

Work Plan: PCSK9 inhibitor Rapid Cycle Research

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1. Query Metadata

PCSK9 inhibitor Rapid Cycle Research
Name: RCRPCSK9_WP001_NSD_V02
Priority: Normal
Due Date:12/01/2017
Purpose of use:
Level of PHI Disclosure: Aggregated
Description:(NOTE: limited to 400 characters)
Query identifies four mutually exclusive groups (CHD/CAD, FH, LDL \geq 130 (LDL), and dyslipidemia) from 1/1/2015-3/31/2017 with DX and lab data. Descriptive analysis will be done on demographics, diagnosis, procedures, vital, lab_result_cm, and prescribing/dispensing data. Aggregate output at the DataMart- level produced. See 'Additional Instructions' and Workplan for Planned Use and further information.
Additional Instructions (NOTE: character limit 3000):
<p>Planned Use:</p> <p>Program Package Contents: 1 workplan & 4 folders to organize program inputs/outputs. Folder structure described in Sect. 4 of workplan. Instructions to execute master.sas program in Sect. 5 of workplan</p> <p>Query Request:</p> <ul style="list-style-type: none">• Identify four groups and total population: CHD/CAD, FH, LDL, and dyslipidemia<ul style="list-style-type: none">○ Demographics<ul style="list-style-type: none">▪ Age group▪ Gender▪ Race▪ Ethnicity○ Vitals<ul style="list-style-type: none">▪ Systolic▪ Diastolic▪ BMI▪ HT▪ WT

- Smoking
- Lab_results_cm
 - LDL
 - HDL
 - Total Cholesterol
 - Triglycerides
 - Lipoprotein(a)
- Prescribing/Dispensing
 - Lipid lowering meds
 - Other meds (antihypertensive and aspirin)
- Supplemental_Table
 - Taxonomy (Provider_type)
- ASCVD Risk Score
 - Combine demographics, vitals, and lab data

Query Period: 1/1/2015-3/31/2017

Scenarios will be stratified by age, sex, race, Hispanic, & will execute against SAS tables (demographic, encounter, diagnosis, procedure, vital, lab_result_cm, prescribing and/or dispensing) in PCORnet CDM V3.1 format. Each datamart will need to supply a supplemental table containing Rx_Providerid, ProviderID, and Healthcare Provider Taxonomy Code. This will be used to classify the Rx_Providerid field (local codes and National Provider Identifier codes) for descriptive analysis on the prescriber.

Output: The SAS program will generate output files based on the tables available at each datamart. If run with vital, lab, medication data, the program will produce 22 output files (15 drnoc & 7 in dmlocal)

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2. Purpose and Scope

The purpose of this document is to describe the program developed by OneFL. The query executes against local SAS data in the PCORnet Common Data Model (CDM) V3.1 format and an additional supplemental table. The table shells below illustrate the output that will be generated. The table shells in this document are for illustrative purposes only.

3. Codes Queried in the Request

Codes are available upon request or at <https://pcornet.imeetcentral.com/pcsk9ircrproject/home>

4. Program package and file structure

The package contains several folders to organize program inputs and output:

- dmlocal: folder containing output generated by the request that should be saved locally.
- drnoc: These tables consist of aggregate data/output and transfer the minimum information required to answer the analytical question.
- sasprograms: folder containing the master SAS program that must be edited and then executed locally.

- infolder: folder containing all input and lookup files needed to execute request.

5. Running the SAS Program

- The package is contained in a zip file
 1. Unzip the file
- Open the *sasprograms* folder and open the SAS file 'master.sas' using SAS 9.3+
 1. In step 1, edit the various locations as follows:
 - i. Edit the indata libname to contain the filepath location where the static SAS datasets are stored.
 - ii. Edit the infolder %LET statement to contain the filepath for the *infolder* folder that was included in the zip file.
 - iii. Edit the dmlocal %LET statement to contain the filepath for the *dmlocal* folder that was included in the zip file.
 - iv. Edit the drnoc %LET statement to contain the filepath for the *drnoc* folder that was included in the zip file.
 - v. Edit the tax, supplemental_table, location.
 - vi. Indicate if tables are available:
 - Dispensing %LET statement Y/N
 - Prescribing %LET statement Y/N
 - Vital %LET statement Y/N
 - Lab_result_cm %LET statement Y/N
 - vii. NOTE: the default value for low cell count masking is 11
 - viii. Edit the DMID %LET statement and the SITEID %LET statement to contain your designated DataMart ID and Site ID.
 2. Save and run 'master.sas'
 3. Check the output in the *drnoc* and *dmlocal* folders. The *drnoc* folder should now contain a log file and SAS datasets depending on data tables available.

6. Low Cell-Count Masking

'Threshold' %Let statement will be applied to all cohort counts and frequencies. NOTE: the default value for the low cell count masking is 11.

7. Output Tables

Denom_grp:

DMID	SITEID	Group	Denominator
<i>DMID the site has entered in the master.sas file. Will be removed and de-identified during report generation</i>	<i>SiteID the site has entered in the master.sas file. Will be removed and de-identified during report generation.</i>	Defined in Proposal: CHD/CAD FH LDL Dyslipidemia Total	Number of patients meeting criteria

Demo_freq:

DMID	SITEID	Group	Demog	Demogval	Sex	Race	Hispanic	Count
		Defined in Proposal: CHD/CAD FH LDL Dyslipidemia Total	<i>Demographic CDM variable for stratification</i>	<i>Demographic variable values for stratification</i>	<i>Sex stratification column. If blank represents non-stratified by sex.</i>	<i>Race stratification column. If blank represents non-stratified by race.</i>	<i>Hispanic stratification column. If blank represents non-stratified by Hispanic.</i>	Number of patients meeting criteria

Demo_mean (age):

DMID	SITEID	Summary	Group	N	mean	std	min	max	median	qrange
		Age								

Ascvd_mean (if vital data, HDL, and total cholesterol lab records are available):

DMID	SITEID	Summary	Group	Sex	Race	Hispanic	N	mean	std	min	max	median	qrange
		ASCVD											

Demo_ASCVD (if vital data, HDL, and total cholesterol lab records are available):

DMID	SITEID	Group	Demog	Demogval	Race	Hispanic	Count

Vital_freq (smoking, BMI summary):

DMID	SITEID	Group	Demog	Demogval	Count

Vital_mean:

DMID	SITEID	Summary	Group	Sex	Race	Hispanic	N	mean	std	min	max	median	qrange
		Vital											

Lab_mean:

DMID	SITEID	Summary	Group	Sex	Race	Hispanic	N	mean	std	min	max	median	qrange
		Lab_test											

Lab_results:

DMID	SITEID	Group	Lab_test	Classify	Count

Lipid_lower_cnt:

DMID	SITEID	Group	Six_month	Drug	Rxnorm_cui	Count	analysis
			YYYY1 (Jan-Jun) YYYY2 (Jul-Dec) Blank indicates no stratification				Total, drug code Total Six month, drug code Six month Total, drug code, group Total, group Six month, drug code, group Six month, group

Lipid_low_taxo:

DMID	SITEID	Group	Six_month	taxo	analysis	Count

Other_med_cnt:

DMID	SITEID	Group	Six_month	Drug	Rxnorm_cui	Count	analysis

Total_Lab (number of unique people with a record in study period)

DMID	SITEID	Total_Count

Total_Medication (number of unique people with a record in study period)

DMID	SITEID	Total_Count

8. Files included in Query Request

1. Workplan
2. SAS program file
 - a. Master.sas
3. Infolder files

- code_list_disp.sas7bdat
- code_list_dx.sas7bdat
- code_list_lab.sas7bdat
- code_list_pres.sas7bdat
- PCSK9i_RCR_v4.sas
- PCSK9i_RCR_medication.sas
- PCSK9i_RCR_lab.sas
- PCSK9i_RCR_case.sas
- PCSK9i_RCR_ascvd.sas
- PCSK9i_RCR_vital.sas
- PCSK9i_RCR_analysis.sas

9. Output files

The SAS program package will need to be edited to specify your DataMart and site id. The program must also be pointed to the correct SAS datasets and folder structures, as described in the above instructions. Alterations can be discussed to achieve study goals.

This package will create outputs depending on available data.

Output files from the drnoc folder should be zipped into a folder with the name of the file distribution query.

Dmlocal

1. runID.log
2. runID_condition_dx.sas7bdat
3. runID_dispense.sas7bdat
4. runID_population.sas7bdat
5. runID_lab_data.sas7bdat
6. runID_pres.sas7bdat
7. runID_vittable.sas7bdat

Drnoc

1. runID.log
2. runID_ascvd_mean.sas7bdat (vital and specific lab availability)
3. runID_demo_mean.sas7bdat
4. runID_demo_ascvd.sas7bdat (vital and specific lab availability)
5. runID_demo_freq.sas7bdat
6. runID_denom_grp.sas7bdat
7. runID_lab_mean.sas7bdat
8. runID_lab_results.sas7bdat
9. runID_lipid_low_cnt.sas7bdat
10. runID_lipid_low_taxo.sas7bdat
11. runID_oth_med_cnt.sas7bdat
12. runID_total_lab.sas7bdat
13. total_medication.sas7bdat
14. vital_freq.sas7bdat
15. vital_mean.sas7bdat