

# Sodium-Associated Comorbidity Risk Profiles in Individuals With Narcolepsy and Idiopathic Hypersomnia in the US

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## Introduction

- Narcolepsy and idiopathic hypersomnia are rare neurological conditions that cause excessive daytime sleepiness and irregular sleep patterns<sup>1-4</sup>
- Individuals with narcolepsy and idiopathic hypersomnia often experience a high prevalence of cardiovascular, cardiometabolic, and renal comorbidities, which can be exacerbated by excessive sodium intake<sup>4-8</sup>

## Objective

- To characterize the prevalence and comorbidity profiles of risk factors for sodium-associated negative clinical outcomes among individuals with narcolepsy or idiopathic hypersomnia and individuals without narcolepsy or idiopathic hypersomnia

## Methods

### Study Design and Population:

- Data Source:** Komodo Research Database, containing administrative claims data for a large, diverse cohort of over 330 million individuals<sup>9</sup> (01/01/2016–01/31/2024)
- Study Design:** Retrospective, observational cohort study
- Study Population:**
  - Narcolepsy and idiopathic hypersomnia cohorts:** Continuously enrolled individuals aged ≥7 years with ≥2 claims with a diagnosis for narcolepsy (*International Classification of Diseases, Tenth Revision, Clinical Modification* [ICD-10-CM]: G47.411, G47.421, G47.419, G47.429) or idiopathic hypersomnia (ICD-10-CM: G47.11, G47.12) on distinct dates ≥30 days apart were identified separately (**Figure 1**)
    - The *index date* was defined as the first-observed diagnosis of narcolepsy or idiopathic hypersomnia, respectively
    - The *baseline period* was defined as the continuously-enrolled 12-month period prior to the index date
  - Non-narcolepsy and non-idiopathic hypersomnia cohorts:** Individuals aged ≥7 years without narcolepsy or idiopathic hypersomnia (ie, no diagnosis code or oxybate prescription) at any time in the available data were identified and assigned to mutually exclusive cohorts (**Figure 2**)
    - The *index date* was a randomly selected date in a period of continuous healthcare plan eligibility of ≥48 months, bounded between the 12 months of prior and subsequent continuous health plan enrollment
    - The *baseline period* was defined as the continuously-enrolled 12-month period prior to the index date

Figure 1. Study Population Selection for Narcolepsy and Idiopathic Hypersomnia Cohorts

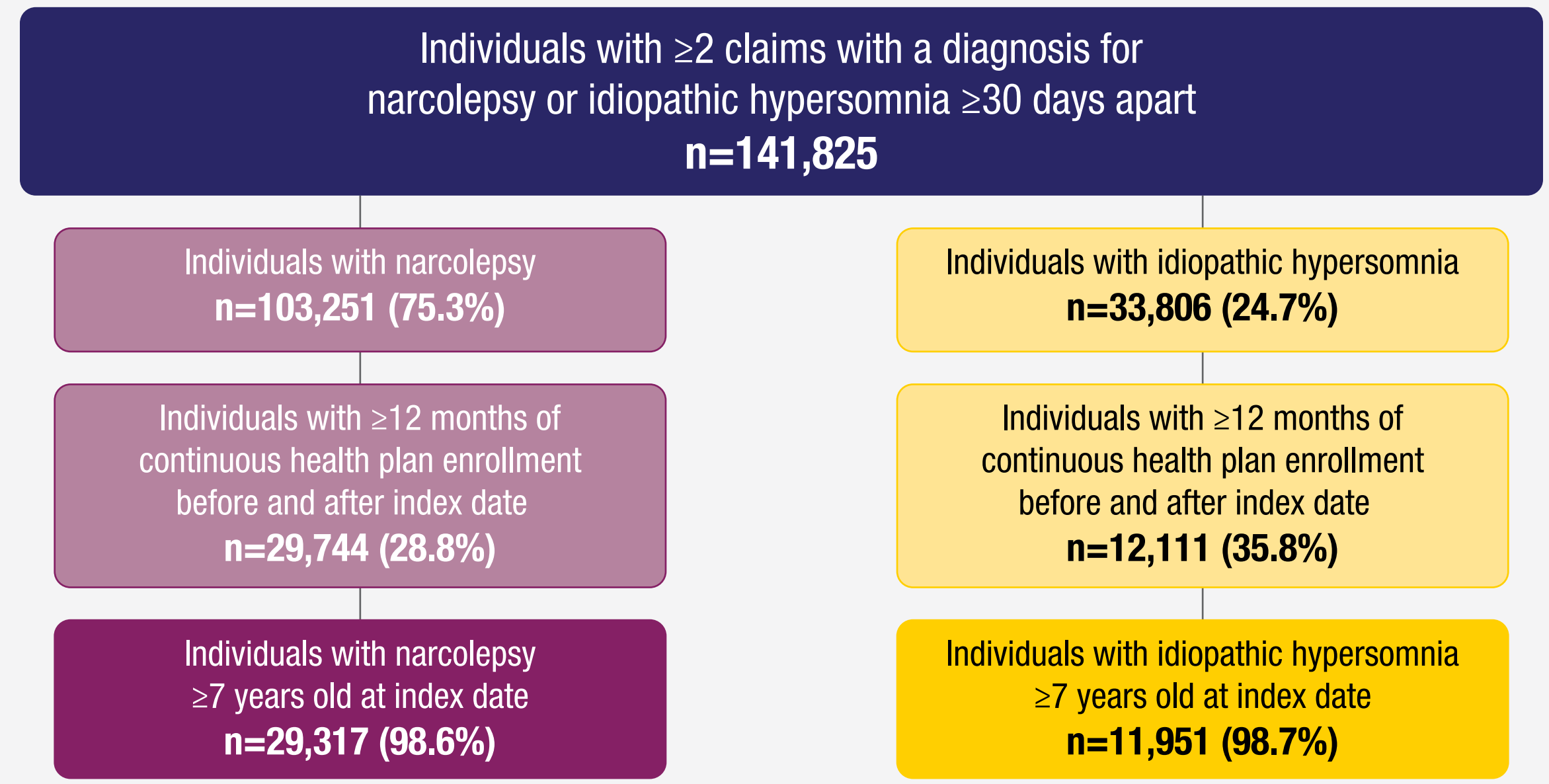
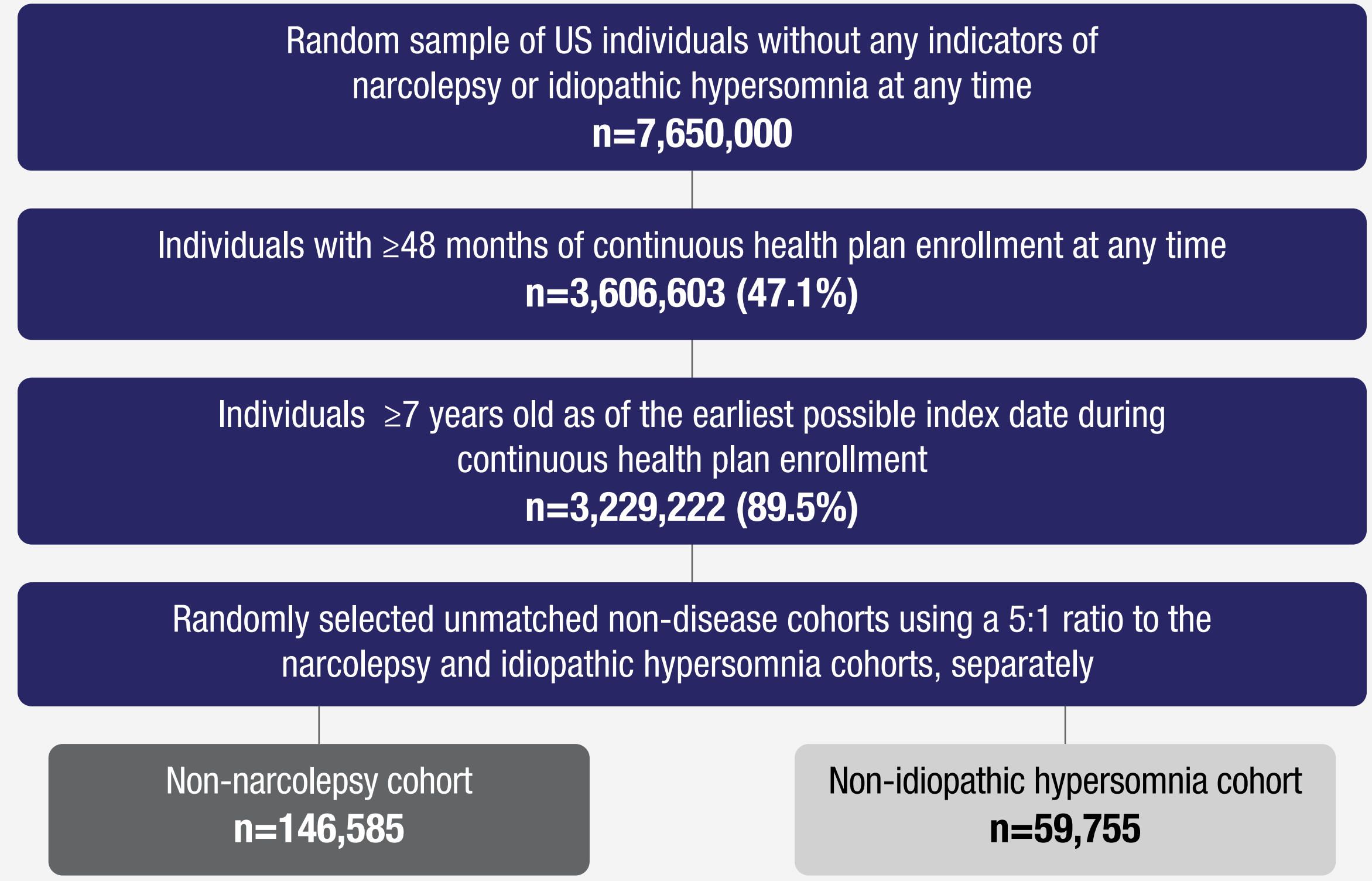


Figure 2. Study Population Selection for Non-Narcolepsy and Non-Idiopathic Hypersomnia Cohorts



### Measures, Outcomes, and Statistical Analyses:

- Demographic characteristics were assessed on the index date
- Sodium-associated risk factors were defined as ≥1 diagnosis code for each comorbidity during the baseline period
  - Risk factors were identified through literature review and clinical expert discussion and included cardiovascular, cardiometabolic, and renal conditions; liver cirrhosis; and sleep apnea (see **Figure 4** for comorbidities assessed as risk factors)
  - For hypertension, hyperlipidemia, and diabetes/obesity, prescription fills for related medications were also considered an indicator of the risk factor
  - An additional analysis was conducted requiring ≥2 diagnosis codes on distinct dates to define risk factor presence
- Entropy balancing was used to balance characteristics (demographics, health plan type, and year of index date) between the narcolepsy and non-narcolepsy cohort and the idiopathic hypersomnia and non-idiopathic hypersomnia cohort
  - Weights from entropy balancing were applied to all analyses using the non-narcolepsy and non-idiopathic hypersomnia cohorts
- Means and medians were reported for continuous variables; counts and frequencies were reported for categorical variables

## Results

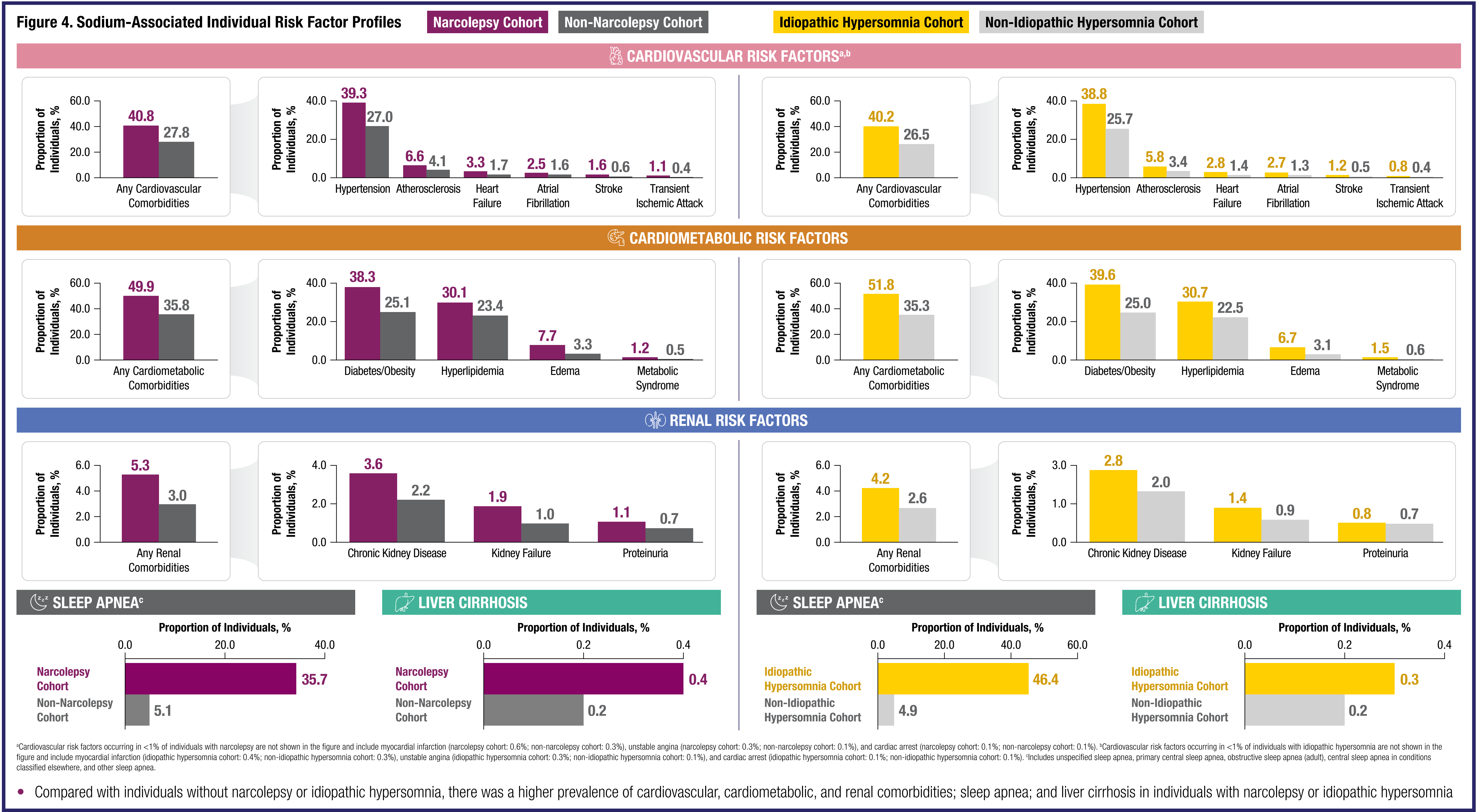
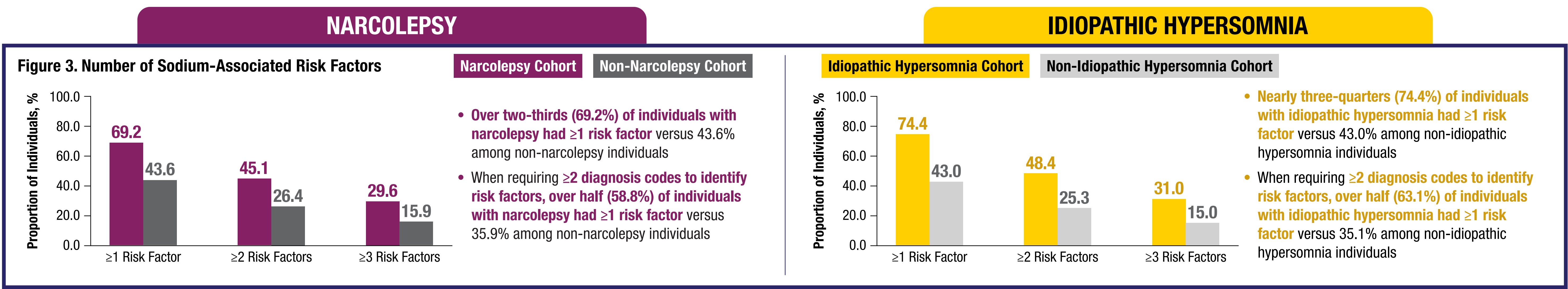


Table 1. Individual Characteristics			
	Narcolepsy Cohort n=29,317	Non-Narcolepsy Cohort n=146,585	
Age, years, mean (SD) [median]	41.4 (17.0) [40.2]	41.5 (17.3) [40.4]	
Female, n (%)	18,199 (62.1)	90,994 (62.1)	
Race/ethnicity, n (%)			
Known	21,233 (72.4)	106,165 (72.4)	
White	16,523 (77.8)	82,616 (77.8)	
Black or African American	2060 (9.7)	10,300 (9.7)	
Asian or Pacific Islander	491 (2.3)	2455 (2.3)	
Hispanic or Latino	1499 (7.1)	7495 (7.1)	
Other	660 (3.1)	3300 (3.1)	
Unknown	8084 (27.6)	40,420 (27.6)	
Health plan, n (%)			
Commercial	22,126 (75.5)	110,630 (75.5)	
Medicare	3771 (12.9)	18,895 (12.9)	
Medicaid	3420 (11.7)	17,100 (11.7)	

	Idiopathic Hypersomnia Cohort n=11,951	Non-Idiopathic Hypersomnia Cohort n=59,755
Age, years, mean (SD) [median]	41.7 (15.7) [40.6]	41.8 (16.0) [40.7]
Female, n (%)	7936 (66.4)	39,680 (66.4)
Race/ethnicity, n (%)		
Known	8463 (70.8)	42,315 (70.8)
White	6862 (81.1)	34,310 (81.1)
Black or African American	616 (7.3)	3080 (7.3)
Asian or Pacific Islander	218 (2.6)	1090 (2.6)
Hispanic or Latino	537 (6.3)	2685 (6.3)
Other	230 (2.7)	1150 (2.7)
Unknown	3488 (29.2)	17,440 (29.2)
Health plan, n (%)		
Commercial	9581 (80.2)	47,905 (80.2)
Medicare	1140 (9.5)	5700 (9.5)
Medicaid	1230 (10.3)	6150 (10.3)

## Conclusions

- Individuals with narcolepsy or idiopathic hypersomnia have a high comorbidity burden relative to those without narcolepsy or idiopathic hypersomnia prior to initial diagnosis, with most having ≥1 risk factor for sodium-associated negative clinical outcomes, commonly cardiovascular or cardiometabolic outcomes
  - Hypertension and diabetes/obesity were the most prevalent cardiovascular and cardiometabolic conditions, respectively
- This study is subject to common limitations of claims data, including missing data and misclassification due to billing inaccuracies
- Findings underscore the sodium-relevant comorbidity burden in individuals with narcolepsy and idiopathic hypersomnia and reinforce the need to mitigate underlying risks and excess sodium exposure associated with negative clinical outcomes

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