Table 1: ACT and pACT Identification Logic

	Logic
ACT Logic (Trials started on or after 18 Jan 2017)	Study Type is *Interventional* **AND** FDA Regulated Drug **OR** Device is *Yes* **AND** Phase is *1/2, 2, 2/3, 3, 4 or N/A* **AND** Primary Purpose is **NOT** *Device Feasibility* **AND** Study Status is **NOT** *Withdrawn*
pACT Logic (Trials started prior to, but completed on or after, 18 Jan 2017)	Study Type is *Interventional* **AND** Phase is *1/2, 2, 2/3, 3, 4 or N/A* **AND** Primary Purpose is **NOT** *Device Feasibility* **AND** Study Status is **NOT** *Withdrawn* **AND** **IF** FDA Regulated Drug OR Device field is available: FDA Regulated Drug **OR** Device is *Yes* **IF** FDA Regulated Drug OR Device field is **NOT** available: Intervention Type is *Biological* **OR** *Drug* **OR** *Device* **OR** *Genetic* **OR** *Radiation* **OR** *Combination Product* **OR** *Diagnostic Test* **AND** Study Location includes *United States* **OR** *US Territories* **AND** "Is FDA Regulated" is *True* OR *Null*[a]

[a] "Is FDA Regulated" field was used prior to the Final Rule and no longer exists in the ClinicalTrials.gov record. We use an archived version of this field as a conservative check on pACTs. Data was retrieved from a 5 January 2017 archive of the database at https://aact.ctti-clinicaltrials.org/snapshots

Table 2: Proportion of Applicable Trials that are Reported, and Compliant, by Trial Category

Variables		Total Trials (% of Total)	Trials with Any Results	% with Any Results	95% CI	Compliant Trials	% Compliant	95% CI
Trials		4209	2686	63·8	62·4 to 65·3	1722	40·9	39·4 to 42·4
Sponsor Class:	Non-Industry	2178 (51·8)	1358	62·4	60·3 to 64·4	737	33·8	31·9 to 35·9
	Industry	1837 (43·6)	1184	64·5	62·2 to 66·6	924	50·3	48·0 to 52·6
	US Gov	194 (4·6)	144	74·2	67·6 to 79·9	61	31·4	25·3 to 38·3
Industry Collaborator		715 (17·0)	482	67·4	63·9 to 70·8	310	43·4	39·8 to 47·0
US Gov Collaborator		461 (11·0)	330	71·6	67·3 to 75·5	180	39·0	34·7 to 43·6
Phase:	Phase 1/2	327 (7·8)	191	58·4	53·0 to 63·6	117	35·8	30·8 to 41·1
	Phase 2	1329 (31·6)	916	68·9	66·4 to 71·4	575	43·3	40·6 to 45·9
	Phase 2/3	99 (2·4)	56	56·6	46·6 to 66·0	40	40·4	31·2 to 50·4
	Phase 3	750 (17·8)	557	74·3	71·0 to 77·3	415	55·3	51·8 to 58·9
	Phase 4	600 (14·3)	392	65·3	61·4 to 69·0	242	40·3	36·5 to 44·3
	N/A	1104 (26·2)	574	52·0	49·0 to 54·9	333	30·2	27·5 to 32·9
Terminated		663 (15·8)	475	71·6	68·1 to 74·9	301	45·4	41·6 to 49·2
Reached Full Completion		3811 (90·5)	2434	63·9	62·3 to 65.4	1547	40·6	39·0 to 42·2
Trial Contains a Drug		2968 (70·5)	2025	68·2	66·5 to 69·9	1320	44·5	42·7 to 46·3
Trial Contains a Biological/Vaccine		369 (8·8)	265	71·8	67·0 to 76·2	180	48·8	43·7 to 53·9
Trial Contains a Device		1020 (24·2)	533	52·3	49·2 to 55·3	314	30·8	28·0 to 33·7
Trial Contains a Diagnostic Test		25 (·6)	14	56·0	36.2 to 74·0	7	28·0	13·8 to 48·7
Trial Contains a Radiation Treatment		103 (2·5)	64	62·1	52·4 to 71·0	34	33·0	24·6 to 42·7
Trial Contains a Combination Product		13 (·3)	7	53·8	27.3 to 78·4	2	15·4	3·6 to 46·6
Trial Contains a Genetic Treatment		11 (·3)	5	45.5	19·4 to 74·3	4	36·4	13·6 to 67·5

Trial Location:	US Only	3000 (71·3)	1843	61·4	59·7 to 63·2	1046	34·9	33·2 to 36·6
	US and Other County	876 (20·8)	700	79·9	77·1 to 82.4	565	64·5	61·3 to 67·6
	No US Location	242 (5·8)	99	40·9	34·9 to 47·2	79	32·6	27·0 to 38·8
	No Location Data Available	91 (2·2)	44	48·4	38·2 to 58·6	32	35·2	26·0 to 45·5
Total No. of Trials on Register for Trial's Sponsor	First Quarter (1-12)	1128 (26·8)	451	40·0	37·2 to 42·9	241	21·4	19·1 to 23·9
	Second Quarter (13-219)	1119 (26·6)	601	53·7	50·8 to 56·6	362	32·4	29·7 to 35·2
	Third Quarter (221-910)	1004 (23·9)	766	76·3	73·6 to 78·8	491	48·9	45·8 to 52·0
	Fourth Quarter (925-3276)	958 (22·8)	868	90·6	88·6 to 92·3	628	65·6	62·5 to 68·5

Table 3: Crude and Adjusted Odds Ratios for Factors Associated with Reporting under FDAAA 2007

Variables		Any Results Crude OR	95% CI	P value	Any Results Adjusted OR	95% CI	P value	Compliant Crude OR	95% CI	P value	Compliant Adjusted OR	95% CI	P value
Sponsor Class:	Non-Industry	Reference	--	--	Reference	--	--	Reference	--	--	Reference	--	--
	Industry	1·09	·96 to 1·25	0·169	1·62	1·35 to 1·96	<0·001	1·98	1·74 to 2·25	<0·001	3·08	2·52 to 3·77	<0·001
	US Gov	1·74	1·25 to 2·43	0·001	·82	·54 to 1·23	0·337	·90	·65 to 1·23	0·499	·48	·33 to ·69	<0·001
Industry Collaborator		1·21	1·02 to 1·44	0·028	1·29	1·06 to 1·58	0·013	1·13	·96 to 1·33	0·145	1·30	1·08 to 1·58	0·007
US Gov Collaborator		1·49	1·20 to 1·84	<0·001	1·45	1·12 to 1·87	0.005	·92	·75 to 1·12	0·388	1·19	·94 to 1·51	0·150
Phase:	Phase 1/2	·49	·37 to ·64	<0·001	·65	·47 to ·90	0·009	·45	·34 to ·59	<0·001	·91	·66 to 1·24	0·550
	Phase 2	·77	·63 to .94	0·010	·99	·78 to 1·25	0·900	·62	·51 to ·74	<0·001	1·05	·84 to 1·30	0·686
	Phase 2/3	·45	·29 to ·69	<0·001	·52	·32 to ·86	0·010	·55	·36 to ·84	0·006	0.94	·58 to 1·51	0·785
	Phase 3	Reference	--	--	Reference	--	--	Reference	--	--	Reference	--	--
	Phase 4	·65	·52 to ·83	<0·001	1·01	·75 to 1·34	0·970	·55	·44 to ·68	<0·001	1·15	·88 to 1·52	0·305
	N/A	·38	·31 to ·46	<0·001	·65	·46 to ·92	0·014	·35	·29 to ·42	<0·001	·87	·62 to 1·21	0·401
Terminated		1·53	1·27 to 1·83	<0·001	1·42	1·16 to 1·74	0·001	1·24	1·05 to 1·47	0·011	1·16	·96 to 1·41	0·114
Reached Full Completion		1·02	·83 to 1·27	0·828	1·67	1·29 to 2·17	<0·001	·87	·71 to 1·07	0·193	1·28	1·00 to 1·65	0·050
Trial Contains a Drug		1·88	1·65 to 2·16	<0·001	1·71	1.20 to 2·44	0·003	1·67	1·45 to 1·92	<0·001	1·45	1·05 to 2·01	0·024
Trial Contains a Biological/Vaccine		1·49	1·18 to 1·89	0·001	1·64	1·14 to 2·35	0·007	1·42	1·15 to 1·76	0·001	1·51	1·11 to 2·08	0·010
Trial Contains a Device		·53	·46 to ·61	<0·001	1·90	1·30 to 2·77	0·001	·56	·48 to ·65	<0·001	1·35	·95 to 1·92	0·099
Trial Contains a Diagnostic Test		·72	·33 to 1·59	0·482	1·51	·60 to 3·79	0·378	·56	·23 to 1·34	0·194	1·14	·43 to 3·01	0·798
Trial Contains a Radiation Treatment		·93	·62 to 1·39	0·720	·81	·50 to 1·32	0·403	·71	·47 to 1·07	0·100	1·00	·63 to 1·59	0·991
Trial Contains a Combination Product		·66	·22 to 1·97	0·457	1·48	·44 to 5·00	0·528	·26	·06 to 1·18	0·081	·48	·10 to 2·30	0·356

Trial Contains a Genetic Treatment		·47	·14 to 1·55	0·215	·94	·25 to 3·54	0·931	·82	·24 to 2·82	0·759	1·73	·46 to 6·41	0·415
Trial Location:	US Only	Reference	--	--	Reference	--	--	Reference	--	--	Reference	--	--
	US and Other County	2·50	2·08 to 2·99	<0·001	1·85	1·48 to 2·32	<0·001	3·39	2·90 to 3·97	<0·001	1·93	1·57 to 2·38	<0·001
	No US Location	·43	·33 to ·57	<0·001	·44	·32 to ·60	<0·001	·91	·68 to 1·20	0·485	·77	·55 to 1·06	0·441
	No Location Data Available	·59	·39 to ·89	0·013	·42	·26 to ·70	0·001	1·01	·65 to 1·57	0·953	·67	·4 to 1·13	0·130
Total No. of Trials on Register for Trial's Sponsor	First Quarter (1-12)	Reference	--	--	Reference	--	--	Reference	--	--	Reference	--	--
	Second Quarter (13-225)	1·74	1·47 to 2·06	<0·001	1·72	1·44 to 2·06	<0·001	1·76	1·46 to 2·13	<0·001	1·76	1·44 to 2·16	<0·001
	Third Quarter (229-874)	4·83	4·00 to 5·83	<0·001	6·09	4·93 to 7·53	<0·001	3·52	2·92 to 4·25	<0·001	6·18	4·94 to 7·73	<0·001
	Fourth Quarter (887-3254)	14·48	11·30 to 18·54	<0·001	17·11	13·00 to 22·54	<0·001	7·00	5·76 to 8·51	<0·001	11·84	9·36 to 14·99	<0·001
Start Year (Increase of one year)		·91	·90 to ·94	<0·001	1·00	·97 to 1·04	0·824	1·00	·97 to 1·02	0·747	1·05	1·02 to 1·08	0·001

Table 4: Reporting Performance of Large Sponsors (>30 due trials)

Sponsor	Trials Due	Any Results	% with Any Results	Compliant Trials	% Compliant
M.D. Anderson Cancer Center	85	71	83·5	29	34·1
National Cancer Institute (NCI)	79	65	82·3	24	30·4
Massachusetts General Hospital	58	46	79·3	32	55·2
Mayo Clinic	47	45	95·7	10	21·3
Novartis Pharmaceuticals	46	46	100	46	100
Gilead Sciences	45	45	100	43	95·6
GlaxoSmithKline	43	43	100	42	97·7
Pfizer	42	42	100	39	92·9
Hoffmann-La Roche	38	38	100	36	94·7
University of California, San Francisco	38	26	68·4	6	15·8
AstraZeneca	37	37	100	37	100
Memorial Sloan Kettering Cancer Center	36	34	94·4	33	91·7
University of North Carolina, Chapel Hill	32	32	100	26	81·3