

MINI-SENTINEL ASSESSMENT PROTOCOL

METABOLIC EFFECTS OF SECOND GENERATION ANTIPSYCHOTICS IN YOUTH

ADDENDUM 1

UPDATED WORKPLAN 2

Workplan 1 results showed significantly lower than expected event counts. Based these results the inferential analyses outlined in the original workplan 2 specifications (see APY protocol) are not feasible. Instead, a modified workplan 2 (below) will be used to generate descriptive data on antipsychotic utilization in the MSDD.

The descriptive analyses will, for each calendar year with complete data, generate overall and site-specific estimates of new SGA use (calculated as an incidence proportion). The APY cohort as specified under workplan 1 supplies counts for the numerator. The denominator counts are generated from non-users of antipsychotic medications, specifically of all MSDD enrollees age 2-24 who meet the inclusion/exclusion criteria of the APY cohort with the exception of those directly relating to SGA initiation (Protocol Table 2; except criteria 3 and 7f). The index date for the denominator is July 1 of each calendar year with available data. The numerator for each calendar year is number of individuals in the APY cohort with an index date during that year. The denominator for each calendar year is the number of MSDD enrollees who on July 1 of that year meet all eligibility criteria (Protocol Table 2; except criteria 3 and 7f). Stratified analyses will be performed for age and sex (numerator and denominator will be stratified based on sex and the age at the index date), as well as by individual SGA (see Tables 1-4 below).

Table 1: All Antipsychotics

	Year A	Year B	Year C	...	Year N
<u>Data Partner 1</u>					
Numerator	x				
Denominator	y				
Incidence Proportion	x/y				
<u>Data Partner 2</u>					
Numerator	x1				
Denominator	y1				
Incidence Proportion	x1/y1				
...					
<u>Data Partner N</u>					
Numerator	xn				
Denominator	yn				
Incidence Proportion	xn/yn				
Total					
Numerator	sum(x-xn)				
Denominator	sum(y-yn)				
Incidence Proportion	sum(x-xn)/sum(y-yn)				

Year A: First calendar year with complete data; Year N: most recent calendar year with complete data

Numerator: Number of individuals in the AP Youth Cohort with index date during each respective calendar year.

Denominator: Number of individuals meeting all inclusion exclusion criteria for the AP Youth Cohort (except for criteria 3 and 7f) on July 1 of each respective calendar year.

Table 2: Individual Antipsychotics (separate tables for each study APM)

	Year A	Year B	Year C	...	Year N
<u>Data Partner 1</u>					
Numerator	X				
Denominator	Y				
Incidence Proportion	x/y				
<u>Data Partner 2</u>					
Numerator	x1				
Denominator	y1				
Incidence Proportion	$x1/y1$				
...					
<u>Data Partner N</u>					
Numerator	Xn				
Denominator	Yn				
Incidence Proportion	xn/yn				
Total					
Numerator	$\text{sum}(x-xn)$				
Denominator	$\text{sum}(y-yn)$				
Incidence Proportion	$\text{sum}(x-xn)/\text{sum}(y-yn)$				

Year A: First calendar year with complete data; Year N: most recent calendar year with complete data.

Numerator: Number of individuals in the AP Youth Cohort with index date for each respective APM during each respective calendar year.

Denominator: Number of individuals meeting all inclusion exclusion criteria for the AP Youth Cohort (except for criteria 3 and 7f) on July 1 of each respective calendar year.

Table 3: By age group (2-5, 6-12, 13-17, 18-24); separate tables for each age group

	Year A	Year B	Year C	...	Year N
<u>Data Partner 1</u>					
Numerator	X				
Denominator	Y				
Incidence Proportion	x/y				
<u>Data Partner 2</u>					
Numerator	x1				
Denominator	y1				
Incidence Proportion	$x1/y1$				
...					
<u>Data Partner N</u>					
Numerator	Xn				
Denominator	Yn				
Incidence Proportion	xn/yn				
Total					
Numerator	$\text{sum}(x-xn)$				
Denominator	$\text{sum}(y-yn)$				
Incidence Proportion	$\text{sum}(x-xn)/\text{sum}(y-yn)$				

Year A: First calendar year with complete data; Year N: most recent calendar year with complete data

Numerator: Number of individuals in the AP Youth Cohort with index date during the calendar year and age at July 1 of that calendar year in the range of each respective age group.

Denominator: Number of individuals meeting all inclusion exclusion criteria for the AP Youth Cohort (except for criteria 3 and 7f) on July 1 of the calendar year and age on July 1 of the calendar year in the range of each respective age group.

Table 4: By sex (separate tables for each study APM)

	Year A	Year B	Year C	...	Year N
<u>Data Partner 1</u>					
Numerator	x				
Denominator	y				
Incidence Proportion	x/y				
<u>Data Partner 2</u>					
Numerator	x1				
Denominator	y1				
Incidence Proportion	$x1/y1$				
...					
<u>Data Partner N</u>					
Numerator	xn				
Denominator	yn				
Incidence Proportion	xn/yn				
Total					
Numerator	$\text{sum}(x-xn)$				
Denominator	$\text{sum}(y-xn)$				
Incidence Proportion	$\text{sum}(x-xn)/\text{sum}(y-xn)$				

Year A: First calendar year with complete data; Year N: most recent calendar year with complete data

Numerator: Number of male (female) individuals in the AP Youth Cohort with index date during each respective calendar.

Denominator: Number of male (female) individuals meeting all inclusion exclusion criteria for the AP Youth Cohort (except for criteria 3 and 7f) on July 1 of each respective calendar year.