

Supplemental File S8. Characteristics of industry and non-industry post-marketing studies when only incorporating those whose launch started after the first regulatory approval.

Characteristics		All (n=6443)	Industry studies (n=4012)	Non-industry studies (n=2431)
Primary sponsor	Industry	2564 (39.8%)		
	NIH	244 (3.8%)		
	US Fed	15 (0.2%)		
	Other	3620 (56.2%)		
Industry involved either as a primary sponsor or a collaborator		4012 (62.5%)		
No. of post-marketing studies per drug	Min/max	3/498		
	Median [Q1-Q3]	51 [19-118]		
	Mean (SD)	93.4 (105.5)		
Population size per drug	Min/max	67/1.04E6		
	Median [Q1-Q3]	15212 [4819-36262]		
	Mean (SD)	61719 (166183)		

Therapeutic class according to the ATC				
Alimentary tract and metabolism		809 (12.6%)	547 (67.6%)	262 (32.4%)
Anti-infectives for systemic use		814 (12.6%)	495 (60.8%)	319 (39.2%)
Antineoplastic and immunomodulating agents		2900 (45.5%)	1742 (60.1%)	1158 (39.9%)
Blood and blood forming organs		429 (6.7%)	261 (60.8%)	168 (39.2%)
Nervous system		468 (7.3%)	288 (61.5%)	180 (38.5%)
Other*		1023 (15.9%)	679 (66.4%)	344 (33.6%)
Study design with respect to primary label	Another indication than the originally approved indication	2342 (36.4%)	1259 (53.8%)	1083 (46.2%)
	Originally approved indication	3859 (59.9%)	2631 (68.2%)	1228 (31.8%)
	Both the originally approved indication and another indication	242 (3.7%)	122 (50.4%)	120 (49.6%)
Study type	Observational	703 (10.9%)	466 (66.3%)	237 (33.7%)
	Interventional	5740 (89.1%)	3546 (61.8%)	2194 (38.2%)

Randomization	Missing data	2393	1412	981
	Yes	2950 (72.8%)	1875 (63.6%)	1075 (36.4%)
	No	1100 (27.2%)	725 (65.9%)	375 (34.1%)
Study phase	Missing data	1046	551	495
	0	33 (0.6%)	12 (36.4%)	21 (63.6%)
	I	886 (16.4%)	622 (70.2%)	264 (29.8%)
	I/II	406 (7.5%)	235 (57.9%)	171 (42.1%)
	II	1746 (32.4%)	992 (56.8%)	754 (43.2%)
	II/III	104 (1.9%)	49 (47.1%)	55 (52.9%)
	III	1180 (21.9%)	957 (81.1%)	223 (18.9%)
	IV	1042 (19.3%)	594 (57.0%)	448 (43.0%)
Centers	Missing data	468	394	74
	Min/max	1/1616	1/1616	1/922
	Median [Q1-Q3]	2 [1-12]	4 [1-23]	1 [1-2]
	Mean (SD)	19.7 (62.2)	26.1 (70.4)	9.8 (45.0)
Countries	Missing data	466	393	73
	Min/max	1/45	1/46	1/15
	Median [Q1-Q3]	1 [1-1]	1 [1-2]	1 [1-1]

	Mean (SD)	2.6 (4.6)	3.5 (5.7)	1.1 (0.7)
Planned enrollment	Missing data	14	9	5
	Min/max	1/904585	1/904585	1/61050
	Median [Q1-Q3]	60 [27-180]	70 [29-241]	48 [24-100]
	Mean (SD)	662.4 (13044.2)	966.4 (16495.6)	160.9 (1293.2)
Status at the time of data exportation	Not yet recruiting	319 (4.8%)	136 (42.6%)	183 (57.4%)
	Recruiting	1888 (29.3%)	883 (46.8%)	1005 (53.2%)
	Active, not recruiting	991 (15.4%)	619 (62.5%)	372 (37.5%)
	Enrolling by invitation	64 (1.0%)	42 (65.6%)	22 (34.4%)
	Completed	2705 (42.0%)	2000 (73.9%)	705 (26.1%)
	Terminated	476 (7.4%)	332 (69.8%)	144 (30.3%)

NIH, US National Institutes of Health

*includes cardiovascular system, dermatological, genitourinary system and sex hormones, musculoskeletal system, sensory organs, systemic hormonal preparations, excluding sex hormones, and other