Afternoon Session B: Overview of Cohort Identification and Descriptive Analysis (CIDA) SAS Analytic Package Creation

Agenda

- Review Sentinel Operations Center Process Flow

- Create a CIDA SAS Package
    1. Complete Specifications and Compile Code Lists
    2. Input Files
    3. RUN_PROGRAMS (Main Program)
    4. SASPROGRAM (Master Program)

Recap of this Morning's Session

- Introduced our case study problem
  - Stroke following antipsychotics use
- Evaluated medical product utilization data
  - Sentinel Query Builder (Simplified Type 5 CIDA) Analysis Tool
- Introduced design diagram and query specifications for an incidence rates query with associated propensity score matching analysis
  - How to parameterize the regulatory question

Medical Products Only	Outcomes Only	Medical Products & Outcomes

Incidence Rates
Type 2
(L1)

Propensity Score Analysis
Type 2 or 4
(L2) (L3)

Multiple Factor Matching
Type 2 or 4
(L2) (L3)

Self-Controlled Risk Interval Design
Type 3
(L2) (L3)

Develop Unadjusted Incidence Rates (Type 2)

- Identifies an exposure of interest and looks for the occurrence of health outcomes of interest (HOIs) during exposed time.

- Output metrics include number of exposure episodes and number of patients, number of health outcomes of interest, and days at-risk.

- Example
  - SGLT-2 Inhibitor Use and Incidence of Diabetic Ketoacidosis

Operations Center Process Flow

Operations Center Process Flow

Specification → SAS Analytic Package → Testing → Distribution → Report
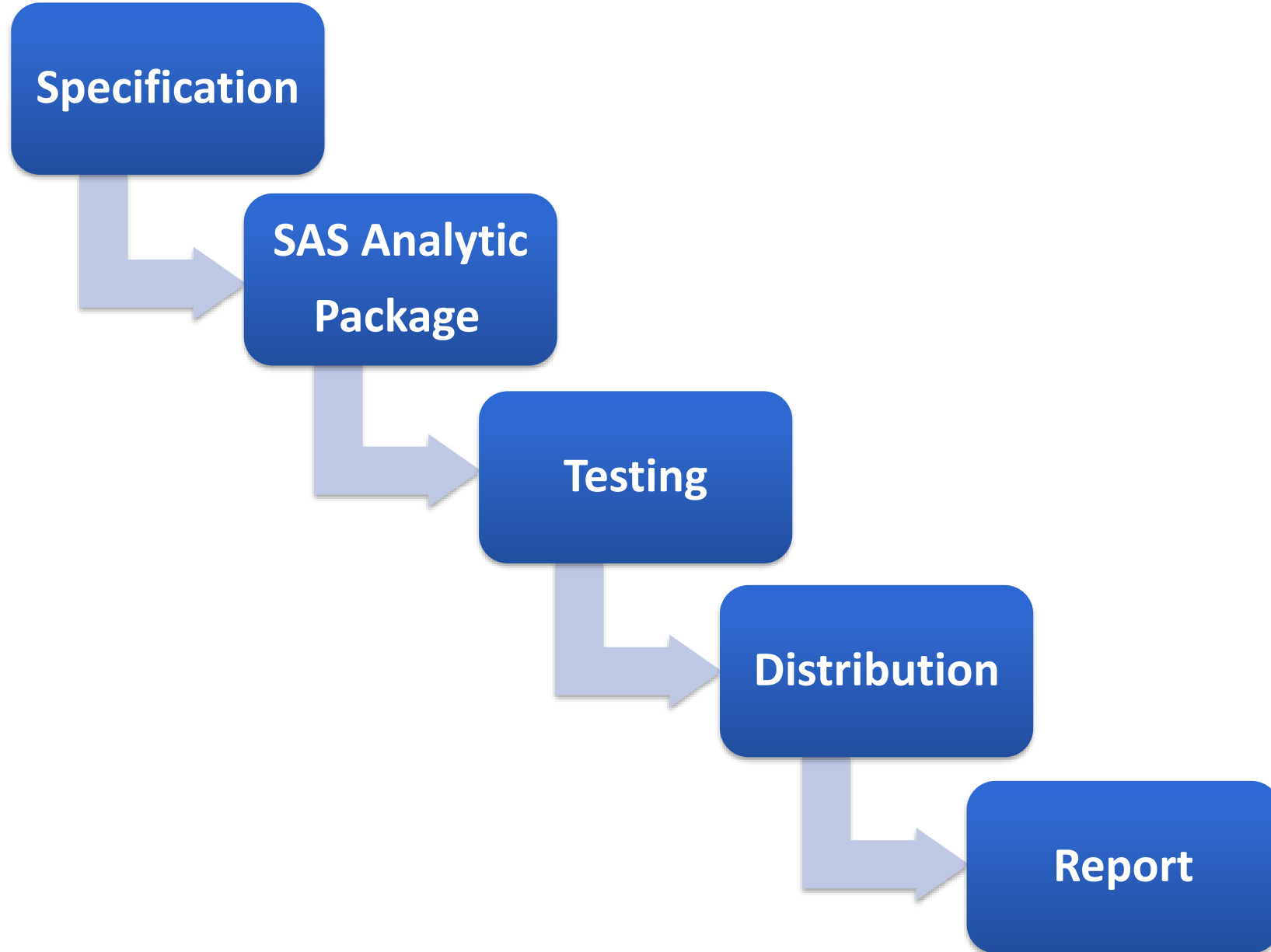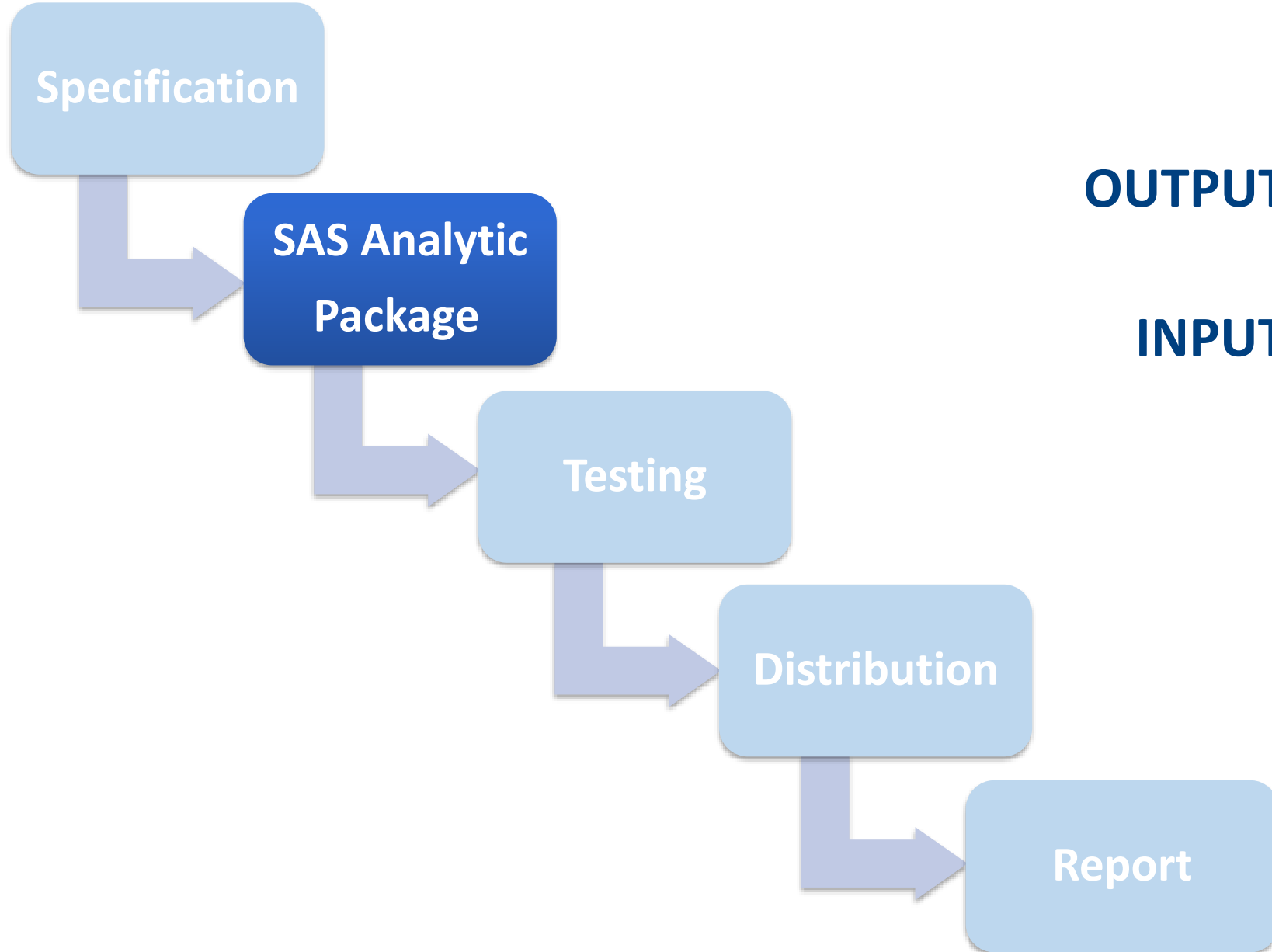
OUTPUT
- dplocal
- msoc

INPUT
- inputfiles
- sasprograms

SAS Analytic Package (Program) Runs Against Data

- DPLOCAL (Data Partner Local) – left empty
  - Location for patient-level data output that stays at Data Partner

- MSOC (Mini-Sentinel Operating Center) – left empty
  - Location for aggregate-level data output that is returned

- INPUTFILES contains SAS data sets with necessary parameters, CIDA look-up tables, and CIDA macros

- SASPROGRAMS contains the single SAS macro to be executed in order to run the package

📁 dplocal
📁 msoc
📁 inputfiles
📁 sasprograms
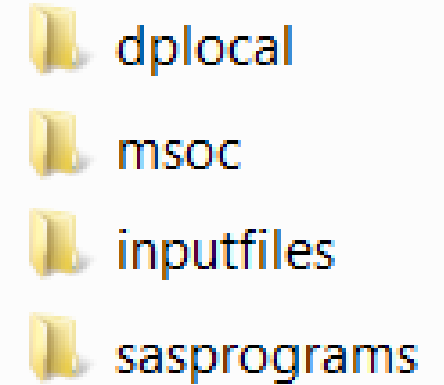
Creating a SAS Analytic Package

Sentinel

Specifications
- **Parameters**
- **Codes**

→

Input Files
- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

→

Main (run) Program
- **Input file names**

→

Master (SAS) Program
- **Package location**
- **Dataset location**

*Global Parameter Files

8
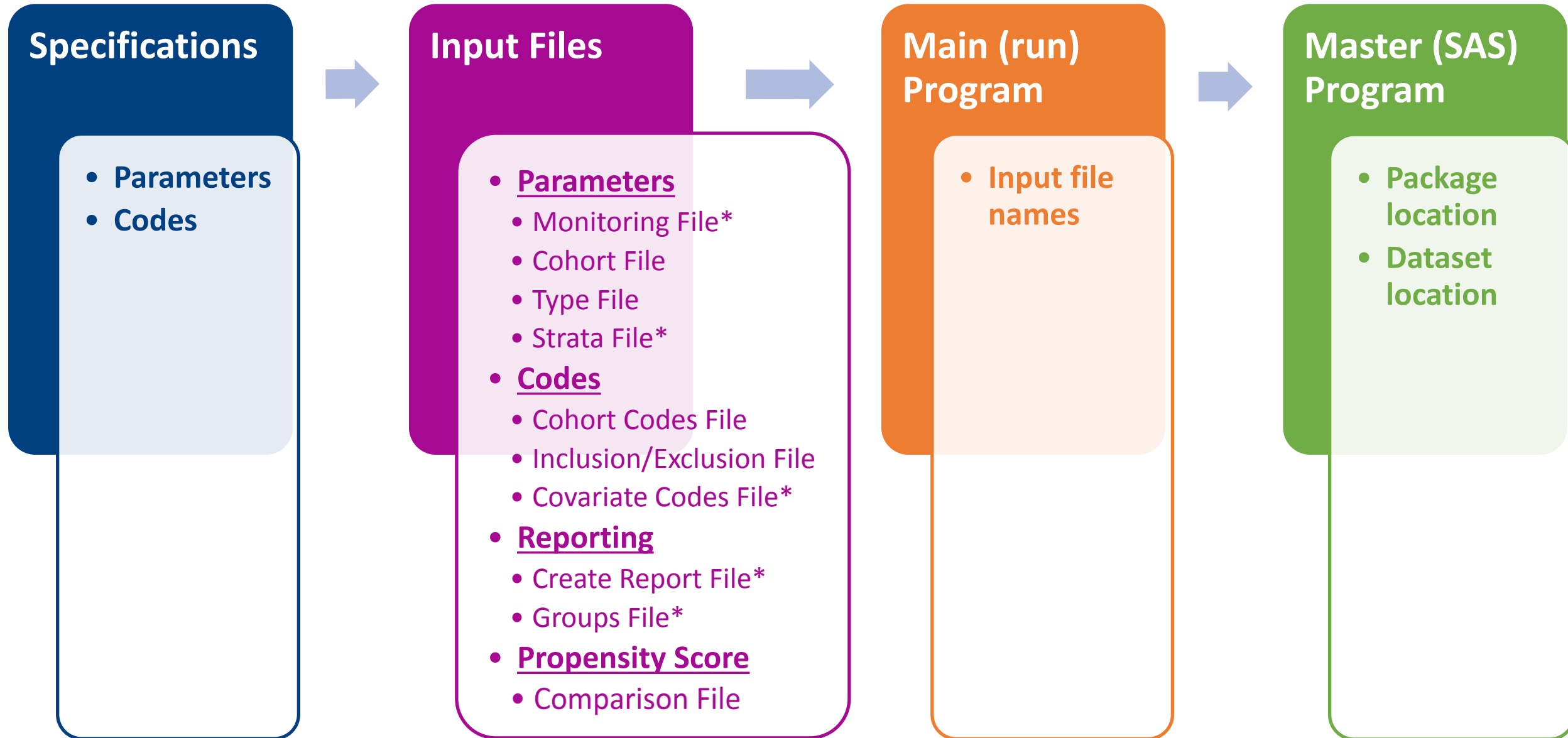
Step 1: Finalize Design Diagram and Specifications

Specifications

- **Parameters**
- **Codes**

Input Files

- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

Main (run) Program

- Input file names

Master (SAS) Program

- Package location
- Dataset location

*Global Parameter Files

Step 2: Parameterize Input Files

Sentinel

Specifications	Input Files	Main (run) Program	Master (SAS) Program

• Parameters
• Codes
	Parameters
	  • Monitoring File*
	  • Cohort File
	  • Type File
	  • Strata File*
	Codes
	  • Cohort Codes File
	  • Inclusion/Exclusion File
	  • Covariate Codes File*
	Reporting
	  • Create Report File*
	  • Groups File*
	Propensity Score
	  • Comparison File
		• Input file names	• Package location
			• Dataset location

*Global Parameter Files

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Step 3: Name and Locate Input Files

Sentinel

Specifications
- Parameters
- Codes

→

Input Files
- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

→

Main (run) Program
- **Input file names**

→

Master (SAS) Program
- Package location
- Dataset location

*Global Parameter Files

Step 4: Name and Locate Formatted Data

Sentinel

| Specifications	Input Files	Main (run) Program	Master (SAS) Program

• Parameters
 • Codes
	• **Parameters**
	  • Monitoring File*
	  • Cohort File
	  • Type File
	  • Strata File*
	 • **Codes**
	  • Cohort Codes File
	  • Inclusion/Exclusion File
	  • Covariate Codes File*
	 • **Reporting**
	  • Create Report File*
	  • Groups File*
	 • **Propensity Score**
	  • Comparison File
		• Input file names	• **Package location**
			 • **Dataset location**

*Global Parameter Files

Making a CIDA SAS Analytic Package: Let's work on the Input Files

Getting Setup

- Navigate to the "Lab" folder
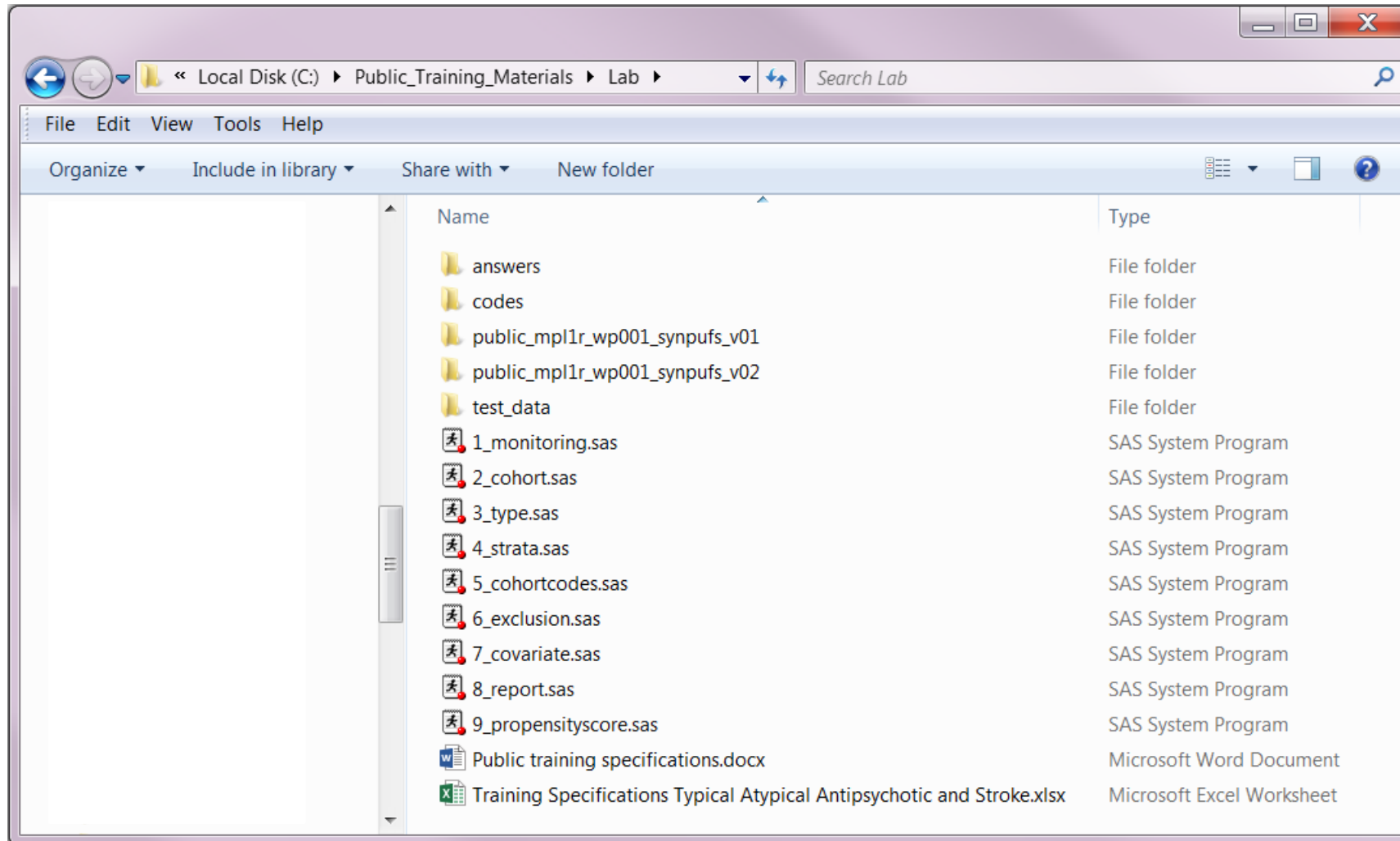
Materials

- Printed:
  - Specifications
  - Answer Key

- Webpage:
  - Sentinel Routine Querying Tool Documentation

- SAS files:
  - 9 SAS programs to create input files
  - SynPUFs Test Data

CIDA Documentation (dev.sentinelsystem.org)

CIDA Type 2 Documentation

EXPOSURES AND FOLLOW-UP TIME COHORT IDENTIFICATION STRATEGY

The exposures and follow-up time cohort creation strategy defines episodes of new use of a medical product of interest and evaluates the occurrence of HOIs. There are numerous requester options, including defining new use, exposed time, and episode censoring rules.

Identifying Exposure and Creating Exposure Episodes

An exposure can be defined using any set of NDCs, procedure and/or diagnosis codes, and laboratory result values found in the SCDM. Procedure and diagnosis codes can be restricted to those observed in specific care settings (*e.g.,* inpatient, outpatient) and diagnosis codes can be restricted by position (*e.g.,* principal discharge diagnosis, secondary diagnosis). For example, exposure to a drug product dispensed in the outpatient setting can be defined as observation of one or more NDCs in the pharmacy dispensing table, whereas exposure to a vaccine can be defined based on observation of specific procedure codes in the procedure table.

The CIDA tool queries the SDD and extracts all codes indicative of exposure during the query period. NDCs are processed and those with a part of their days supply outside enrollment episodes are truncated to constrain the supply within eligibility. Dispensing dates are modified using the stockpiling algorithm and supply is truncated again to make sure they are still in eligibility periods (stockpiling can push claims outside enrollment period).

After dispensing dates are adjusted using the stockpiling algorithm, exposure episodes are created. Exposure episodes can be defined in one of two ways: a) using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure, and b) defining a specific number of days after exposure initiation as exposed time.

Creating Exposure Episodes using Dispensing Days Supplied

An exposure episode using outpatient pharmacy dispensing days supplied is defined as a sequence of treatment that ends when interrupted by a gap in days supply greater than a requester-defined episode gap. Consider an example where five outpatient pharmacy dispensings of the exposure of interest are observed during the query period (Figure 1).

Technical Documentation by Type

Calculate background rate (Type 1)	Exposures and follow-up time (Type 2)	Self-controlled risk interval (SCRI) design (Type 3)	Pregnancy episodes and identify medical product use (Type 4)	Medical product utilization (Type 5)	Manufacturer-level product utilization and switching patterns (Type 6)
…	…	…	…	…	…
Technical Documentation					
Program Package and Execution	Program Package and Execution	Program Package and Execution	Program Package and Execution	Program Package and Execution	Program Package and Execution
Main Program Parameters	Main Program Parameters	Main Program Parameters	Main Program Parameters	Main Program Parameters	Main Program Parameters
Lookup Tables	Lookup Tables	Lookup Tables	Lookup Tables	Lookup Tables	Lookup Tables
				Additional Type 5 Lookup Table	
Input Files	Input Files	Input Files	Input Files	Input Files	Input Files
Output Files	Output Files	Output Files	Output Files	Output Files	Output Files

(excerpt)

Input Files by Type

COHORT IDENTIFICATION AND DESCRIPTIVE ANALYSIS (CIDA) TOOL INPUT TOOLS

Calculate background rate (Type 1)	Exposures and follow-up time (Type 2)	Self-controlled risk interval (SCRI) design (Type 3)	Pregnancy episodes and identify medical product use (Type 4)	Medical product utilization (Type 5)	Manufacturer-level product utilization and switching patterns (Type 6)
Introduction					
Input Files					
Required					
Cohort File	Cohort File	Cohort File	Cohort File	Cohort File	Cohort File
Type 1 File	Type 2 File	Type 3 File	Type 4 File	Type 5 File	Type 6 File
Monitoring File	Monitoring File	Cohort Codes File	Monitoring File	Monitoring File	Monitoring File
Cohort Codes File	Cohort Codes File	User-defined Strata Levels Lookup Table	Cohort Codes File	Cohort Codes File	Cohort Codes File
User-defined Strata Levels Lookup Table	User-defined Strata Levels Lookup Table		User-defined Strata Levels Lookup Table	User-defined Strata Levels Lookup Table	User-defined Strata Levels Lookup Table
			Pregnancy Duration File		
Optional					
Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File
Covariate Codes File	Covariate Codes File	Covariate Codes File	Covariate Codes File	Covariate Codes File	Stockpiling File
Comorbidity Score File	Comorbidity Score File	Comorbidity Score File	Mother-Infant Cohort File	Comorbidity Score File	Treatment Pathways File
Utilization File	Utilization File	Utilization File	Comorbidity Score File	Utilization File	

(excerpt)

https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse/files/file003-typeall-toccidainput.md

Back to Step 2: Input File Creation

Sentinel

Specifications	Input Files	Main (run) Program	Master (SAS) Program
• Parameters • Codes	**Parameters** • Monitoring File* • Cohort File • Type File • Strata File* **Codes** • Cohort Codes File • Inclusion/Exclusion File • Covariate Codes File* **Reporting** • Create Report File* • Groups File* **Propensity Score** • Comparison File	• Input file names	• Package location • Dataset location

*Global Parameter Files

Incidence Rates Design Diagram Recap

Covariate Evaluation Window
183 days to 1 day prior to index

Exclusion
Dementia 183 days to 0 day prior to index

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Definition
First valid exposure episode; no cohort re-entry

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

12/31/2010

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

Episode Censored at Event

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Event Incidence
No stroke in 60 days prior

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Inputs: Monitoring File

Covariate Evaluation Window
183 days to 1 day prior to index

Exclusion
Dementia 183 days to 0 day prior to index

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Definition
First valid exposure episode; no cohort re-entry

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Monitoring File

Episode Censored at Event

Monitoring File

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Event Incidence
No stroke in 60 days prior

22

Inputs: Cohort File

Covariate Evaluation Window
183 days to 1 day prior to index

Exclusion
Dementia 183 days to 0 day prior to index

Cohort Definition
First valid exposure episode; no cohort re-entry

Cohort File ←

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

1/1/2008

12/31/2010

Monitoring File

Monitoring File

Episode Censored at Event

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Event Incidence
No stroke in 60 days prior

23

Inputs: Type 2 File

Covariate Evaluation Window
183 days to 1 day prior to index

Exclusion
Dementia 183 days to 0 day prior to index

Cohort Definition
First valid exposure episode; no cohort re-entry

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort File ←

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Monitoring File

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Episode Censored at Event

Monitoring File

Event Incidence
No stroke in 60 days prior

→ **Type 2 File**

24

Inputs: Cohort Codes File

Covariate Evaluation Window
183 days to 1 day prior to index

Cohort Definition
First valid exposure episode; no cohort re-entry

Exclusion
Dementia 183 days to 0 day prior to index

Cohort File ←

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008   Cohort Codes File ←

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Monitoring File

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Episode Censored at Event

Monitoring File

Event Incidence
No stroke in 60 days prior

→ **Type 2 File and Cohort Codes File**

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Inputs: Inclusion/Exclusion and Covariate Codes File

Sentinel

Covariate Codes File ←

Covariate Evaluation Window
183 days to 1 day prior to index

Cohort Definition
First valid exposure episode; no cohort re-entry

Inclusion/Exclusion File ←

Exclusion
Dementia 183 days to 0 day prior to index

Cohort File ←

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

Cohort Codes File ←

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Monitoring File

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Episode Censored at Event

Monitoring File

Event Incidence
No stroke in 60 days prior

→ **Type 2 File and Cohort Codes File**

Step 2: Starting with the Parameter Files

Specifications

- Parameters
- Codes

Input Files

- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

Main (run) Program
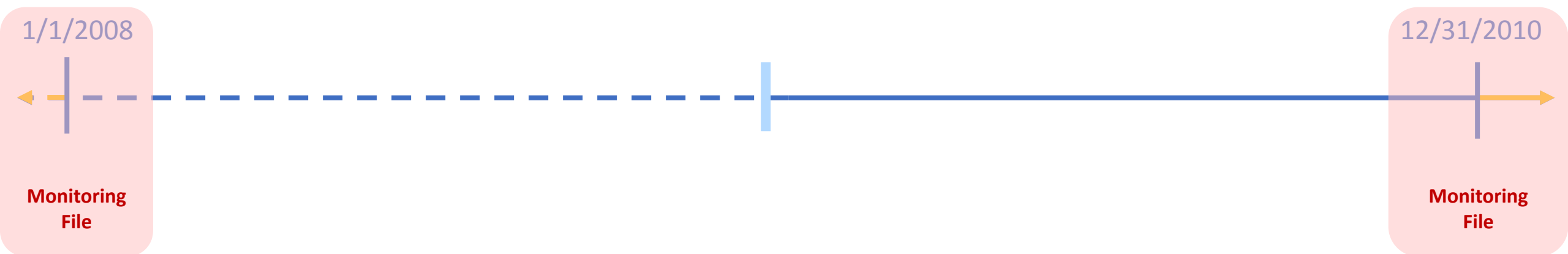
- Input file names

Master (SAS) Program

- Package location
- Dataset location

*Global Parameter Files

MONITORING FILE

PURPOSE: To establish the time period in which index dates can occur
PARAMETERS: 3

1/1/2008

12/31/2010

Monitoring File

Monitoring File

Exercise: Create Monitoring File

- Open **1_monitoring.sas** program
- Assign library: `%let basename = [FILL IN FILE PATH]/Public_Training_Materials/Lab;`

	periodid	startfollowup	enddate
1	1	.	.

```
data out.&wpnum._monitoring;
    format periodid 8. startfollowup date9. enddate date9.;
    periodid = 1;
    startfollowup =" "d; /* Type the query start date in format "04APR2019"d */
    enddate = " "d;      /* Type the query end date in format "04APR2019"d */
run;
```

Specifications – Defining Query Period

* **Query period:** 1/1/2008 - 12/31/2010
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: 183 days
Post-index enrollment requirement: 0
Enrollment gap: 45 days
Age groups: 18-39, 40-54, 55-65 years
* **Stratifications:** Age group, Sex, Calendar Year
Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days
* **Envelope macro:** Reclassify encounters during inpatient stay as inpatient
Propensity score analysis: 1:1 matching
Propensity score caliper: 0.05

* Global Parameters
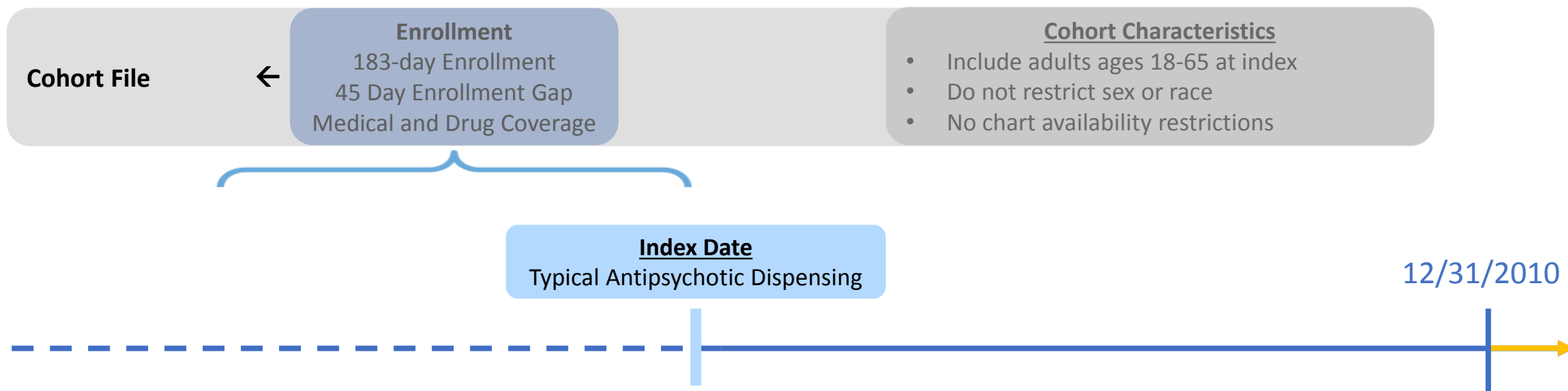
Finished Monitoring File

	periodid	startfollowup	enddate
1	1	01JAN2008	31DEC2010

```sas
data out.&wpnum._monitoring;
    format periodid 8. startfollowup date9. enddate date9.;
    periodid = 1;
    startfollowup ="01JAN2008"d; /* Type the query start date in format "04APR2019"d */
    enddate = "31DEC2010"d;      /* Type the query end date in format "04APR2019"d */
run;
```

COHORT FILE

PURPOSE: To define high level parameters for exposure-outcome cohorts
PARAMETERS: 16

Cohort File ← **Enrollment**
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

Index Date
Typical Antipsychotic Dispensing

1/1/2008

12/31/2010

Exercise: Create Cohort File

- Open **2_cohort.sas** program

- Assign library: `%let basename = [FILL IN FILE PATH]/Public_Training_Materials/Lab;`

	cohortgrp	coverage	enrolgap	enrdays	enrdaysaftind	type1	type2	type3	type4	type5	type6	chartres	sex	race	hispanic	agestrat
1	typ_is		.	.	.							N				18-39 40-54 55-65
2	typ_ich		.	.	.							N				18-39 40-54 55-65
3	atyp_is		.	.	.							N				18-39 40-54 55-65
4	atyp_ich		.	.	.							N				18-39 40-54 55-65

```
data work.cht;
format cohortgrp $40. coverage $2. enrolgap 8. enrdays 8. enrdaysaftind 8. type1 $1. type2 $1. type3 $1. type4 $1. type5 $1. type6 $1.
       chartres $1. sex $3. race $1. hispanic $1. agestrat $100.;
cohortgrp = "&curr_name";
```

How Many Scenarios/Groups do I Have?

Sentinel

Query purpose: to assess risk of <u>ischemic stroke</u> or <u>intracranial hemorrhage</u> among users of typical and atypical antipsychotics

- 2 exposure cohorts * 2 outcomes = 4 groups

Exposures

Users atypical antipsychotics	
Users atypical antipsychotics	
Users typical antipsychotics	
Users typical antipsychotics	

Outcomes

atyp_is → Ischemic stroke

atyp_ich → Intracranial hemorrhage

typ_is → Ischemic stroke

typ_ich → Intracranial hemorrhage

Specifying Scenarios

	Group	Index Exposure	Cohort definition	Incident exposure washout period	Incident w/ respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
1	typ_IS	Typical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
2	typ_ICH	Typical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
3	atyp_IS	Atypical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
4	atyp_ICH	Atypical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics

Exposure

Exercise: Create Cohort File

```
data work.cht;
format cohortgrp $40. coverage $2. enrolgap 8. enrdays 8. enrdaysaftind 8. type1 $1. type2 $1. type3 $1. type4 $1. type5 $1. type6 $1.
        chartres $1. sex $3. race $1. hispanic $1. agestrat $100.;
cohortgrp = "&curr_name";
coverage = ' '; /* Coverage Type Requirement; Valid values: 'MD' 'M' or 'D' for medical and drug, medical only, or drug only*/
enrolgap = . ; /* Enrollment Gap; Numerical */
enrdays = . ; /* Minimum Pre-Index Enrollment Days; Numerical*/
```

*Query period: 1/1/2008 - 12/31/2010

Coverage requirement: Medical and Drug

Pre-index enrollment requirement: 183 days

Post-index enrollment requirement: 0

Enrollment gap: 45 days

Age groups: 18-39, 40-54, 55-65 years

***Stratifications:** Age group, Sex, Calendar Year

Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days

***Envelope macro:** Reclassify encounters during inpatient stay as inpatient

Propensity score analysis: 1:1 matching

Propensity score caliper: 0.05

* Global Parameters

Exercise: Create Cohort File

```
data work.cht;
format cohortgrp $40. coverage $2. enrolgap 8. enrdays 8. enrdaysaftind 8. type1 $1. type2 $1. type3 $1. type4 $1. type5 $1. type6 $1.
        chartres $1. sex $3. race $1. hispanic $1. agestrat $100.;
cohortgrp = "&curr_name";
coverage = ' '; /* Coverage Type Requirement; Valid values: 'MD' 'M' or 'D' for medical and drug, medical only, or drug only*/
enrolgap = . ; /* Enrollment Gap; Numerical */
enrdays = . ; /* Minimum Pre-Index Enrollment Days; Numerical*/
type1 = ' '; /* Type 1 Cohort Identification Strategy Indicator; Valid values: 'Y' or 'N' */
type2 = ' '; /* Type 2 Cohort Identification Strategy Indicator; Valid values: 'Y' or 'N' */
type3 = ' '; /* Type 3 Cohort Identification Strategy Indicator; Valid values: 'Y' or 'N' */
type4 = ' '; /* Type 4 Cohort Identification Strategy Indicator; Valid values: 'Y' or 'N' */
type5 = ' '; /* Type 5 Cohort Identification Strategy Indicator; Valid values: 'Y' or 'N' */
type6 = ' '; /* Type 6 Cohort Identification Strategy Indicator; Valid values: 'Y' or 'N' */
sex = " "; /* Sex criteria to apply to cohort; Valid values: 'A' 'F' 'M' 'U'; Leave blank if no restrictions */
race = " "; /* Race criteria to apply to cohort; Leave blank if no restrictions */
hispanic = " "; /* Hispanic criteria to apply to cohort; Leave blank if no restrictions */
agestrat = '18-39 40-54 55-65';
enrdaysaftind = .;
chartres = 'N';
run;
```

Specifications – Stratifications and Demographics

* Query period: 1/1/2008 - 12/31/2010

Coverage requirement: Medical and Drug

Pre-index enrollment requirement: 183 days

Post-index enrollment requirement: 0

Enrollment gap: 45 days

Age groups: 18-39, 40-54, 55-65 years

* Stratifications: Age group, Sex, Calendar Year

Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days

* Envelope macro: Reclassify encounters during inpatient stay as inpatient

Propensity score analysis: 1:1 matching

Propensity score caliper: 0.05

* Global Parameters

Finished Cohort File

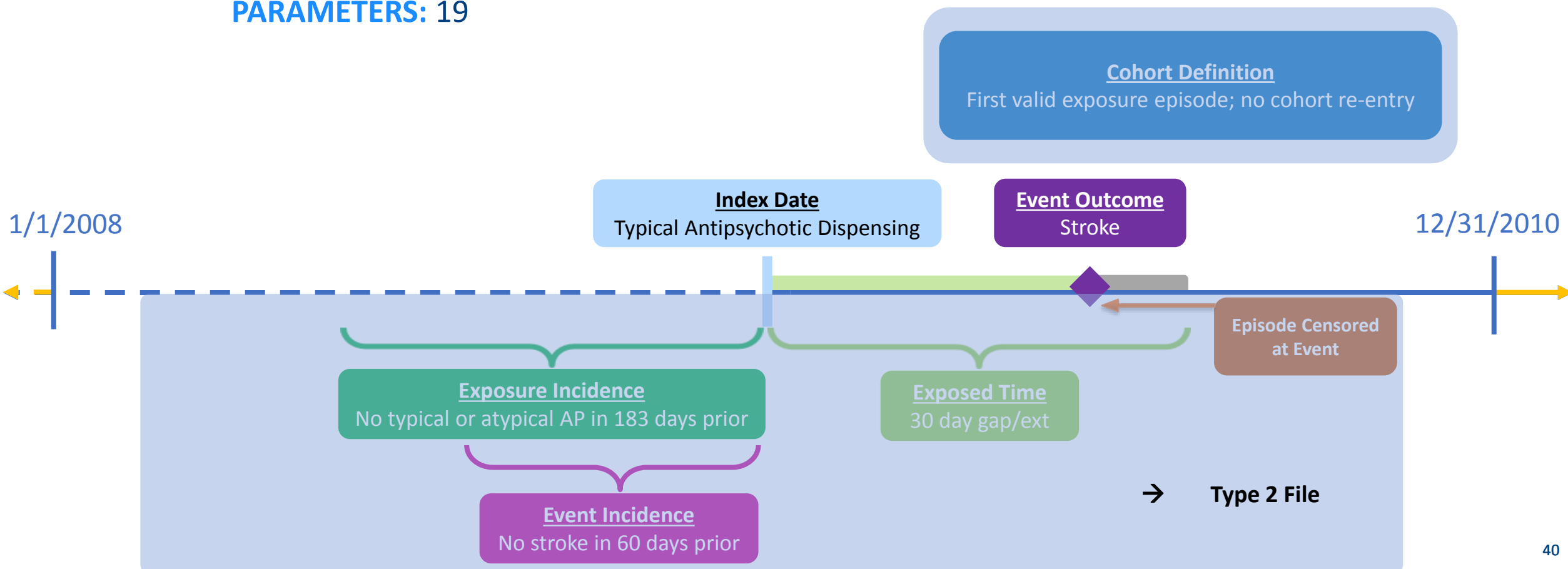|	cohortgrp	coverage	enrolgap	enrdays	enrdaysaftind	type1	type2	type3	type4	type5	type6	chartres	sex	race	hispanic	agestrat
1	typ_is	MD	45	183	. N	Y	N	N	N	N	N					18-39 40-54 55-65
2	atyp_is	MD	45	183	. N	Y	N	N	N	N	N					18-39 40-54 55-65
3	typ_ich	MD	45	183	. N	Y	N	N	N	N	N					18-39 40-54 55-65
4	atyp_ich	MD	45	183	. N	Y	N	N	N	N	N					18-39 40-54 55-65

Tips

- Match group names across all input files.

- Watch syntax around demographic restrictions.
    - Need to include single quotations around each letter

- Specify "Y" to 1 CIDA type per execution.

TYPE 2 FILE

PURPOSE: To define exposure and follow-up time strategies, per cohort
PARAMETERS: 19

Cohort Definition
First valid exposure episode; no cohort re-entry

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

1/1/2008

12/31/2010

Episode Censored at Event

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Event Incidence
No stroke in 60 days prior

→ **Type 2 File**

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Exercise: Create Type 2 File

- Open **3_type.sas** program
- Assign library: `%let basename = [FILL IN FILE PATH]/Public_Training_Materials/Lab;`

	group	t2cohortdef	t2washper	ittdays	episodegaptype	episodegap	expextper	minepisdur	maxepisdur	mindaysupp	enrdaysaftepi
1	typ_is		.	.		.	.	.	.	.	.
2	typ_ich		.	.		.	.	.	.	.	.
3	atyp_is		.	.		.	.	.	.	.	.
4	atyp_ich		.	.		.	.	.	.	.	.

t2fupwashper	blackoutper	eventcount	censor_output_cat	censor_dth	censor_dpend	censor_qryend	neverexposedcohort
.	.	2	0-364 365-729 730-1094 1095+				N
.	.	2	0-364 365-729 730-1094 1095+				N
.	.	2	0-364 365-729 730-1094 1095+				N
.	.	2	0-364 365-729 730-1094 1095+				N

```
data work.type;
format group $40. t2cohortdef $2. t2washper 8. ittdays 8. episodegaptype $1. episodegap 8. expextper 8.
       minepisdur 8. maxepisdur 8. mindaysupp 8. enrdaysaftepi 8. t2fupwashper 8. blackoutper 8. eventcount 8.
       censor_output_cat $30. censor_dth $1. censor_dpend $1. censor_qryend $1. neverexposedcohort $1. ;
group = "&curr_name";
t2cohortdef = ' '; /* Allowed Number of Exposure Episodes per Individual;
                    Valid values: '01' '02' '03' for first episode only, all episodes, or all episodes until event*/
```

How Many Valid Index Dates? Cohort Definition
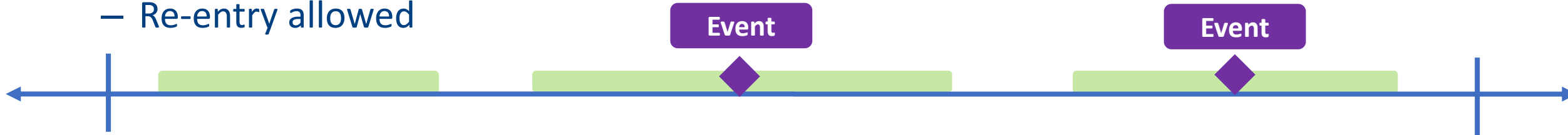
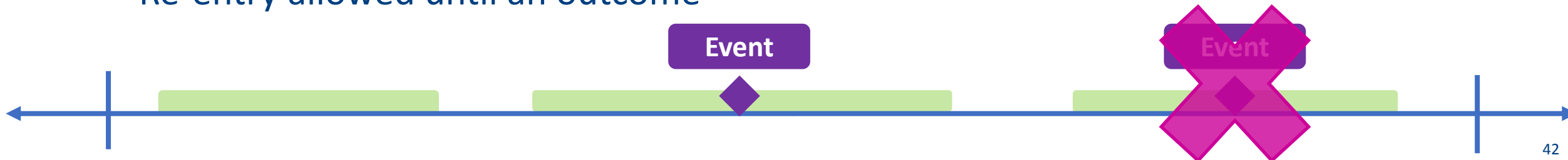- Cohort Definition 01
  - No re-entry
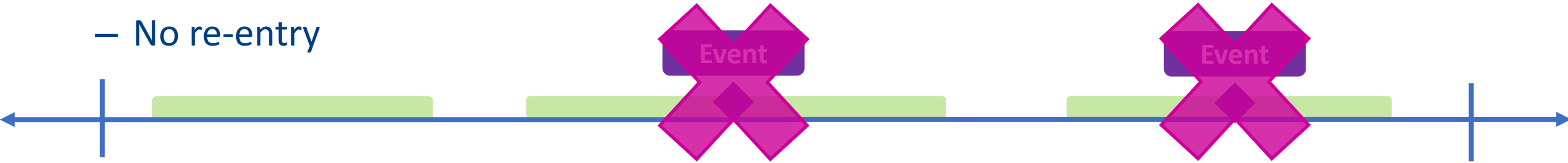
- Cohort Definition 02:
  - Re-entry allowed

- Cohort Definition 03:
  - Re-entry allowed until an outcome

Specifications – Groups

Group	Exposure Index Exposure	Cohort definition	Incident exposure washout period	Incident w/ respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
1 typ_IS	Typical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
2 typ_ICH	Typical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
3 atyp_IS	Atypical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
4 atyp_ICH	Atypical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics

Specifications – Event Outcome

	Group		Event Outcome					
	Group	Event	Care setting	Principal diagnosis position	Event washout conditions	Event washout care setting	Event washout period	Blackout period
1	typ_IS	Ischemic stroke	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1
2	typ_ICH	Intracranial hemorrhage	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1
3	atyp_IS	Ischemic stroke	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1
4	atyp_ICH	Intracranial hemorrhage	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1

Exercise: Create Type 2 File

- Fill in type 2 file parameters in your **3_type.sas** program

```sas
data work.type;
format group $40. t2cohortdef $2. t2washper 8. ittdays 8. episodegaptype $1. episodegap 8. expextper 8.
        minepisdur 8. maxepisdur 8. mindaysupp 8. enrdaysaftepi 8. t2fupwashper 8. blackoutper 8. eventcount 8.
        censor_output_cat $30. censor_dth $1. censor_dpend $1. censor_qryend $1. neverexposedcohort $1. ;
group = "&curr_name";
t2cohortdef = ' '; /* Allowed Number of Exposure Episodes per Individual;
                        Valid values: '01' '02' '03' for first episode only, all episodes, or all episodes until event*/
t2washper = . ; /* Type 2 Exposure Washout Period; Numerical; Required – enter 0 if not using */
ittdays = . ; /* Requester-defined Exposure Episode Length; Numerical; Leave blank if creating as-treated episodes */
episodegaptype= ' '; /* Treatment Episode Gap Type; Valid values: 'F' or 'P' for fixed or percent */
episodegap = . ; /* Exposure Episode Gap; Numerical; Required – enter 0 if not using */
expextper = . ; /* Exposure Episode Extension Period; Numerical; Optional */
minepisdur = . ; /* Minimum Exposure Episode Duration; Numerical; Required – enter 0 if not using */
maxepisdur = . ; /* Maximum Exposure Episode Duration; Numerical; Optional */
mindaysupp = . ; /* Minimum Days Supplied; Numerical; Required – enter 0 if not using */
t2fupwashper = . ; /* Type 2 HOI Washout Period; Numerical; Required – enter 0 if not using */
blackoutper = . ; /* HOI Blackout Period; Numerical; Required – enter 0 if not using */
censor_dth = ' '; /* Censor Episodes at Evidence of Death; Valid values: 'Y' or 'N'; Required*/
censor_dpend = ' '; /* Censor Episodes at Data End Date; Valid values: 'Y' or 'N'; Required*/
censor_qryend = ' '; /* Censor Episodes at Query End Date; Valid values: 'Y' or 'N'; Required*/
censor_output_cat = '0-364 365-729 730-1094 1095+';
enrdaysaftepi = .;
eventcount = 2;
neverexposedcohort= 'N';
run;
```

Finished Type 2 File

	group	t2cohortdef	t2washper	ittdays	episodegaptype	episodegap	expextper	minepisdur	maxepisdur	mindaysupp	enrdaysaftepi
1	typ_is	01	183	. F		30	30	1	.	1	.
2	atyp_is	01	183	. F		30	30	1	.	1	.
3	typ_ich	01	183	. F		30	30	1	.	1	.
4	atyp_ich	01	183	. F		30	30	1	.	1	.

t2fupwashper	blackoutper	eventcount	censor_output_cat	censor_dth	censor_dpend	censor_qryend	neverexposedcohort
60	1 2		0-364 365-729 730-1094 1095+	Y	Y	Y	N
60	1 2		0-364 365-729 730-1094 1095+	Y	Y	Y	N
60	1 2		0-364 365-729 730-1094 1095+	Y	Y	Y	N
60	1 2		0-364 365-729 730-1094 1095+	Y	Y	Y	N

Tips

- A blackout period of 0 does not invoke blackout; a blackout period of '1' invokes blackout on day 0 (index date)

- Know whether your parameter is a timeline label or numeric quantity

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USER-DEFINED STRATA FILE

PURPOSE: To define both the output tables that will be returned as well as the stratifications of each output table
PARAMETERS: 3

Specifications – Stratifications

* Query period: 1/1/2008 - 12/31/2010
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: 183 days
Post-index enrollment requirement: 0
Enrollment gap: 45 days
Age groups: 18-39, 40-54, 55-65 years
* Stratifications: Age group, Sex, Calendar Year
Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days
* Envelope macro: Reclassify encounters during inpatient stay as inpatient
Propensity score analysis: 1:1 matching
Propensity score caliper: 0.05

* Global Parameters

Input Files by Type

Table of Contents

COHORT IDENTIFICATION AND DESCRIPTIVE ANALYSIS (CIDA) TOOL INPUT TOOLS

Calculate background rate (Type 1)	Exposures and follow-up time (Type 2)	Self-controlled risk interval (SCRI) design (Type 3)	Pregnancy episodes and identify medical product use (Type 4)	Medical product utilization (Type 5)	Manufacturer-level product utilization and switching patterns (Type 6)
Introduction					
Input Files					
Required					
Cohort File	Cohort File	Cohort File	Cohort File	Cohort File	Cohort File
Type 1 File	Type 2 File	Type 3 File	Type 4 File	Type 5 File	Type 6 File
Monitoring File	Monitoring File	Cohort Codes File	Monitoring File	Monitoring File	Monitoring File
Cohort Codes File	Cohort Codes File	User-defined Strata Levels Lookup Table	Cohort Codes File	Cohort Codes File	Cohort Codes File
User-defined Strata Levels Lookup Table	User-defined Strata Levels Lookup Table		User-defined Strata Levels Lookup Table	User-defined Strata Levels Lookup Table	User-defined Strata Levels Lookup Table
			Pregnancy Duration File		
Optional					
Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File	Inclusion/Exclusion Codes File
Covariate Codes File	Covariate Codes File	Covariate Codes File	Covariate Codes File	Covariate Codes File	Stockpiling File
Comorbidity Score File	Comorbidity Score File	Comorbidity Score File	Mother-Infant Cohort File	Comorbidity Score File	Treatment Pathways File
Utilization File	Utilization File	Utilization File	Comorbidity Score File	Utilization File	
...	...	...	...	...	...

(excerpt)

Lookup Valid Stratifications for a Type 2

Table 4. Valid Stratification Variables for a Type 2 Analysis (Exposure and Follow-up Time)

Variable Name	t2_cida	t2_censor
agegroup	X	X
cb_reg	X	
censdays_value		X
censdays_value_cat		X
covarn	X	
Event_Flag		X
hhs_reg	X	
hispanic	X	
month	X	
race	X	
sex	X	X
state	X	
year	X	X
zip_uncertain	X	
zip3	X	

* **Query period:** 1/1/2008 – 12/31/2010
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: 183 days
Post-index enrollment requirement: 0
Enrollment gap: 45 days
Age groups: 18-39, 40-54, 55-65 years
* **Stratifications:** Age group, Sex, Calendar Year
Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days
* **Envelope macro:** Reclassify encounters during inpatient stay as inpatient
**Propensity score analysis:** 1:1 matching
Propensity score caliper: 0.05

Standard Strata Levels

Table 2. Standard Strata Level IDs

These stratfication levels apply for the following datasets: ([RUNID]_ prefix and sas7bdat extension removed): t1_cida, t2_cida,

LevelID	LevelVars
000	*blank*
001	year
002	sex
003	agegroup
004	sex agegroup
005	sex agegroup year
006	sex agegroup year month
007	agegroup year
008	agegroup year month
009	sex year
010	sex year month
011	year month
020	zip3
021	zip3 zip_uncertain
022	zip3 sex
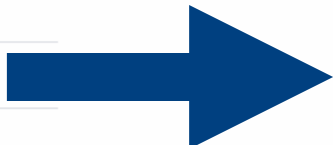
	tableid	levelid	levelvars
1	t2cida	000	
2	t2cida	001	year
3	t2cida	002	sex
4	t2cida	003	agegroup
5	t2censor	701	censdays_value_cat

https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse/files/file626-typeall-strata.md

User-defined Strata File Overview

- Specify which output tables should be produced and with which strata levels

```sas
data out.&wpnum._type2strata;
format tableid $20. levelid $3. levelvars $30.;
tableid = "t2cida";
levelid = "000";
levelvars = "";
output;

tableid = "t2cida";
levelid = "001";
levelvars = "year";
output;

tableid = "t2cida";
levelid = "002";
levelvars = "sex";
output;

tableid = "t2cida";
levelid = "003";
levelvars = "agegroup";
output;

tableid = "t2censor";
levelid = "701";
levelvars = "censdays_value_cat";
output;
run;
```

Step 2: Moving on to Code Files

Specifications
- Parameters
- Codes

Input Files
- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

Main (run) Program
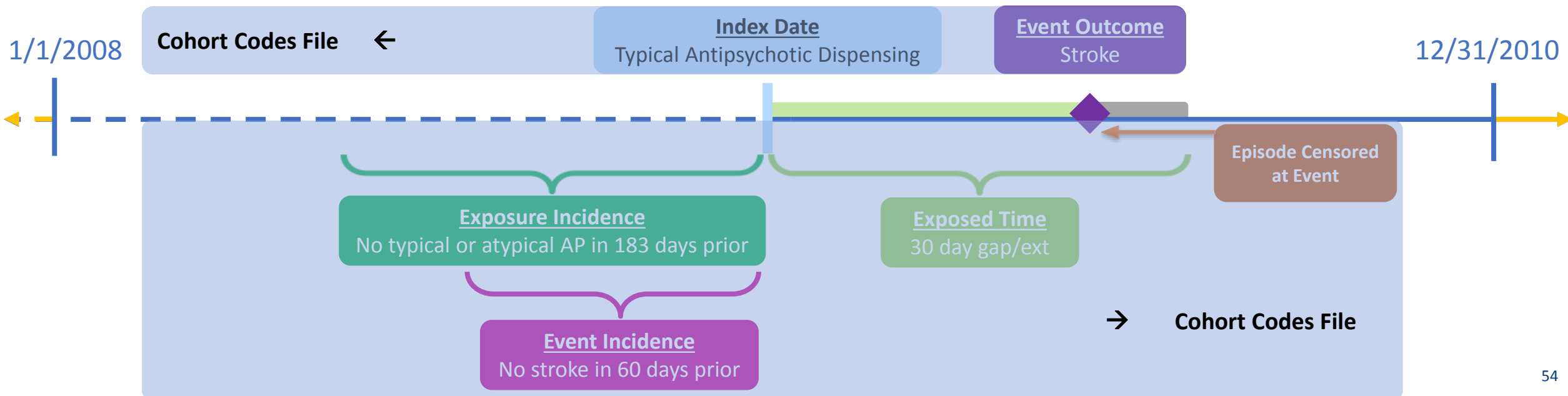- Input file names

Master (SAS) Program
- Package location
- Dataset location

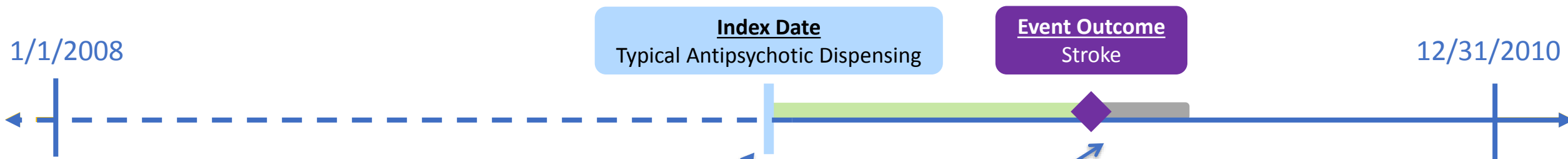*Global Parameter Files

COHORT CODES FILE

PURPOSE: Assignment of roles to relevant codes for roles in cohort identification
PARAMETERS: 23

Exercise: Create Cohort Codes File

- Open **5_cohortcodes.sas** program
- Assign library: `%let basename = [FILL IN FILE PATH]/Public_Training_Materials/Lab;`
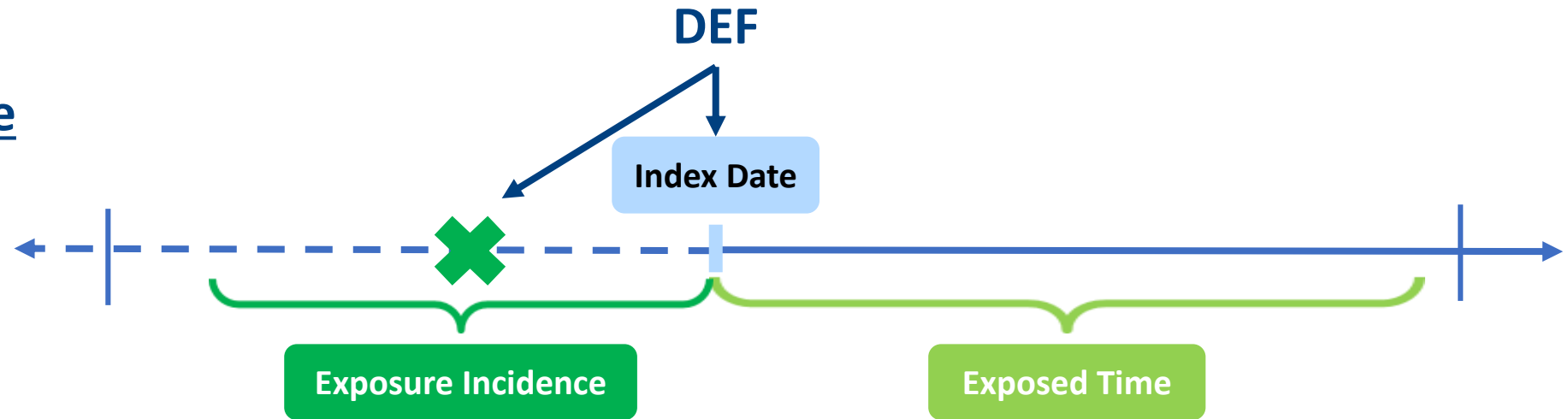

1/1/2008

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

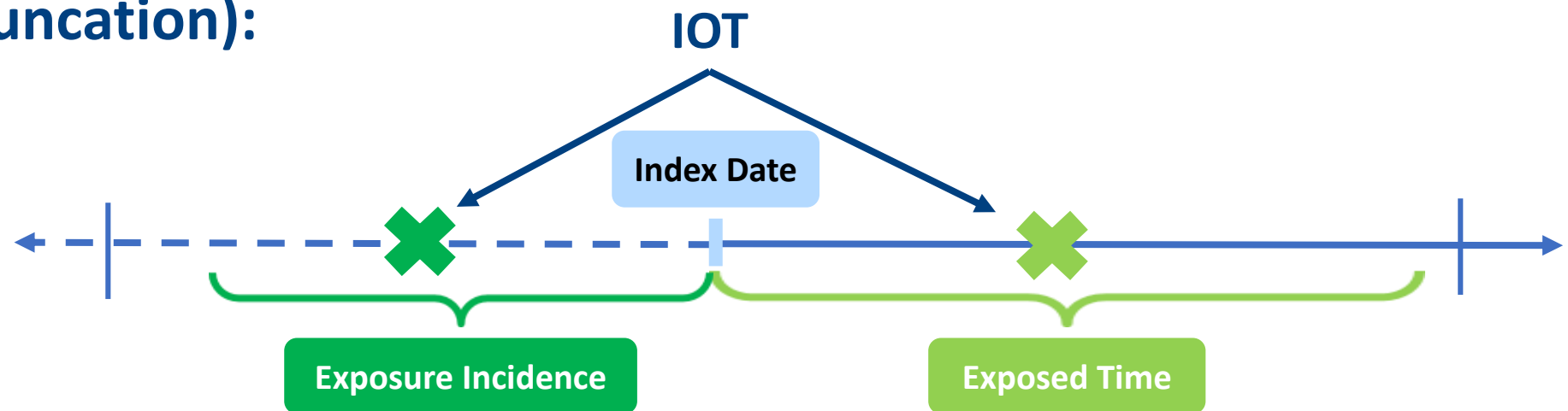Focused on 2 Anchor Points

1. Index (t#_index in CIDA)

2. Outcome (t#_fup in CIDA)

Cohort Codes File – Parameter T2_INDEX

DEF (Definition):
Code defines <u>index date</u> and <u>incidence</u> criteria

DEF

Index Date

Exposure Incidence

Exposed Time

IOT (Incidence or Truncation):
Code defines <u>incidence</u> and <u>truncation</u> criteria

IOT

Index Date

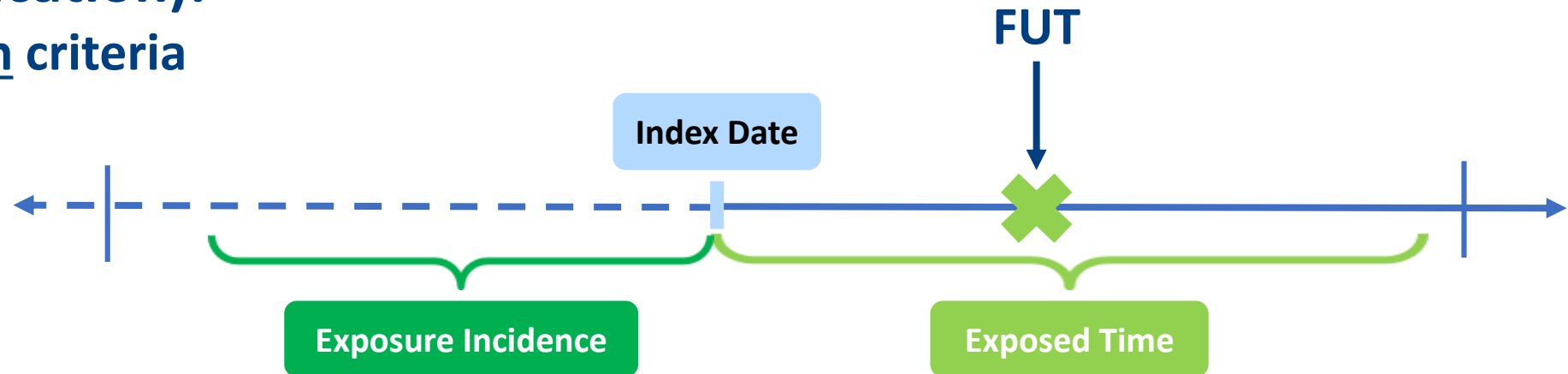Exposure Incidence

Exposed Time

Cohort Codes File – Parameter T2_INDEX

IOD (Incidence Only Duration):
Code defines <u>incidence</u> criteria
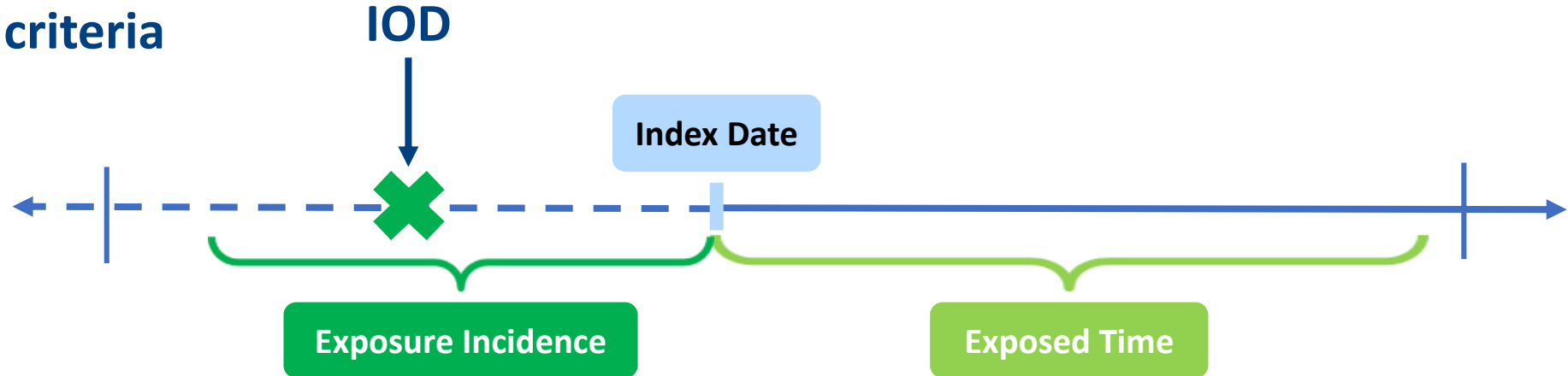
FUT (Follow-up Truncation):
Code defines <u>truncation</u> criteria

Cohort Codes File – Specifications

	Group	Index Exposure	Cohort definition	Incident exposure washout period	Incident w/ respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
1	typ_IS	Typical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
2	typ_ICH	Typical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
3	atyp_IS	Atypical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics
4	atyp_ICH	Atypical Antipsychotics	First valid exposure episode during query period	183 days	Typical and atypical antipsychotics	30 days	30 days	1	1	None	Death; DP end date; Query end date; Atypical antipsychotics

Exposure

Index

Incidence

Censoring

Cohort Codes File – Inputs

- Input code lists to define exposure and outcome using National Drug Codes (NDCs) and diagnosis codes
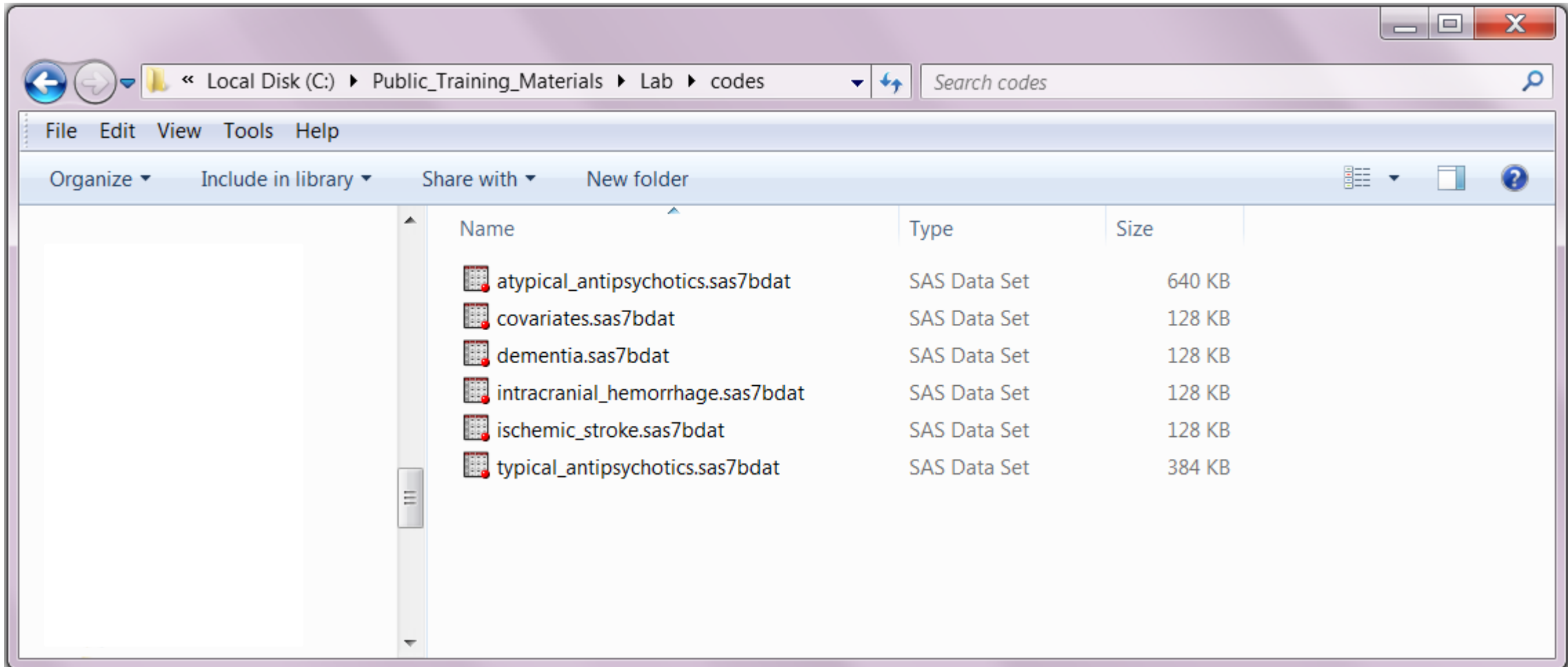
Exercise: Create Cohort Codes File

Group	t2_index = DEF	t2_index = IOT
typ_is	typical_antipsychotics	
typ_ich		
atyp_is		
atyp_ich		

Code List Key	
Clinical Concept	**SAS Dataset with Codes**
Typical antipsychotics	**typical_antipsychotics**
Atypical antipsychotics	**atypical_antipsychotics**
Ischemic stroke	**ischemic_stroke**
Intracranial hemorrhage	**intracranial_hemorrhage**

Exercise Part 1: Create Cohort Codes File

- Set index codes in your **5_cohortcodes.sas** program

```sas
%macro indexcodes (title,group,codes);
    data indexcodes&title.;
    format group $40. stockgroup $30. codecat $2. codetype $3. code1 $11. code $11. caresettingprincipal $41.
            t1_index $3. t2_index $3. t2_fup $3. conc_fup $3. t3_index $3. t3_fup $3. t4_index $3. t4_fup $3. t5_index $3. t6_index $3.
            productapprovaldate Date9. productmarketingdate Date9. otherproductdate Date9. excludesupply $1. codesupply 8.
            rawlabdatetype $3. rawlabresult $3. ;
    set in.&codes.;
    group = "&group.";
    stockgroup = compress (descrip, ', ./\_-<>=;&[](){}%');
    codecat = CodeCat1;
    codetype = CodeType1;
    code = compress (code1, ".");
    caresettingprincipal = " ";

    t1_index = 'NOT';
    t2_index = 'DEF'; /*When defining index-defining codes for exposure, t2_index must = 'DEF' */
    t2_fup = 'NOT';    /*When defining exposure, t2_fup must = 'NOT' */
...
%mend;

%indexcodes (1,typ_is, typical_antipsychotics);     /*Fill in group 1 name and code list to define index exposure */
%indexcodes (2,typ_ich, typical_antipsychotics);   /*Fill in group 2 name and code list to define index exposure */
%indexcodes (3,atyp_is, atypical_antipsychotics);   /*Fill in group 3 name and code list to define index exposure */
%indexcodes (4,atyp_ich, atypical_antipsychotics); /*Fill in group 4 name and code list to define index exposure */
```

Exercise Part 2: Create Cohort Codes File

- Set incidence-defining codes in your **5_cohortcodes.sas** program

```
%macro inc_trunc_codes (title,group,codes);
    data inc_trunc_codes&title.;
    format group $40. stockgroup $30. codecat $2. codetype $3. code1 $11. code $11. caresettingprincipal $41.
        t1_index $3. t2_index $3. t2_fup $3. conc_fup $3. t3_index $3. t3_fup $3. t4_index $3. t4_fup $3. t5_index $3. t6_index $3.
        productapprovaldate Date9. productmarketingdate Date9. otherproductdate Date9. excludesupply $1. codesupply 8.
        rawlabdatetype $3. rawlabresult $3. ;
    set in.&codes.;
    group = "&group.";
    stockgroup = compress (descrip, ', ./\_-<>=;&[](){}%');
    codecat = CodeCat1;
    codetype = CodeType1;
    code = compress (code1, ".");
    caresettingprincipal = " ";

    t1_index = 'NOT';
    t2_index = 'IOT'; /*When defining incidence and truncation criteria for exposure, t2_index should = 'IOT' */
    t2_fup = 'NOT';   /*When defining exposure, t2_fup must = 'NOT' */
    ...

%mend;
```

```
%inc_trunc_codes (1,typ_is, atypical_antipsychotics);  /*Fill in group 1 name and code list to define incidence and truncation criteria */
%inc_trunc_codes (2,typ_ich, atypical_antipsychotics); /*Fill in group 2 name and code list to define incidence and truncation criteria */
%inc_trunc_codes (3,atyp_is, typical_antipsychotics);  /*Fill in group 3 name and code list to define incidence and truncation criteria */
%inc_trunc_codes (4,atyp_ich, typical_antipsychotics); /*Fill in group 4 name and code list to define incidence and truncation criteria */
```

Exercise: Create Cohort Codes File

Group	t2_index = DEF	t2_index = IOT	t2_fup = DEF	t2_fup = IOC
typ_is	typical_antipsychotics	atypical_antipsychotics		
typ_ich	typical_antipsychotics	atypical_antipsychotics		
atyp_is	atypical_antipsychotics	typical_antipsychotics		
atyp_ich	atypical_antipsychotics	typical_antipsychotics		

Code List Key	
Clinical Concept	**SAS Dataset with Codes**
Typical antipsychotics	**typical_antipsychotics**
Atypical antipsychotics	**atypical_antipsychotics**
Ischemic stroke	**ischemic_stroke**
Intracranial hemorrhage	**intracranial_hemorrhage**

Cohort Codes File - Sample

	group	stockgroup	codecat	codetype	code	caresettingprincipal	t2_index	t2_fup
1	typ_is	FLUPHENAZINEHCL	RX	11	00003080110		DEF	NOT
2	typ_is	FLUPHENAZINEHCL	RX	11	00003082030		DEF	NOT
3	typ_is	FLUPHENAZINEHCL	RX	11	00003082050		DEF	NOT
4	typ_is	FLUPHENAZINEHCL	RX	11	00003086350		DEF	NOT
5	typ_is	FLUPHENAZINEHCL	RX	11	00003087750		DEF	NOT
6	typ_is	FLUPHENAZINEHCL	RX	11	00003095650		DEF	NOT
7	typ_is	CHLORPROMAZINEHCL	RX	11	00007506315		DEF	NOT
8	typ_is	CHLORPROMAZINEHCL	RX	11	00007506415		DEF	NOT
9	typ_is	CHLORPROMAZINEHCL	RX	11	00007506615		DEF	NOT
10	typ_is	CHLORPROMAZINEHCL	RX	11	00007507244		DEF	NOT
11	typ_is	CHLORPROMAZINEHCL	RX	11	00007507320		DEF	NOT
12	typ_is	CHLORPROMAZINEHCL	RX	11	00007507420		DEF	NOT
13	typ_is	CHLORPROMAZINEHCL	RX	11	00007507430		DEF	NOT
14	typ_is	CHLORPROMAZINEHCL	RX	11	00007507620		DEF	NOT
15	typ_is	CHLORPROMAZINEHCL	RX	11	00007507630		DEF	NOT
16	typ_is	CHLORPROMAZINEHCL	RX	11	00007507720		DEF	NOT
17	typ_is	CHLORPROMAZINEHCL	RX	11	00007507730		DEF	NOT
18	typ_is	CHLORPROMAZINEHCL	RX	11	00007507920		DEF	NOT
19	typ_is	CHLORPROMAZINEHCL	RX	11	00007507930		DEF	NOT
20	typ_is	HALOPERIDOLLACTATE	RX	11	00045025004		DEF	NOT

Exercise: Create Cohort Codes File
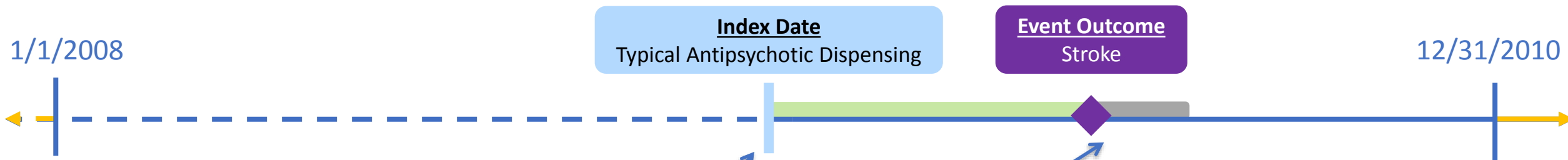
Sentinel

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Focused on 2 Anchor Points

1. Index (t#_index in CIDA)

2. Outcome (t#_fup in CIDA)

Cohort Codes File – Parameter T2_FUP

DEF (Definition):
Code defines event outcome and incidence criteria

DEF

Index Date

Event Outcome

Event Incidence

Exposed Time
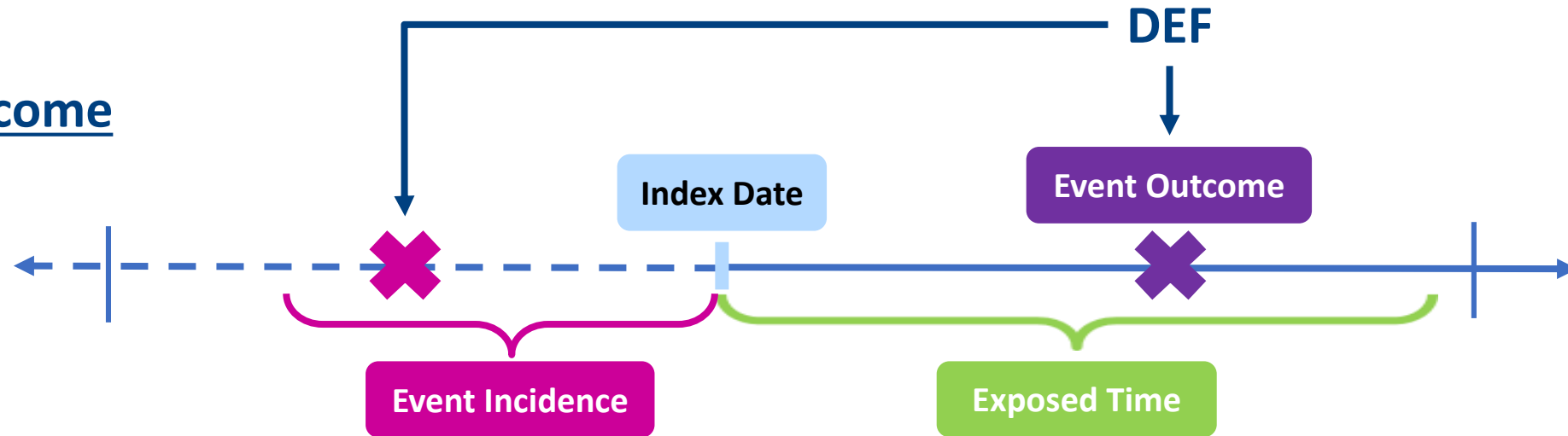
IOC (Incidence Only Criteria):
Code defines event incidence criteria

IOC

Index Date

Event Outcome

Event Incidence

Exposed Time

Cohort Codes File – Specifications

Group	Event	Care setting	Principal diagnosis position	Event washout conditions	Event washout care setting	Event washout period	Blackout period
	Event Outcome						
1 typ_IS	Ischemic stroke	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1
2 typ_ICH	Intracranial hemorrhage	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1
3 atyp_IS	Ischemic stroke	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1
4 atyp_ICH	Intracranial hemorrhage	Inpatient hospital stay	Principal	Stroke (ischemic stroke and intracranial hemorrhage)	Any care setting	60	1

Outcome

Exercise Part 3: Create Cohort Codes File

- Set outcome-defining codes in your **5_cohortcodes.sas** program

```sas
%macro outcomecodes (title,group,codes);
    data outcomecodes&title.;
    format group $40. stockgroup $30. codecat $2. codetype $3. code1 $11. code $11. caresettingprincipal $41.
        t1_index $3. t2_index $3. t2_fup $3. conc_fup $3. t3_index $3. t3_fup $3. t4_index $3. t4_fup $3. t5_index $3. t6_index $3.
        productapprovaldate Date9. productmarketingdate Date9. otherproductdate Date9. excludesupply $1. codesupply 8.
        rawlabdatetype $3. rawlabresult $3. ;
    set in.&codes.;
    group = "&group.";
    stockgroup = compress (descrip, ', ./\_-<>=;&[](){}%');
    codecat = CodeCat1;
    codetype = CodeType1;
    code = compress (code1, ".");
    caresettingprincipal = "'IPP'";

    t1_index = 'NOT';
    t2_index = 'NOT'; /*When defining outcome, t2_index must = 'NOT' */
    t2_fup = 'DEF';   /*When defining outcome, t2_fup must = 'DEF' */

    ...

%mend;
```

```sas
%outcomecodes (1,typ_is,  ischemic_stroke);         /*Fill in group 1 name and code list to define outcome */
%outcomecodes (2,typ_ich, intracranial_hemorrhage); /*Fill in group 2 name and code list to define outcome */
%outcomecodes (3,atyp_is, ischemic_stroke);         /*Fill in group 3 name and code list to define outcome */
%outcomecodes (4,atyp_ich, intracranial_hemorrhage); /*Fill in group 4 name and code list to define outcome */
```

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Exercise Part 4: Create Cohort Codes File

- Set outcome incidence-defining codes in your **5_cohortcodes.sas** program

```sas
%macro outcomeinccodes (title,group,codes);
    data outcomeinccodes&title.;
    format group $40. stockgroup $30. codecat $2. codetype $3. code1 $11. code $11. caresettingprincipal $41.
           t1_index $3. t2_index $3. t2_fup $3. conc_fup $3. t3_index $3. t3_fup $3. t4_index $3. t4_fup $3. t5_index $3. t6_index $3.
           productapprovaldate Date9. productmarketingdate Date9. otherproductdate Date9. excludesupply $1. codesupply 8.
           rawlabdatetype $3. rawlabresult $3. ;
    set in.&codes.;
    group = "&group.";
    stockgroup = compress (descrip, ', ./\_-<>=;&[](){}%');
    codecat = CodeCat1;
    codetype = CodeType1;
    code = compress (code1, ".");
    caresettingprincipal = " ";

    t1_index = 'NOT';
    t2_index = 'NOT'; /*When defining outcome incidence, t2_index must = 'NOT' */
    t2_fup = 'IOC';    /*When defining outcome incidence, t2_fup must = 'IOC' */
    ...
%mend;

%outcomeinccodes (1,typ_is,intracranial_hemorrhage);  /*Fill in group 1 name and code list to define outcome incidence*/
%outcomeinccodes (2,typ_ich,ischemic_stroke);         /*Fill in group 2 name and code list to define outcome incidence */
%outcomeinccodes (3,atyp_is,intracranial_hemorrhage); /*Fill in group 3 name and code list to define outcome incidence */
%outcomeinccodes (4,atyp_ich,ischemic_stroke);        /*Fill in group 4 name and code list to define outcome incidence*/
```

Exercise: Create Cohort Codes File

Group	t2_index = DEF	t2_index = IOT	t2_fup = DEF	t2_fup = IOC
typ_is	typical_antipsychotics	atypical_antipsychotics		
typ_ich	typical_antipsychotics	atypical_antipsychotics		
atyp_is	atypical_antipsychotics	typical_antipsychotics		
atyp_ich	atypical_antipsychotics	typical_antipsychotics		

Code List Key	
Clinical Concept	**SAS Dataset with Codes**
Typical antipsychotics	**typical_antipsychotics**
Atypical antipsychotics	**atypical_antipsychotics**
Ischemic stroke	**ischemic_stroke**
Intracranial hemorrhage	**intracranial_hemorrhage**

Exercise: Create Cohort Codes File

Group	t2_index = DEF	t2_index = IOT	t2_fup = DEF	t2_fup = IOC
typ_is	typical_antipsychotics	atypical_antipsychotics	ischemic_stroke	
typ_ich	typical_antipsychotics	atypical_antipsychotics		
atyp_is	atypical_antipsychotics	typical_antipsychotics		
atyp_ich	atypical_antipsychotics	typical_antipsychotics		

Code List Key	
Clinical Concept	**SAS Dataset with Codes**
Typical antipsychotics	**typical_antipsychotics**
Atypical antipsychotics	**atypical_antipsychotics**
Ischemic stroke	**ischemic_stroke**
Intracranial hemorrhage	**intracranial_hemorrhage**

Exercise: Create Cohort Codes File

Group	t2_index = DEF	t2_index = IOT	t2_fup = DEF	t2_fup = IOC
typ_is	typical_antipsychotics	atypical_antipsychotics	ischemic_stroke	intracranial_hemorrhage
typ_ich	typical_antipsychotics	atypical_antipsychotics	intracranial_hemorrhage	ischemic_stroke
atyp_is	atypical_antipsychotics	typical_antipsychotics	ischemic_stroke	intracranial_hemorrhage
atyp_ich	atypical_antipsychotics	typical_antipsychotics	intracranial_hemorrhage	ischemic_stroke

Code List Key	
Clinical Concept	**SAS Dataset with Codes**
Typical antipsychotics	**typical_antipsychotics**
Atypical antipsychotics	**atypical_antipsychotics**
Ischemic stroke	**ischemic_stroke**
Intracranial hemorrhage	**intracranial_hemorrhage**

Finished Cohort Codes File - Sample

	group	stockgroup	codecat	codetype	code	caresettingprincipal	t2_index	t2_fup
12069	typ_is	Ischemicstroke	DX	09	43301	'IPP'	NOT	DEF
12070	typ_is	Ischemicstroke	DX	09	43311	'IPP'	NOT	DEF
12071	typ_is	Ischemicstroke	DX	09	43321	'IPP'	NOT	DEF
12072	typ_is	Ischemicstroke	DX	09	43331	'IPP'	NOT	DEF
12073	typ_is	Ischemicstroke	DX	09	43381	'IPP'	NOT	DEF
12074	typ_is	Ischemicstroke	DX	09	43391	'IPP'	NOT	DEF
12075	typ_is	Ischemicstroke	DX	09	43401	'IPP'	NOT	DEF
12076	typ_is	Ischemicstroke	DX	09	43411	'IPP'	NOT	DEF
12077	typ_is	Ischemicstroke	DX	09	43491	'IPP'	NOT	DEF
12078	typ_is	Ischemicstroke	DX	09	436	'IPP'	NOT	DEF
12079	typ_ich	Intracranialhemorrhage	DX	09	430	'IPP'	NOT	DEF
12080	typ_ich	Intracranialhemorrhage	DX	09	431	'IPP'	NOT	DEF
12081	atyp_is	Ischemicstroke	DX	09	43301	'IPP'	NOT	DEF
12082	atyp_is	Ischemicstroke	DX	09	43311	'IPP'	NOT	DEF
12083	atyp_is	Ischemicstroke	DX	09	43321	'IPP'	NOT	DEF
12084	atyp_is	Ischemicstroke	DX	09	43331	'IPP'	NOT	DEF
12085	atyp_is	Ischemicstroke	DX	09	43381	'IPP'	NOT	DEF
12086	atyp_is	Ischemicstroke	DX	09	43391	'IPP'	NOT	DEF
12087	atyp_is	Ischemicstroke	DX	09	43401	'IPP'	NOT	DEF
12088	atyp_is	Ischemicstroke	DX	09	43411	'IPP'	NOT	DEF
12089	atyp_is	Ischemicstroke	DX	09	43491	'IPP'	NOT	DEF
12090	atyp_is	Ischemicstroke	DX	09	436	'IPP'	NOT	DEF
12091	atyp_ich	Intracranialhemorrhage	DX	09	430	'IPP'	NOT	DEF
12092	atyp_ich	Intracranialhemorrhage	DX	09	431	'IPP'	NOT	DEF

INCLUSION/EXCLUSION CODES FILE

PURPOSE: Assignment of roles to relevant codes for restriction of cohort due to inclusion/exclusion criteria

PARAMETERS: 19
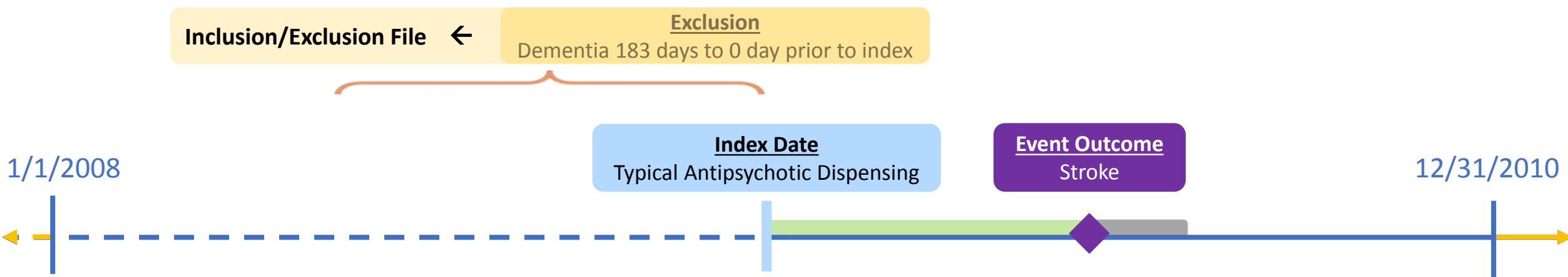
Exercise: Create Inclusion/Exclusion Codes File

- Open **6_exclusion.sas** program

- Assign library: `%let basename = [FILL IN FILE PATH]/Public_Training_Materials/Lab;`

```
data work.excl;
format group $40. stockgroup $30. caresettingprincipal $30. code $11. codecat $2. codetype $3.
       condinclusion 8. subcondinclusion 8. condlevel $30. subcondlevel $30.
       condfrom 8. condto 8. codedays 8. codesupply 8. excludesupply $1.
       codepop $2. indexdate $30. rawlabdatetype $3. rawlabresult $30. ;

set in.dementia;
group = "&curr_name";
stockgroup = compress (descrip, ", .//_-<>=;&[]'(){}%");
caresettingprincipal = " ";
code = compress (code1, ' .//_-()%');
codecat = codecat1;
codetype = codetype1;

condinclusion = . ; /* Condition Exclusion Indicator; Numerical; Valid values: 0 or 1 to exclude or include if evidence of condition;
condlevel = " "; /* Name of inclusion/exclusion condition; Required*/
condfrom = . ; /* Evaluation Period Start; Numerical; Required */
condto = . ; /* Evaluation Period End; Numerical; Required */
codedays = . ; /* Indicates number of instances the criteria should be found in evaluation period; Numerical; Required */
```

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Inclusion/Exclusion Codes – Specifications

| Group | | Inclusion/Exclusion Criteria | | | | | |
		Inclusion/ exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start	Evaluation period end	Number of instances the criteria should be found in evaluation period
1	typ_IS	Dementia	Exclude	Any care setting	Any position	-183	0	1
2	typ_ICH	Dementia	Exclude	Any care setting	Any position	-183	0	1
3	atyp_IS	Dementia	Exclude	Any care setting	Any position	-183	0	1
4	atyp_ICH	Dementia	Exclude	Any care setting	Any position	-183	0	1

# Finished Inclusion/Exclusion Codes File Sample

	group	stockgroup	caresettingprincipal	code	codecat	codetype	condinclusion	subcondinclusion	condlevel	subcondlevel	condfrom	condto	codedays
1	typ_is	Seniledementiauncomplicated		2900	DX	09	0	1	dementia	dementia	-183	0	1
2	typ_is	Preseniledementiauncomplicated		29010	DX	09	0	1	dementia	dementia	-183	0	1
3	typ_is	Preseniledementiawithdelirium		29011	DX	09	0	1	dementia	dementia	-183	0	1
4	typ_is	Preseniledementiawithdelusiona		29012	DX	09	0	1	dementia	dementia	-183	0	1
5	typ_is	Preseniledementiawithdepressiv		29013	DX	09	0	1	dementia	dementia	-183	0	1
6	typ_is	Seniledementiawithdelusionalfe		29020	DX	09	0	1	dementia	dementia	-183	0	1
7	typ_is	Seniledementiawithdepressivefe		29021	DX	09	0	1	dementia	dementia	-183	0	1
8	typ_is	Seniledementiawithdelirium		2903	DX	09	0	1	dementia	dementia	-183	0	1
9	typ_is	Vasculardementiauncomplicated		29040	DX	09	0	1	dementia	dementia	-183	0	1
10	typ_is	Vasculardementiawithdelirium		29041	DX	09	0	1	dementia	dementia	-183	0	1
11	typ_is	Vasculardementiawithdelusions		29042	DX	09	0	1	dementia	dementia	-183	0	1
12	typ_is	Vasculardementiawithdepressedm		29043	DX	09	0	1	dementia	dementia	-183	0	1
13	typ_is	Amnesticdisorderinconditionscl		2940	DX	09	0	1	dementia	dementia	-183	0	1
14	typ_is	Dementiainconditionsclassified		29410	DX	09	0	1	dementia	dementia	-183	0	1
15	typ_is	Dementiainconditionsclassified		29411	DX	09	0	1	dementia	dementia	-183	0	1
16	typ_is	Dementiaunspecifiedwithoutbeha		29420	DX	09	0	1	dementia	dementia	-183	0	1
17	typ_is	Dementiaunspecifiedwithbehavio		29421	DX	09	0	1	dementia	dementia	-183	0	1
18	typ_is	Otherpersistentmentaldisorders		2948	DX	09	0	1	dementia	dementia	-183	0	1
19	typ_is	Alzheimersdisease		3310	DX	09	0	1	dementia	dementia	-183	0	1
20	typ_is	Picksdisease		33111	DX	09	0	1	dementia	dementia	-183	0	1
21	typ_is	Otherfrontotemporaldementia		33119	DX	09	0	1	dementia	dementia	-183	0	1
22	typ_is	Seniledegenerationofbrain		3312	DX	09	0	1	dementia	dementia	-183	0	1
23	typ_is	Cerebraldegenerationindiseases		3317	DX	09	0	1	dementia	dementia	-183	0	1
24	typ_is	Senilitywithoutmentionofpsycho		797	DX	09	0	1	dementia	dementia	-183	0	1

COVARIATE CODES FILE

PURPOSE: Assignment of codes for evaluation of covariates, relative to the exposure index
PARAMETERS: 13
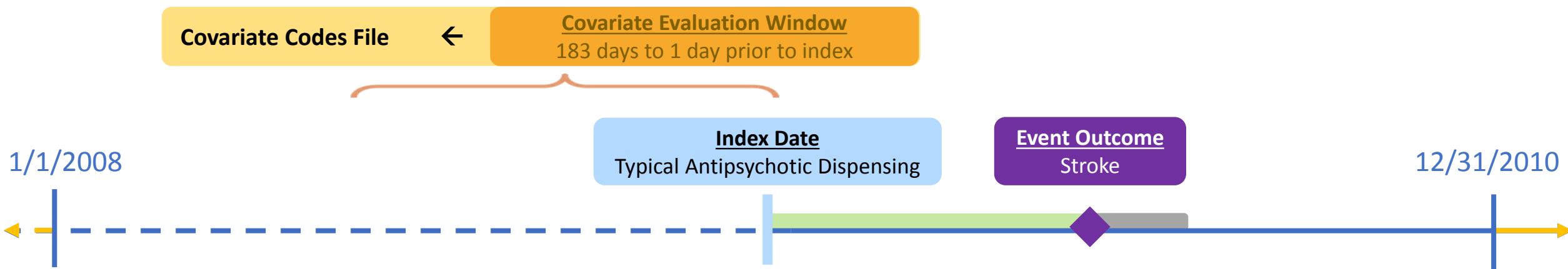
Covariate Codes – Overview

- NDCs, ICD procedure and diagnosis codes, and HCPCS codes can be used in any combination and can be restricted to specific care settings and diagnosis code positions

- All cohorts (GROUPs) included in a CIDA tool execution will extract information for the same covariates

- Covariates can be differentiated for description-only versus description and inferential adjustment

Exercise: Create Covariate Codes File

```sas
data out.&wpnum._covariates;
    format studyname $50. covarnum 8. code $50. stockgroup $30. codecat $2. codetype $3.
           caresettingprincipal $30. covfrom 8. covto 8. keep 8. codedays 8. codesupply 8. excludesupply $1.;
    set in.covariates;

        if studyname = 'AMI' then covarnum=1;
        if studyname = 'Diabetes' then covarnum=2;
        if studyname = 'Heart failure' then covarnum=3;
        if studyname = 'Hypercholesterolemia' then covarnum=4;
        if studyname = 'Hypertension' then covarnum=5;
        if studyname = 'Kidney failure' then covarnum=6;
        if studyname = 'Depression' then covarnum=7;
        if studyname = 'Anxiety' then covarnum=8;
        if studyname = 'Bipolar' then covarnum=9;
        if studyname = 'Schizophrenia/psychotic' then covarnum=10;
        if studyname = 'Substance abuse' then covarnum=11;
        if studyname = 'Transient ischemic attack' then covarnum=12;

stockgroup = compress (studyname, ", './{};[]_-()%");
studyname = studyname;
codecat = codecat1;
codetype = codetype1;
code = compress (code1, '.');
caresettingprincipal = " ";
covfrom = -183;
covto = -1;
keep = 0;
codedays = 1;
codesupply = .;
excludesupply = "";
drop codecat1 codetype1 code1;
run;
```

Specifications – Covariates

			Covariates		
Covariate	**Care setting**	**Principal diagnosis position**	**Evaluation period start**	**Evaluation period end**	**Number of instances the covariate should be found in evaluation period**
Acute myocardial infarction	Any	Any	-183	-1	1
Diabetes	Any	Any	-183	-1	1
Heart failure	Any	Any	-183	-1	1
Hypercholesterolemia	Any	Any	-183	-1	1
Hypertension	Any	Any	-183	-1	1
Kidney failure	Any	Any	-183	-1	1
Transient ischemic attack	Any	Any	-183	-1	1
Depression	Any	Any	-183	-1	1
Anxiety	Any	Any	-183	-1	1
Bipolar	Any	Any	-183	-1	1
Schizophrenia/psychotic disorder	Any	Any	-183	-1	1
Substance abuse	Any	Any	-183	-1	1

Finished Covariate Codes File

	studyname	covarnum	code	stockgroup	codecat	codetype	caresettingprincipal	covfrom	covto	keep	codedays	codesupply	excludesupply
1	AMI	1	4100	AMI	DX	09		-183	-1	0	1		.
2	AMI	1	410	AMI	DX	09		-183	-1	0	1		.
3	AMI	1	41000	AMI	DX	09		-183	-1	0	1		.
4	AMI	1	41001	AMI	DX	09		-183	-1	0	1		.
5	AMI	1	41002	AMI	DX	09		-183	-1	0	1		.
6	AMI	1	4101	AMI	DX	09		-183	-1	0	1		.
7	AMI	1	41010	AMI	DX	09		-183	-1	0	1		.
8	AMI	1	41011	AMI	DX	09		-183	-1	0	1		.
9	AMI	1	41012	AMI	DX	09		-183	-1	0	1		.
10	AMI	1	4102	AMI	DX	09		-183	-1	0	1		.
11	AMI	1	41020	AMI	DX	09		-183	-1	0	1		.
12	AMI	1	41021	AMI	DX	09		-183	-1	0	1		.
13	AMI	1	41022	AMI	DX	09		-183	-1	0	1		.
14	AMI	1	41030	AMI	DX	09		-183	-1	0	1		.
15	AMI	1	4103	AMI	DX	09		-183	-1	0	1		.
16	AMI	1	41031	AMI	DX	09		-183	-1	0	1		.
17	AMI	1	41032	AMI	DX	09		-183	-1	0	1		.
18	AMI	1	41040	AMI	DX	09		-183	-1	0	1		.
19	AMI	1	4104	AMI	DX	09		-183	-1	0	1		.
20	AMI	1	41041	AMI	DX	09		-183	-1	0	1		.
21	AMI	1	41042	AMI	DX	09		-183	-1	0	1		.
22	AMI	1	4105	AMI	DX	09		-183	-1	0	1		.
23	AMI	1	41050	AMI	DX	09		-183	-1	0	1		.
24	AMI	1	41051	AMI	DX	09		-183	-1	0	1		.

Step 2: Moving on to Reporting Files

Sentinel

Specifications

- Parameters
- Codes

Input Files

- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

Main (run) Program

- Input file names

Master (SAS) Program

- Package location
- Dataset location

*Global Parameter Files

LOCAL REPORT FILES

PURPOSE: Specify what to include in the automated report

Local Report Files

- The local report input files have been created for you
  - createreport.sas7bdat and groups_table.sas7bdat
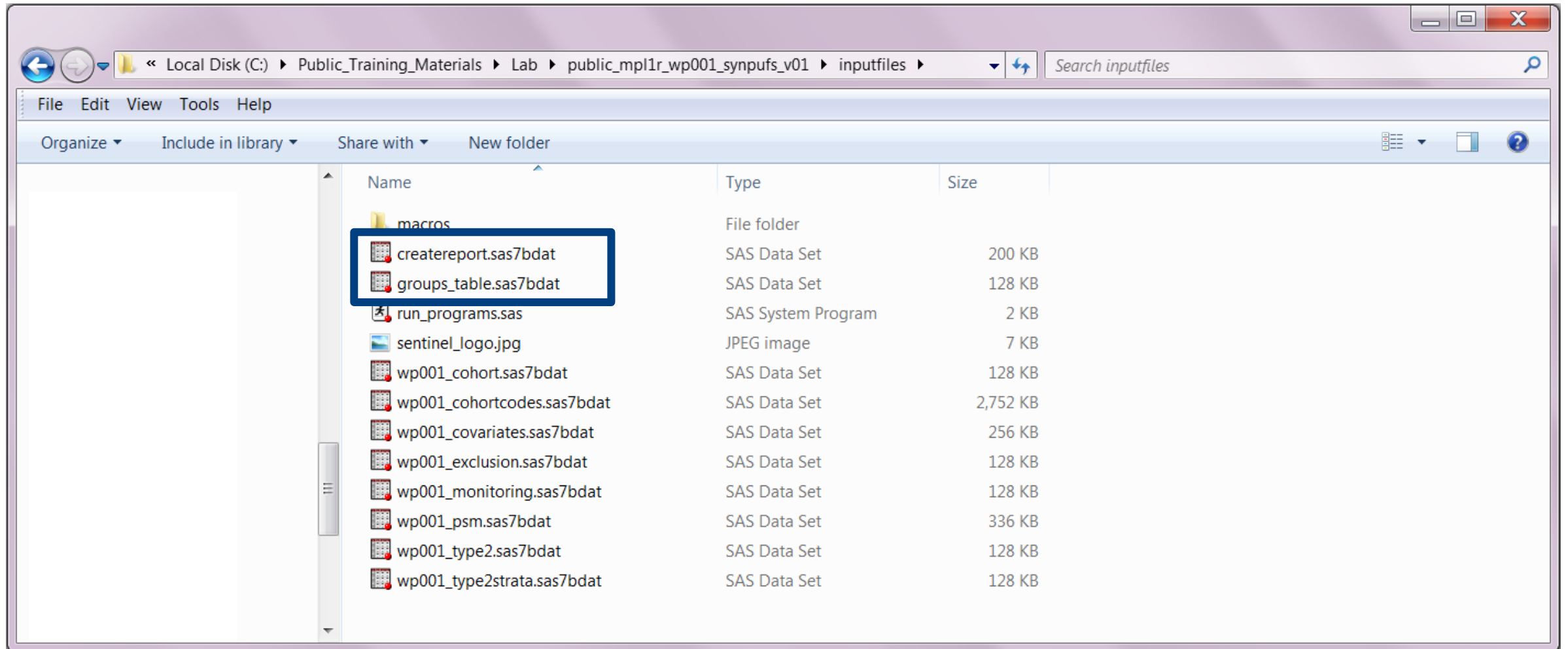
Create Report File (Excerpt)

	requestid	groups_table	columns_table	type	alltypefiles	monitoringfile	cohortfile	userstrata	covariatecodes
1	public_mpl1r_wp001	groups_table		2	wp001_type2	wp001_monitoring	wp001_cohort	wp001_type2strata	wp001_covariates

customtitle	exclude	stratify_by_level	zipfile	agegroupfmt	logo	output_baselinetable	look_start	look_end	output_cdf_km
Typical and Atypical Antipsychotics and Stroke	8	000 001 002 003			sentinel_logo.jpg	Y		1	1	N

...

Create Report File

```sas
data out.createreport;
format type 1. requestid $23. groups_table $30. columns_table $30. alltypefiles $50.
monitoringfile $30. cohortfile $30. userstrata $30. covariatecodes $30.
customtitle $50. exclude $50. stratify_by_level $50.
zipfile $15. agegroupfmt $100. logo $30. output_baselinetable $1. look_start 1. look_end 1.
output_cdf_km $1. cdf_title1 $50. km_title1 $50. km_title2 $50. cdf_footnote1 $50. cdf_footnote2 $50.
km_footnote1 $50. km_footnote2 $50. cdf_xmin 8. cdf_xmax 8. cdf_xtick 8. km_xmin 8. km_xmax 8. km_xtick 8.
cdf_ymin 8. cdf_ymax 8. cdf_ytick 8. km_ymin 8. km_ymax 8. km_ytick 8. km_ep_xmin 8. km_ep_xmax 8. km_ep_xtick 8.
km_ep_ymin 8. km_ep_ymax 8. km_ep_ytick 8. censoring_display $40. cens_elig $20. cens_dth $20. cens_dpend $20. cens_qryend $20.
cens_episend $20. cens_spec $20. cens_event $20. displayn $1. line_spacing 8.;

type=2;
requestid= 'public_mpl1r_wp001';
groups_table= 'groups_table';
columns_table= '';
alltypefiles='wp001_type2';
monitoringfile= 'wp001_monitoring';
cohortfile= 'wp001_cohort';
userstrata= 'wp001_type2strata';
covariatecodes = 'wp001_covariates';
customtitle= 'Typical and Atypical Antipsychotics and Stroke';
exclude= '8';
stratify_by_level= '000 001 002 003';
zipfile= '';
agegroupfmt= '';
logo= 'sentinel_logo.jpg';
output_baselinetable= 'Y';
look_start= 1;
look_end= 1;
output_cdf_km= 'N';

...
```

Groups File

```sas
%macro groups (title,group,grouplabel,header);
data groups_table&title.;
    format header $60. group1 $30. runid1 $10. group2 $30. runid2 $10. grouplabel $100.
           combinedgroupname $50. order 8. Historyofuse $50. Recordedhistory $50.
           Utilizationintensity $50. highlight_vars $60. alphabetical_covarsort $1. Baselinelabel $50.;
    header = "&header.";
    group1 = "&group.";
    runid1= 'r01';
    group2 = "";
    runid2 = "";
    grouplabel= "&grouplabel.";
    combinedgroupname= "";
    order = &title.;
    Historyofuse = "";
    Recordedhistory = "";
    Utilizationintensity = "";
    highlight_vars = "";
    alphabetical_covarsort = 'N';
    Baselinelabel = "";
    run;
%mend;

%groups (1,typ_is, Typical Antipsychotics, Ischemic Stroke);
%groups (2,typ_ich, Typical Antipsychotics, Intracranial Hemorrhage);
%groups (3,atyp_is, Atypical Antipsychotics, Ischemic Stroke);
%groups (4,atyp_ich, Atypical Antipsychotics, Intracranial Hemorrhage);
```

Groups File

	header	group1	runid1	group2	runid2	grouplabel	combinedgroupname
1	Ischemic Stroke	typ_is	r01			Typical Antipsychotics	
2	Intracranial Hemorrhage	typ_ich	r01			Typical Antipsychotics	
3	Ischemic Stroke	atyp_is	r01			Atypical Antipsychotics	
4	Intracranial Hemorrhage	atyp_ich	r01			Atypical Antipsychotics	

order	Historyofuse	Recordedhistory	Utilizationintensity	highlight_vars	alphabetical_covars	Baselinelabel
1					N	
2					N	
3					N	
4					N	

Step 2: Moving on to Propensity Score Files

Sentinel

Specifications		Input Files		Main (run) Program		Master (SAS) Program

Specifications
- Parameters
- Codes

Input Files
- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

Main (run) Program
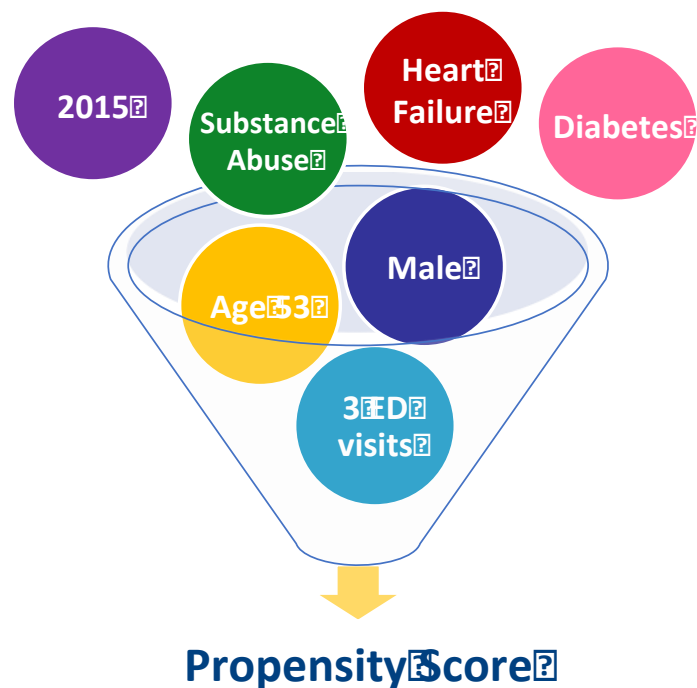- Input file names

Master (SAS) Program
- Package location
- Dataset location

*Global Parameter Files

PROPENSITY SCORE COMPARISON FILE

PURPOSE: Specify all exposure/comparator pairs that should be evaluated in the propensity score analysis

PARAMETERS: 10

Propensity Score

Exercise: Create Propensity Score Comparison File

- Open **9_propensityscore.sas** program

- Assign library: `%let basename = [FILL IN FILE PATH]/Public_Training_Materials/Lab;`

	comp_order	comp	control	caliper	ratio	class	noclass	hdps	hdpswinfrom	hdpswinto
1	1			.		Sex Covar1 Covar2 Covar3 Covar4 Covar5 Covar6 Covar7 Covar8 Covar9 Covar10 Covar11 Covar12	Age	N	.	.
2	2			.		Sex Covar1 Covar2 Covar3 Covar4 Covar5 Covar6 Covar7 Covar8 Covar9 Covar10 Covar11 Covar12	Age	N	.	.

```sas
%macro psm (title,comp,control);
    data psm&title.;
    format comp_order 8. comp $40. control $40. caliper best12. ratio $1. class $999. noclass $999.
           hdps $1. hdpswinfrom 8.  hdpswinto 8.;
    comp_order = &title.;
    comp = "&comp"; /* Exposure of Interest; Valid values: typ_is typ_ich atyp_is atyp_ich; Required */
    control = "&control"; /* Comparator of Interest; Valid values: typ_is typ_ich atyp_is atyp_ich; Required */
    caliper= . ; /* Matching Caliper; Numerical; Valid values: Any value between 0-1; Required */
    ratio= ' '; /* Matching Ratio; Valid values: 'F' or 'V' for fixed 1:1 matching or variable 1:n matching; Required */
    class="Sex Covar1 Covar2 Covar3 Covar4 Covar5 Covar6 Covar7 Covar8 Covar9 Covar10 Covar11 Covar12";
    noclass="Age";
    hdps='N';
    hdpswinfrom=.;
    hdpswinto=.;
    run;
%mend;

%psm (1, , ); /* Fill in group 1 name (exposure) and group 3 name (comparator) */
%psm (2, , ); /* Fill in group 2 name (exposure) and group 4 name (comparator) */
```

Specifications – Propensity Score

Sentinel

* Query period: 1/1/2008 - 12/31/2010
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: 183 days
Post-index enrollment requirement: 0
Enrollment gap: 45 days
Age groups: 18-39, 40-54, 55-65 years
* Stratifications: Age group, Sex, Calendar Year
Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days
* Envelope macro: Reclassify encounters during inpatient stay as inpatient
Propensity score analysis: 1:1 matching
Propensity score caliper: 0.05

* Global Parameters

Finished Propensity Score Comparison File

	comp_order	comp	control	caliper	ratio	class	noclass	hdps	hdpswinfrom	hdpswinto
1	1	typ_is	atyp_is	0.05	F	Sex Covar1 Covar2 Covar3 Covar4 Covar5 Covar6 Covar7 Covar8 Covar9 Covar10 Covar11 Covar12	Age	N	.	.
2	2	typ_ich	atyp_ich	0.05	F	Sex Covar1 Covar2 Covar3 Covar4 Covar5 Covar6 Covar7 Covar8 Covar9 Covar10 Covar11 Covar12	Age	N	.	.

Step 3: Name and Locate Input Files

Sentinel

Specifications

- Parameters
- Codes

→

Input Files

- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

→

Main (run) Program

- **Input file names**

→

Master (SAS) Program

- Package location
- Dataset location

*Global Parameter Files

RUN_PROGRAMS

PURPOSE: Reference names of all input files and specify run level parameters

Run_Programs

```
/*** Macro Parameters ***/
/*** Do not include file extensions for any dataset names ***/
%let RUNID=r01;
%let PERIODIDSTART=1;
%let PERIODIDEND=1;
%let ANALYSIS=PS;
%let MONITORINGFILE=wp001_monitoring;
%let USERSTRATA=wp001_type2strata;
%let COMBOFILE=;
%let COHORTFILE=wp001_cohort;
%let COHORTCODES=wp001_cohortcodes;
%let INCLUSIONCODES=wp001_exclusion;
%let STOCKPILINGFILE=;
%let RUN_ENVELOPE=;
%let FREEZEDATA=N;
%let ZIPFILE=;
%let LABSCODEMAP=;
%let SURVEILLANCEMODE=;
%let DISTINDEX =;

*Type files;
%let TYPE1FILE=;
%let TYPE2FILE=wp001_type2;
%let TYPE3FILE=;
%let T3METADATA=;
%let TYPE4FILE=;
%let PREGDUR=;
%let TYPE5FILE=;
%let TYPE6FILE=;

*Baseline Table files;
%let COVARIATECODES=wp001_covariates;
%let UTILFILE=;
%let COMORBFILE=;
%let DRUGCLASSFILE=;
%let PROFILE = ;
%let MFUFILE = ;
```

Run ID ← (points to %let RUNID=r01;)

Input Files (MONITORINGFILE through INCLUSIONCODES)

Additional Options (RUN_ENVELOPE through SURVEILLANCEMODE)

Input Files (TYPE1FILE through MFUFILE)

Run_Programs

```
*Additional analyses files: multiple events, overlap,
 adherence, ITS, switching, concomittant episodes;
%let MULTEVENTFILE=;
%let MULTEVENTFILE_ADHERE=;
%let OVERLAPFILE=;
%let OVERLAPFILE_ADHERE=;
%let ITSFILE = ;
%let CONCFILE=;
%let TREATMENTPATHWAYS=;

*Mother-Infant Cohort file;
%let MICOHORTFILE=;
```

Type Specific Optional Parameters

```
** PSA Parameters ** ;
%let COMPARISON = wp001_psm;
%let COVARIATES_CONSIDERED= ;
%let COVARIATES_SELECTED= ;
%let RANKING= ;
%let ZERO_CELL_CORR= ;
%let PERCENTILES=10;
%let DIAGNOSTICS=;

** Multiple Factor Matching **;
%let MFMFILE = ;

** Matching Parameters **;
%let INDLEVEL=;
%let UNCONDITIONAL=;
%let ANALYTICSUBGROUPS=;

** Macro Call RUN 1 ** ;

%include "&sasmacr.runcida.sas";
```

Inferential L2 Related Parameters

```
/** Report Macro Parameters **/
%let CREATEREPORT_TYPE = 2;
%let CREATEREPORT_T1T2_FILE = createreport;
%let CREATEREPORT_T5_FILE = ;

%include "&reportmacr.runreport.sas";
```

Reporting Files

Run_Programs – Specifications

* Query period: 1/1/2008 - 12/31/2010
Coverage requirement: Medical and Drug
Pre-index enrollment requirement: 183 days
Post-index enrollment requirement: 0
Enrollment gap: 45 days
Age groups: 18-39, 40-54, 55-65 years
* Stratifications: Age group, Sex, Calendar Year
Censor output categorization: 0-364, 365-729, 730-1094, 1095+ days
* Envelope macro: Reclassify encounters during inpatient stay as inpatient
Propensity score analysis: 1:1 matching
Propensity score caliper: 0.05

* Global Parameters

Common Errors

- Typos in input file names will result in an error

- Absence of 'PS' in the ANALYSIS parameter will result in no baseline table for a propensity score analysis, even if the covariate codes input file is present

RUN_PROGRAMS.SAS

- Referred to as **"main program"** in CIDA documentation
- Review the completed run_programs.sas file in your inputfiles folder
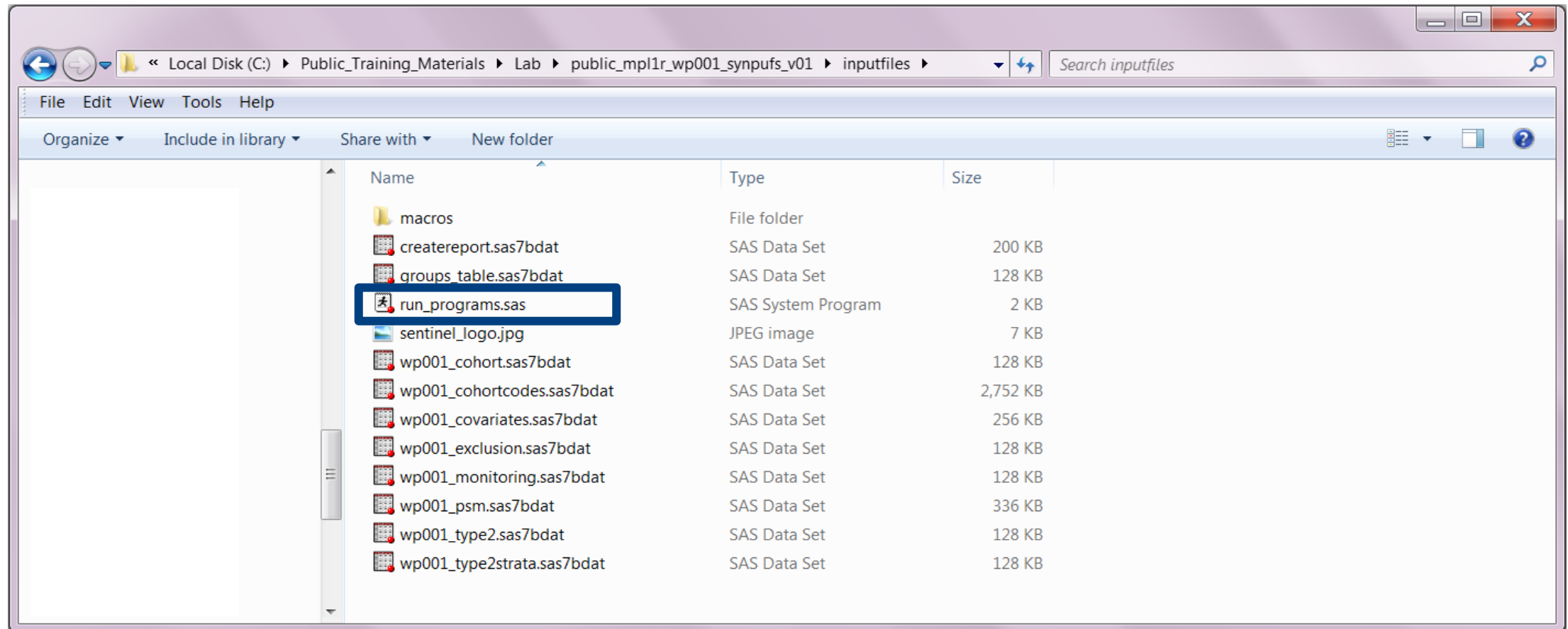
Final 'inputfiles' Folder

- Check to ensure all files were exported correctly into your 'inputfiles' folder
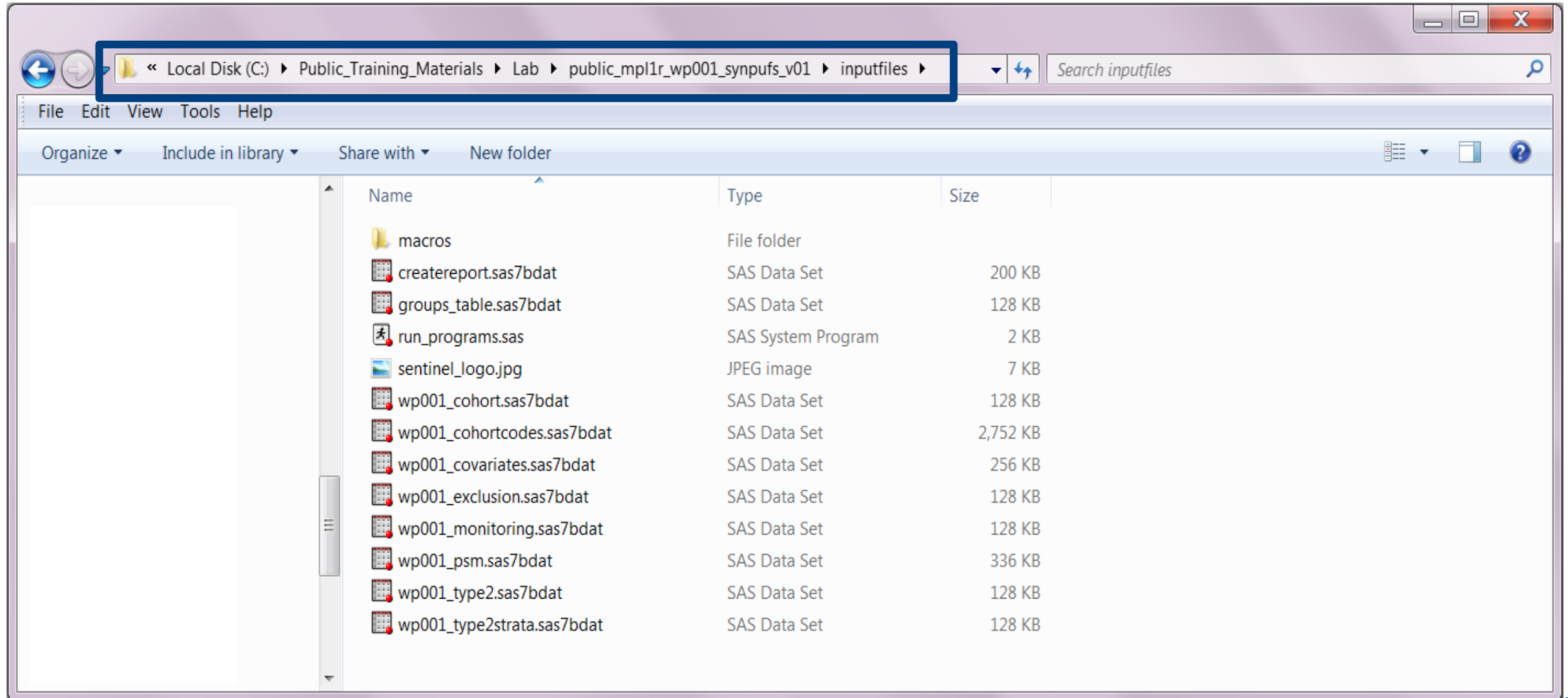
SASPROGRAMS

PURPOSE: Establish test data location and execute package on test data

Step 4: Name and Locate Formatted Data

Sentinel

Specifications

- Parameters
- Codes

→

Input Files

- **Parameters**
  - Monitoring File*
  - Cohort File
  - Type File
  - Strata File*
- **Codes**
  - Cohort Codes File
  - Inclusion/Exclusion File
  - Covariate Codes File*
- **Reporting**
  - Create Report File*
  - Groups File*
- **Propensity Score**
  - Comparison File

→

Main (run) Program

- Input file names

→

Master (SAS) Program

- **Package location**
- **Dataset location**

*Global Parameter Files

Prepare Request Package
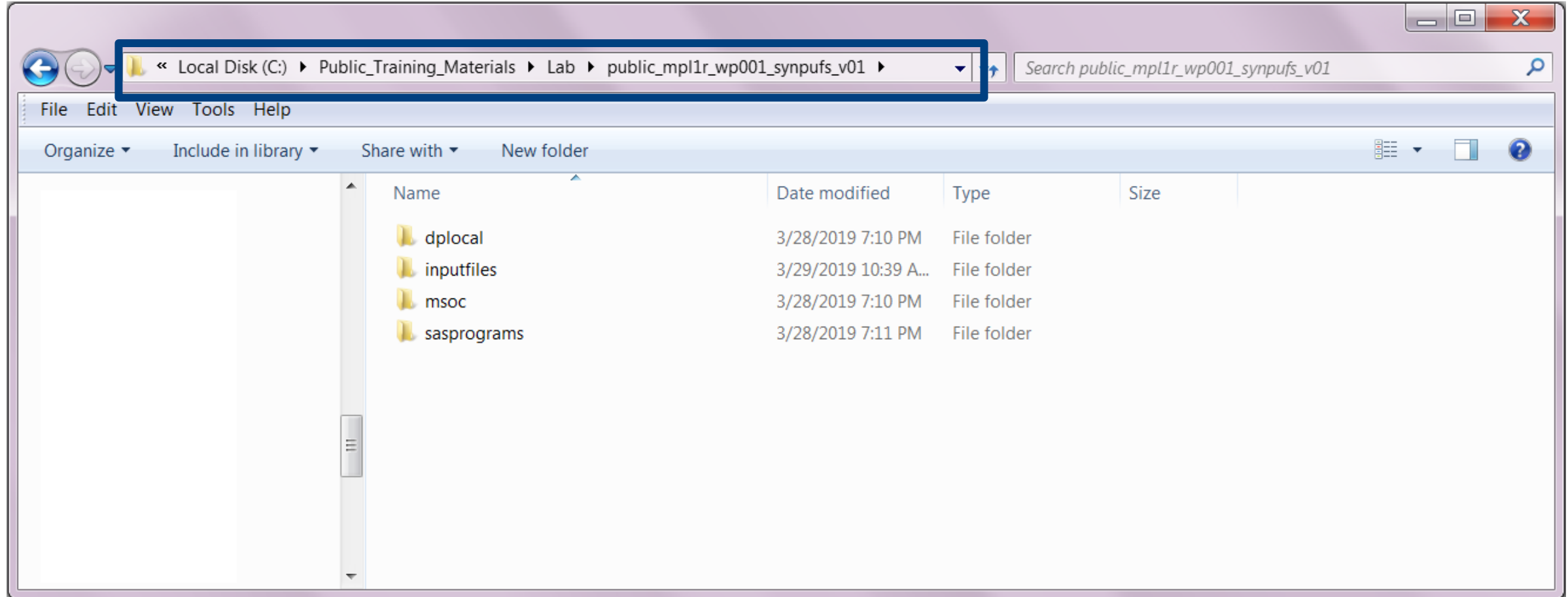
Name and Locate Formatted Data
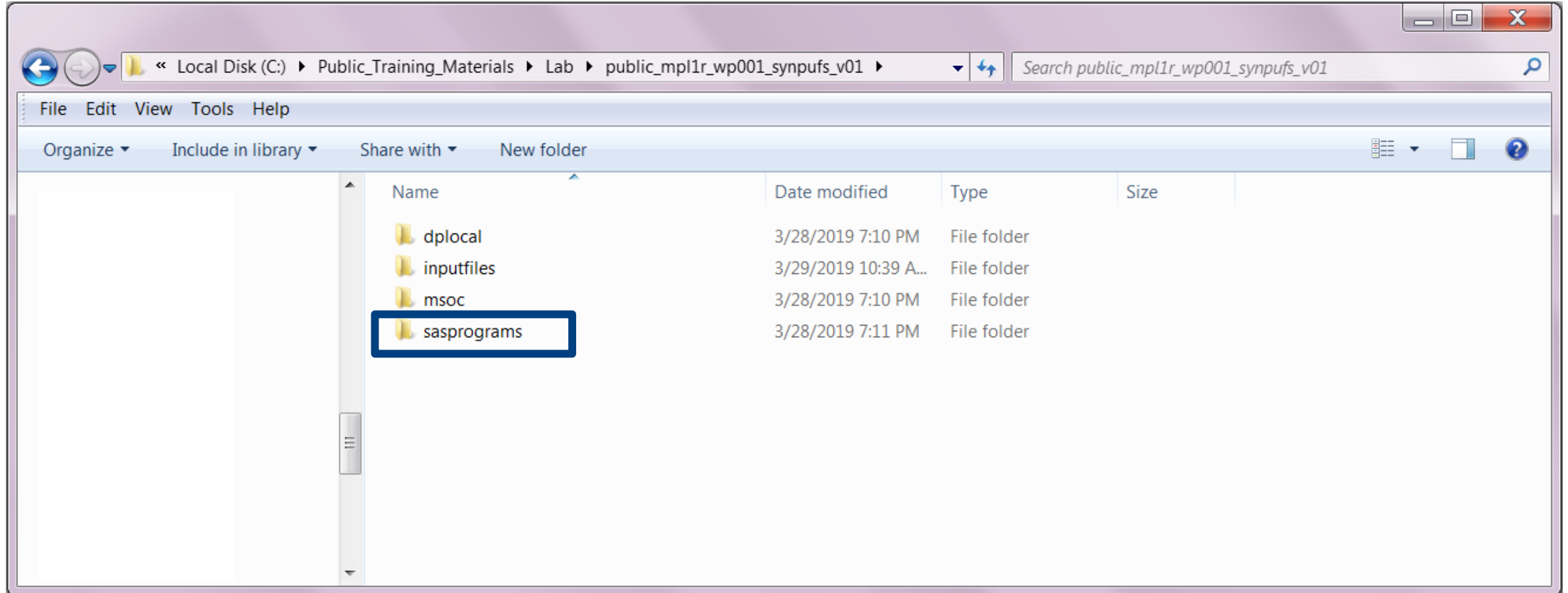
Name and Locate Formatted Data

- Referred to as **"master program"** in CIDA documentation
- Identifies claims database for analysis
- Specifies package location using multiple identifiers
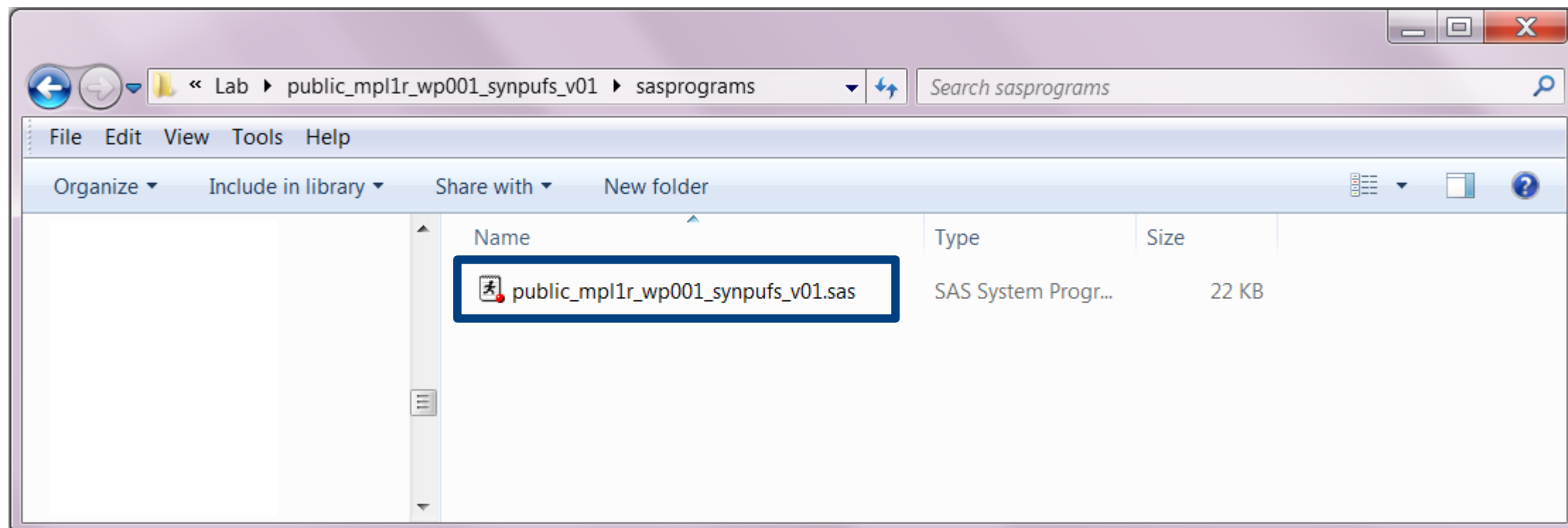
Exercise: Update Master (SAS) Program

- Update file paths under %let _packageroot and %let prod_scdm

```
/*************************************************************************/
/* 1c. OPTIONAL: Organizations WITHOUT Common Components define parameters in this
        section, leaving STEP 1a. above blank.                          */

     /* _DP is a descriptive identifier for your organization. Specify a 3-6 UPPERCASE
        character abbreviation for _DP. Example: %let DP=ABCDE ;         */
     %let _DP= synpuf;

     /* Specify the location of this request package, containing the 4 subfolders:
        dplocal, msoc, inputfiles, and sasprograms */
     /* Example: %let packageroot = A:/sentinel/qa_mil_package/          */
        %let _packageroot = C:\Public_Training_Materials\Lab\public_mpl1r_wp001_synpufs_v01;

     /* Specify the file path to the location of your Phase A Sentinel Common Data Model
       (SCDM) datasets.  Example: %let prod_scdm=A:/sentinel/etl1/phaseA/scdm/ ;     */
        %let prod_scdm= C:\Public_Training_Materials\Lab\test_data;

     /* The following metadata describe characteristics of your SCDM. If known, modify the
        following parameters:
     /* DP_MinDate: Specify the overall SCDM minimum date in the format "DDMMMYYYY"d
                    Default value is "01Jan2000"d                        */
        %let _DP_MinDate="01Jan2008"d ;

     /* DP_MaxDate: Specify the overall SCDM maximum date in the format "DDMMMYYYY"d
                    Default value is today's date (e.g. "&sysdate."d)     */
        %let _DP_MaxDate = "01Dec2010"d ;
```
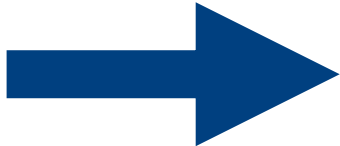
Exercise: Update Master (SAS) Program

```
/*----------------------------------------------------------------------*/
/* SECTION 2: SOC Programmer/Analyst preparing the Request sets each parameter prior
             to distributing to DP
/*----------------------------------------------------------------------*/
 /* Specific request IDs are made up of the following 5 tokens:
    project-ID, workplan-type, workplan-ID, unique-DPID, version-ID */
 /*----------------------------------------------------------------------*/
 *   If this is your request   . . . . . . . then set parameter values as follows
 *   -----------------------------          --------------------------------------
 *    [Project-ID: CDER]                         %let ProjID= cder ;
 *    [Workplan-Type: ad hoc request]            %let WPType = ahr ;
 *    [Workplan-ID: 5]                           %let WPID =   wp005 ;
 *    [Unique-DPID: non-specific DP]             %let DPID =   nsdp ;
 *    [Version-ID: beta 3]                       %let VerID =  b03 ;
 *    [use underscores as delimiter]             %let dlm = _ ;
 *
 *    The example values above would produce Request-ID --> cder_ahr_wp005_nsdp_b03 ;
 /*----------------------------------------------------------------------*/
 /* Specify project-ID, workplan-type, workplan-ID, workplan-type, dpid, version-ID    */
   %let ProjID = public ;
   %let WPType = mpl1r ;
   %let WPID =   wp001 ;
   %let DPID =   synpufs ;
   %let VerID =  v01 ;

   /* Create request-id delimiter - Default is underscore (_)                          */
   %let dlm = _ ;  /* Do not edit */
```

Exercise: Execute Request Package

- Right click on master program and batch submit the program
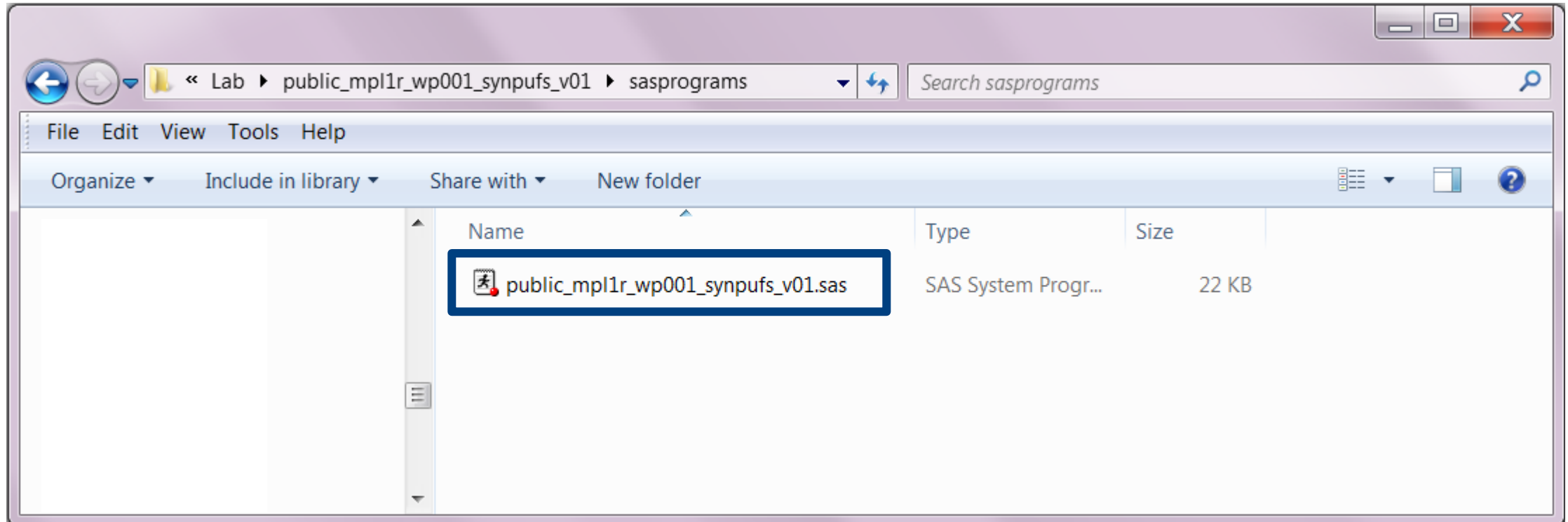
Questions?

info@sentinelsystem.org

CIDA Output and Report Interpretation

Agenda

- Review of Query Design
- By Topic
  - SAS Output
  - Interpretation of Report Contents

Topics
  - Signature file
  - Baseline characteristics
  - Type 2 Report
  - Attrition
  - Censor
  - Propensity Score Analysis

Incidence Rates Design Diagram and File Map

Sentinel

Covariate Codes File ←

Covariate Evaluation Window
183 days to 1 day prior to index

Cohort Definition
First valid exposure episode; no cohort re-entry

Inclusion/Exclusion File ←

Exclusion
Dementia 183 days to 0 day prior to index

Cohort File ←

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

Cohort Codes File ←

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Monitoring File

Episode Censored at Event

Monitoring File

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

→ **Type 2 File and Cohort Codes File**

Event Incidence
No stroke in 60 days prior

SAS Output from a CIDA Type 2 Analysis - Overview

- Data gets output to *msoc* and *dplocal* folders

OUTPUT

- dplocal
- msoc
- inputfiles
- sasprograms
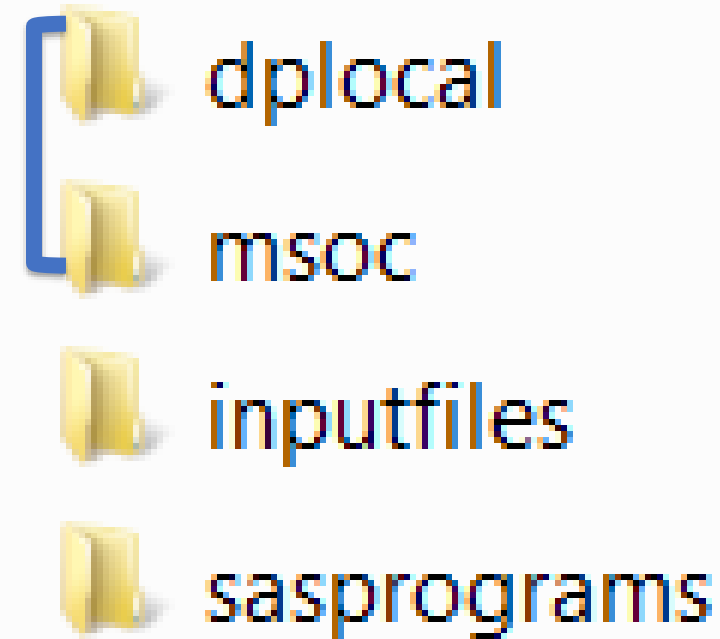
For Sentinel queries, the Sentinel Operations Center does not have access to datasets in *dplocal*.

SAS Output from a CIDA Type 2 Analysis

📁 **msoc**

- Signature
- Baseline
- T2_CIDA
- Attrition
- Censor_CIDA

SAS Output from a CIDA Type 2 Analysis

📁 msoc

- **Signature**
- Baseline
- T2_CIDA
- Attrition
- Censor_CIDA

Signature Output

- Provides metadata associated with the request
  - Request identifiers
    - Workplan number
    - CIDA QRP Version
    - Scenario count
    - Input files referenced
  - Database characteristics
    - Data Partner max and min dates
    - If 'Patients to Exclude' macro was utilized
    - If data was frozen
  - Run time metrics
    - Execution time
    - Start and stop time stamps

Signature Output File - Example

Sentinel

Request identifiers

	NAME OF FORMER VARIABLE	VALUE
1	DP	synpufs
2	ReqID	public_mpl1r_wp001_synpufs_v01
3	ProjID	public
4	WPType	mpl1r
5	WPID	wp001
6	DPID	synpufs
7	VerID	v01
8	RunID	r01

QRP version

| 9 | MPNum | QRP |
| 10 | MPVer | 7.2.1 |

Run time metrics

11	StartTime	15MAR2019:17:04:42.40
12	StopTime	15MAR2019:17:12:47.60
13	Seconds	485 s
14	ExecutionTime	0 h 8 m 5 s
15	ScenarioCnt	4
16	PERIODIDSTART	1
17	PERIODIDEND	1
18	ANALYSIS	ps
19	MONITORINGFILE	wp001_monitoring

Input files

20	USERSTRATA	wp001_type2strata
21	COMBOFILE	
22	COHORTFILE	wp001_cohort

Input files

23	COHORTCODES	wp001_cohortcodes
24	INCLUSIONCODES	wp001_exclusion
25	STOCKPILINGFILE	
26	RUN_ENVELOPE	
27	FREEZEDATA	n
28	ZIPFILE	
29	LABSCODEMAP	
30	SURVEILLANCEMODE	
31	DISTINDEX	
32	TYPE1FILE	
33	TYPE2FILE	wp001_type2
34	TYPE3FILE	
35	T3METADATA	
36	TYPE4FILE	
37	PREGDUR	
38	TYPE5FILE	
39	TYPE6FILE	
40	COVARIATECODES	wp001_covariates
41	UTILFILE	
42	COMORBFILE	
43	DRUGCLASSFILE	
44	PROFILE	
45	MFUFILE	
46	MULTEVENTFILE	
47	MULTEVENTFILE_ADHERE	
48	CONCFILE	
49	OVERLAPFILE	
50	OVERLAPFILE_ADHERE	
51	ITSFILE	
52	TREATMENTPATHWAYS	
53	PATIDEXCL	No
54	ETLNUMBER	1
55	DPMINDATE	01JAN2008
56	DPMAXDATE	15MAR2019
57	BYPASSCC	Y

Database characteristics

*
*
*

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SAS Output from a CIDA Type 2 Analysis

📁 msoc

- Signature
- Baseline
- T2_CIDA
- Attrition
- Censor_CIDA

Baseline Output

- Default output table characterizes each exposure/outcome scenario for:
  - Age
  - Sex
  - Race
  - Year of exposure
  - User-defined conditions
  - Medical and drug utilization metrics
  - Comorbidity score
- Evaluation for conditions occurs in flexible periods of time relative to the index date

Baseline Output

User specified age categories

Sex

Year

Covariates

	Group	patient	AGE40_54	AGE55_65	AGE18_39	Sex_M	Sex_F	Year_2010	Year_2009	Year_2008	Race_5	Race_0	Race_3	Hispanic_N	Hispanic_Y	Hispanic_U	AMI	Diabetes	Heart failure
1	atyp_ich	18919	7165	8693	3061	8813	10106	4912	8845	5162	13845	1446	3628	13845	719	4355	2408	10719	5239
2	atyp_is	19470	7384	8945	3141	9072	10398	5006	9122	5342	14237	1480	3753	14237	731	4502	2560	11176	5526
3	typ_ich	24004	9314	10615	4075	11224	12780	5631	11302	7071	17607	1755	4642	17607	862	5535	3166	13836	6848
4	typ_is	24720	9585	10949	4186	11543	13177	5733	11669	7318	18130	1797	4793	18130	879	5711	3335	14444	7207

Report - Baseline Table

Table 1a. Baseline table for Typical Antipsychotics		
	Typical Antipsychotics	
Characteristic[1]	**N/Mean**	**%/Std Dev[2]**
Number of episodes	24,720	
Number of unique patients	24,720	
Demographics		
Mean Age	51.6	10.6
Age: 18-39	4,186	16.9%
Age: 40-54	9,585	38.8%
Age: 55-65	10,949	44.3%
Gender (Female)	13,177	53.3%
Gender (Male)	11,543	46.7%
Year (2008)	7,318	29.6%
Year (2009)	11,669	47.2%
Year (2010)	5,733	23.2%
Recorded history of:		
AMI	3,335	13.5%
Diabetes	14,444	58.4%
Heart failure	7,207	29.2%
Hypercholesterolemia	13,612	55.1%
Hypertension	17,000	68.8%
Kidney failure	7,491	30.3%
Depression	7,537	30.5%
Anxiety	4,006	16.2%
Bipolar	6,708	27.1%
Schizophrenia/psychotic	5,834	23.6%
Substance abuse	2,348	9.5%
Transient ischemic attack	991	4.0%

- Table 1s show baseline characteristics
- Baseline table created for each exposure/outcome scenario (Tables 1a – 1d)
- Note: Stroke appears here because the baseline table covers days (-183,-1) but the outcome washout is days (-60,-1).

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SAS Output from a CIDA Type 2 Analysis

📁 msoc

- Signature
- Baseline
- **T2_CIDA**
- Attrition
- Censor_CIDA

T2_CIDA Output

	group	Level	Npts	Episodes	AdjustedCodeCount	RawCodeCount	DaySupp	AmtSupp	Eps_wEvents	All_Events	tte	DenNumPts	DenNumMemDays
1	atyp_ich	000	18919	18919	19412	19414	599796	992024.507	1	1	1117446	275322	136453261
2	atyp_ich	001	5162	5162	5302	5302	161529	274545.583	0	0	303902	191249	28990970
3	atyp_ich	001	8845	8845	9099	9100	283298	464256.068	0	0	529185	217430	55052960
4	atyp_ich	001	4912	4912	5011	5012	154969	253222.855	1	1	284359	185873	52409331

Labels:
- **New Users** → Npts
- **New Episodes** → Episodes
- **Relevant for Drug Dispensings** → AdjustedCodeCount, RawCodeCount, DaySupp, AmtSupp
- **Days at Risk** → tte
- **Eligible Members** → DenNumPts
- **Eligible Member Days** → DenNumMemDays

Counts of
- **New Episodes with an event**
- **All events**

(→ Eps_wEvents, All_Events)

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T2_CIDA Output

	group	Level	sex	agegroup	agegroupnum	year	month	zip3	state	hhs_reg	cb_reg	zip_uncertain	race	hispanic	Npts	Episodes	AdjustedCodeCount	RawCodeCount	DaySupp	AmtSupp	Eps_wEvents	All_Events	tte	DenNumPts	DenNumMemDays
1	atyp_ich	000			.	.	.	.							18919	18919	19412	19414	599796	992024.507	1	1	1117446	275322	136453261
2	atyp_ich	001			.	2008	.	.							5162	5162	5302	5302	161529	274545.583	0	0	303902	191249	28990970
3	atyp_ich	001			.	2009	.	.							8845	8845	9099	9100	283298	464256.068	0	0	529185	217430	55052960
4	atyp_ich	001			.	2010	.	.							4912	4912	5011	5012	154969	253222.855	1	1	284359	185873	52409331
5	atyp_ich	002	F		.	.	.	.							10106	10106	10356	10357	321108	525719.424	0	0	597851	140512	69815671
6	atyp_ich	002	M		.	.	.	.							8813	8813	9056	9057	278688	466305.083	1	1	519595	134810	66637590
7	atyp_ich	002	O		.	.	.	.							0	0	0	0	0	0	0	0	0	0	0
8	atyp_ich	003		18-39	1	.	.	.							3061	3061	3133	3134	95266	156517.689	0	0	178854	35884	18902512
9	atyp_ich	003		40-54	2	.	.	.							7165	7165	7387	7387	226578	368903.889	0	0	421781	93304	48342059
10	atyp_ich	003		55-65	3	.	.	.							8693	8693	8892	8893	277952	466602.929	1	1	516811	163212	69208690

- Data reported overall and stratified by age group, sex, and year
- Stratifications are user-defined

New Users = New Episodes when No Cohort Re-entry

Table 2. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 Overall

	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke												
Typical Antipsychotics												
	24,720	275,462	24,720	1,466,593	4,015.3	25,963	25,964	780,011	1,215,820	19	138,151,408	378,237.9
Atypical Antipsychotics												
	19,470	275,462	19,470	1,149,639	3,147.5	19,977	19,979	616,789	1,019,508	10	139,376,883	381,593.1
Intracranial Hemorrhage												
Typical Antipsychotics												
	24,004	275,322	24,004	1,425,097	3,901.7	25,215	25,216	757,906	1,181,054	3	135,311,139	370,461.7
Atypical Antipsychotics												
	18,919	275,322	18,919	1,117,446	3,059.4	19,412	19,414	599,796	992,025	1	136,453,261	373,588.7

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Three Variables for Denominators

Table 2. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 Overall											
	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke												
Typical Antipsychotics												
	24,720	275,462	24,720	1,466,593	4,015.3	25,963	25,964	780,011	1,215,820	19	138,151,408	378,237.9
Atypical Antipsychotics												
	19,470	275,462	19,470	1,149,639	3,147.5	19,977	19,979	616,789	1,019,508	10	139,376,883	381,593.1
Intracranial Hemorrhage												
Typical Antipsychotics												
	24,004	275,322	24,004	1,425,097	3,901.7	25,215	25,216	757,906	1,181,054	3	135,311,139	370,461.7
Atypical Antipsychotics												
	18,919	275,322	18,919	1,117,446	3,059.4	19,412	19,414	599,796	992,025	1	136,453,261	373,588.7

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

CIDA Denominators – for Types 1 and 2

- **Eligible members**
  - Restricted to health plan members at participating Data Partners and may not be nationally representative
  - Number of members eligible for an index date
  - Must meet enrollment requirements, washout criteria, and inclusion/exclusion criteria for at least one day during the query period

- **Eligible member days**
  - All the days during the query period that an eligible member is eligible for <u>inclusion in the cohort</u>

> - Tool assesses members every day of query period and counts eligible member days
> - If you have at least 1 eligible day, you are an eligible member

Incidence Rates: Denominators

Exclusion
Dementia 183 days to 0 day prior to index

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Definition
First valid exposure episode; no cohort re-entry

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

12/31/2010
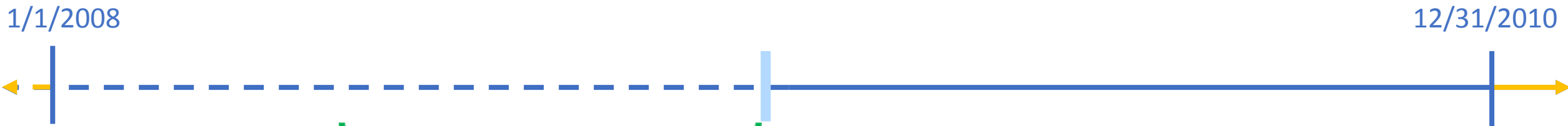
Exposure Incidence
No typical or atypical AP in 183 days prior

Event Incidence
No stroke in 60 days prior

Total Person-Time-At-Risk

Table 2. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 Overall											
	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke											
Typical Antipsychotics											
	24,720	275,462	24,720	1,466,593	4,015.3	25,963	25,964	780,011	1,215,820	19	138,151,408	378,237.9
Atypical Antipsychotics											
	19,470	275,462	19,470	1,149,639	3,147.5	19,977	19,979	616,789	1,019,508	10	139,376,883	381,593.1
Intracranial Hemorrhage											
Typical Antipsychotics											
	24,004	275,322	24,004	1,425,097	3,901.7	25,215	25,216	757,906	1,181,054	3	135,311,139	370,461.7
Atypical Antipsychotics											
	18,919	275,322	18,919	1,117,446	3,059.4	19,412	19,414	599,796	992,025	1	136,453,261	373,588.7

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Total Dispensing (Code Count) Information

	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Table 2. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 Overall												
Ischemic Stroke												
Typical Antipsychotics												
	24,720	275,462	24,720	1,466,593	4,015.3	25,963	25,964	780,011	1,215,820	19	138,151,408	378,237.9
Atypical Antipsychotics												
	19,470	275,462	19,470	1,149,639	3,147.5	19,977	19,979	616,789	1,019,508	10	139,376,883	381,593.1
Intracranial Hemorrhage												
Typical Antipsychotics												
	24,004	275,322	24,004	1,425,097	3,901.7	25,215	25,216	757,906	1,181,054	3	135,311,139	370,461.7
Atypical Antipsychotics												
	18,919	275,322	18,919	1,117,446	3,059.4	19,412	19,414	599,796	992,025	1	136,453,261	373,588.7

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Compare Days Supplied with Days at Risk

Table 2. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 Overall											
	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke												
Typical Antipsychotics												
	24,720	275,462	24,720	1,466,593	4,015.3	25,963	25,964	780,011	1,215,820	19	138,151,408	378,237.9
Atypical Antipsychotics												
	19,470	275,462	19,470	1,149,639	3,147.5	19,977	19,979	616,789	1,019,508	10	139,376,883	381,593.1
Intracranial Hemorrhage												
Typical Antipsychotics												
	24,004	275,322	24,004	1,425,097	3,901.7	25,215	25,216	757,906	1,181,054	3	135,311,139	370,461.7
Atypical Antipsychotics												
	18,919	275,322	18,919	1,117,446	3,059.4	19,412	19,414	599,796	992,025	1	136,453,261	373,588.7

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Event Counts for Sample Size Calculations

Table 2. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 Overall

	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke												
Typical Antipsychotics												
	24,720	275,462	24,720	1,466,593	4,015.3	25,963	25,964	780,011	1,215,820	19	138,151,408	378,237.9
Atypical Antipsychotics												
	19,470	275,462	19,470	1,149,639	3,147.5	19,977	19,979	616,789	1,019,508	10	139,376,883	381,593.1
Intracranial Hemorrhage												
Typical Antipsychotics												
	24,004	275,322	24,004	1,425,097	3,901.7	25,215	25,216	757,906	1,181,054	3	135,311,139	370,461.7
Atypical Antipsychotics												
	18,919	275,322	18,919	1,117,446	3,059.4	19,412	19,414	599,796	992,025	1	136,453,261	373,588.7

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Stratification of Results

- The CIDA tool can stratify select results from all cohort identification strategies by age, sex, year, month, race, and certain geographic information.

  – Documentation includes information on available stratifications.

- Custom strata may be defined in the CIDA tool from lists of valid stratification variables specific to each method of cohort identification.

  – Denominators are not calculated for custom stratifications.

- Results may also be stratified by defined covariates.

Summary Counts by Year

Table 3. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 by Year

Year	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke												
Typical Antipsychotics												
2008	7,318	191,531	7,318	435,402	1,192.1	7,746	7,746	230,664	365,169	5	29,714,745	81,354.5
2009	11,669	215,929	11,669	697,925	1,910.8	12,283	12,284	370,533	575,547	12	56,115,817	153,636.7
2010	5,733	181,814	5,733	333,266	912.4	5,934	5,934	178,814	275,104	2	52,320,846	143,246.7
Atypical Antipsychotics												
2008	5,342	191,531	5,342	314,868	862.1	5,484	5,484	167,421	284,231	5	29,714,745	81,354.5
2009	9,122	217,542	9,122	545,085	1,492.4	9,386	9,387	291,619	478,554	5	56,437,421	154,517.2
2010	5,006	185,584	5,006	289,686	793.1	5,107	5,108	157,749	256,723	0	53,224,717	145,721.3
Intracranial Hemorrhage												
Typical Antipsychotics												
2008	7,071	191,249	7,071	421,342	1,153.6	7,488	7,488	223,218	353,963	0	28,990,970	79,373.0
2009	11,302	215,865	11,302	676,659	1,852.6	11,897	11,898	359,173	556,422	1	54,757,842	149,918.8
2010	5,631	182,242	5,631	327,096	895.5	5,830	5,830	175,515	270,670	2	51,562,327	141,170.0
Atypical Antipsychotics												
2008	5,162	191,249	5,162	303,902	832.0	5,302	5,302	161,529	274,546	0	28,990,970	79,373.0
2009	8,845	217,430	8,845	529,185	1,448.8	9,099	9,100	283,298	464,256	0	55,052,960	150,726.8
2010	4,912	185,873	4,912	284,359	778.5	5,011	5,012	154,969	253,223	1	52,409,331	143,488.9

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Summary Counts by Sex

Sex	New Users	Eligible Members[1]	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days[1]	Eligible Member Years[1]
Ischemic Stroke												
Typical Antipsychotics												
Female	13,177	140,584	13,177	780,156	2,136.0	13,798	13,798	413,993	646,209	13	70,699,963	193,565.9
Male	11,543	134,878	11,543	686,437	1,879.4	12,165	12,166	366,018	569,611	6	67,451,445	184,672.0
Other	0	0	0	0	0.0	0	0	0	0	0	0	0.0
Atypical Antipsychotics												
Female	10,398	140,584	10,398	614,964	1,683.7	10,658	10,659	330,189	540,240	3	71,337,275	195,310.8
Male	9,072	134,878	9,072	534,675	1,463.9	9,319	9,320	286,600	479,268	7	68,039,608	186,282.3
Other	0	0	0	0	0.0	0	0	0	0	0	0	0.0
Intracranial Hemorrhage												
Typical Antipsychotics												
Female	12,780	140,512	12,780	757,302	2,073.4	13,381	13,381	401,711	626,103	2	69,220,817	189,516.3
Male	11,224	134,810	11,224	667,795	1,828.3	11,834	11,835	356,195	554,951	1	66,090,322	180,945.4
Other	0	0	0	0	0.0	0	0	0	0	0	0	0.0
Atypical Antipsychotics												
Female	10,106	140,512	10,106	597,851	1,636.8	10,356	10,357	321,108	525,719	0	69,815,671	191,144.9
Male	8,813	134,810	8,813	519,595	1,422.6	9,056	9,057	278,688	466,305	1	66,637,590	182,443.8
Other	0	0	0	0	0.0	0	0	0	0	0	0	0.0

Table 4. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 by Sex

[1]Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

Summary Counts by Age Group

Table 5. Summary of Typical and Atypical Antipsychotics and Stroke in the Sentinel Distributed Database between January 1, 2008 and December 31, 2010 by Age Group

Age Group	New Users	Eligible Members¹	New Episodes	Days At Risk	Years at Risk	Adjusted Dispensings	Raw Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Eligible Member-Days¹	Eligible Member Years¹
Ischemic Stroke												
Typical Antipsychotics												
18-39	4,186	35,895	4,186	248,735	681.0	4,424	4,424	132,553	208,283	3	19,059,333	52,181.6
40-54	9,585	93,218	9,585	571,154	1,563.7	10,099	10,100	304,448	468,993	8	48,842,100	133,722.4
55-65	10,949	163,112	10,949	646,704	1,770.6	11,440	11,440	343,010	538,544	8	70,249,975	192,333.9
Atypical Antipsychotics												
18-39	3,141	35,895	3,141	183,465	502.3	3,214	3,215	97,693	161,229	4	19,294,889	52,826.5
40-54	7,384	93,324	7,384	434,722	1,190.2	7,615	7,615	233,557	378,916	3	49,376,179	135,184.6
55-65	8,945	163,308	8,945	531,452	1,455.0	9,148	9,149	285,539	479,363	3	70,705,815	193,582.0
Intracranial Hemorrhage												
Typical Antipsychotics												
18-39	4,075	35,884	4,075	242,248	663.2	4,305	4,305	129,060	203,352	1	18,686,759	51,161.6
40-54	9,314	93,198	9,314	555,627	1,521.2	9,817	9,818	296,104	454,983	2	47,836,512	130,969.2
55-65	10,615	163,017	10,615	627,222	1,717.2	11,093	11,093	332,742	522,720	0	68,787,868	188,330.9
Atypical Antipsychotics												
18-39	3,061	35,884	3,061	178,854	489.7	3,133	3,134	95,266	156,518	0	18,902,512	51,752.3
40-54	7,165	93,304	7,165	421,781	1,154.8	7,387	7,387	226,578	368,904	0	48,342,059	132,353.3
55-65	8,693	163,212	8,693	516,811	1,415.0	8,892	8,893	277,952	466,603	1	69,208,690	189,483.1

¹Eligible Members, Member-Days, and Member-Years are reflective of the number of patients that met all cohort entry criteria on at least one day during the query period

SAS Output from a CIDA Type 2 Analysis

📁 **msoc**

- Signature
- Baseline
- T2_CIDA
- Attrition
- Censor_CIDA

Attrition Output (Patient Level)

- Includes the number of individuals excluded and remaining after each cohort criterion is applied during the CIDA tool execution
  - Attrition repeats by GROUP (i.e., scenario) and is irrespective to other GROUPs
  - Type and detailed description of criterion, eg 'Exclusion - Members must satisfy the age range condition within the query period'

Attrition: First Losses are Enrollment-based

group	level	descr	remaining	Excluded
typ_is	1	Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	2,224,739	.
typ_is	2	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	2,049,969	174770
typ_is	3	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	1,654,330	395639
typ_is	4	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	1,554,312	100018
typ_is	5	Exclusion - Members must satisfy the age range condition within the query period	379,164	1175148
typ_is	6	Exclusion - Members must meet chart availability criterion within the query period	379,164	0
typ_is	7	Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	379,164	0
typ_is	8	Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	39,569	339595
typ_is	9	Exclusion - Members must have at least one cohort episode beginning within the age range condition	34,664	4905
typ_is	10	Exclusion - Members must have at least one episode defining index claim during the query period	34,664	0
typ_is	11	Exclusion - Members must have at least one cohort episode incident with respect to other criteria	32,240	2424
typ_is	12		32,240	0
typ_is	13	Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	24,853	7387
typ_is	14	Exclusion - Members must have at least one cohort episode satisfying the HOI-defined enrollment criterion	24,853	0
typ_is	15	Exclusion - Members must have at least one cohort episode that meets HOI incidence criterion	24,741	112
typ_is	16	Exclusion - Members must have at least one cohort episode satisfying the exclusion enrollment requirement	24,741	0
typ_is	17	Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	24,741	0
typ_is	18	Exclusion - Members must have at least one cohort episode satisfying the inclusion enrollment requirement	24,741	0
typ_is	19	Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	24,741	0
typ_is	20	Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	24,741	0
typ_is	21	Exclusion - Members must have at least one cohort episode with at least minimum days supplied	24,741	0
typ_is	22	Exclusion - Members must have at least one cohort episode with at least minimum days duration	24,741	0
typ_is	23	Exclusion - Members must have at least one cohort episode with longer than blackout days duration	24,720	21
typ_is	24	Exclusion - Members must have at least one cohort episode that meets HOI blackout criterion	24,720	0
typ_is	25		24,720	0
typ_is	26	Information - Members with at least one cohort claim with supply and/or amount outside specified ranges	.	0
typ_is	27	Information - Members with at least one HOI claim with supply and/or amount outside specified ranges	.	0
typ_is	28	Information - Members with at least one INCL/EXCL claim with supply and/or amount outside specified ranges	.	0
typ_is	29	Information - Members lost to follow-up up to end of monitoring period (Type 2, surveillance mode only)	.	0
typ_is	30	Information - Members still at risk at the end of monitoring period (Type 2, surveillance mode only)	24,720	.

Attrition: Next Losses are Demographic

group	level	descr	remaining	Excluded
typ_is	1	Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	2,224,739	.
typ_is	2	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	2,049,969	174770
typ_is	3	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	1,654,330	395639
typ_is	4	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	1,554,312	100018
typ_is	5	Exclusion - Members must satisfy the age range condition within the query period	379,164	1175148
typ_is	6	Exclusion - Members must meet chart availability criterion within the query period	379,164	0
typ_is	7	Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	379,164	0
typ_is	8	Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	39,569	339595
typ_is	9	Exclusion - Members must have at least one cohort episode beginning within the age range condition	34,664	4905
typ_is	10	Exclusion - Members must have at least one episode defining index claim during the query period	34,664	0
typ_is	11	Exclusion - Members must have at least one cohort episode incident with respect to other criteria	32,240	2424
typ_is	12		32,240	0
typ_is	13	Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	24,853	7387
typ_is	14	Exclusion - Members must have at least one cohort episode satisfying the HOI-defined enrollment criterion	24,853	0
typ_is	15	Exclusion - Members must have at least one cohort episode that meets HOI incidence criterion	24,741	112
typ_is	16	Exclusion - Members must have at least one cohort episode satisfying the exclusion enrollment requirement	24,741	0
typ_is	17	Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	24,741	0
typ_is	18	Exclusion - Members must have at least one cohort episode satisfying the inclusion enrollment requirement	24,741	0
typ_is	19	Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	24,741	0
typ_is	20	Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	24,741	0
typ_is	21	Exclusion - Members must have at least one cohort episode with at least minimum days supplied	24,741	0
typ_is	22	Exclusion - Members must have at least one cohort episode with at least minimum days duration	24,741	0
typ_is	23	Exclusion - Members must have at least one cohort episode with longer than blackout days duration	24,720	21
typ_is	24	Exclusion - Members must have at least one cohort episode that meets HOI blackout criterion	24,720	0
typ_is	25		24,720	0
typ_is	26	Information - Members with at least one cohort claim with supply and/or amount outside specified ranges	.	0
typ_is	27	Information - Members with at least one HOI claim with supply and/or amount outside specified ranges	.	0
typ_is	28	Information - Members with at least one INCL/EXCL claim with supply and/or amount outside specified ranges	.	0
typ_is	29	Information - Members lost to follow-up up to end of monitoring period (Type 2, surveillance mode only)	.	0
typ_is	30	Information - Members still at risk at the end of monitoring period (Type 2, surveillance mode only)	24,720	.

Attrition: Next Losses are Index-related

group	level	descr	remaining	Excluded
typ_is	1	Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	2,224,739	.
typ_is	2	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	2,049,969	174770
typ_is	3	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	1,654,330	395639
typ_is	4	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	1,554,312	100018
typ_is	5	Exclusion - Members must satisfy the age range condition within the query period	379,164	1175148
typ_is	6	Exclusion - Members must meet chart availability criterion within the query period	379,164	0
typ_is	7	Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	379,164	0
typ_is	8	Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	39,569	339595
typ_is	9	Exclusion - Members must have at least one cohort episode beginning within the age range condition	34,664	4905
typ_is	10	Exclusion - Members must have at least one episode defining index claim during the query period	34,664	0
typ_is	11	Exclusion - Members must have at least one cohort episode incident with respect to other criteria	32,240	2424
typ_is	12		32,240	0
typ_is	13	Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	24,853	7387
typ_is	14	Exclusion - Members must have at least one cohort episode satisfying the HOI-defined enrollment criterion	24,853	0
typ_is	15	Exclusion - Members must have at least one cohort episode that meets HOI incidence criterion	24,741	112
typ_is	16	Exclusion - Members must have at least one cohort episode satisfying the exclusion enrollment requirement	24,741	0
typ_is	17	Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	24,741	0
typ_is	18	Exclusion - Members must have at least one cohort episode satisfying the inclusion enrollment requirement	24,741	0
typ_is	19	Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	24,741	0
typ_is	20	Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	24,741	0
typ_is	21	Exclusion - Members must have at least one cohort episode with at least minimum days supplied	24,741	0
typ_is	22	Exclusion - Members must have at least one cohort episode with at least minimum days duration	24,741	0
typ_is	23	Exclusion - Members must have at least one cohort episode with longer than blackout days duration	24,720	21
typ_is	24	Exclusion - Members must have at least one cohort episode that meets HOI blackout criterion	24,720	0
typ_is	25		24,720	0
typ_is	26	Information - Members with at least one cohort claim with supply and/or amount outside specified ranges	.	0
typ_is	27	Information - Members with at least one HOI claim with supply and/or amount outside specified ranges	.	0
typ_is	28	Information - Members with at least one INCL/EXCL claim with supply and/or amount outside specified ranges	.	0
typ_is	29	Information - Members lost to follow-up up to end of monitoring period (Type 2, surveillance mode only)	.	0
typ_is	30	Information - Members still at risk at the end of monitoring period (Type 2, surveillance mode only)	24,720	.

Attrition: Last Losses are Query-Specific

group	level	descr	remaining	Excluded
typ_is	1	Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	2,224,739	.
typ_is	2	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y during the query period	2,049,969	174770
typ_is	3	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	1,654,330	395639
typ_is	4	Exclusion – Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y during the query period	1,554,312	100018
typ_is	5	Exclusion - Members must satisfy the age range condition within the query period	379,164	1175148
typ_is	6	Exclusion - Members must meet chart availability criterion within the query period	379,164	0
typ_is	7	Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	379,164	0
typ_is	8	Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	39,569	339595
typ_is	9	Exclusion - Members must have at least one cohort episode beginning within the age range condition	34,664	4905
typ_is	10	Exclusion - Members must have at least one episode defining index claim during the query period	34,664	0
typ_is	11	Exclusion - Members must have at least one cohort episode incident with respect to other criteria	32,240	2424
typ_is	12		32,240	0
typ_is	13	Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	24,853	7387
typ_is	14	Exclusion - Members must have at least one cohort episode satisfying the HOI-defined enrollment criterion	24,853	0
typ_is	15	Exclusion - Members must have at least one cohort episode that meets HOI incidence criterion	24,741	112
typ_is	16	Exclusion - Members must have at least one cohort episode satisfying the exclusion enrollment requirement	24,741	0
typ_is	17	Exclusion - Members must have at least one cohort episode satisfying the exclusion conditions	24,741	0
typ_is	18	Exclusion - Members must have at least one cohort episode satisfying the inclusion enrollment requirement	24,741	0
typ_is	19	Exclusion - Members must have at least one cohort episode satisfying the inclusion conditions	24,741	0
typ_is	20	Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	24,741	0
typ_is	21	Exclusion - Members must have at least one cohort episode with at least minimum days supplied	24,741	0
typ_is	22	Exclusion - Members must have at least one cohort episode with at least minimum days duration	24,741	0
typ_is	23	Exclusion - Members must have at least one cohort episode with longer than blackout days duration	24,720	21
typ_is	24	Exclusion - Members must have at least one cohort episode that meets HOI blackout criterion	24,720	0
typ_is	25		24,720	0
typ_is	26	Information - Members with at least one cohort claim with supply and/or amount outside specified ranges	.	0
typ_is	27	Information - Members with at least one HOI claim with supply and/or amount outside specified ranges	.	0
typ_is	28	Information - Members with at least one INCL/EXCL claim with supply and/or amount outside specified ranges	.	0
typ_is	29	Information - Members lost to follow-up up to end of monitoring period (Type 2, surveillance mode only)	.	0
typ_is	30	Information - Members still at risk at the end of monitoring period (Type 2, surveillance mode only)	24,720	.

Attrition Table – Proposed Revision

- Reports the initial member count in a population
- Reports the loss in eligible members due to required enrollment coverage, inclusion and exclusion criteria, incidence washout, etc.

	Remaining	Excluded
Members meeting enrollment and demographic requirements		
Enrolled at any point during the query period		
Had required coverage type(s)		
Enrolled during specified age range		
Had requestable medical charts		
Met demographic requirements		
Members with a valid index event		
Had any cohort-defining claim		
Claim recorded during specified age range		
Met all episode definitions		
Met episode incidence requirement		
Had single NDC on index date		
Members with required pre-index history		
Had sufficient pre-index continuous enrollment		
Met event incidence criteria		
Had no recorded history of exclusion condition(s)		
Had recorded history of inclusion condition(s)		

SAS Output from a CIDA Type 2 Analysis

📁 **msoc**

- Signature
- Baseline
- T2_CIDA
- Attrition
- Censor_CIDA

Censoring Table

- Optional output that provides:
  - Length of enrollment following index
  - Reason censored
    - Disenrollment, death, end of query period, end of DP data, truncation criteria
- Descriptive statistics (e.g., min, Q1, median, Q3, max) can be provided overall, but not for stratifications
- Categories of user-defined follow-up time can be reported

Censor_CIDA Output

group	level	censorcat_sort	censdays_value_cat	episodes	cens_elig	cens_dth	cens_dpend	cens_qryend	cens_episend	cens_spec	cens_event
atyp_ich	701	1	0-364	18919	630	34	0	353	17535	769	1
atyp_ich	701	2	365-729	0	0	0	0	0	0	0	0
atyp_ich	701	3	730-1094	0	0	0	0	0	0	0	0
atyp_ich	701	4	1095+	0	0	0	0	0	0	0	0
atyp_is	701	1	0-364	19470	639	35	0	356	18046	792	10
atyp_is	701	2	365-729	0	0	0	0	0	0	0	0
atyp_is	701	3	730-1094	0	0	0	0	0	0	0	0
atyp_is	701	4	1095+	0	0	0	0	0	0	0	0
typ_ich	701	1	0-364	24004	667	38	0	344	22706	648	3
typ_ich	701	2	365-729	0	0	0	0	0	0	0	0
typ_ich	701	3	730-1094	0	0	0	0	0	0	0	0
typ_ich	701	4	1095+	0	0	0	0	0	0	0	0
typ_is	701	1	0-364	24720	684	43	0	343	23371	664	19
typ_is	701	2	365-729	0	0	0	0	0	0	0	0
typ_is	701	3	730-1094	0	0	0	0	0	0	0	0
typ_is	701	4	1095+	0	0	0	0	0	0	0	0

DPLocal Files

- The DPLocal folder contains output generated by the request that remains with the Data Partner and may be used to facilitate follow-up queries

- Includes patient level information about the exposure or health outcome of interest (episode start/end dates, enrollment start/end dates, patid, etc)

- Denomcounts: source dataset for eligible members and member-days metrics for the T1_CIDA and T2_CIDA tables

- Numcounts: source dataset for cohort metrics for the T#_CIDA table

- MSTR:
  - Generated for every type of cohort identification strategy (every Type in CIDA)
  - Contains one record per individual per index date for every cohort specified
  - Useful for investigating odd/outlier results

MSTR Output (Excerpt)

	Group	IndexDt	EpisodeEndDt	ENR_START	ENR_END	PatID	Birth_date	sex	race	hispanic	Age	DeathDt	IndexLook	NumEvent	FEventDt	tte	Year	Type	EpisodeType	timetocensor	cens_elig	cens_dth
1	atyp_ich	05FEB2010	05APR2010	01JAN2008	31DEC2010	0006BDEDF47C3915	05/01/1959	M	5	N	50.767967146	.	1	.	.	59	2010	2	EPI	59	0	0
2	atyp_ich	30JUL2009	07SEP2009	01JAN2008	01DEC2010	000954C72AF82508	04/01/1955	M	5	N	54.32991102	01DEC2010	1	.	.	39	2009	2	EPI	39	0	0
3	atyp_ich	27JAN2009	31JAN2009	01JAN2008	31JAN2009	000D5CA946B7C4C9	02/01/1943	F	5	N	65.987679671	.	1	.	.	4	2009	2	EPI	4	1	0
4	atyp_ich	20OCT2009	08DEC2009	01JAN2008	31DEC2010	000DAAA45900EE70	09/01/1957	M	5	N	52.134154689	.	1	.	.	49	2009	2	EPI	49	0	0
5	atyp_ich	11JUL2010	08SEP2010	01NOV2010	000FDF324E1A7584		03/01/1946	F	5	N	64.361396304	01NOV2010	1	.	.	59	2010	2	EPI	59	0	0
6	atyp_ich	20SEP2009	18NOV2009	01JAN2009	31DEC2010	0011E8ACC825E190	08/01/1982	F	5	N	27.137577002	.	1	.	.	59	2009	2	EPI	59	0	0
7	atyp_ich	19JAN2009	19MAR2009	01FEB2008	31DEC2010	00127D219AD78492	03/01/1948	F	5	N	60.887063655	.	1	.	.	59	2009	2	EPI	59	0	0
8	atyp_ich	15JUL2008	12SEP2008	01JAN2008	31DEC2010	0017AC6D4A5BC1C2	03/01/1958	M	5	N	50.373716632	.	1	.	.	59	2008	2	EPI	59	0	0
9	atyp_ich	01SEP2009	30OCT2009	01JAN2009	31DEC2010	00187DB5DFDE4D18	10/01/1963	F	5	N	45.919233402	.	1	.	.	59	2009	2	EPI	59	0	0
10	atyp_ich	22JAN2010	22MAR2010	01JAN2008	31DEC2010	00230FE94CA7979C	03/01/1950	M	0	Y	59.89596167	.	1	.	.	59	2010	2	EPI	59	0	0
11	atyp_ich	10JAN2010	10MAR2010	01JAN2008	31DEC2010	0023A2F8B5C8BAD1	10/01/1963	F	5	N	46.277891855	.	1	.	.	59	2010	2	EPI	59	0	0
12	atyp_ich	27NOV2008	25JAN2009	01JAN2008	31DEC2009	0025D5E4468E0B75	10/01/1959	M	5	N	49.158110883	.	1	.	.	59	2008	2	EPI	59	0	0
13	atyp_ich	07AUG2008	05OCT2008	01JAN2008	30SEP2010	00265D0E7B3CE85A	04/01/1964	F	3	U	44.350444901	.	1	.	.	59	2008	2	EPI	59	0	0
14	atyp_ich	24MAY2009	20SEP2009	01JAN2008	31DEC2010	002C64B90C47B523	01/01/1962	M	5	N	47.392197125	.	1	.	.	119	2009	2	EPI	119	0	0
15	atyp_ich	25OCT2008	23DEC2008	01JAN2008	31DEC2010	003006CE8F76EFBC	10/01/1948	M	3	U	60.065708419	.	1	.	.	59	2008	2	EPI	59	0	0
16	atyp_ich	30DEC2008	08FEB2009	01JAN2008	31DEC2010	00303F166AE70F9B	10/01/1944	F	3	U	64.246406571	.	1	.	.	40	2008	2	EPI	40	0	0
17	atyp_ich	10JUL2010	07SEP2010	01JAN2008	31DEC2010	0030B7E33556BBA5	11/01/1963	F	5	N	46.688569473	.	1	.	.	59	2010	2	EPI	59	0	0
18	atyp_ich	02MAY2010	20JUN2010	01JAN2008	31DEC2010	0034CE1366E893BA	06/01/1953	F	5	N	56.917180014	.	1	.	.	49	2010	2	EPI	49	0	0
19	atyp_ich	24SEP2009	02NOV2009	01JAN2008	31DEC2010	003D3B2902CC59C1	06/01/1950	M	5	N	59.315537303	.	1	.	.	39	2009	2	EPI	39	0	0
20	atyp_ich	23JUL2009	20SEP2009	01JAN2008	31DEC2010	00408B995D249B7F	01/01/1948	F	3	U	61.557837098	.	1	.	.	59	2009	2	EPI	59	0	0
21	atyp_ich	19NOV2009	17JAN2010	01AUG2008	31DEC2010	00411F49FDB1454E	03/01/1952	F	5	N	57.719370294	.	1	.	.	59	2009	2	EPI	59	0	0
22	atyp_ich	05OCT2009	03DEC2009	01JAN2008	31DEC2010	0042D807940A55B0	06/01/1964	M	3	U	45.344284736	.	1	.	.	59	2009	2	EPI	59	0	0
23	atyp_ich	08SEP2009	06NOV2009	01JAN2008	31DEC2010	004404C039676932	09/01/1949	F	5	N	60.019164956	.	1	.	.	59	2009	2	EPI	59	0	0
24	atyp_ich	23AUG2008	21OCT2008	01JAN2008	31DEC2010	0044503881BEE445	12/01/1950	F	5	N	57.727583847	.	1	.	.	59	2008	2	EPI	59	0	0

Q & A for Level 1 Report

Propensity Score Analysis Report

Propensity Score Analysis

- By assigning an exposure of interest and comparator, the type 2 output can be leveraged in an inferential analysis to:
  - Assign members a **propensity score, based on user-defined criteria**
  - Calculate adjusted risk estimates using **matching or stratification**

- For each comparison, a **Cox proportional hazards regression model** is used to estimate hazard ratios and corresponding 95% confidence intervals.
  - There is an option for risk-set level return, and patient-level return.

- Propensity score analysis has a pre-processing step
  - Each patient is ONLY allowed to be in either the treatment or comparator cohort.

Propensity Score Match Design Diagram

Propensity Score
- 1:1 Matching
- Caliper: 0.05
- Age, Sex
- Recorded History Parameters

Covariate Evaluation Window
183 days to 1 day prior to index

Exclusion
Dementia 183 days to 0 day prior to index

Enrollment
183-day Enrollment
45 Day Enrollment Gap
Medical and Drug Coverage

Cohort Definition
First valid exposure episode; no cohort re-entry

Cohort Characteristics
- Include adults ages 18-65 at index
- Do not restrict sex or race
- No chart availability restrictions

1/1/2008

Index Date
Typical Antipsychotic Dispensing

Event Outcome
Stroke

12/31/2010

Exposure Incidence
No typical or atypical AP in 183 days prior

Exposed Time
30 day gap/ext

Episode Censored at Event

Event Incidence
No stroke in 60 days prior

Propensity Score Adjustment Output

Sentinel

Risk sets for entire sample and matched sample

[RUNID]_matched_[COMP_ORDER]_[PERIODID].sas7bdat

[RUNID]_risksetdata_[COMP_ORDER]_[PERIODID].sas7bdat

[RUNID]_riskdiffdata_[COMP_ORDER]_[PERIODID].sas7bdat

[RUNID]_survivaldata_[COMP_ORDER]_[PERIODID].sas7bdat

KM Survival Curve Creation

Baseline Characteristics

[RUNID]_matched_tables_[COMP_ORDER]_[PERIODID].sas7bdat

[RUNID]_timing.sas7bdat

[RUNID]_varinfo_[COMP_ORDER]_[PERIODID].sas7bdat

Indicators for Model Convergence

[RUNID]_estimates_[COMP_ORDER]_[PERIODID].sas7bdat

[RUNID]_corr_[COMP_ORDER]_[PERIODID].sas7bdat

Pair-wise Correlation Coefficients

[RUNID]_runreg_[COMP_ORDER]_[PERIODID].rtf

[RUNID]_runmodel_out_[COMP_ORDER]_[PERIODID].rtf

[RUNID]_psdistribution_out_[COMP_ORDER]_[PERIODID].sas7bdat

[RUNID]_signature_ps_[COMP_ORDER]_[PERIODID].sas7bdat

Unmatched Baseline Characteristics

Table 1a. Cohort of New Initiators of Typical Antipsychotics and Atypical Antipsychotics, Ischemic Stroke (Unmatched, Aggregated), Ratio: 1:1, Caliper:0.05

Characteristic	Medical Product				Covariate Balance	
	Typical Antipsychotics		Atypical Antipsychotics			
	N/Mean	%/Std Dev[1]	N/Mean	%/Std Dev[1]	Absolute Difference	Standardized Difference
Patients (N)	23,186	100.0%	17,797	100.0%	-	-
Demographics						
Mean age	51.6	10.6	52.0	10.5	-0.376	-0.036
Age: 18-39	3,899	16.8%	2,845	16.0%	0.830	0.022
Age: 40-54	8,954	38.6%	6,698	37.6%	0.983	0.020
Age: 55-65	10,333	44.6%	8,254	46.4%	-1.813	-0.036
Gender (Female)	12,358	53.3%	9,508	53.4%	-0.125	-0.003
Gender (Male)	10,828	46.7%	8,289	46.6%	0.125	0.003
Year (2008)	7,318	31.6%	5,342	30.0%	1.546	0.033
Year (2009)	11,034	47.6%	8,448	47.5%	0.120	0.002
Year (2010)	4,834	20.8%	4,007	22.5%	-1.666	-0.040
Recorded history of:						
Prior combined comorbidity raw score	0.0	0.0	0.0	0.0	0.000	-
AMI	3,138	13.5%	2,354	13.2%	0.307	0.009
Anxiety	3,745	16.2%	2,593	14.6%	1.582	0.044
Bipolar	6,233	26.9%	4,079	22.9%	3.963	0.092
Depression	7,030	30.3%	4,637	26.1%	4.265	0.095
Diabetes	13,582	58.6%	10,215	57.4%	1.181	0.024
Heart failure	6,795	29.3%	5,061	28.4%	0.869	0.019
Hypercholesterolemia	12,805	55.2%	9,621	54.1%	1.168	0.023
Hypertension	15,961	68.8%	11,907	66.9%	1.934	0.041
Kidney failure	7,009	30.2%	5,116	28.7%	1.483	0.033
Schizophrenia/psychotic	5,372	23.2%	3,416	19.2%	3.975	0.097
Substance abuse	2,178	9.4%	1,449	8.1%	1.252	0.044
Transient ischemic attack	941	4.1%	684	3.8%	0.215	0.011

Matched Baseline Characteristics

Table 1b. Cohort of New Initiators of Typical Antipsychotics and Atypical Antipsychotics, Ischemic Stroke (Matched, Aggregated), Ratio: 1:1, Caliper:0.05

Characteristic	Medical Product				Covariate Balance	
	Typical Antipsychotics		Atypical Antipsychotics			
	N/Mean	%/Std Dev[1]	N/Mean	%/Std Dev[1]	Absolute Difference	Standardized Difference
Patients (N)	17,797	76.8%	17,797	100.0%	-	-
Demographics						
Mean age	52.0	10.5	52.0	10.5	0.033	0.003
Age: 18-39	2,820	15.8%	2,845	16.0%	-0.140	-0.004
Age: 40-54	6,733	37.8%	6,698	37.6%	0.197	0.004
Age: 55-65	8,244	46.3%	8,254	46.4%	-0.056	-0.001
Gender (Female)	9,548	53.6%	9,508	53.4%	0.225	0.005
Gender (Male)	8,249	46.4%	8,289	46.6%	-0.225	-0.005
Year (2008)	5,572	31.3%	5,342	30.0%	1.292	0.028
Year (2009)	8,421	47.3%	8,448	47.5%	-0.152	-0.003
Year (2010)	3,804	21.4%	4,007	22.5%	-1.141	-0.028
Recorded history of:						
Prior combined comorbidity raw score	0.0	0.0	0.0	0.0	0.000	-
AMI	2,359	13.3%	2,354	13.2%	0.028	0.001
Anxiety	2,624	14.7%	2,593	14.6%	0.174	0.005
Bipolar	4,040	22.7%	4,079	22.9%	-0.219	-0.005
Depression	4,624	26.0%	4,637	26.1%	-0.073	-0.002
Diabetes	10,206	57.3%	10,215	57.4%	-0.051	-0.001
Heart failure	5,063	28.4%	5,061	28.4%	0.011	0.000
Hypercholesterolemia	9,583	53.8%	9,621	54.1%	-0.214	-0.004
Hypertension	11,890	66.8%	11,907	66.9%	-0.096	-0.002
Kidney failure	5,086	28.6%	5,116	28.7%	-0.169	-0.004
Schizophrenia/psychotic	3,453	19.4%	3,416	19.2%	0.208	0.005
Substance abuse	1,434	8.1%	1,449	8.1%	-0.084	-0.003
Transient ischemic attack	708	4.0%	684	3.8%	0.135	0.007

Risk Estimates

| Table 2: Effect Estimates for Ischemic Stroke by Analysis Type											
Medical Product	Number of New Users	Person Years at Risk	Average Person Days at Risk	Average Person Years at Risk	Number of Events	Incidence Rate per 1000 Person Years	Risk per 1000 New Users	Incidence Rate Difference per 1000 Person Years	Difference in Risk per 1000 New Users	Hazard Ratio (95% CI)	Wald P-Value
Unmatched Analysis (Site-adjusted only)											
Typical Antipsychotics	23,186	3,768.57	59.37	0.16	19	5.04	0.82	1.58	0.26	1.48 (0.69, 3.20)	0.314
Atypical Antipsychotics	17,797	2,887.43	59.26	0.16	10	3.46	0.56				
1:1 Matched Unconditional Predefined Analysis; Caliper= 0.05											
Typical Antipsychotics	17,797	2,886.62	59.24	0.16	15	5.20	0.84	1.73	0.28	1.54 (0.69, 3.43)	0.293
Atypical Antipsychotics	17,797	2,887.43	59.26	0.16	10	3.46	0.56				

Propensity Score Distribution

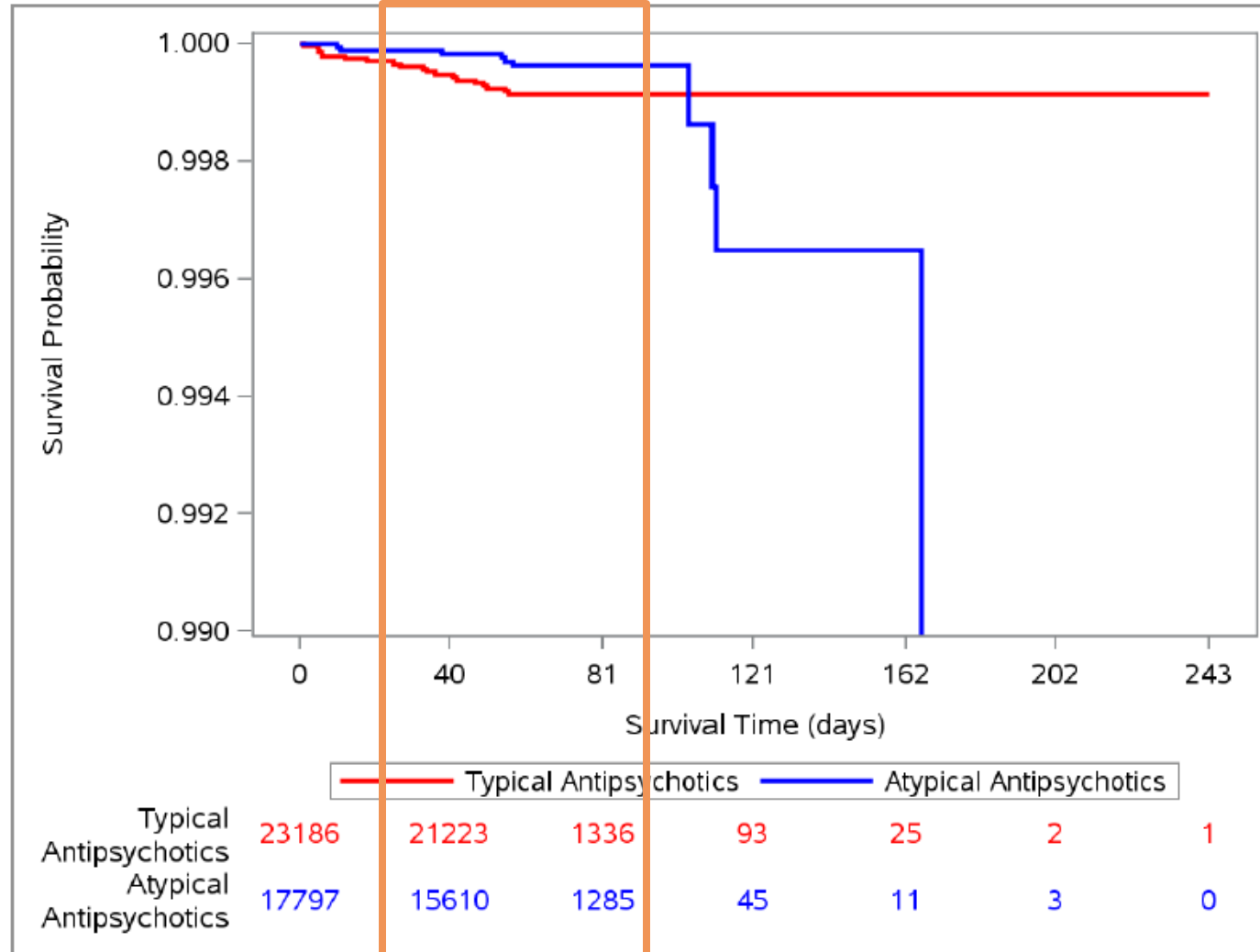Histograms of Propensity Score Distribution Aggregated
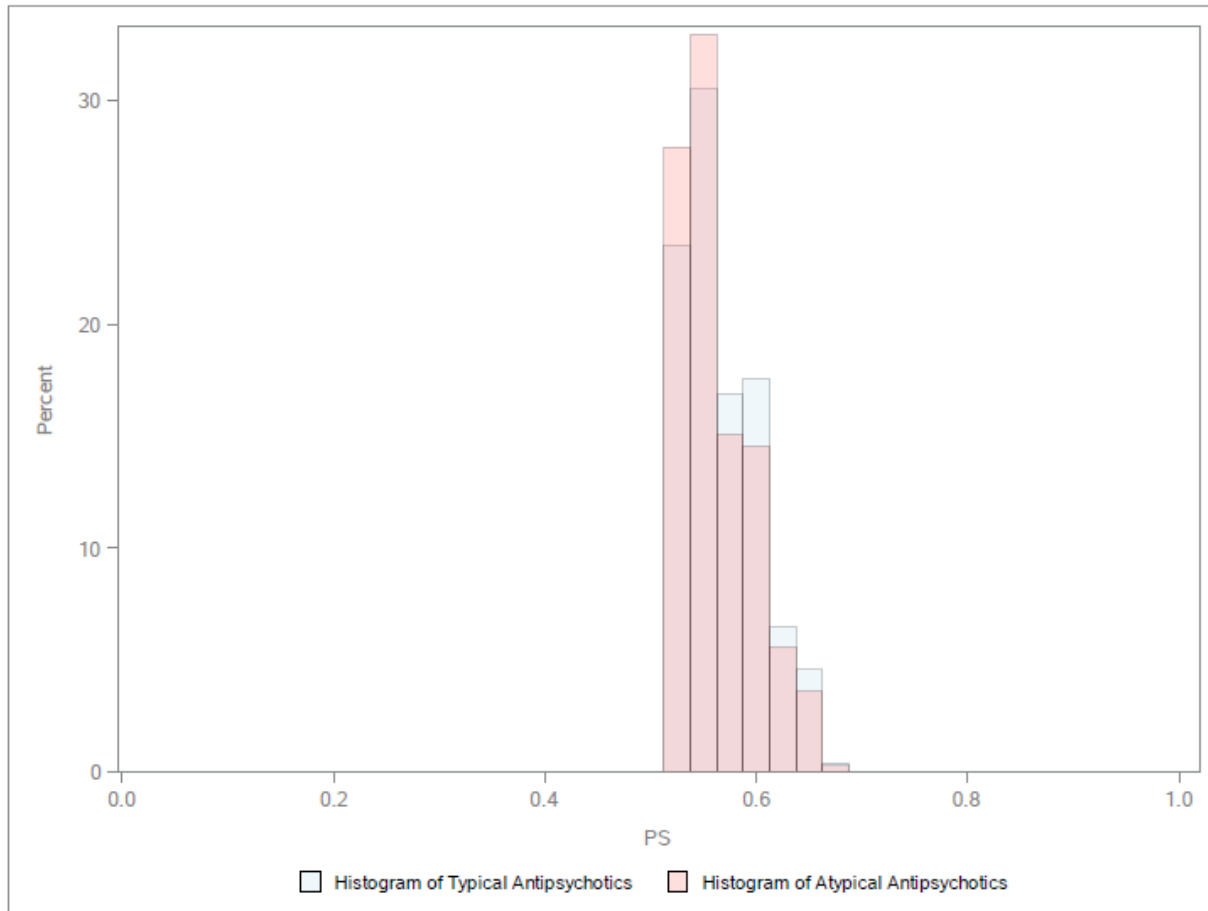
Propensity score 1:1 Aggregated Matched Cohort, Matched Caliper = 0.05
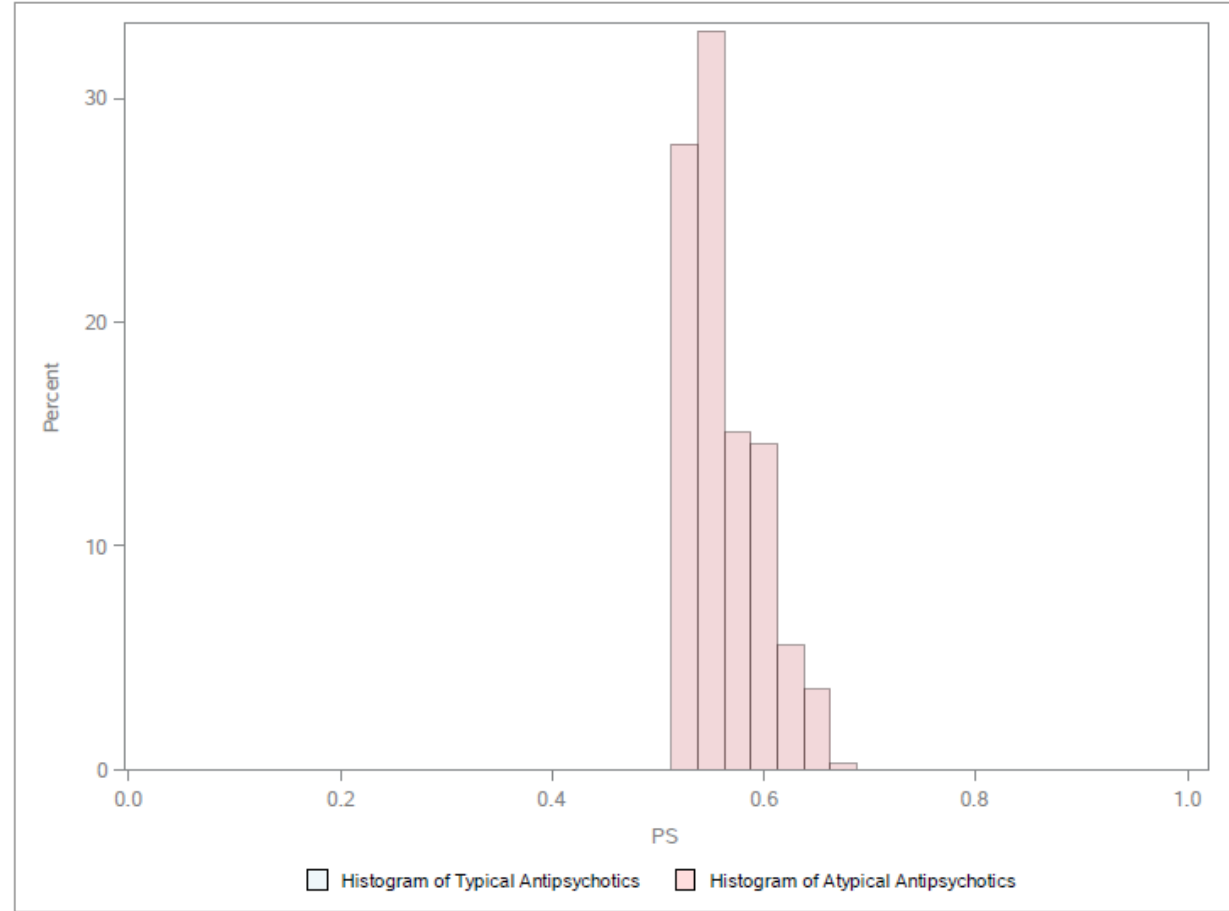
Kaplan Meier Survival Curve

Kaplan Meier Survival Curves of Events and Followup Time for Ischemic Stroke, Full Cohort.

Q & A for Propensity Score Output

Please complete the survey for this session in the Guidebook Mobile App
(Find under "Outputs and Interpreting Reports")

Reference Materials

Commonly Used Acronyms

- CIDA = Cohort Identification and Descriptive Analysis

- DP = Data Partner

- QF = Query Fulfillment

- SCDM = Sentinel Common Data Model

- SDD = Sentinel Distributed Database

- SOC = Sentinel Operations Center

- QRP = Query Request Package

Inclusion/Exclusion Codes – Overview

- Provides a means of restricting the cohort, based on the presence or absence of another condition
  - **Inclusion:** The <u>presence</u> of another condition is <u>required</u>
  - **Exclusion:** The <u>absence</u> of another condition is <u>required</u>

- Evaluation for the inclusion/exclusion condition is relative to the exposure date

- Boolean logic (i.e., AND, OR) can be used to create more complex inclusion or exclusion criteria (e.g., evidence of treatment AND diagnosis)

Propensity Score Comparison File – Overview

- **Specify covariates for inclusion in the propensity score estimation model**
  - Age, sex, year of exposure initiation
  - Any clinical concept that can be defined using a list of codes available in the distributed database
  - Healthcare and/or drug utilization metrics

- **Define the matching ratio**
  - Fixed 1:1 matching
  - Variable 1:n ($n \leq 10$) matching

- **Define caliper as any value between 0 and 1**
  - Maximum distance allowed between two matched patients' PS
  - Natural scale of PS (e.g., 0.01, 0.05)

Censor_CIDA Output

Includes information on the number of episodes, event status, and reason for censoring for every day of follow-up

- GROUP
  - Scenario of interest, repeats by group and irrespective to other groups
- LEVEL
  - Stratification identifier, to break down by sex, agegroup, and year
- CENSDAYS_VALUE
  - Number of days from index date to censoring
  - Episodes censored on the index date have value of 1
- CENSOR_OUTPUT_CAT
  - Categorizes CENSDAYS_VALUE variable in user-defined ranges.
- EPISODES
  - Number of episodes censored at CENSDAYS_VALUE

Censor_CIDA Output

The episodes are additionally identified for the reason for censoring

- EVENT_FLAG

  – Binary stratification of censoring due to occurrence of outcome

- CENS_ELIG

  – Number of episodes censored due to disenrollment

- CENS_DTH

  – Number of episodes censored due to evidence of death.

- CENS_QRYEND

  – Number of episodes censored due to DP data end date CENS_EPISEND

- CENS_SPEC

  – Number of episodes censored due to additional requester-defined criteria

- CENS_EVENT

  – Number of episodes censored due to occurrence of outcome

Questions?

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