Are Women Underrepresented in Cerebrovascular Disease Clinical Trials? A Systematic Review using the FDA Database

Supplementary Material

Table 1: Diseases and conditions under the diagnosis codes for CVD.

Diagnosis code	Classification of disease
ICD-9: 430	Subarachnoid hemorrhage
ICD-9: 431	Intracerebral hemorrhage
ICD-9: 432	Other and unspecified intracranial hemorrhage
ICD-9: 433	Occlusion and stenosis of precerebral arteries
ICD-9: 434	Occlusion of cerebral arteries
ICD-9: 435	Transient cerebral ischemia
ICD-9: 436	Acute, but ill-defined, cerebrovascular disease
ICD-9: 437	Other and ill-defined cerebrovascular disease
ICD-9: 438	Late effects of cerebrovascular disease
ICD-10: I60	Nontraumatic subarachnoid hemorrhage
ICD-10: I61	Nontraumatic intracerebral hemorrhage

ICD-10: I62	Other and unspecified nontraumatic intracranial hemorrhage
ICD-10: I63	Cerebral infarction
ICD-10: I65	Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction
ICD-10: I66	Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
ICD-10: I67	Other cerebrovascular diseases
ICD-10: I68	Cerebrovascular disorders in diseases classified elsewhere
ICD-10: I69	Sequelae of cerebrovascular disease
The ICD-9 and ICD-10 codes for CVD were based on the heart disease and stroke statistics annual report.	

Table 2: Prevalence of CVD among patients of age ≥ 18 years by gender (females vs. males) in the United States between 2002 and 2017.

Year	Female			Male			Overall			Ratio of women to men among CVD patients
	Population size*	Prevalence rate†	Estimated N of patients‡	Population size[1]	Prevalence rate[2]	Estimated N of patients	Population size	Prevalence rate	Estimate N of patients	
2002	108712	2.5%	2717.80	100610	2.5%	2515.25	209322	2.5%	5233.05	1.08:1
2003	110190	2.5%	2754.75	102431	2.5%	2560.78	212621	2.5%	5315.53	1.08:1
2004	110883	2.5%	2772.08	103641	2.5%	2591.03	214524	2.5%	5363.10	1.07:1
2005	112409	2.6%	2922.63	104966	2.5%	2624.15	217375	2.6%	5546.78	1.11:1

2006	113503	2.6%	2951.08	106346	2.5%	2658.65	219849	2.6%	5609.73	1.11:1
2007	114880	2.8%	3216.64	107843	2.6%	2803.92	222723	2.7%	6020.56	1.15:1
2008	115842	2.5%	2896.05	108863	2.7%	2939.30	224705	2.6%	5835.35	0.99:1
2009	116946	2.5%	2923.65	110027	2.7%	2970.73	226973	2.6%	5894.38	0.98:1
2010	118079	2.5%	2951.98	111163	2.7%	3001.40	229242	2.6%	5953.38	0.98:1
2011	118892	2.5%	2972.30	112301	2.7%	3032.13	231193	2.6%	6004.43	0.98:1
2012	121442	2.6%	3157.49	113279	2.6%	2945.25	234721	2.6%	6102.75	1.07:1
2013	122481	2.6%	3184.51	114448	2.7%	3090.10	236929	2.6%	6274.60	1.03:1
2014	129959	2.9%	3768.81	115880	2.9%	3360.52	245839	2.9%	7129.33	1.07:1
2015	125196	2.7%	3380.29	117051	2.7%	3160.38	242247	2.7%	6540.67	1.07:1
2016	126338	2.7%	3411.13	118468	2.7%	3198.64	244806	2.7%	6609.76	1.07:1
2017	127156	2.8%	3560.37	119168	2.8%	3336.70	246324	2.8%	6897.07	1.07:1
2018	128488	2.7%	3469.18	120708	2.7%	3259.12	249196	2.7%	6728.29	1.06:1
2019	129262	2.8%	3619.34	121300	2.9%	3517.70	250562	2.8%	7137.04	1.03:1

Note: *The population sizes (numbers in 1000s) were obtained from the data released by the US Census Bureau (https://www.census.gov).

†The prevalence rates were based on the heart disease and stroke statistics annually updated report from circulation.

‡The estimated number N of patients was calculated as the population multiplied by the prevalence rate.

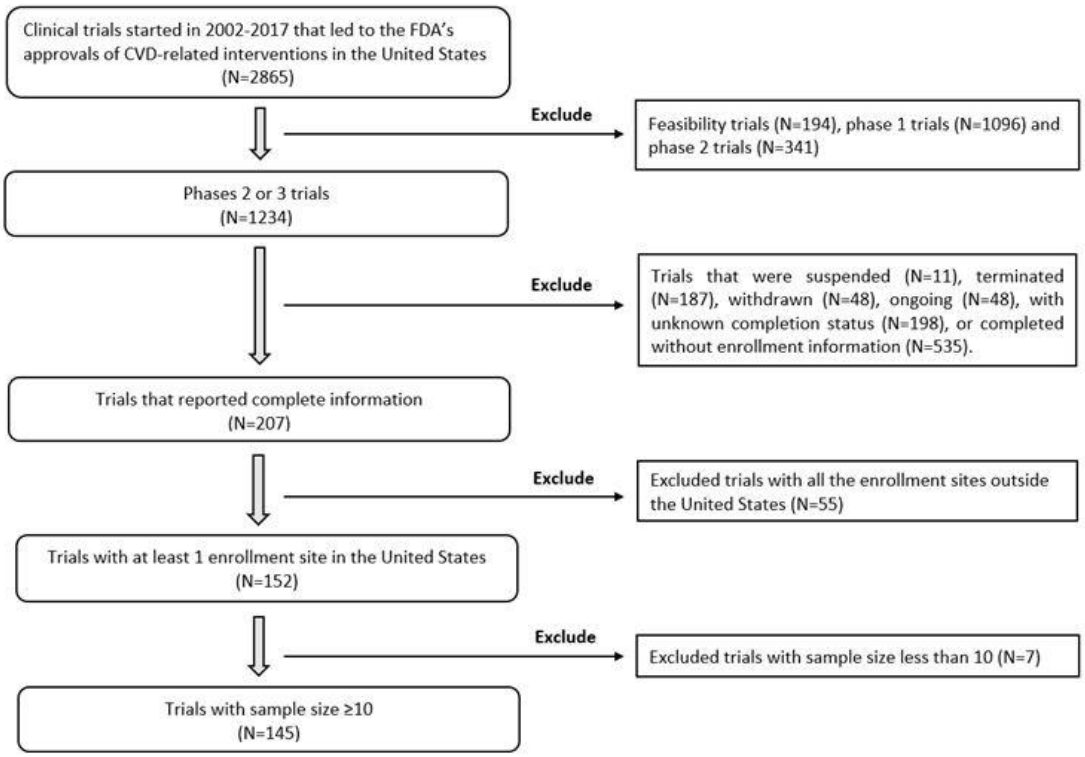

Figure 1: Selection of study trials in FDA database.