

# Prevalence of Selected Health Conditions among Individuals with Childbearing Potential to Inform the Development of the Pregnancy Safety Study Framework

Presented at the 2024 ISPE Annual Meeting

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**Disclosure:** This project was supported by Task Order 75F40123F19009 under Master Agreement 75F40119D10037 from the U.S. Food and Drug Administration (FDA). Some co-authors on this poster are employed at organizations which conduct work for government and private organizations, including pharmaceutical companies. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.



## Background

- As part of the Food and Drug Administration (FDA) User Fee Reauthorization Act of 2022, FDA has been developing the pregnancy safety study framework to address **gaps in knowledge about the appropriate use of different study types for medication safety assessment**
- The framework can leverage the predicted magnitude of product exposure during pregnancy and study goal (signal identification or evaluation) to help identify the most appropriate study type to assess safety

## Objectives

To estimate the **prevalence of key conditions in individuals with childbearing potential (ICBP)** to generate an informed estimation of potential product magnitude of exposure during pregnancy upon approval

## Methods

- Data source:** Merative™ MarketScan® Research Databases from October 1, 2015, to December 31, 2022
- Study population:** Women aged 10 to 54 years old who were enrolled in health plans with medical and drug coverage for at least one day during the query period. A gap in coverage of up to 45 days was allowed and treated as continuous enrollment
- Health conditions of interest**
  - 29 different psychiatric, pulmonary, neurologic, cardiovascular, metabolic, and renal conditions using International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes
  - We adapted the Centers for Medicare and Medicaid Services' (CMS) Chronic Conditions Data Warehouse (CCW) algorithms<sup>1</sup> to define our selected conditions
- The prevalence of health conditions** was calculated by dividing the number of ICBP with the evaluated condition by the total number of eligible ICBP and was further stratified by age and calendar year. Each health condition was treated as unique and individual cohorts
  - Main analysis: we identified the first valid episode of a particular health condition among eligible ICBP without allowing cohort re-entry
  - Stratified analyses by age and calendar year: we allowed cohort re-entry from one stratum to others, and within each stratum, we selected the first valid episode

## Results

- The study identified 24,607,370 ICBP who met all cohort entry criteria on at least one day during the query period
- The most prevalent health condition was anxiety disorder (N=3,402,869, 14%), followed by depression (N=2,662,403, 11%), obesity (N=2,326,897, 9%), hypertension (N=2,037,886, 8%), and hyperlipidemia (N= 1,815,086, 7%) (**Table 1**)
- The prevalence of depression and anxiety disorders was similar in all age groups, except for ICBP aged 10-14 years (**Figure 1**)

<sup>1</sup><https://www.ccwdata.org/web/guest/condition-categories>

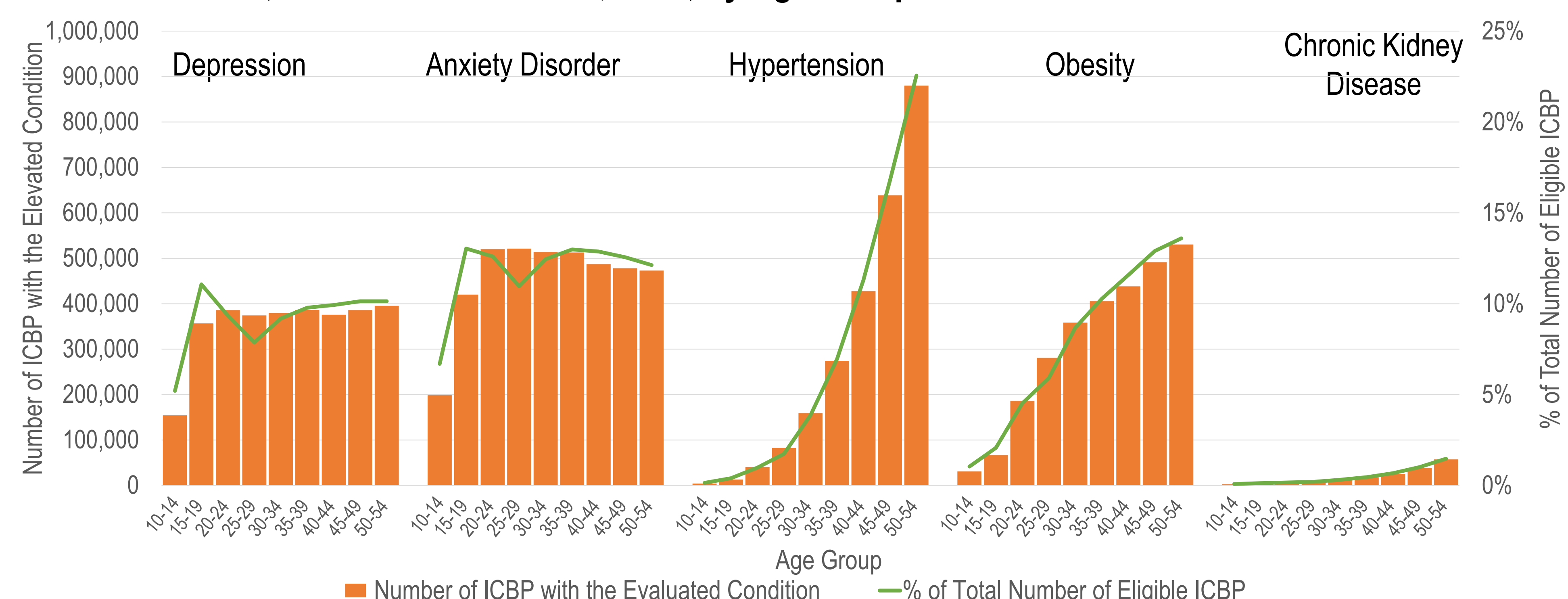
## Results

**Table 1. Prevalence of 29 Health Conditions among 24,607,370 Individuals with Childbearing Potential in the Merative™ MarketScan® Research Databases from October 1, 2015 to December 31, 2022**

Health Condition	N	%	Health Condition	N	%
Anxiety Disorder	3,402,869	14%	Stroke/Transient Ischemic Attack <sup>2</sup>	146,046	1%
Depression	2,662,403	11%	Epilepsy/Convulsions	126,417	1%
Obesity	2,326,897	9%	Diabetes Type 1	112,000	0%
Hypertension	2,037,886	8%	Ischemic Heart Disease	104,972	0%
Hyperlipidemia	1,815,086	7%	Personality Disorders	71,769	0%
Pain Conditions	1,770,685	7%	Heart Failure /Non-Ischemic Heart Disease	70,237	0%
Migraine/Headache	1,220,414	5%	Schizophrenia/Psychotic Disorders	68,974	0%
Asthma	1,060,387	4%	Multiple Sclerosis	59,559	0%
Attention Deficit Hyperactivity Disorders	849,451	3%	Atrial Fibrillation and Flutter	43,689	0%
Overweight	758,738	3%	Pulmonary Embolism	36,653	0%
Diabetes Type 2	747,885	3%	Acute Myocardial Infarction	21,547	0%
Bipolar Disorder	409,365	2%	Non-Alzheimer's Dementia	10,613	0%
Post-Traumatic Stress Disorder	333,642	1%	Parkinson's Disease/Secondary Parkinsonism	2,725	0%
Chronic Obstructive Pulmonary Disease	210,261	1%	Alzheimer's Disease	644	0%
Chronic Kidney Disease	148,078	1%			

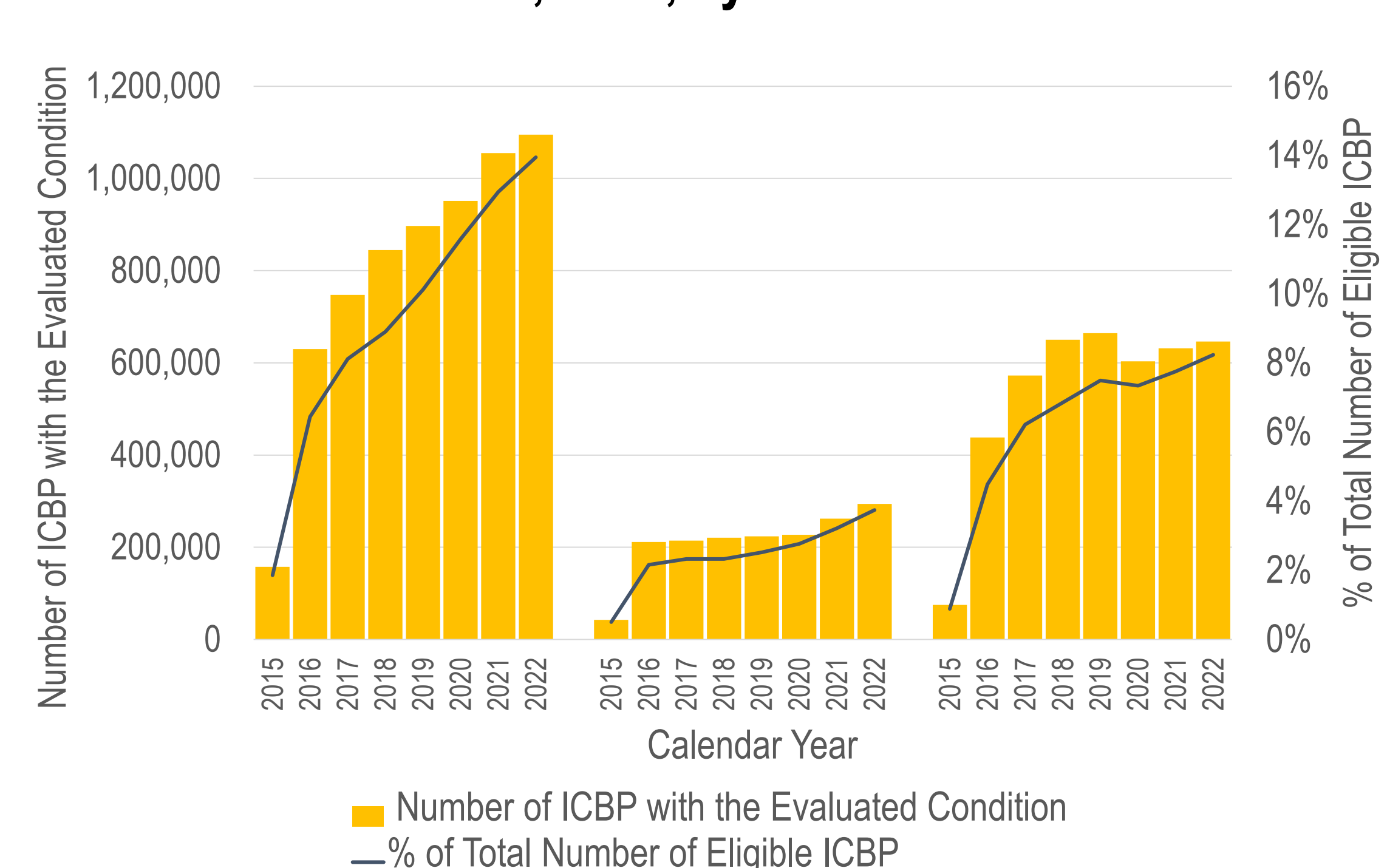
<sup>2</sup>An individual was not eligible to have a stroke/transient ischemic attack event on the same day or days in which that individual also had a stroke/transient ischemic attack excluding code

**Figure 1. Prevalence of Selected Health Conditions among Individuals with Childbearing Potential from October 1, 2015 to December 31, 2022, by Age Group**



- Hypertension, obesity, and chronic kidney disease were more prevalent among older ICBP (**Figure 1**)
- Alzheimer's disease, Parkinson's disease/secondary Parkinsonism, and non-Alzheimer's dementia were rare among ICBP (<0.05%), and the prevalence was highest in the 50-54 age group (data not shown)
- Index year-stratified analysis showed that the prevalence of some psychiatric and metabolic conditions increased over time (**Figure 2**)

**Figure 2. Prevalence of Selected Health Conditions among Individuals with Childbearing Potential from October 1, 2015<sup>3</sup> to December 31, 2022, by Calendar Year**



<sup>3</sup>As the query start date was October 1, 2015, the year 2015 only included data from October 1 to December 31.

## Conclusion

- Our analysis successfully captured the prevalence of a range of health conditions in ICBP. Further analyses evaluating additional conditions are underway
- These findings are expected to be **useful to predict magnitude of product exposure during pregnancy at the moment of approval**, which in turn will help the FDA in the development of pregnancy safety frameworks