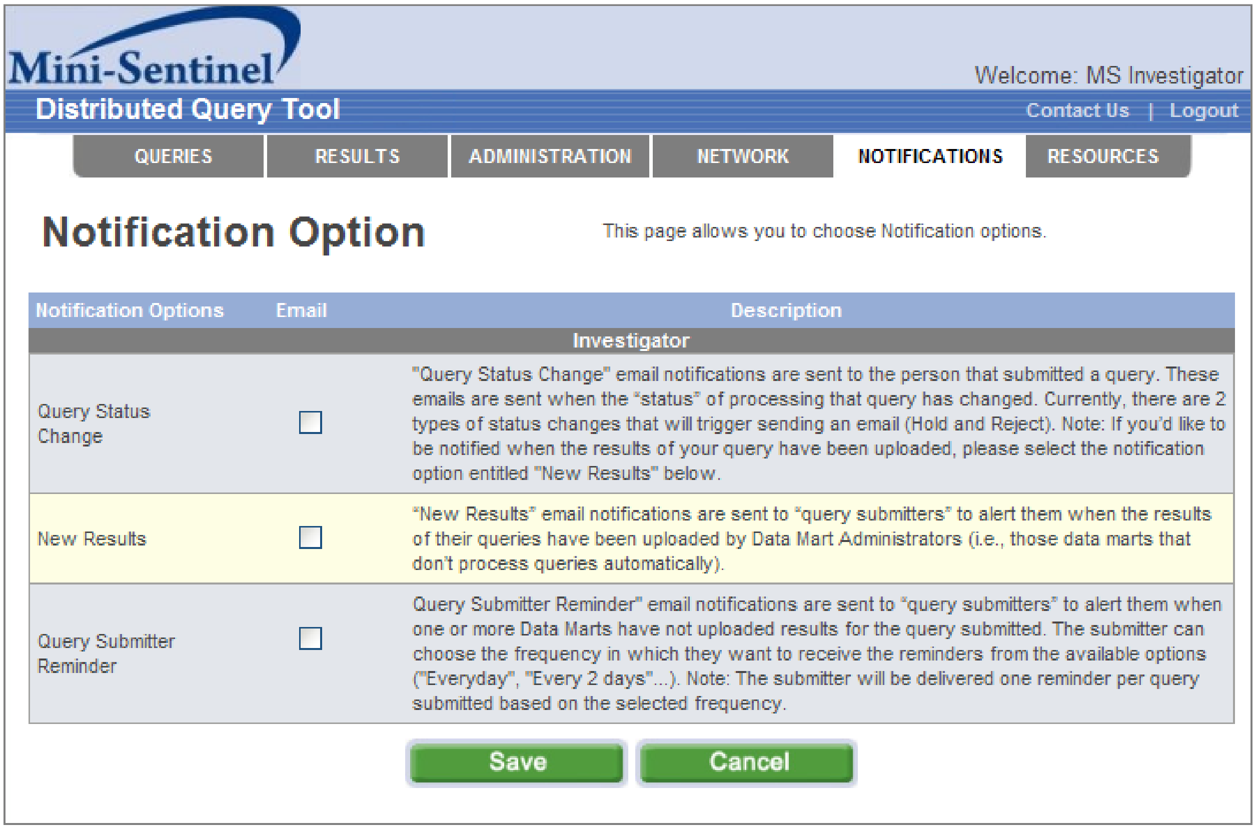
- Total Enrollment in Strata (Members)-Total count includes members with both medical and drug coverage plus those with medical coverage only.
- Prevalence Rates (Users per 1000 enrollees)
- Event Rate (Events per 1000 enrollees)
- Events per Member

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.

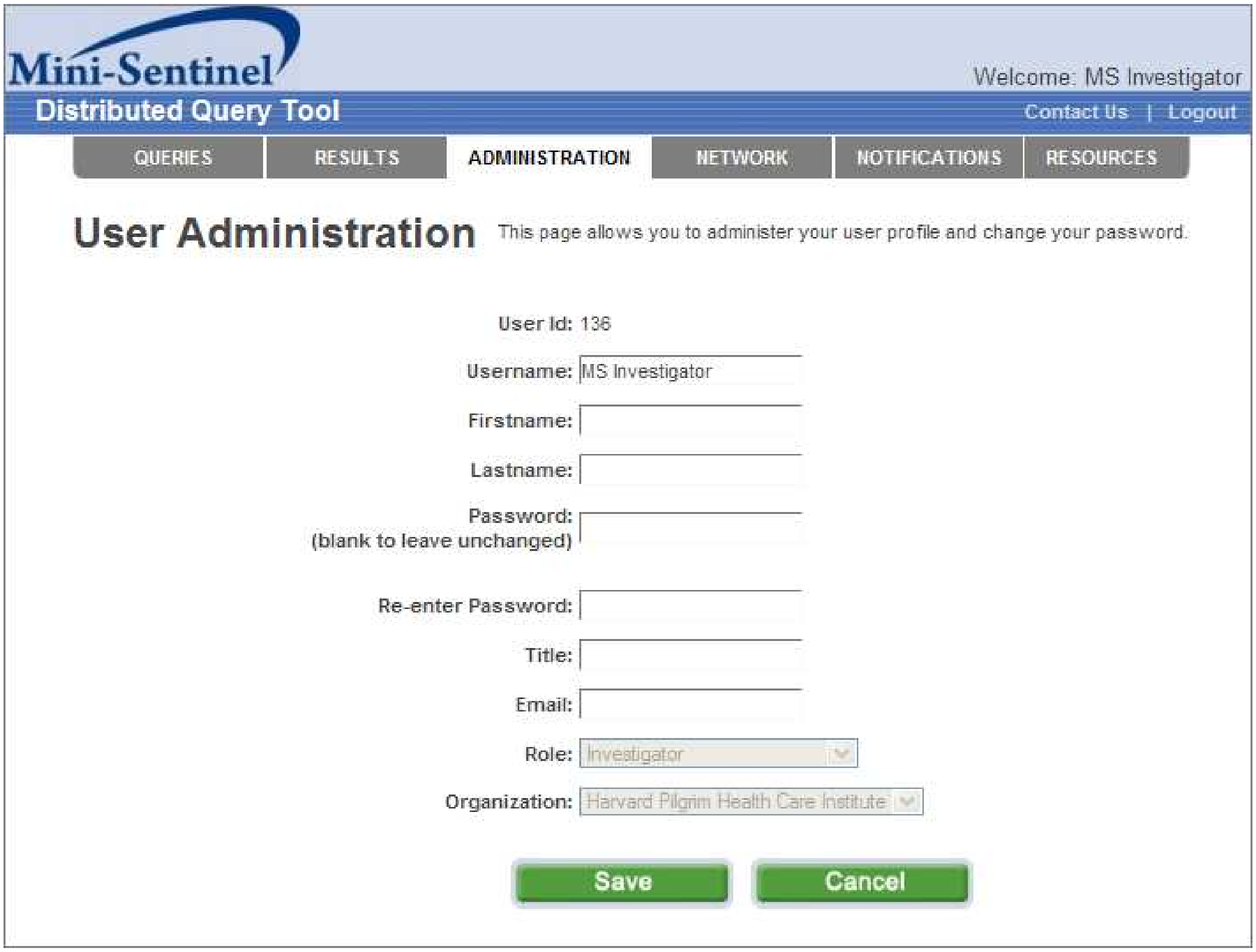


The notification options for the Investigator role are:

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.



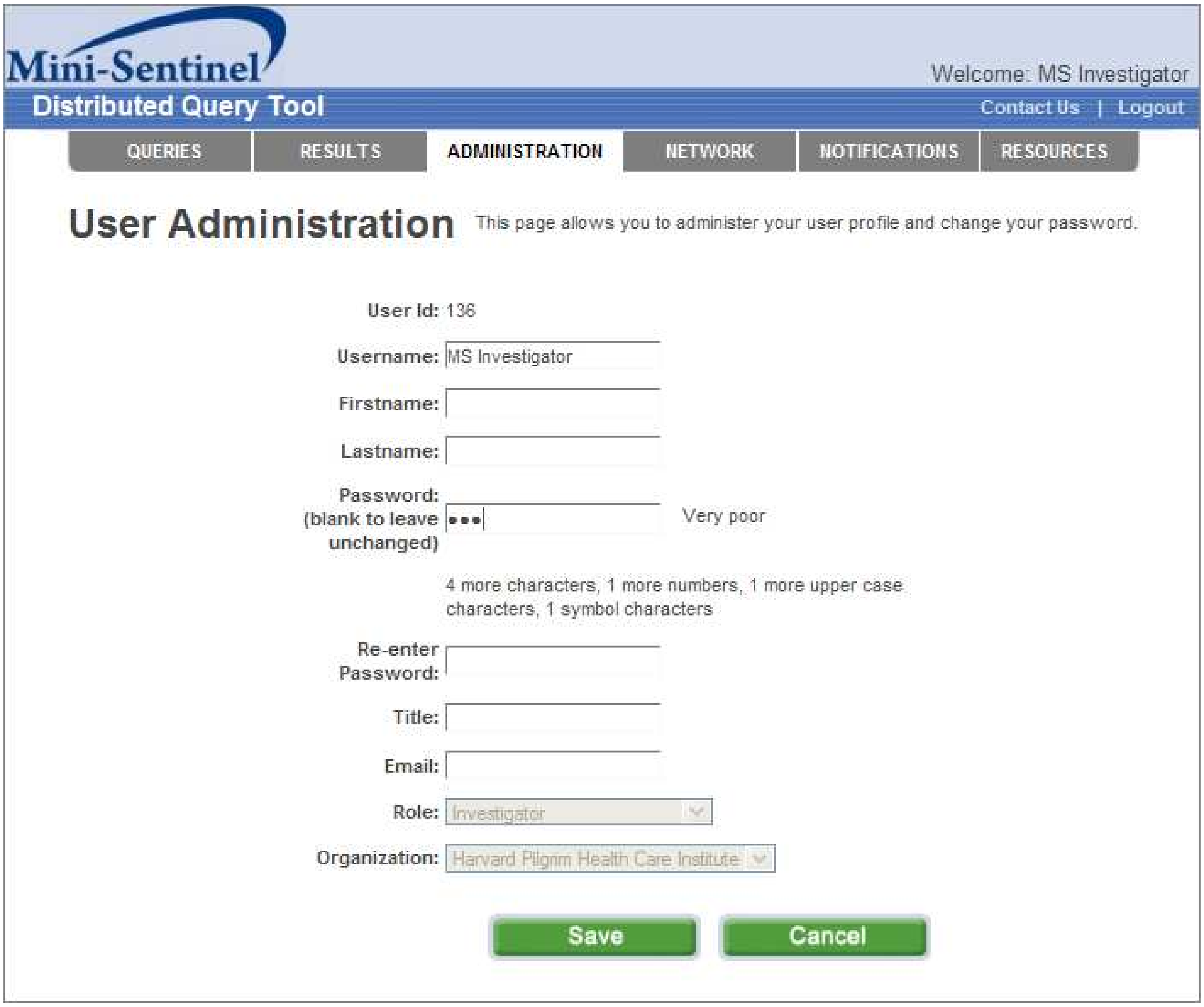
6.1 How to Reset your Password

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:

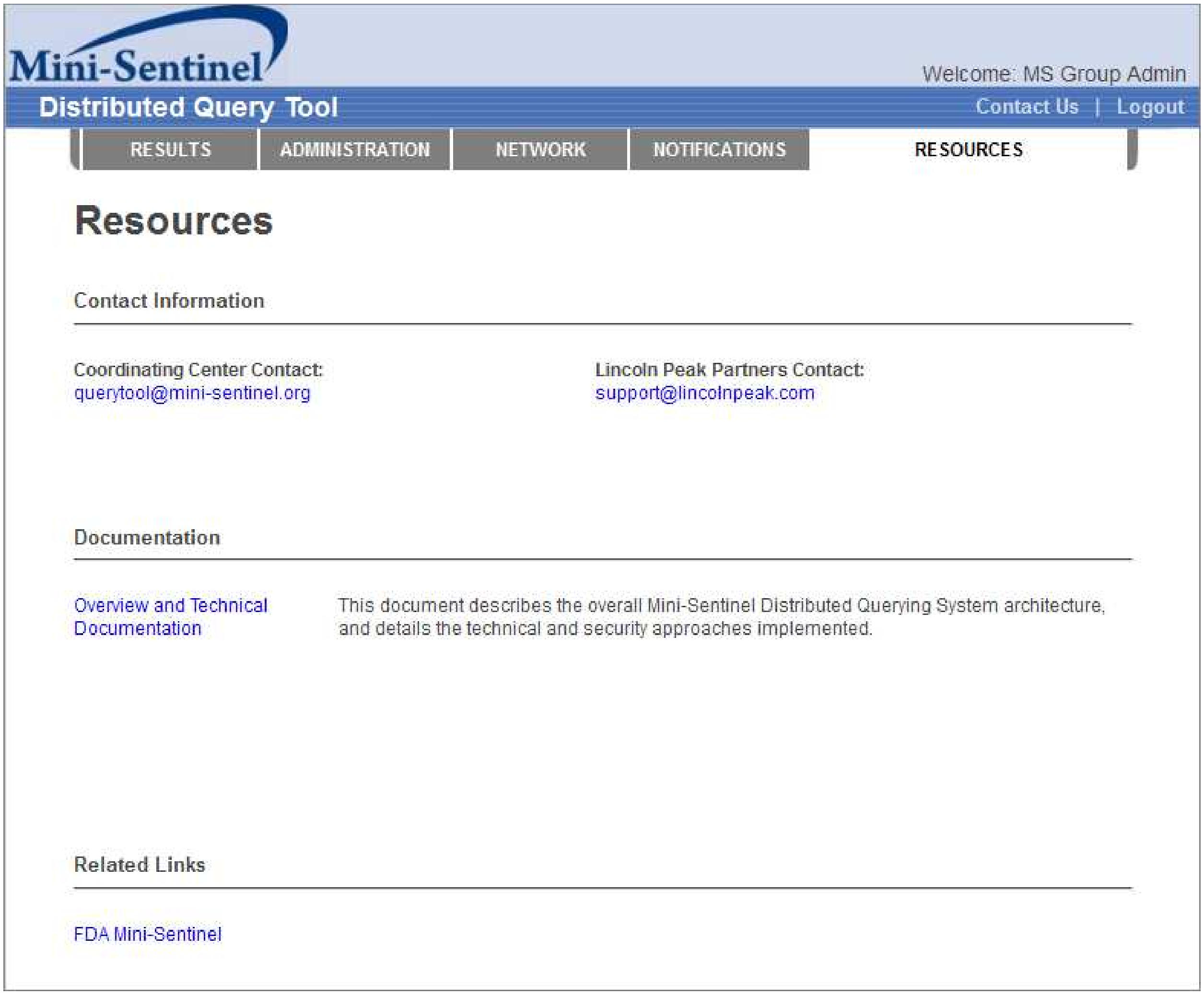
- Length must be at least 7 characters
- Password must include at least 1 upper case letter, 1 lower case, 1 number, and 1 symbol.



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