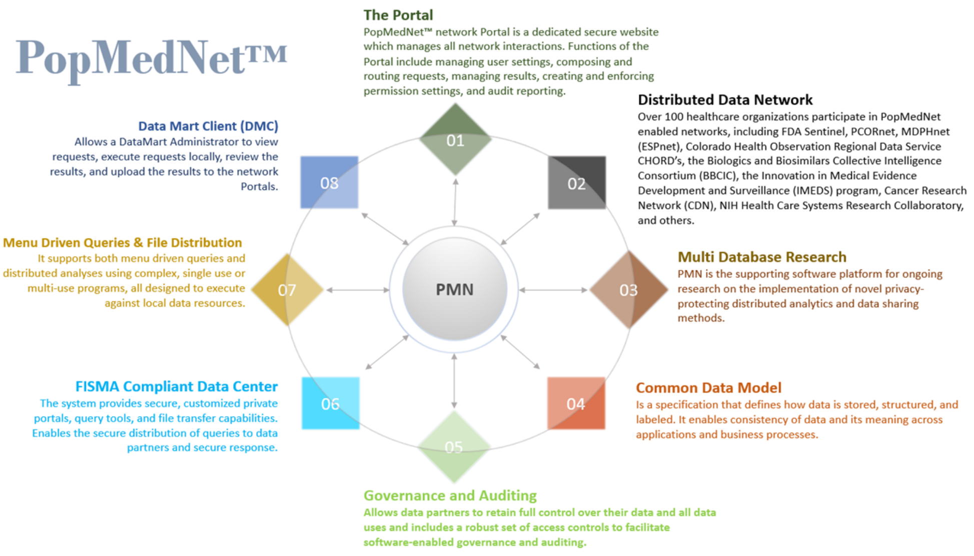
DEPARTMENT OF POPULATION MEDICINE
HARVARD MEDICAL SCHOOL
Harvard Pilgrim Health Care Institute

TIDE
THERAPEUTICS RESEARCH AND INFECTIOUS DISEASE EPIDEMIOLOGY

PopMedNet: Introduction



The Portal
PopMedNet™ network Portal is a dedicated secure website which manages all network interactions. Functions of the Portal include managing user settings, composing and routing requests, managing results, creating and enforcing permission settings, and audit reporting.

Distributed Data Network
Over 100 healthcare organizations participate in PopMedNet enabled networks, including FDA Sentinel, PCORnet, MDPHnet (ESPnet), Colorado Health Observation Regional Data Service CHORD's, the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), the Innovation in Medical Evidence Development and Surveillance (IMEDS) program, Cancer Research Network (CDN), NIH Health Care Systems Research Collaboratory, and others.

Multi Database Research
PMN is the supporting software platform for ongoing research on the implementation of novel privacy-protecting distributed analytics and data sharing methods.

Common Data Model
Is a specification that defines how data is stored, structured, and labeled. It enables consistency of data and its meaning across applications and business processes.

Governance and Auditing
Allows data partners to retain full control over their data and all data uses and includes a robust set of access controls to facilitate software-enabled governance and auditing.

FISMA Compliant Data Center
The system provides secure, customized private portals, query tools, and file transfer capabilities. Enables the secure distribution of queries to data partners and secure response.

Menu Driven Queries & File Distribution
It supports both menu driven queries and distributed analyses using complex, single use or multi-use programs, all designed to execute against local data resources.

Data Mart Client (DMC)
Allows a DataMart Administrator to view requests, execute requests locally, review the results, and upload the results to the network Portals.

Figure 1: Overview of PopMedNet™

Overview

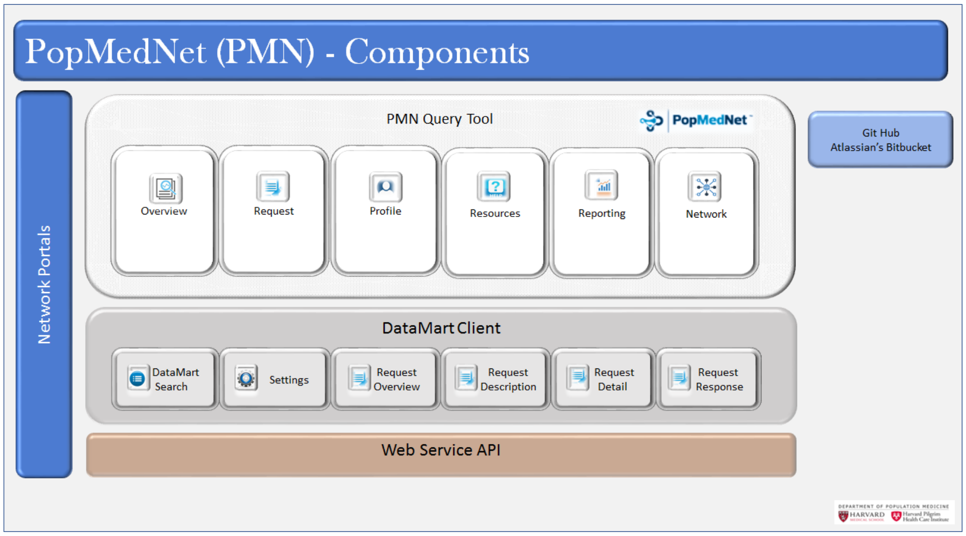
PopMedNet™'s development was pioneered by the Therapeutics Research and Infectious Disease Epidemiology (TIDE) group of the Department of Population Medicine (DPM) of the Harvard Pilgrim Health Care Institute (HPHCI), an appointing department of the Harvard Medical School. PopMedNet currently supports several large DDNs, including the Sentinel System, PCORnet, and the NIH Collaboratory.

PopMedNet™ is an open-source application used to facilitate multi-site health data networks. It uses a distributed network design that enables data partners to retain full control of their data. Investigators send questions to data partners[1] for review and response. PopMedNet eliminates the need for assembling patient records in a centralized repository, thus preserving patient privacy and confidentiality.

PopMedNet is made up of three primary components:

- **PopMedNet Query Tool:** The web-based application from which queries are distributed. It is typically used by the analysis center to create, distribute, and manage queries.
- **DataMart Client:** Is a locally installed application that acts as inbox for data partners to receive packages and transfer results to the analysis center.
- **Web Service API:** API used to implement all application logic that processes requests against a network. The API is also used for integrations with PMN-allied services and applications.

[1] Data partners are data owners who partners with each other in a study.



PopMedNet (PMN) - Components

Network Portals

PMN Query Tool

PopMedNet

Overview

Request

Profile

Resources

Reporting

Network

Git Hub
Atlassian's Bitbucket

DataMart Client

DataMart Search

Settings

Request Overview

Request Description

Request Detail

Request Response

Web Service API

Figure 2: Illustration of PopMedNet™ Components

The following diagram shows the basic operating model of PopMedNet in a single request/response roundtrip. However, it can also operate iteratively until some conditions are met, such as that employed by the Distributed Regression data model (below). Additionally, it can be configured to run unattended.

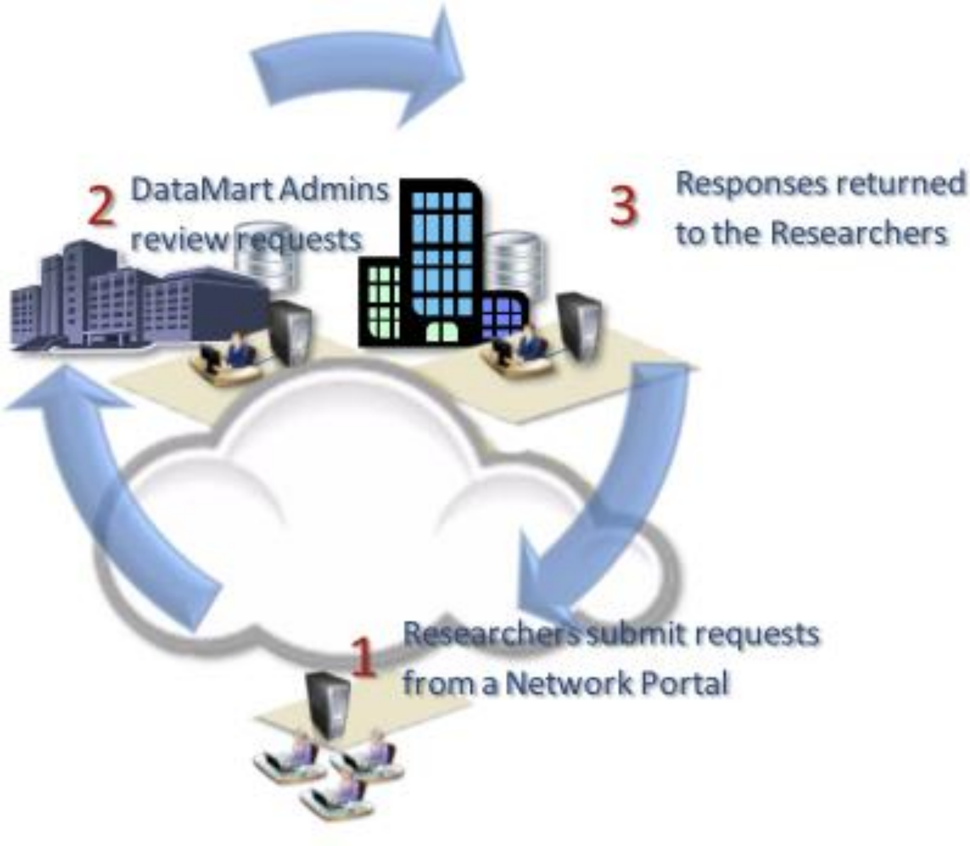

2 DataMart Admins review requests
3 Responses returned to the Researchers
1 Researchers submit requests from a Network Portal

Figure 3: Basic Operating Model of PopMedNet™

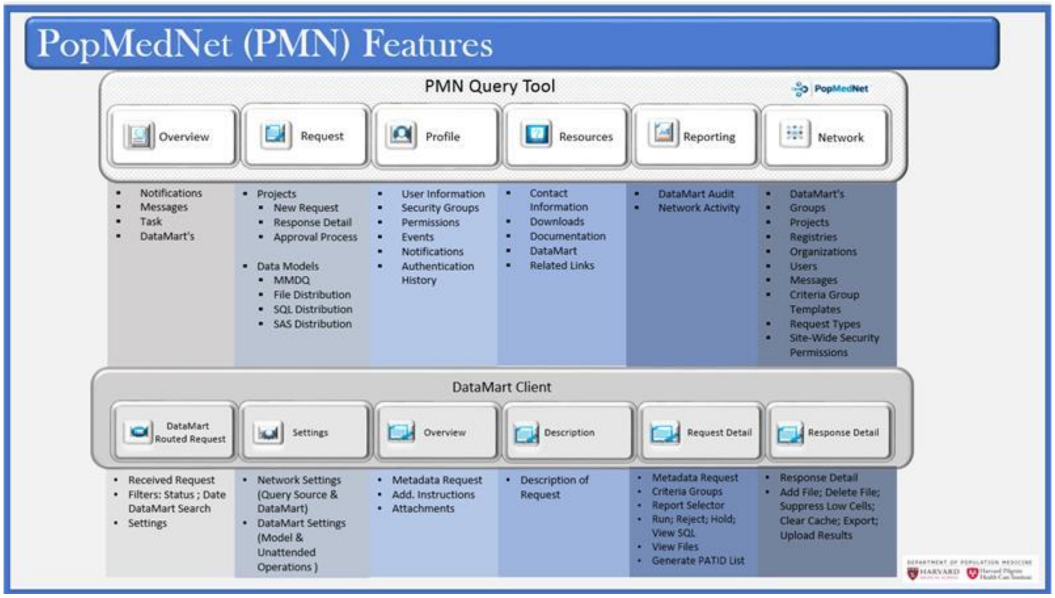
The goal of PopMedNet is to facilitate distributed analysis of electronic health data in order to support medical product safety surveillance, disease surveillance, comparative effectiveness, quality, medical resource use, cost-effectiveness, and related studies. It does this by enabling the creation of health data networks that allows the data owners to keep and control uses of their data, while at the same time allows customized access and governance for each network.

The concerns of the network stakeholders are addressed in the design and governance models of the PopMedNet software platform.

Key Features

PopMedNet features:

- Multiple queries interactively composed and distributed in a single request to multiple data marts[2](Multiple Menu Driven Queries – MMDQ).
- Query responses are asynchronously returned – that is, a query does not have to be responded to immediately and not all data marts have to respond.
- Customizable workflows.
- Auditing and search capabilities.
- Flexible role-based access control system enables the enforcement of varying governance policies.
- Approval processes for submitting and responding to queries
- Easy integration with project management tools such as Jira through API interfaces
- Allows for easy tracking of metadata associated to each request



PopMedNet (PMN) Features

PMN Query Tool

Overview
- Notifications
- Messages
- Task
- DataMart's

Request
- Projects
  - New Request
  - Response Detail
  - Approval Process
- Data Models
  - MMDQ
  - File Distribution
  - SQL Distribution
  - SAS Distribution

Profile
- User Information
- Security Groups
- Permissions
- Events
- Notifications
- Authentication History

Resources
- Contact Information
- Downloads
- Documentation
- DataMart
- Related Links

Reporting
- DataMart Audit
- Network Activity

Network
- DataMart's
- Groups
- Projects
- Registries
- Organizations
- Users
- Messages
- Criteria Group Templates
- Request Types
- Site-Wide Security Permissions

DataMart Client

DataMart Routed Request
- Received Request
- Filters: Status ; Date DataMart Search
- Settings

Settings
- Network Settings (Query Source & DataMart)
- DataMart Settings (Model & Unattended Operations)

Overview
- Metadata Request
- Add. Instructions
- Attachments

Description
- Description of Request

Request Detail
- Metadata Request
- Criteria Groups
- Report Selector
- Run; Reject; Hold; View SQL
- View Files
- Generate PATID List

Response Detail
- Response Detail
- Add File; Delete File; Suppress Low Cells; Clear Cache; Export; Upload Results

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Figure 4: Diagram of PopMedNet™ Components-Feature

[2] Data marts are software components representing the data owners' data sources.

Architecture

PopMedNet has two components. It has a .NET web application component (Portal) and a Windows application or web-based client component (DataMart Client). The .NET web component uses a modern service-oriented architecture (SOA) with a robust API serving a dynamic UI using the MVVM pattern. The DataMart Client (DMC), uses an adapter architecture to support different data models. A variety of adapters are available, and able to support distributed regression, file transfer, ad-hoc SQL queries, and dynamically composed menu-drive queries (MMDQ) against local data sources (supporting SQL Server, Postgres and Oracle).

PopMedNet is a .NET Framework application, utilizing ASP.NET MVC5 for the implementation of the website application and WinForms for the desktop application. Entity Framework 6 is used for data access, and Typescript for client-side scripting.

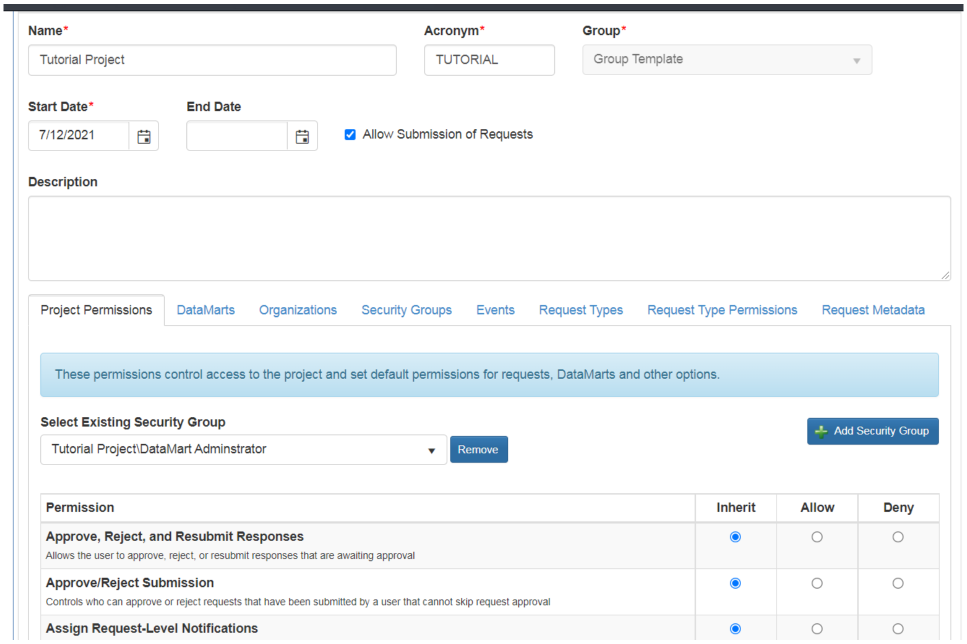
The DataMart Client (DMC) is a locally installed Microsoft Windows® application that acts as an inbox for data partners to receive query packages and transfer results to the analysis center. All file transfers (query requests and responses) between the data partners and the analysis center are achieved through secure HTTPS/SSL/TLS connections. There are no virtual machines, open ports, Virtual Private Networks, or any external access to data partner data, abating concerns about data security and unauthorized access. The system ensures only approved queries are submitted to and responses returned by participating data partners with several levels of software-enabled governance.

Portal (Web)		DataMart Client Application		DataMart Client Server (Web)	
View		WinForm		View	
REST API		Adapters		REST API	
.NET 4.8	EF6	.NET 4.8	EF6	.NET 4.8	EF6

Governance - Permission

Individual permissions are set on different levels within a PopMedNet instance. The permission will always apply to whatever level the permission is set at. For example, if View Request is set on a specific project, it would let that user view all requests sent in that project, but not another project. If the same permission was set on an Organization level, it would let the user view all requests sent to DataMarts that belong to that organization, regardless of which project the requests are sent in. The main levels where we set permissions in practice are:

- Site-wide: affecting everything on the PopMedNet instance
- Project: affecting everything in that project
- Project-DataMart: affecting everything for that DataMart within that project
- Project-Request Types: affecting everything for that request type within that project
- Organization: affecting everything at that organization (including DataMarts owned by that organization)



Name* Tutorial Project

Acronym* TUTORIAL

Group* Group Template

Start Date* 7/12/2021

End Date

☑ Allow Submission of Requests

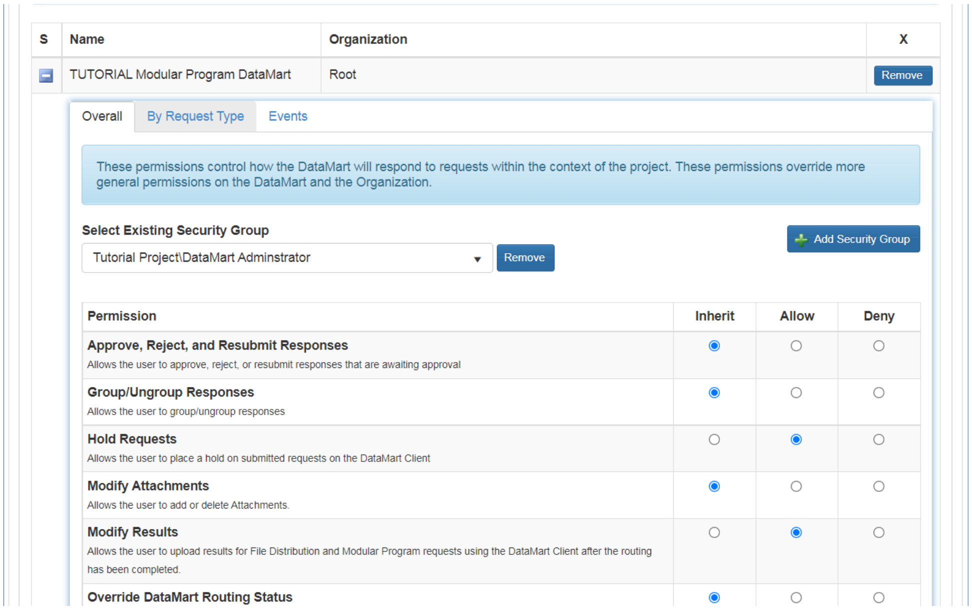
Description

These permissions control access to the project and set default permissions for requests, DataMarts and other options.

Select Existing Security Group: Tutorial Project\DataMart Adminstrator

Permission	Inherit	Allow	Deny
Approve, Reject, and Resubmit Responses Allows the user to approve, reject, or resubmit responses that are awaiting approval	●	○	○
Approve/Reject Submission Controls who can approve or reject requests that have been submitted by a user that cannot skip request approval	●	○	○
Assign Request-Level Notifications	●	○	○

Figure 5: Displays the Project Permissions for a Tutorial project



S	Name	Organization	X
⊟	TUTORIAL Modular Program DataMart	Root	Remove

These permissions control how the DataMart will respond to requests within the context of the project. These permissions override more general permissions on the DataMart and the Organization.

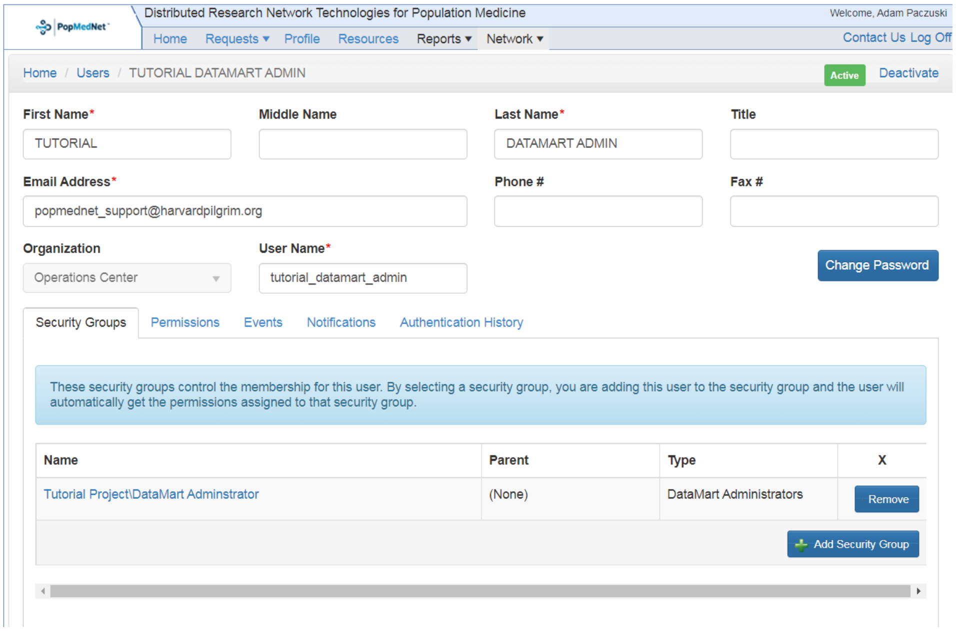
Select Existing Security Group: Tutorial Project\DataMart Adminstrator

Permission	Inherit	Allow	Deny
Approve, Reject, and Resubmit Responses Allows the user to approve, reject, or resubmit responses that are awaiting approval	●	○	○
Group/Ungroup Responses Allows the user to group/ungroup responses	●	○	○
Hold Requests Allows the user to place a hold on submitted requests on the DataMart Client	○	●	○
Modify Attachments Allows the user to add or delete Attachments.	●	○	○
Modify Results Allows the user to upload results for File Distribution and Modular Program requests using the DataMart Client after the routing has been completed.	○	●	○
Override DataMart Routing Status	●	○	○

Figure 6: Displays the permissions for granting access to a specific DataMart within a Project

Other locations that may be used (this is not an exhaustive list):

- Project-Organization: affecting everything for that organization and every DataMart owned by it in that project
- Request Types: affecting that specific request type
- Registries: affecting that specific registry
- User: affecting that specific user



First Name*: TUTORIAL
Middle Name:
Last Name*: DATAMART ADMIN
Title:
Email Address*: popmednet_support@harvardpilgrim.org
Phone #:
Fax #:
Organization: Operations Center
User Name*: tutorial_datamart_admin

These security groups control the membership for this user. By selecting a security group, you are adding this user to the security group and the user will automatically get the permissions assigned to that security group.

Name	Parent	Type	X
Tutorial Project\DataMart Adminstrator	(None)	DataMart Administrators	Remove

Figure 7: Displays how the collections of permissions in groups are assigned to a user

Permissions set on higher, more all-encompassing levels are inherited at lower levels. This means that if an Approve/Reject Results permission is set on a project-level, that permission is effectively inherited at all Project-DataMart and Project-Organization levels within that project. You can deny permissions at a lower level, and that will overrule the inherited permission.

How It Works

In PopMedNet, the Portal handles all the governance and acts as a hub for all queries. That ensures that the coordinating center[3] can expect:

- Consistency of information across data partners
- Quality of data
- Flexibility to handle different network structures with overlapping data partners
- Ability to track and report operational activities
- Managing multiple projects

The DataMart Client (DMC) allows data partners to control access to their data before sending it to the Portal. For the data partners, it will:

- Provide protection of PHI
- Prevent loss of control over proprietary information

The researcher will have no direct access to data but is shielded from the differences among networks' data models.

[3] Coordinating center runs the study and issues queries from the PopMedNet Portal.

A typical PopMedNet™ request-response cycle is as follows:

1. Request: Investigators distribute data requests constructed in the point and click web interface
2. Review: Data Partners receive and review requests in their DataMart Client
3. Respond: Data partners execute the requests against their local data and upload results
4. Download: Investigators access results in the query tool

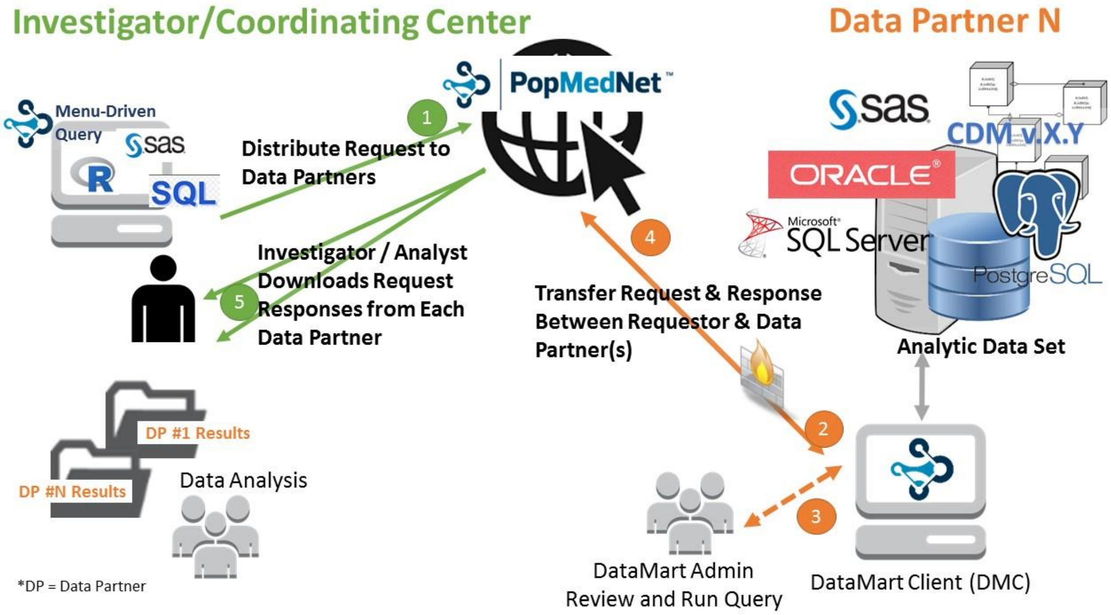

Investigator/Coordinating Center
Data Partner N
PopMedNet™
Menu-Driven Query
sas
R
SQL
1
Distribute Request to Data Partners
Investigator / Analyst Downloads Request Responses from Each Data Partner
5
4
Transfer Request & Response Between Requestor & Data Partner(s)
sas
CDM v.X.Y
ORACLE
Microsoft SQL Server
PostgreSQL
Analytic Data Set
2
3
DP #1 Results
DP #N Results
Data Analysis
*DP = Data Partner
DataMart Admin Review and Run Query
DataMart Client (DMC)

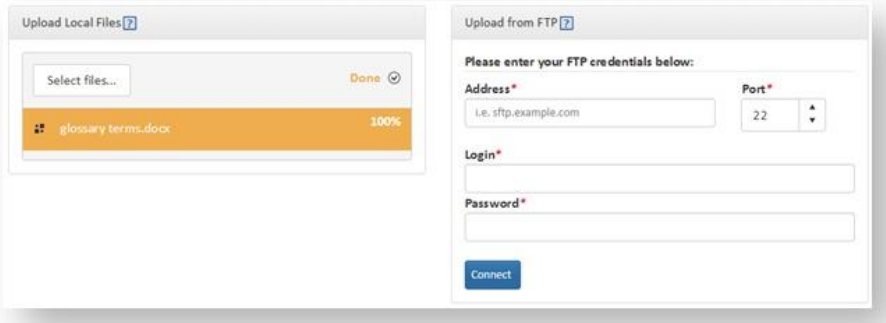
Figure 8: Diagram of PopMedNet™ Request Cycle

Key Data Models Supported

Modular Program Distribution

The Modular Program Distribution request model allows you to distribute modular program packages to the network DataMarts. The Modular Program request model provides two request types: Modular Program. The request specific criteria for these request types is the same and displayed in the figure below.

If data partners upload Modular Program results containing all-run signature files, the signature file information may be automatically read by PopMedNet and displayed on the Request Details page.



glossary terms.docx 100%

Please enter your FTP credentials below:

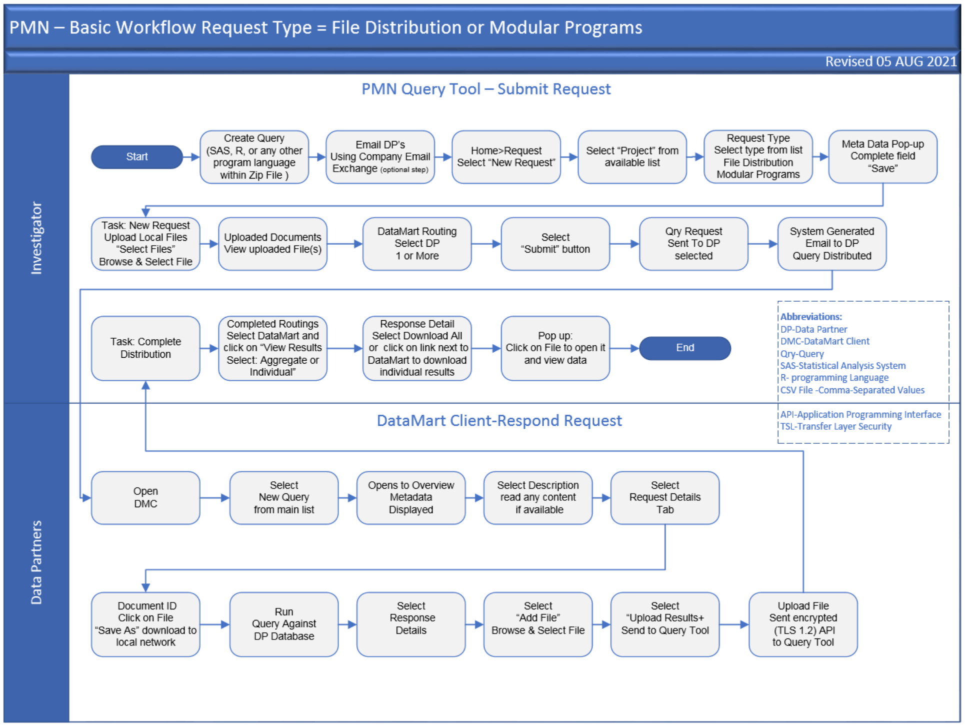
Address* i.e. sftp.example.com

Port* 22

Login*

Password*

Figure 9: Illustrates how a file is attached within a Modular program request



PMN – Basic Workflow Request Type = File Distribution or Modular Programs
Revised 05 AUG 2021
Investigator
PMN Query Tool – Submit Request
Start
Create Query (SAS, R, or any other program language within Zip File)
Email DP's Using Company Email Exchange (optional step)
Home>Request Select "New Request"
Select "Project" from available list
Request Type Select type from list File Distribution Modular Programs
Meta Data Pop-up Complete field "Save"
Task: New Request Upload Local Files "Select Files" Browse & Select File
Uploaded Documents View uploaded File(s)
DataMart Routing Select DP 1 or More
Select "Submit" button
Qry Request Sent To DP selected
System Generated Email to DP Query Distributed
Task: Complete Distribution
Completed Routings Select DataMart and click on "View Results Select: Aggregate or Individual"
Response Detail Select Download All or click on link next to DataMart to download individual results
Pop up: Click on File to open it and view data
End
Abbreviations:
DP-Data Partner
DMC-DataMart Client
Qry-Query
SAS-Statistical Analysis System
R- programming Language
CSV File -Comma-Separated Values
API-Application Programming Interface
TSL-Transfer Layer Security
Data Partners
DataMart Client-Respond Request
Open DMC
Select New Query from main list
Opens to Overview Metadata Displayed
Select Description read any content if available
Select Request Details Tab
Document ID Click on File "Save As" download to local network
Run Query Against DP Database
Select Response Details
Select "Add File" Browse & Select File
Select "Upload Results+ Send to Query Tool
Upload File Sent encrypted (TLS 1.2) API to Query Tool

Figure 10: Modular Program workflow utilized for FDA Request

Multiple Menu Driven Query

Menu-Driven Queries (MDQs) utilize a simple point-and-click interface to add terms to the request criteria that are joined through logical operations (and/or), associations, and then grouped according to the chosen stratification(s). A major benefit is that users do not need programming expertise to create and execute MDQs. MDQs execute against data stored within a Common Data Model and output results based on the criteria entered. Additionally, files can be distributed with a query.

MDQ further supports the ability to send multiple MDQ in a single request. This would include the ability to specify distinct criteria groups and stratifications for each MDQ within the request. Data partners can run and upload the results for all MDQs simultaneously using the DataMart Client.

When an MMDQ is received by a Data Partner, the software gathers all user submitted queries, runs them simultaneously, and results are sorted into appropriate tables based on the request criteria. When this process is complete, results may be returned to the requestor. Data partners may also configure their DMC to automatically run and upload the results of MDQs and MMDQs. This auto-run and upload feature functions by queuing the queries as received by the DMC such that the first query will run and upload results prior to moving onto the next query in the queue.

MDQ adapter uses Entity Framework for conversion into SQL for SQL Server, Oracle and Postgres.

Key features of MDQ architecture include:

- Visual query composition - the MDQ architecture allows users to develop a query using a point-and-click interface using logical operations (and/or), associations (criteria group) and stratifications (group by);
- Flexibility - MDQs can be executed against a variety of database types;
- Grouped querying - the MDQ architecture allows creation and submission of multiple MDQs in a single request;
- Ability to define and share custom query templates;
- Sharing of query specifications, development of sharable phenotypes;
- Electronic workflow that guides users through query composition, governance, distribution, and response viewing;
- Ability to aggregate and export results to multiple file formats; and
- Use of PMN governance and access controls.

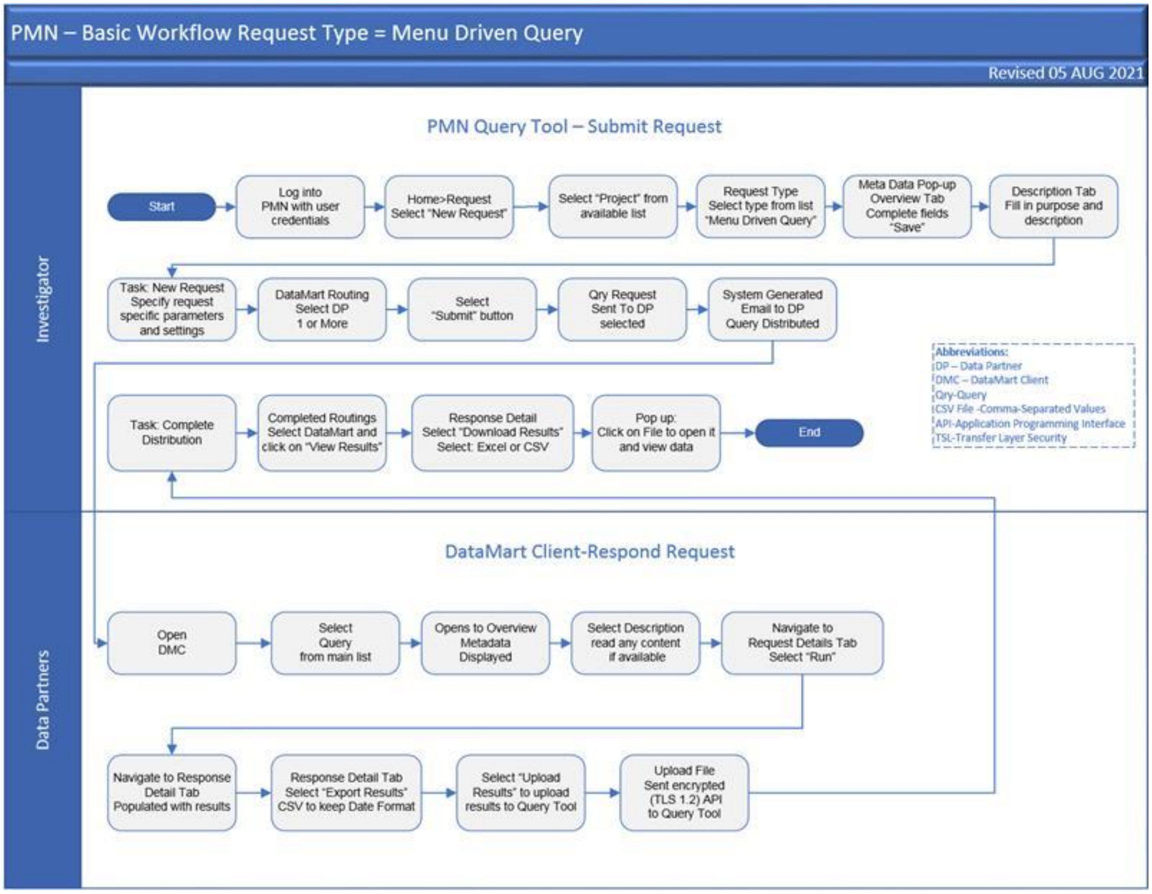
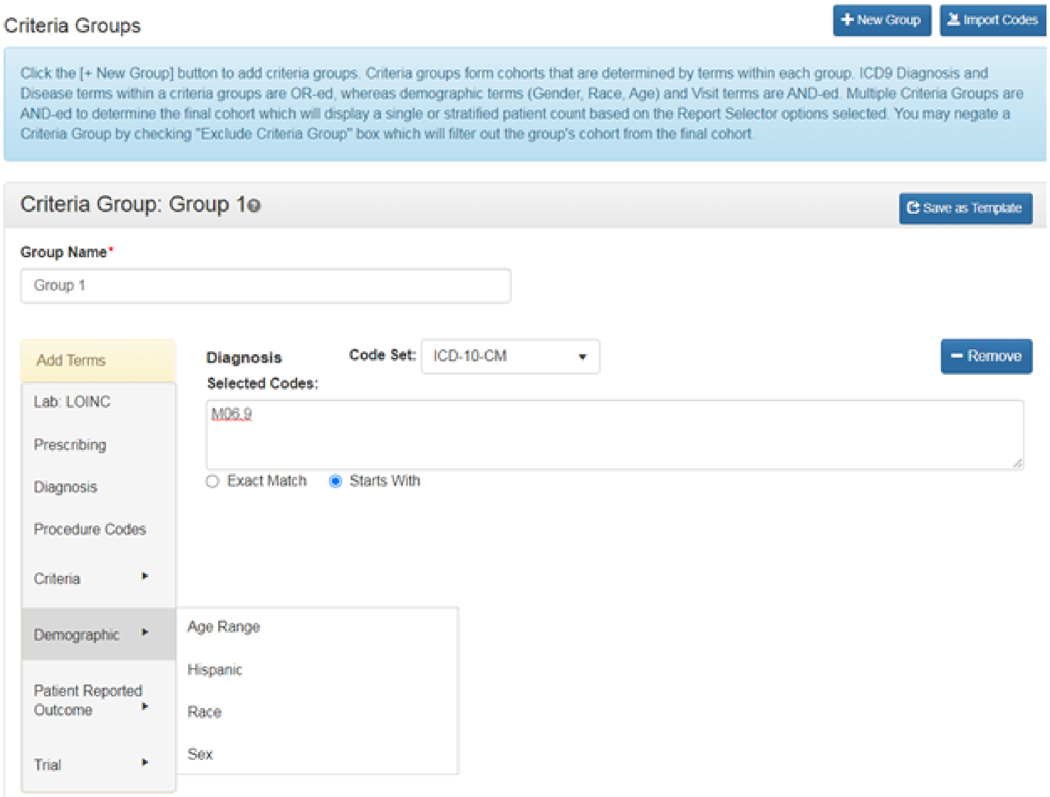

PMN – Basic Workflow Request Type = Menu Driven Query
Revised 05 AUG 2021
Investigator
PMN Query Tool – Submit Request
Start
Log into PMN with user credentials
Home>Request Select "New Request"
Select "Project" from available list
Request Type Select type from list "Menu Driven Query"
Meta Data Pop-up Overview Tab Complete fields "Save"
Description Tab Fill in purpose and description
Task: New Request Specify request specific parameters and settings
DataMart Routing Select DP 1 or More
Select "Submit" button
Qry Request Sent To DP selected
System Generated Email to DP Query Distributed
Abbreviations:
DP – Data Partner
DMC – DataMart Client
Qry-Query
CSV File -Comma-Separated Values
API-Application Programming Interface
TSL-Transfer Layer Security
Task: Complete Distribution
Completed Routings Select DataMart and click on "View Results"
Response Detail Select "Download Results" Select: Excel or CSV
Pop up: Click on File to open it and view data
End
Data Partners
DataMart Client-Respond Request
Open DMC
Select Query from main list
Opens to Overview Metadata Displayed
Select Description read any content if available
Navigate to Request Details Tab Select "Run"
Navigate to Response Detail Tab Populated with results
Response Detail Tab Select "Export Results" CSV to keep Date Format
Select "Upload Results" to upload results to Query Tool
Upload File Sent encrypted (TLS 1.2) API to Query Tool

Figure 11: Menu Driven Query Workflow



Criteria Groups

Click the [+ New Group] button to add criteria groups. Criteria groups form cohorts that are determined by terms within each group. ICD9 Diagnosis and Disease terms within a criteria groups are OR-ed, whereas demographic terms (Gender, Race, Age) and Visit terms are AND-ed. Multiple Criteria Groups are AND-ed to determine the final cohort which will display a single or stratified patient count based on the Report Selector options selected. You may negate a Criteria Group by checking "Exclude Criteria Group" box which will filter out the group's cohort from the final cohort.

Criteria Group: Group 1

Group Name*: Group 1

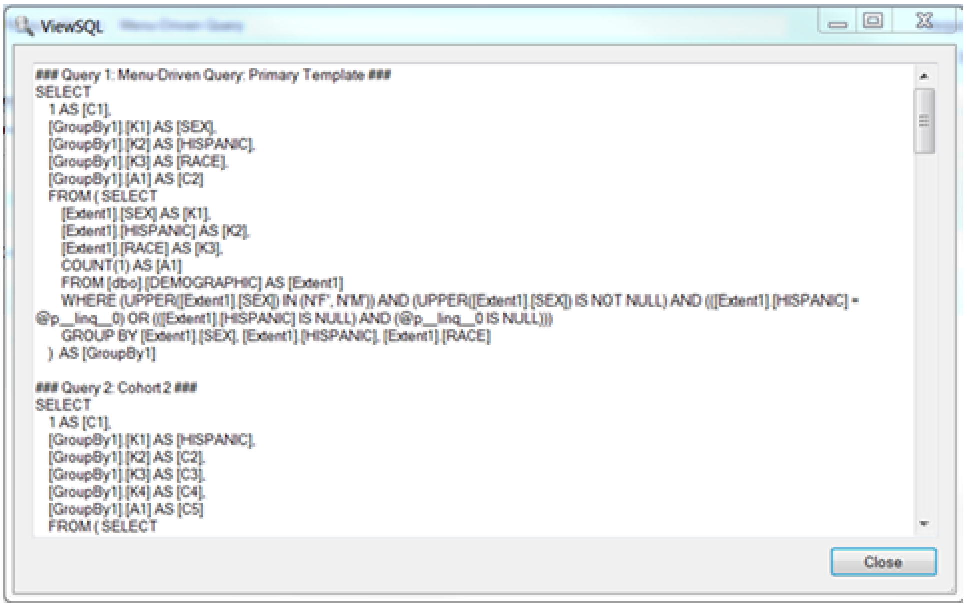
Diagnosis

Code Set: ICD-10-CM

Selected Codes: M06.9

○ Exact Match ● Starts With

Figure 12: Menu-Driven Query User Interface.



ViewSQL

```
### Query 1: Menu-Driven Query: Primary Template ###
SELECT
   1 AS [C1],
   [GroupBy1].[K1] AS [SEX],
   [GroupBy1].[K2] AS [HISPANIC],
   [GroupBy1].[K3] AS [RACE],
   [GroupBy1].[A1] AS [C2]
   FROM ( SELECT
      [Extent1].[SEX] AS [K1],
      [Extent1].[HISPANIC] AS [K2],
      [Extent1].[RACE] AS [K3],
      COUNT(1) AS [A1]
      FROM [dbo].[DEMOGRAPHIC] AS [Extent1]
      WHERE (UPPER([Extent1].[SEX]) IN (N'F', N'M')) AND (UPPER([Extent1].[SEX]) IS NOT NULL) AND (([Extent1].[HISPANIC] =
@p__linq__0) OR (([Extent1].[HISPANIC] IS NULL) AND (@p__linq__0 IS NULL)))
      GROUP BY [Extent1].[SEX], [Extent1].[HISPANIC], [Extent1].[RACE]
   )  AS [GroupBy1]

### Query 2: Cohort 2 ###
SELECT
   1 AS [C1],
   [GroupBy1].[K1] AS [HISPANIC],
   [GroupBy1].[K2] AS [C2],
   [GroupBy1].[K3] AS [C3],
   [GroupBy1].[K4] AS [C4],
   [GroupBy1].[A1] AS [C5]
   FROM ( SELECT
```

Figure 13: Structure of a Multiple Menu Driven Query (MMDQ) as seen in the DataMart Client

Distributed Regression Analysis (DRA)

Distributed Regression provides data infrastructure and methods that support robust statistical analysis for binary, survival, and continuous outcomes. It enables the ability to conduct rapid and secure distributed regression analysis in distributed data networks. DRA is mathematically equivalent to the conventional regression analysis of pooled individual-level data. It achieves the same level of statistical sophistication using only summary-level information, thereby offering better protection for individual and institutional privacy without jeopardizing the scientific rigor of the analysis.

Distributed Regression adaptor (DRA-adapter) has the following unique characteristics:

- Supports multiple data sources with unique populations, which are often needed to answer clinical questions
- Balances analytic data requirements, patient privacy and confidentiality, local governance, and proprietary considerations

It can:

- Automatically download new files (individual and zipped) to specified location when all DataMart's responded.
- Automatically launch SAS or R interpreter and run program delivered as request payload.
- Different levels of workflow automation (completely manual, semi-automated, and fully automated).

Three regression models are supported:

1. Linear Regression
2. Logistic Regression
3. Survival Analysis (Cox Proportional Hazard Model)

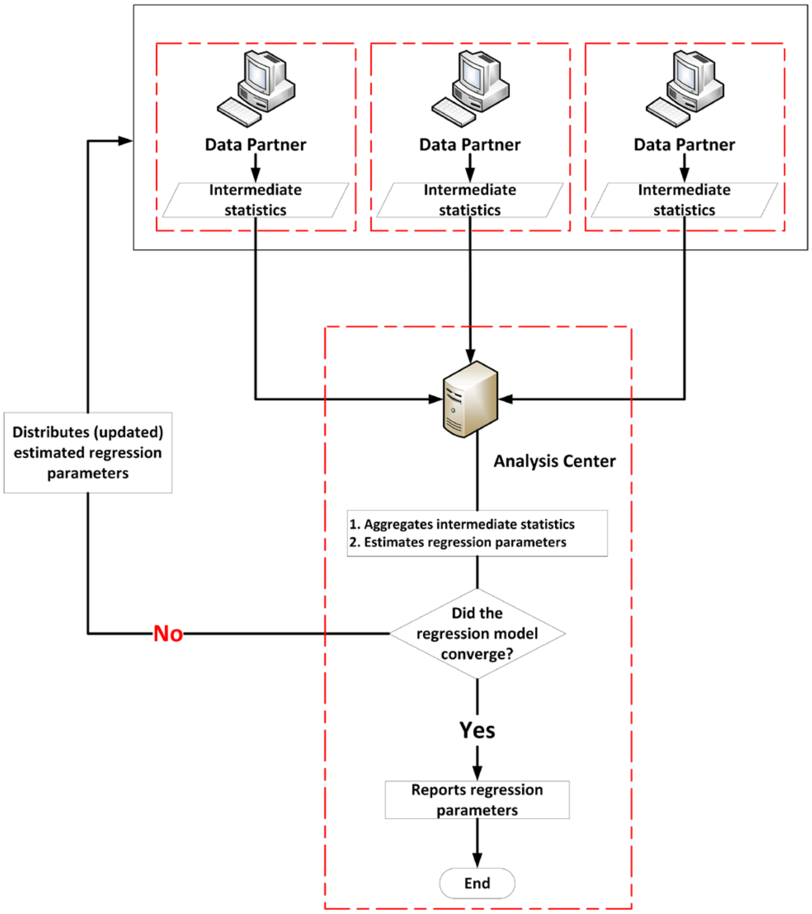

Data Partner
Intermediate statistics
Data Partner
Intermediate statistics
Data Partner
Intermediate statistics
Distributes (updated) estimated regression parameters
Analysis Center
1. Aggregates intermediate statistics
2. Estimates regression parameters
Did the regression model converge?
No
Yes
Reports regression parameters
End

Figure 14: Iterative process to perform distributed regression analysis

A typical DRA includes 3 major steps. Step 1 involves the assembly of a harmonized individual-level analytical dataset at each data partner. In step 2, the analysis center and each data partner execute a DRA algorithm locally. Step 3 involves the iterative transfer of the DRA algorithm outputs between the data partners and the analysis center until the regression model converges or the process reaches a prespecified maximum number of iterations. PopMedNet workflow is utilized to transfer input files and computation directions interactively and automatically between data partners and the analysis center.

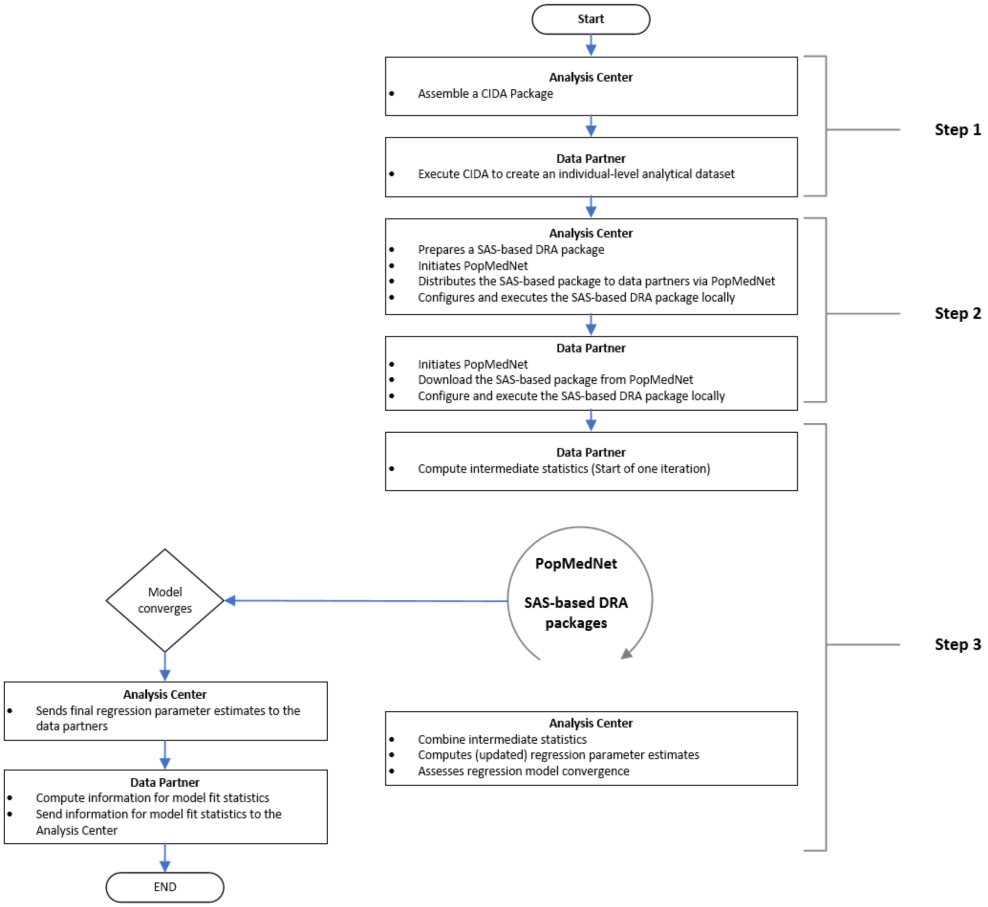
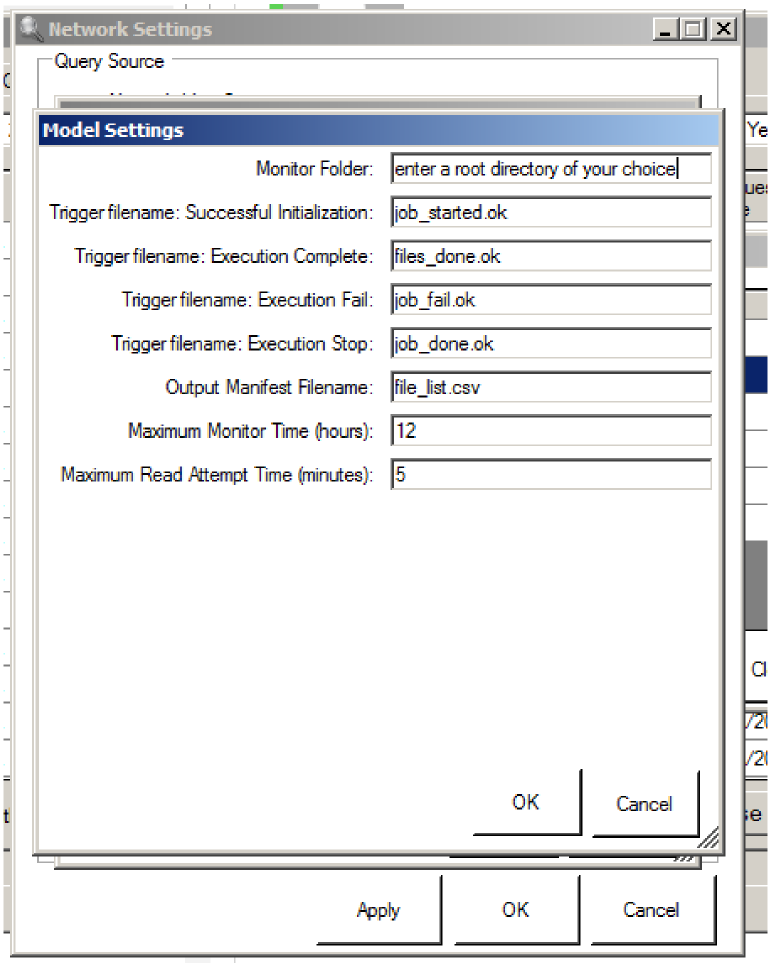

Start
Analysis Center
Assemble a CIDA Package
Data Partner
Execute CIDA to create an individual-level analytical dataset
Step 1
Analysis Center
Prepares a SAS-based DRA package
Initiates PopMedNet
Distributes the SAS-based package to data partners via PopMedNet
Configures and executes the SAS-based DRA package locally
Data Partner
Initiates PopMedNet
Download the SAS-based package from PopMedNet
Configure and execute the SAS-based DRA package locally
Step 2
Data Partner
Compute intermediate statistics (Start of one iteration)
PopMedNet
SAS-based DRA packages
Model converges
Step 3
Analysis Center
Sends final regression parameter estimates to the data partners
Analysis Center
Combine intermediate statistics
Computes (updated) regression parameter estimates
Assesses regression model convergence
Data Partner
Compute information for model fit statistics
Send information for model fit statistics to the Analysis Center
END

Figure 15: Three-Step process to conduct distributor regression analysis with PopMedNet. CIDA: Cohort Identification and Descriptive Analysis Tool; DRA Distributor Regression Analysis

Executing External Programs

The DataMart Client (DMC) supports data models that interoperates with external programs. For example, DataMart Client can be customized to execute an external program like a command interpreter such as R or SAS interpreters or executable programs. Alternatively, it can be customized to deposit files that are monitored by an external program. DR utilizes the latter capability of DMC to perform its iterations automatically without human intervention.



Model Settings

Monitor Folder: enter a root directory of your choice

Trigger filename: Successful Initialization: job_started.ok

Trigger filename: Execution Complete: files_done.ok

Trigger filename: Execution Fail: job_fail.ok

Trigger filename: Execution Stop: job_done.ok

Output Manifest Filename: file_list.csv

Maximum Monitor Time (hours): 12

Maximum Read Attempt Time (minutes): 5

Figure 16: DataMart Client (DMC) Model Settings

Deployment Infrastructure

The PopMedNet team recommend deploying PopMedNet is a load-balanced, clustered configuration.

PopMedNet must be installed on Windows Server running IIS and backed by SQL Server database that is not public facing.

Both the portal and the API are public facing and should require HTTPS/TLS 1.2 communication protocols.

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