

Supplementary Online Content

Shadbolt C, Naufal E, Bunzli S, et al. Analysis of rates of completion, delays, and participant recruitment in randomized clinical trials in surgery. *JAMA Netw Open*. 2023;6(1):e2250996. doi:10.1001/jamanetworkopen.2022.50996

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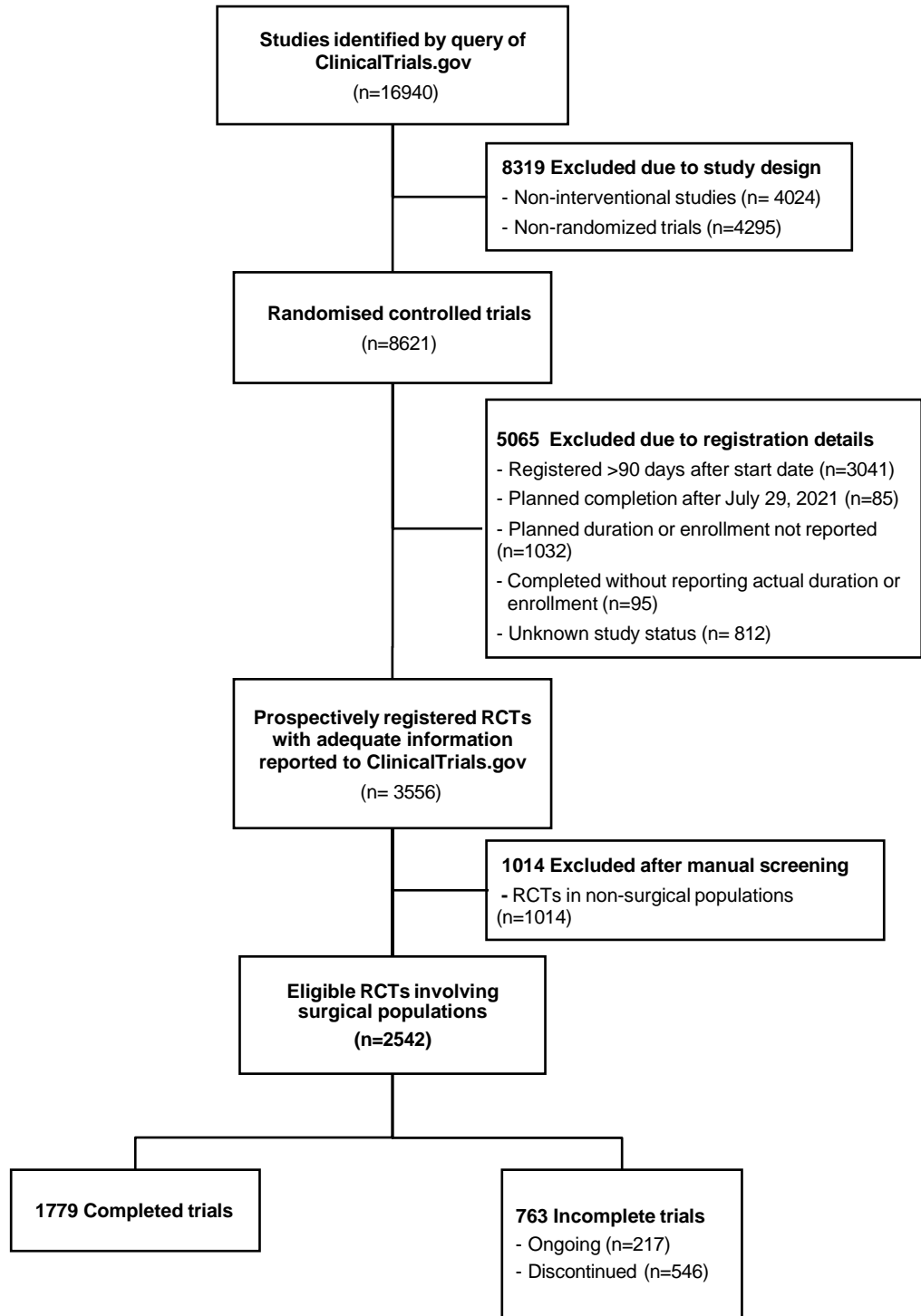
eTable 5. Proportions of Trials Completed Within Selected Thresholds for Recruiting Shortfalls

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Detailed summary of ClinicalTrials.gov search results

Terms	Search Results*	Entire Database**
Surgery	16,940 studies	70,159 studies
Surgical	7,062 studies	29,615 studies
Operations	2,385 studies	9,778 studies
Surgically	402 studies	1,624 studies
Invasive procedures	183 studies	769 studies
Operative procedures	74 studies	227 studies
Operative therapy	21 studies	61 studies
<p>* Number of studies containing the term or synonym that were first posted to ClinicalTrials.gov between 01/01/2010 and 31/12/2014</p> <p>** Number of studies in the entire database containing the term or synonym</p>		

eFigure. Flow diagram summarizing identification of eligible trials



eTable 2. Characteristics of 681 trials excluded due to “Unknown” study status

	Known status	Unknown status*	Total
	N=2,542	N=681	N=3,223
Registration Year			
2010	386 (15.2%)	96 (14.1%)	482 (15.0%)
2011	452 (17.8%)	117 (17.2%)	569 (17.7%)
2012	537 (21.1%)	120 (17.6%)	657 (20.4%)
2013	537 (21.1%)	150 (22.0%)	687 (21.3%)
2014	630 (24.8%)	198 (29.1%)	828 (25.7%)
Body System			
Cardiovascular	370 (14.6%)	90 (13.2%)	460 (14.3%)
Digestive	457 (18.0%)	191 (28.0%)	648 (20.1%)
Eye	124 (4.9%)	32 (4.7%)	156 (4.8%)
Female reproductive	207 (8.1%)	41 (6.0%)	248 (7.7%)
Integumentary	174 (6.8%)	33 (4.8%)	207 (6.4%)
Mixed	248 (9.8%)	53 (7.8%)	301 (9.3%)
Musculoskeletal	551 (21.7%)	122 (17.9%)	673 (20.9%)
Other	290 (11.4%)	79 (11.6%)	369 (11.4%)
Respiratory	121 (4.8%)	40 (5.9%)	161 (5.0%)
Intervention type			
Drug	929 (36.5%)	186 (27.3%)	1,115 (34.6%)
Procedure	513 (20.2%)	211 (31.0%)	724 (22.5%)
Device	331 (13.0%)	75 (11.0%)	406 (12.6%)
Other	367 (14.4%)	97 (14.2%)	464 (14.4%)
Mixed	402 (15.8%)	112 (16.4%)	514 (15.9%)
Lead Sponsor			
Industry	413 (16.2%)	27 (4.0%)	440 (13.7%)
Non-industry	2,129 (83.8%)	654 (96.0%)	2,783 (86.3%)
No. of facilities			
Multi-site	723 (28.4%)	116 (17.0%)	839 (26.0%)
Single site	1,739 (68.4%)	529 (77.7%)	2,268 (70.4%)
Not reported	80 (3.1%)	36 (5.3%)	116 (3.6%)
Masking			
Masked	1,669 (65.7%)	410 (60.2%)	2,079 (64.5%)
None	870 (34.2%)	271 (39.8%)	1,141 (35.4%)
Not reported	3 (0.1%)	0 (0.0%)	3 (0.1%)
Target duration, mo. Med (IQR)	22.3 (12.2-35.5)	24.3 (12.2-36.5)	23.3 (12.2-36.5)
Target enrolment, no. Med (IQR)	100 (58-200)	100 (60-200)	100 (60-200)
* 131/812 studies excluded from study due to reporting an "unknown" study status are not presented here as they would have subsequently been excluded for examining a non-surgical population			

eTable 3. Characteristics of 2542 eligible trials, by trial status.

	Completed on time		Completed w/ delays		Discontinued	Ongoing w/ delays
	Full enrolment	Partial enrolment	Full enrolment	Partial enrolment		
	N=370	N=149	N=796	N=464		
Registration Year						
2010	54 (14.6)	21 (14.1)	142 (17.8)	70 (15.1)	86 (15.8)	13 (6.0)
2011	59 (15.9)	24 (16.1)	134 (16.8)	91 (19.6)	109 (20.0)	35 (16.1)
2012	74 (20.0)	40 (26.8)	164 (20.6)	119 (25.6)	101 (18.5)	39 (18.0)
2013	73 (19.7)	33 (22.1)	173 (21.7)	93 (20.0)	118 (21.6)	47 (21.7)
2014	110 (29.7)	31 (20.8)	183 (23.0)	91 (19.6)	132 (24.2)	83 (38.2)
Body System						
Cardiovascular	44 (11.9)	18 (12.1)	118 (14.8)	88 (19.0)	67 (12.3)	35 (16.1)
Digestive	65 (17.6)	25 (16.8)	133 (16.7)	76 (16.4)	105 (19.2)	53 (24.4)
Eye	17 (4.6)	6 (4.0)	44 (5.5)	24 (5.2)	25 (4.6)	8 (3.7)
Female reproductive	39 (10.5)	11 (7.4)	79 (9.9)	33 (7.1)	32 (5.9)	13 (6.0)
Integumentary	20 (5.4)	14 (9.4)	53 (6.7)	28 (6.0)	43 (7.9)	16 (7.4)
Mixed	44 (11.9)	13 (8.7)	73 (9.2)	40 (8.6)	68 (12.5)	10 (4.6)
Musculoskeletal	66 (17.8)	30 (20.1)	182 (22.9)	95 (20.5)	130 (23.8)	48 (22.1)
Other	51 (13.8)	27 (18.1)	76 (9.5)	49 (10.6)	57 (10.4)	30 (13.8)
Respiratory	24 (6.5)	5 (3.4)	38 (4.8)	31 (6.7)	19 (3.5)	4 (1.8)
Intervention type						
Drug	172 (46.5)	60 (40.3)	301 (37.8)	154 (33.2)	190 (34.8)	52 (24.0)
Procedure	70 (18.9)	28 (18.8)	164 (20.6)	79 (17.0)	107 (19.6)	65 (30.0)
Device	40 (10.8)	19 (12.8)	110 (13.8)	65 (14.0)	71 (13.0)	26 (12.0)
Other	49 (13.2)	25 (16.8)	121 (15.2)	90 (19.4)	68 (12.5)	14 (6.5)
Mixed	39 (10.5)	17 (11.4)	100 (12.6)	76 (16.4)	110 (20.1)	60 (27.6)
Lead Sponsor						
Industry	61 (16.5)	23 (15.4)	139 (17.5)	77 (16.6)	87 (15.9)	26 (12.0)
Non-industry	309 (83.5)	126 (84.6)	657 (82.5)	387 (83.4)	459 (84.1)	191 (88.0)
No. of facilities						
Multi-site	77 (20.8)	36 (24.2)	224 (28.1)	142 (30.6)	141 (25.8)	103 (47.5)
Single site	277 (74.9)	111 (74.5)	559 (70.2)	315 (67.9)	363 (66.5)	114 (52.5)
Not reported	16 (4.3)	2 (1.3)	13 (1.6)	7 (1.5)	42 (7.7)	0 (0.0)
Masking						
Masked	281 (75.9)	101 (67.8)	555 (69.7)	300 (64.7)	328 (60.1)	104 (47.9)
None	89 (24.1)	47 (31.5)	241 (30.3)	162 (34.9)	218 (39.9)	113 (52.1)
Not reported	0 (0.0)	1 (0.7)	0 (0.0)	2 (0.4)	0 (0.0)	0 (0.0)
Target duration, mo. Med (IQR)	16.2 (10.1-27.4)	25.4 (13.2-43.6)	15.3 (10.2-25.4)	23.3 (12.2-32.4)	24.4 (13.2-36.5)	48.7 (27.3-70.1)
Target enrolment, no. Med (IQR)	82.5 (50-150)	144 (69-286)	90 (50-168)	120 (68-231)	90 (50-196)	168 (78-369)

eTable 4. Proportions of trials completed within selected thresholds for delays

	No. (%) of trials completed below threshold		
Percentage of planned duration	Industry (N=413)	Non-industry (N=2129)	Total (N=2542)
110%	103 (24.9)	501 (23.5)	604 (23.8)
125%	140 (33.9)	640 (30.1)	780 (30.7)
150%	193 (46.7)	836 (39.3)	1,029 (40.5)
175%	231 (55.9)	970 (45.6)	1,201 (47.2)
200%	251 (60.8)	1,071 (50.3)	1,322 (52.0)

eTable 5. Proportions of trials completed within selected thresholds for recruiting shortfalls

	No. (%) of trials completed above threshold		
Percentage of planned enrollment	Industry (N=413)	Non-industry (N=2129)	Total (N=2542)
90%	229 (55.4)	1,061 (49.8)	1,290 (50.7)
80%	243 (58.8)	1,139 (53.5)	1,382 (54.4)
70%	254 (61.5)	1,208 (56.7)	1,462 (57.5)
60%	271 (65.6)	1,257 (59.0)	1,528 (60.1)
50%	275 (66.6)	1,308 (61.4)	1,583 (62.3)