# **CaMEO (Chronic Migraine Epidemiology & Outcomes) Study: Design, Methodology, and Baseline Cohort Characteristics**

# INTRODUCTION

- Treatment paradigms for episodic migraine (EM) and chronic migraine (CM) can be optimized by understanding their clinical and epidemiological characteristics.
- Population characteristics for migraine have been well-defined by the American Migraine Study (AMS) I and II<sup>1,2</sup> and the American Migraine Prevalence and Prevention (AMPP) study.<sup>3</sup>
- These studies collected data on an annual basis and used postal mail surveys.
- Newer electronic survey methods have become the standard and offer unique benefits. For example, a web-based approach can provide a convenient method for longitudinal characterization of the headache experience. This is optimal for assessing the progression of EM to CM.
- However, when conducting surveys, some factors must be considered:
- The overall characteristics of the respondents must be taken into account to ensure representativeness of the sample (e.g., age, gender, income).<sup>6</sup>
- Analyses of nonresponse are imperative to understand the implications of survey results, as characteristics of nonrespondents sometimes differ from respondents.<sup>7</sup>
- CaMEO (Chronic Migraine Epidemiology & Outcomes) is a prospective, web-based, cohort study to characterize migraine clinical course and assess aspects of family burden, barriers to care, endophenotypes, and comorbidities among those with CM and EM.

## OBJECTIVES

To describe the methodology and characterize the population surveyed in CaMEO

## METHODS

### **Development of Questionnaires**

 CaMEO questionnaires were developed using multiple methods, including migraine focus groups, expert clinical/scientific judgment, consent review, adaptation from AMPP or AMS questionnaires, and use of other validated instruments.

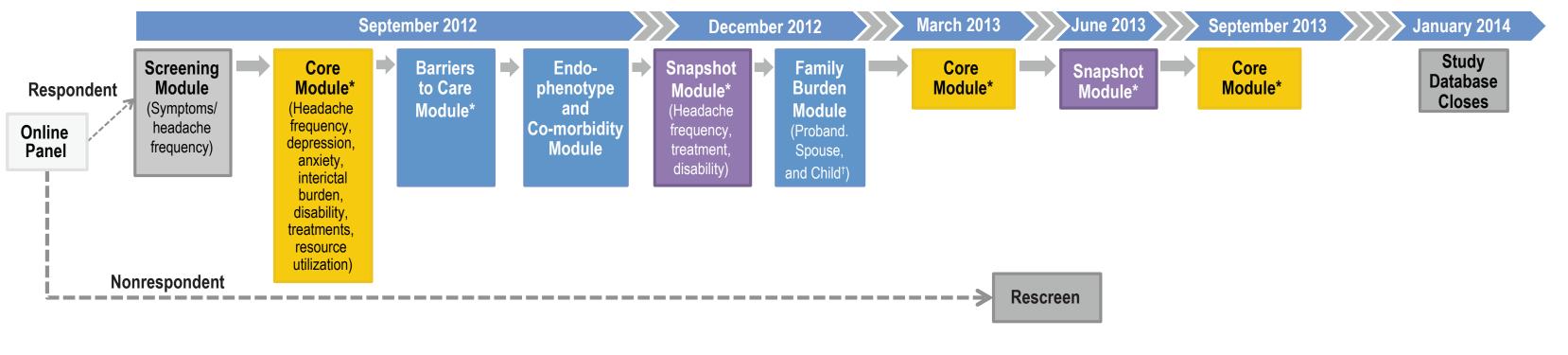
### **Study Population**

- Study participants were recruited from a web-based panel (Research Now) with 2.4 million active members, which has a broad participant demographic and careful membership verification.
- Quota sampling was employed to ensure that the study sample resembled the US population in terms of key demographic variables.
- Participants were screened for headache within the previous year, symptoms relating to the International Classification of Headache Disorders, Second Edition (ICHD-2) migraine criteria,<sup>8</sup> and overall migraine frequency. Respondents meeting *ICHD-2* criteria for migraine were classified as follows:
- − CM:  $\geq$ 15 headache days/month in the past 3 months.
- EM: <15 headache days/month in the past 3 months.</li>
- Those who were enrolled in CaMEO agreed to participate and were considered 'reliable' participants (i.e., they had completed the initial surveys in a reasonable time [ $\geq$ 10 minutes], screened positive for ICHD-2 migraine, were not missing headache frequency data, were  $\geq$ 18 years old, and reported consistent age and sex).

- impact.

### **Study Design**

# Figure 1. Study Design and Data Collection Timeline



\*All assessments of headache day frequency, headache treatment, and burden will be evaluated over the previous 3-months as 12 months of data are collected <sup>†</sup>Proband refers to each migraine subject; spouse/significant other and children must be living in the household for  $\geq 2$  months; children include adolescent/adult children, grandchildren, and stepchildren aged 13–29 years; spouse/significant other is defined for the Proband as "currently in a relationship with a spouse, partner, or significant other."

- for **Table 2**.

### Assessments

- 3 months (Table 1).

- Family Burden Modules:

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Participating migraineurs recruited family members (spouse and adolescent/adult children) living in the household to help assess aspects of headache-related burden and family unit

 Spouse/significant other and children were required to be living in the Proband's (i.e., migraineur's) household for  $\geq 2$  months.

 Spouse/significant other was defined for the Proband as "currently in a relationship with a spouse, partner, or significant other."

- Children included adolescent/adult children, grandchildren, and stepchildren aged 13–29 years. All qualifying children were invited.

• The CaMEO study was initiated in the Fall of 2012, and is ongoing. During the study, participants complete a variety of surveys every 3 months over 1 year (Figure 1).

Reminders were sent to panel members to encourage participation.

- A "nonresponder" survey was sent to panel members who did not respond to the initial screening invitation to obtain headache characteristics and update several demographics. Research Now demographic data for nonrespondents were analyzed

Screening Module: Approximately <5-minute survey to qualify participants (migraineurs) using the Migraine Symptom Severity Score (ICHD-2 criteria), measure baseline headache frequency (Table 1), and collect demographic characteristics. The survey topic was characterized as regarding "overall health and lifestyle."

 Core Module: Approximately 12- to 15-minute survey with 10 assessments monitoring headache frequency, depression, anxiety, interictal burden, headache-related disability, quality of life, stressful life events, treatments, and healthcare resource utilization (Table 1).

Snapshot Module: Approximately 3- to 5-minute survey assessing headache frequency, headache-related disability, and any changes in headache treatments in the last

Barriers to Care Module: Approximately 12- to 15-minute survey relating to the participants' knowledge, attitudes, and behaviors about medical practice related to headache.

Endophenotypes and Comorbidities Module: Approximately 12- to 15-minute survey relating to migraine symptom profiles as well as medical and psychiatric comorbidities. These will be used to identify natural subgroups of migraine sufferers and to assess the aggregation of these migraine profiles within families.

- Proband Module: Approximately 12- to 15-minute survey relating to the impact of migraine on family well-being, including family and social interactions, quality of life, and burden caused by the Proband's migraines. This includes lost productive time (absenteeism/presenteeism) and lost time from family/social activities.

health, and headache (not migraine) frequency for themselves.

Table 1. Screening, Core, and Snapshot Module Assessments							
		Brief Description/	Module				
Domain	Instrument	Scoring Range	Screening	Core	Snapshot		
Headache day frequency	Number of headache days in past 3 months	3-item; rated for past 90 days, 60 days, and 30 days	Х	Х	Х		
Headache treatments	Headache treatments in past 30 days	Acute and preventive Rx and OTC medication usage, frequency of usage, overuse		Х	X		
Headache-resource use	Past 6-month healthcare-resource use	Healthcare Profession and Hospital visits, frequency for headache and for other health reasons		Х			
Activity in school, work/paid employment, household work or chores, and nonwork	Migraine Disability Assessment (MIDAS)*	5-item, lost time and productivity in past 3 months (number of days missed)		Χ	Χ		
Daily performance	Migraine-Specific Quality of Life Questionnaire (MSQ)*	14-item, 6-point frequency scale, on headache-related behavioral and emotional lifestyle impairment over past 4 weeks		Х			
Headache-related burden in work, school, family/ social life, plans/ commitments, and emotion or cognition	Migraine Interictal Burden Scale (MIBS-4)*	4-item, 5-point frequency scale; rated for past 4 weeks		Χ			
Treatment satisfaction over past 4 weeks (or last time headache was treated)	Migraine-Treatment Optimization Questionnaire (M-TOQ)*	5-item, "yes" or "no" questionnaire		Χ	Χ		
Presence of depression over last 2 weeks	Patient Health Questionnaire, 9-item depression screener (PHQ-9)*	9-item 4-point frequency scale; depression is coded as a dichotomous variable using the DSM-IV and PHQ-9 clinical algorithm		Х			
Presence/severity of generalized anxiety disorder over last 2 weeks	Generalized Anxiety Disorder, 7-item screener (GAD-7)	7-item, 4-point frequency scale		Х			
Severity of 7 <i>ICHD-2</i> migraine- defining features plus visual aura	Migraine Symptom Severity (MSS) Score	8-item, 4-point frequency scale; 1 "yes" or "no" question	Χ				
Presence/severity of stressful events in previous 12 months	Stressful Life Events Scale (SLE) <sup>†</sup>	5-item "yes" or "no" questionnaire with 6-point severity scale		Х			

DSM-IV=Diagnostic and Statistical Manual for Mental Health, Fourth Edition; NRS=numerical rating schedule; OTC=over the counter; PHQ=Patient Health Questionnaire; Rx=prescription. Validated assessment.

<sup>†</sup>Adapted from Horowitz, et al. *Psychosomatic Medicine*. 1977. Nov-Dec;39(6):413-31.

### **Statistical Analyses**

The majority of results are descriptive. Inferential statistics were employed to explore be viewed as descriptive.

 Spouse and Child Modules: Spouse and adolescent household members received an adapted version of the Proband survey (approximately 15–20 minutes each) via email. The Spouse and Child Modules included matching or similar questions to the Proband survey (from the point of view of the Spouse/Child), plus depression, anxiety, overall

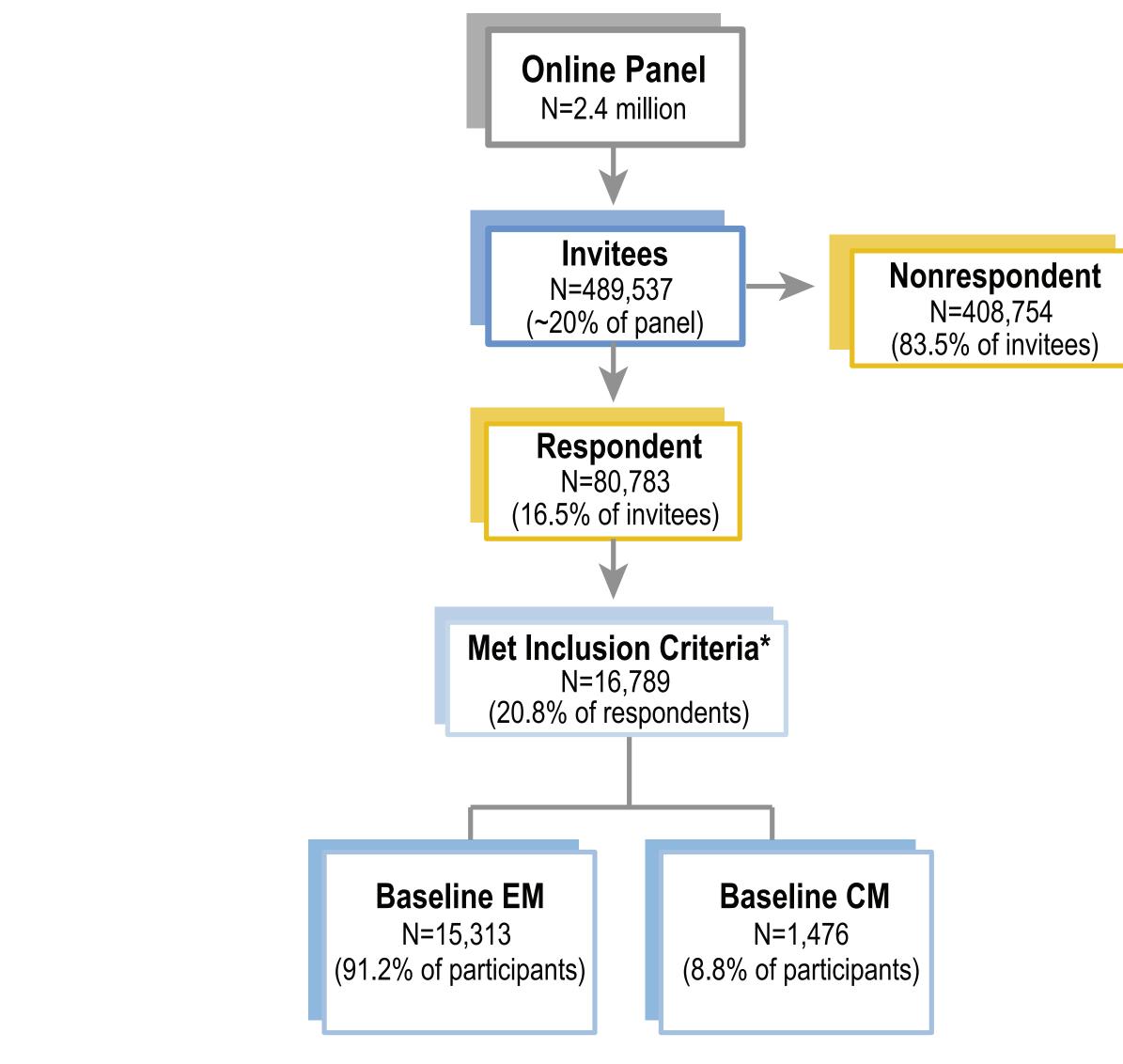
non-response bias. Because of exceedingly large sample sizes, even inferential tests must

# RESULTS

### **Participant Demographics**

Of 489,537 invitees, 16.5% responded to the screening survey (Figur

# Figure 2. Participant Disposition



CM=chronic migraine; EM=episodic migraine.

\*Met inclusion criteria (i.e., agreed to participate, screened positive for ICHD-2 migraine, completed initial surve  $\geq 10$  minutes], were  $\geq 18$  vears old, were not missing headache frequency data, and reported consistent age

- 3.4% (16,789/489,537) of invitees, and 20.8% (16,789/80,783) of re inclusion criteria.
- 91.2% of included respondents were characterized as having EM;
- Compared with nonrespondents, survey respondents were older, more white, and married, and less likely to be employed full-/part-time or ha household income  $\leq$  median (*P*<0.001 for all) (Table 2).
- Additional data are being collected to assess whether respondents differ in headache or migraine characteristics or other demographi

### Table 2. Demographics of Respondents and Nonro

Table Zi Demographics of Respondents and Nonrespondents						
			Nonrespondent vs Respondent			
	Nonrespondent	Respondent	Point Estimate <sup>†</sup>			
Characteristic	(N=408,754)	(N=80,783)	(95% CI)	P value		
Age (years), mean (SD)	39.2 (14.7)	45.8 (16.6)	6.65 (6.54–6.77)	<0.001		
Female, n (%) <sup>‡</sup>	232,996 (57.0)	47,480 (58.8)	1.08 (1.06–1.09)	<0.001		
Race, n (%) White <sup>‡</sup>	262,340 (65.8)	60,216 (76.2)	1.67 (1.64–1.70)	<0.001		
Married, n (%) <sup>‡</sup>	187,923 (46.7)	44,015 (54.8)	1.38 (1.36–1.40)	<0.001		
Employed, n (%) <sup>‡</sup>	250,173 (61.7)	45,170 (56.2)	0.80 (0.79–0.81)	<0.001		
Annual household income >median, n (%) <sup>‡</sup>	113,648 (30.5)	28,440 (38.3)	1.42 (1.40–1.44)	<0.001		

OR=odds ratio.

\*Continuous variable contrasts based on t test for mean difference; binary variable contrasted based on logistic regression OR for difference

<sup>†</sup>All point estimates are OR, except for age, which is mean difference.

Reference values are men, other race, not married, not employed, and annual household income  $\leq$  median income bracket (\$50,000-\$74,999).



**P60** 

	CONCLUSIONS
re 2).	<ul> <li>Similar to other epidemiological studies,<sup>7</sup> demographics differed between CaMEO respondents and nonrespondents; however, inferential statistics in such large samples should be interpreted with caution.</li> </ul>
	<ul> <li>Future data will detail demographic differences between respondents and nonrespondents.</li> </ul>
	<ul> <li>Final CaMEO data will provide a naturalistic understanding of the course of EM and CM, quantify variations in headache frequency, headache-related disability, comorbidities, medication use, impact of migraine on the family unit, and contribute a wealth of information to the limited amount of epidemiologic data on CM.</li> </ul>
	REFERENCES
eys in a reasonable time and sex).	<ol> <li>Stewart WF, et al. JAMA. 1992;267(1):64-69.</li> <li>Lipton RB, et al. Headache. 2001;41(7):646-657.</li> <li>Lipton RB, et al. Neurology. 2007;68(5):343-349.</li> <li>Buse DC, et al. Headache. 2012;52(10):1456-1470.</li> <li>Lipton RB. Headache. 2011;51 (suppl 2):77-83.</li> <li>Cook C, et al. Educational and Psychological Measurement 2000;60:821-836.</li> <li>Ekholm O, et al. Scand J Public Health. 2010;38(7):699-706.</li> <li>Headache Classification Subcommittee of the International Headache Society (IHS). Cephalalgia. 2004;24 (suppl 1)(England):9-160.</li> </ol>
espondents met the	ACKNOWLEDGMENTS
8.8% were CM. re likely to be female, ave an annual	This research was supported by Allergan, Inc. (Irvine, CA). Allergan also funded editorial support for poster development, provided by Nicole Gudleski, PhD, and Kris Schuler, MS, of Complete Healthcare Communications, Inc. (Chadds Ford, PA).
s/nonrespondents ics.	DISCLOSURES
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<ul> <li>&lt; 0.001</li> <li>&lt; 0.001</li> <li>&lt; 0.001</li> </ul>	in eNeura Therapeutics; serves as consultant, advisory board member, or has received honoraria from Allergan, American Headache Society, Autonomic Technologies, Boehringer-Ingelheim Pharmaceuticals, Boston Scientific, Bristol Myers Squibb, Cognimed, Colucid, Eli Lilly, Endo Pharmaceuticals, eNeura

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