

Estimate of Women and Men in Clinical Drug Trials by Drug Class

	NDA Overall			Small-Scale Safety Trials			Subsequent Safety and Efficacy Trials		
	Total	Percent Women	Percent Men	Total	Percent Women	Percent Men	Total	Percent Women	Percent Men
Analgesics and Anesthetics (3)									
A	28,815	66	34	813	23	77	28,002	67	33
B ^a	10,702	44	17	1,531	14	18	9,171	49	17
C ^a	5,659	24	35	523	24	73	5,136	24	32
Anti-Infectives and Immunosuppressants (9)									
A ^a	5,924	40	59	482	21	74	5,442	42	57
B ^a	6,578	52	44	490	28	72	6,088	54	42
C	1,545	15	79	418	11	68	1,127	17	83
D	6,860	51	49	722	34	66	6,138	53	47
E ^a	4,272	53	45	274	17	83	3,998	55	42
F ^a	9,327	51	49	557	9	79	8,770	54	46
G	2,995	32	68	730	22	78	2,265	35	65
H	1,673	21	79	675	27	73	998	16	84
I ^a	7,544	46	36	1,103	10	78	6,441	52	28
Cancer (5)									
A ^a	1,195	34	53	202	21	32	933	37	57
B	3,527	99	1	123	73	27	3,404	100	0
C ^a	1,472	4	5	40	50	50	1,432	3	4
D ^a	684	31	64	186	38	55	498	28	67
E ^a	927	51	48	184	45	55	743	52	46
Diabetes & Cholesterol (5)									
A ^a	1,543	42	43	240	4	4	1,303	50	50
B	2,455	40	60	155	8	92	2,300	43	57
C ^a	4,689	37	53	529	11	89	4,160	41	48
D ^a	8,084	34	65	528	19	81	7,556	35	64
E	4,465	43	57	720	23	77	3,745	47	53
Neuropharmacological (6)									
A	3,226	50	50	307	20	80	2,919	53	47
B	5,480	83	17	352	31	69	5,128	87	13
C	5,042	84	16	289	43	57	4,753	86	14
D ^a	5,833	52	37	391	31	69	5,442	54	35
E ^a	9,333	56	15	578	15	81	8,755	58	11
F ^a	955	26	39	104	0	100	851	29	32
Ophthalmological (5)									
A	1,557	58	42	82	44	56	1,475	59	41
B ^a	1,084	34	33	40	20	80	1,044	35	32
C	5,238	52	48	22	50	50	5,216	52	48
D ^a	2,438	39	33	34	41	59	2,404	39	33
E ^a	988	46	44	271	39	61	717	48	38
Other (3)									
A	1,855	77	22	220	23	71	1,635	85	15
B	6,895	52	48	207	17	83	6,688	53	47
C ^a	5,847	66	28	1,443	28	72	4,044	85	15
Total^a	176,706	52	39	15,565	22	67	160,781	55	36

^aIndicated NDAs where the sex of some or all of the participants was not specified by clinical drug development stage (sum of percent women and percent men does not equal 100).

Source: Estimated from GAO analysis of 36 NDAs and FDA medical Officer Reviews.

Estimate of Women and Men in Pivotal Drug Trials by Drug Class

	Total	Overall Women	Men	Total	Comparison Group Women	Men	Total	Treatment Group Women	Men
Analgesics and Anesthetics (3)									
A ^a	19,082								
B	3,022	2,279	743	1,111	850	261	1,911	1,429	482
C	931	253	678	373	106	267	558	147	411
Anti-Infectives and Immunosuppressants (9)									
A	1,572	649	923	790	337	453	782	312	470
B	5,829	3,258	2,571	2,102	1,201	901	3,727	2,057	1,670
C	736	128	608	366	67	299	370	61	309
D	1,588	808	780	775	419	356	813	389	424
E	1,346	670	676	443	228	215	903	442	461
F	7,246	3,617	3,629	2,967	1,506	1,461	4,279	2,111	2,168
G	1,295	438	857	291	109	182	1,004	329	675
H ^a	998	164	834	386	66	320	385	75	310
I ^a	5,644	3,021	1,556	2,508	1,836	672	2,145	1,302	843
Cancer (5)									
A	387	145	242	113	41	72	274	104	170
B	1,176	1,176	0	597	597	0	579	579	0
C	59	29	30	0	0	0	59	29	30
D ^a	178	58	94	0	0	0	152	58	94
E	287	118	169	103	45	58	184	73	111
Diabetes & Cholesterol (5)									
A ^a	561	283	278	110	56	54	450	227	223
B	2,090	961	1,129	715	324	391	1,375	637	738
C	2,826	1,300	1,526	1,406	642	764	1,420	658	762
D	2,635	932	1,703	753	233	520	1,882	699	1,183
E ^a	2,319	1,047	1,272	789	366	423	1,512	677	835
Neuropharmacological (6)									
A	904	431	473	312	156	156	592	275	317
B ^a	2,319	1,987	332	549	463	86	1,768	1,522	246
C ^a	4,057	3,520	537	319	273	46	1,123	961	162
D	1,289	803	486	428	263	165	861	540	321
E ^a	5,986	5,100	886						
F	366	167	199	126	57	69	240	110	130
Ophthalmological (5)									
A	305	167	138	25	17	8	280	150	130
B	388	194	194	193	94	99	195	100	95
C	2,406	1,237	1,169	923	473	450	1,483	764	719
D	1,127	583	544	470	242	228	657	341	316
E	609	344	265	207	130	77	402	214	188
Other (3)									
A	484	453	31	164	155	9	320	298	22
B	3,177	1,766	1,411	1,597	915	682	1,580	851	729
C	881	731	150	288	240	48	593	491	102
Total^a	86,105	38,817	27,113	22,299	12,507	9,792	34,858	19,012	15,846

^aIndicated NDAs in which the sex of some or all of the participants was not specified for some 0-09 or all of the pivotal studies overall, the comparison group, or the treatment group.

Source: Estimated from GAO analysis of 36 NDAs and FDA medical Officer Reviews.