



Dr Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

16th April 2018

Dear Dr. Gottlieb

AllTrials recently wrote to you about the launch of the FDAAA TrialsTracker, developed by the EBM Datalab at the University of Oxford. This publicly accessible website checks compliance with the results reporting requirements of the FDAAA 2007 and HHS regulations 42 CFR Part 11 (the Final Rule). It then displays all the individual trials that have breached. We said that we would write to you every week with a list of the trials that have breached their reporting requirements, and a rolling total of the fines that these trials should incur.

The tracker has been live at <https://fdaaa.trialstracker.net/> for 8 week. As of 12pm GMT today, 421 trials on ClinicalTrials.gov are assessed as due to report results. 264 of those have reported results. That is a reporting rate of 62.7%. The potential fines the FDA could have collected is now estimated at \$56,769,083. 157 trials have not reported results. Those trials are listed below.

Registry ID	Completion Date	Day Late	URL	Sponsor Name
NCT02349178	16/03/2017	31	https://clinicaltrials.gov/show/NCT02349178	Medical College of Wisconsin
NCT02858726	14/03/2017	33	https://clinicaltrials.gov/show/NCT02858726	Cara Therapeutics, Inc.
NCT02415608	14/03/2017	33	https://clinicaltrials.gov/show/NCT02415608	Jason Robert Gotlib
NCT02735551	13/03/2017	34	https://clinicaltrials.gov/show/NCT02735551	Oregon Health and Science University
NCT01010126	13/03/2017	34	https://clinicaltrials.gov/show/NCT01010126	National Cancer Institute (NCI)
NCT01834235	13/03/2017	34	https://clinicaltrials.gov/show/NCT01834235	Precision Biologics, Inc
NCT02215902	10/03/2017	37	https://clinicaltrials.gov/show/NCT02215902	Aethlon Medical Inc.
NCT02805790	10/03/2017	37	https://clinicaltrials.gov/show/NCT02805790	Stealth BioTherapeutics Inc.
NCT02097641	09/03/2017	38	https://clinicaltrials.gov/show/NCT02097641	Michael A. Matthay
NCT00942357	09/03/2017	38	https://clinicaltrials.gov/show/NCT00942357	Gynecologic Oncology Group
NCT03093662	09/03/2017	38	https://clinicaltrials.gov/show/NCT03093662	Brooke Army Medical Center
NCT01707992	09/03/2017	38	https://clinicaltrials.gov/show/NCT01707992	Teva Pharmaceutical Industries
NCT02552277	07/03/2017	40	https://clinicaltrials.gov/show/NCT02552277	Celularity Incorporated
NCT03121092	07/03/2017	40	https://clinicaltrials.gov/show/NCT03121092	State University of New York - Downstate Medical Center

NCT03200912	07/03/2017	40	https://clinicaltrials.gov/show/NCT03200912	Actavis Inc.
NCT01875237	07/03/2017	40	https://clinicaltrials.gov/show/NCT01875237	M.D. Anderson Cancer Center
NCT01732107	06/03/2017	41	https://clinicaltrials.gov/show/NCT01732107	Noah Hahn, M.D.
NCT02410278	06/03/2017	41	https://clinicaltrials.gov/show/NCT02410278	Biogen
NCT02144610	06/03/2017	41	https://clinicaltrials.gov/show/NCT02144610	AnGes USA, Inc.
NCT01883817	03/03/2017	44	https://clinicaltrials.gov/show/NCT01883817	University of Cincinnati
NCT02309385	03/03/2017	44	https://clinicaltrials.gov/show/NCT02309385	Aciont Inc
NCT00255346	03/03/2017	44	https://clinicaltrials.gov/show/NCT00255346	M.D. Anderson Cancer Center
NCT02539342	02/03/2017	45	https://clinicaltrials.gov/show/NCT02539342	Medical College of Wisconsin
NCT02013674	02/03/2017	45	https://clinicaltrials.gov/show/NCT02013674	Joshua M Hare
NCT02752646	01/03/2017	46	https://clinicaltrials.gov/show/NCT02752646	MDbackline, LLC
NCT02947178	01/03/2017	46	https://clinicaltrials.gov/show/NCT02947178	Walter Reed National Military Medical Center
NCT02419014	28/02/2017	47	https://clinicaltrials.gov/show/NCT02419014	Tripler Army Medical Center
NCT02078895	28/02/2017	47	https://clinicaltrials.gov/show/NCT02078895	University of California, Irvine
NCT02492880	28/02/2017	47	https://clinicaltrials.gov/show/NCT02492880	Boston Scientific Corporation
NCT02978183	28/02/2017	47	https://clinicaltrials.gov/show/NCT02978183	Noveome Biotherapeutics, formerly Stemnion
NCT02076893	28/02/2017	47	https://clinicaltrials.gov/show/NCT02076893	Children's Hospitals and Clinics of Minnesota
NCT02618759	28/02/2017	47	https://clinicaltrials.gov/show/NCT02618759	Taro Pharmaceuticals USA
NCT02595073	28/02/2017	47	https://clinicaltrials.gov/show/NCT02595073	Taro Pharmaceuticals USA
NCT01612806	28/02/2017	47	https://clinicaltrials.gov/show/NCT01612806	Integra LifeSciences Corporation
NCT02336373	28/02/2017	47	https://clinicaltrials.gov/show/NCT02336373	Baylor College of Medicine
NCT02310100	28/02/2017	47	https://clinicaltrials.gov/show/NCT02310100	St. Jude Medical
NCT02762929	28/02/2017	47	https://clinicaltrials.gov/show/NCT02762929	Heron Therapeutics
NCT02558491	28/02/2017	47	https://clinicaltrials.gov/show/NCT02558491	University of Virginia
NCT02559895	28/02/2017	47	https://clinicaltrials.gov/show/NCT02559895	Alder Biopharmaceuticals, Inc.
NCT00729586	28/02/2017	47	https://clinicaltrials.gov/show/NCT00729586	National Cancer Institute (NCI)
NCT01117844	28/02/2017	47	https://clinicaltrials.gov/show/NCT01117844	Abramson Cancer Center of the University of Pennsylvania
NCT02498418	28/02/2017	47	https://clinicaltrials.gov/show/NCT02498418	Actavis Inc.
NCT02151175	28/02/2017	47	https://clinicaltrials.gov/show/NCT02151175	BrainSonix Inc.
NCT01922258	28/02/2017	47	https://clinicaltrials.gov/show/NCT01922258	Otsuka Pharmaceutical Development & Commercialization, Inc.
NCT02347111	28/02/2017	47	https://clinicaltrials.gov/show/NCT02347111	Vanderbilt University
NCT03115177	28/02/2017	47	https://clinicaltrials.gov/show/NCT03115177	Rush University Medical Center
NCT01695291	28/02/2017	47	https://clinicaltrials.gov/show/NCT01695291	New York State Psychiatric Institute
NCT02384200	28/02/2017	47	https://clinicaltrials.gov/show/NCT02384200	University of California, San Diego
NCT02446847	28/02/2017	47	https://clinicaltrials.gov/show/NCT02446847	Rockefeller University
NCT01215253	28/02/2017	47	https://clinicaltrials.gov/show/NCT01215253	University of Rochester
NCT00640133	28/02/2017	47	https://clinicaltrials.gov/show/NCT00640133	Butler Hospital
NCT01774578	28/02/2017	47	https://clinicaltrials.gov/show/NCT01774578	NewLink Genetics Corporation

NCT02882022	28/02/2017	47	https://clinicaltrials.gov/show/NCT02882022	University of Virginia
NCT02932891	28/02/2017	47	https://clinicaltrials.gov/show/NCT02932891	Taro Pharmaceuticals USA
NCT02634853	28/02/2017	47	https://clinicaltrials.gov/show/NCT02634853	Mimetogen Pharmaceuticals USA, Inc.
NCT02626780	28/02/2017	47	https://clinicaltrials.gov/show/NCT02626780	The GID Group
NCT01592383	28/02/2017	47	https://clinicaltrials.gov/show/NCT01592383	University of Chicago
NCT01162551	28/02/2017	47	https://clinicaltrials.gov/show/NCT01162551	Children's Hospital of Philadelphia
NCT03327831	28/02/2017	47	https://clinicaltrials.gov/show/NCT03327831	University of California, Irvine
NCT02646826	28/02/2017	47	https://clinicaltrials.gov/show/NCT02646826	Wellesley Pharmaceuticals, LLC
NCT02665234	28/02/2017	47	https://clinicaltrials.gov/show/NCT02665234	Mimetogen Pharmaceuticals USA, Inc.
NCT02657655	28/02/2017	47	https://clinicaltrials.gov/show/NCT02657655	Great Lakes NeuroTechnologies Inc.
NCT02665741	28/02/2017	47	https://clinicaltrials.gov/show/NCT02665741	University of California, Davis
NCT01596751	28/02/2017	47	https://clinicaltrials.gov/show/NCT01596751	Hope Rugo, MD
NCT01627314	28/02/2017	47	https://clinicaltrials.gov/show/NCT01627314	Fate Therapeutics
NCT02980224	28/02/2017	47	https://clinicaltrials.gov/show/NCT02980224	OmegaD LLC
NCT02691728	28/02/2017	47	https://clinicaltrials.gov/show/NCT02691728	Peter J. Ruane, M.D., Inc.
NCT02473198	28/02/2017	47	https://clinicaltrials.gov/show/NCT02473198	The New England Baptist Hospital
NCT02511301	28/02/2017	47	https://clinicaltrials.gov/show/NCT02511301	Cyrcadia Health
NCT00692276	28/02/2017	47	https://clinicaltrials.gov/show/NCT00692276	VertiFlex, Incorporated
NCT03057132	28/02/2017	47	https://clinicaltrials.gov/show/NCT03057132	3M
NCT01309126	28/02/2017	47	https://clinicaltrials.gov/show/NCT01309126	Biothera
NCT03052231	28/02/2017	47	https://clinicaltrials.gov/show/NCT03052231	Landon Pediatric Foundation
NCT02897557	28/02/2017	47	https://clinicaltrials.gov/show/NCT02897557	Insulet Corporation
NCT02213926	28/02/2017	47	https://clinicaltrials.gov/show/NCT02213926	Acerta Pharma BV
NCT02595008	26/02/2017	49	https://clinicaltrials.gov/show/NCT02595008	Taro Pharmaceuticals USA
NCT02601469	26/02/2017	49	https://clinicaltrials.gov/show/NCT02601469	Taro Pharmaceuticals USA
NCT03088267	25/02/2017	50	https://clinicaltrials.gov/show/NCT03088267	Tris Pharma, Inc.
NCT02511431	23/02/2017	52	https://clinicaltrials.gov/show/NCT02511431	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
NCT02189629	23/02/2017	52	https://clinicaltrials.gov/show/NCT02189629	Galderma R&D
NCT01548690	23/02/2017	52	https://clinicaltrials.gov/show/NCT01548690	William Lee
NCT02210325	22/02/2017	53	https://clinicaltrials.gov/show/NCT02210325	Cempra Inc
NCT02129738	17/02/2017	58	https://clinicaltrials.gov/show/NCT02129738	Wellspect HealthCare
NCT02468336	15/02/2017	60	https://clinicaltrials.gov/show/NCT02468336	Everist Genomics, Inc
NCT02660242	15/02/2017	60	https://clinicaltrials.gov/show/NCT02660242	Jaeb Center for Health Research
NCT02215161	15/02/2017	60	https://clinicaltrials.gov/show/NCT02215161	University of California, San Francisco
NCT03294538	15/02/2017	60	https://clinicaltrials.gov/show/NCT03294538	Actavis Inc.
NCT01986140	10/02/2017	65	https://clinicaltrials.gov/show/NCT01986140	Julie Nangia
NCT02498717	09/02/2017	66	https://clinicaltrials.gov/show/NCT02498717	Florida Hospital
NCT02784613	07/02/2017	68	https://clinicaltrials.gov/show/NCT02784613	Sue Goldstein
NCT02718157	07/02/2017	68	https://clinicaltrials.gov/show/NCT02718157	GenePOC
NCT02556788	07/02/2017	68	https://clinicaltrials.gov/show/NCT02556788	Galderma R&D

NCT01832259	07/02/2017	68	https://clinicaltrials.gov/show/NCT01832259	University of Utah
NCT00217594	06/02/2017	69	https://clinicaltrials.gov/show/NCT00217594	National Heart, Lung, and Blood Institute (NHLBI)
NCT01814813	06/02/2017	69	https://clinicaltrials.gov/show/NCT01814813	Alliance for Clinical Trials in Oncology
NCT02388932	06/02/2017	69	https://clinicaltrials.gov/show/NCT02388932	Case Comprehensive Cancer Center
NCT00054756	03/02/2017	72	https://clinicaltrials.gov/show/NCT00054756	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
NCT02103634	03/02/2017	72	https://clinicaltrials.gov/show/NCT02103634	Case Comprehensive Cancer Center
NCT01240629	02/02/2017	73	https://clinicaltrials.gov/show/NCT01240629	University of Southern California
NCT01883648	01/02/2017	74	https://clinicaltrials.gov/show/NCT01883648	University of South Florida
NCT02780869	01/02/2017	74	https://clinicaltrials.gov/show/NCT02780869	Biom'Up SA
NCT02059265	31/01/2017	75	https://clinicaltrials.gov/show/NCT02059265	National Cancer Institute (NCI)
NCT01656187	31/01/2017	75	https://clinicaltrials.gov/show/NCT01656187	University of Texas Southwestern Medical Center
NCT01543776	31/01/2017	75	https://clinicaltrials.gov/show/NCT01543776	University of Chicago
NCT02318368	31/01/2017	75	https://clinicaltrials.gov/show/NCT02318368	AVEO Pharmaceuticals, Inc.
NCT02648620	31/01/2017	75	https://clinicaltrials.gov/show/NCT02648620	SurModics, Inc.
NCT02132520	31/01/2017	75	https://clinicaltrials.gov/show/NCT02132520	University of Minnesota - Clinical and Translational Science Institute
NCT02133326	31/01/2017	75	https://clinicaltrials.gov/show/NCT02133326	Tufts University School of Dental Medicine
NCT01213082	31/01/2017	75	https://clinicaltrials.gov/show/NCT01213082	University of California, Davis
NCT02449681	31/01/2017	75	https://clinicaltrials.gov/show/NCT02449681	Threshold Pharmaceuticals
NCT01192828	31/01/2017	75	https://clinicaltrials.gov/show/NCT01192828	University of Colorado, Denver
NCT02391545	31/01/2017	75	https://clinicaltrials.gov/show/NCT02391545	Verastem, Inc.
NCT01711970	31/01/2017	75	https://clinicaltrials.gov/show/NCT01711970	Vascular Biogenics Ltd. operating as VBL Therapeutics
NCT02128646	31/01/2017	75	https://clinicaltrials.gov/show/NCT02128646	Michael Moncure, MD
NCT02547805	31/01/2017	75	https://clinicaltrials.gov/show/NCT02547805	Allena Pharmaceuticals
NCT02555150	31/01/2017	75	https://clinicaltrials.gov/show/NCT02555150	Rhodes Pharmaceuticals, L.P.
NCT02797808	31/01/2017	75	https://clinicaltrials.gov/show/NCT02797808	University of Minnesota - Clinical and Translational Science Institute
NCT01497860	31/01/2017	75	https://clinicaltrials.gov/show/NCT01497860	Eugene Hwang
NCT02542046	31/01/2017	75	https://clinicaltrials.gov/show/NCT02542046	University of California, San Francisco
NCT02335905	31/01/2017	75	https://clinicaltrials.gov/show/NCT02335905	Baylor College of Medicine
NCT02197104	31/01/2017	75	https://clinicaltrials.gov/show/NCT02197104	Rush University Medical Center
NCT01845740	31/01/2017	75	https://clinicaltrials.gov/show/NCT01845740	Immunomedics, Inc.
NCT02818556	31/01/2017	75	https://clinicaltrials.gov/show/NCT02818556	The Maas Clinic
NCT03296345	31/01/2017	75	https://clinicaltrials.gov/show/NCT03296345	Children's Hospital & Research Center Oakland
NCT02621593	31/01/2017	75	https://clinicaltrials.gov/show/NCT02621593	Lumenis Ltd.
NCT02604485	31/01/2017	75	https://clinicaltrials.gov/show/NCT02604485	XOMA (US) LLC

NCT00777439	31/01/2017	75	https://clinicaltrials.gov/show/NCT00777439	Arnold, George, M.D.
NCT01860287	31/01/2017	75	https://clinicaltrials.gov/show/NCT01860287	University of Chicago
NCT02431468	31/01/2017	75	https://clinicaltrials.gov/show/NCT02431468	Neurotrope Bioscience, Inc.
NCT01969123	31/01/2017	75	https://clinicaltrials.gov/show/NCT01969123	FORUM Pharmaceuticals Inc
NCT01969136	31/01/2017	75	https://clinicaltrials.gov/show/NCT01969136	FORUM Pharmaceuticals Inc
NCT02033876	31/01/2017	75	https://clinicaltrials.gov/show/NCT02033876	Mayo Clinic
NCT00390325	31/01/2017	75	https://clinicaltrials.gov/show/NCT00390325	National Cancer Institute (NCI)
NCT02348359	31/01/2017	75	https://clinicaltrials.gov/show/NCT02348359	Tyrogenex
NCT02423330	31/01/2017	75	https://clinicaltrials.gov/show/NCT02423330	Rush University Medical Center
NCT01370213	31/01/2017	75	https://clinicaltrials.gov/show/NCT01370213	Masonic Cancer Center, University of Minnesota
NCT02633969	31/01/2017	75	https://clinicaltrials.gov/show/NCT02633969	Iroko Pharmaceuticals, LLC
NCT01823705	31/01/2017	75	https://clinicaltrials.gov/show/NCT01823705	Medtronic Corporate Technologies and New Ventures
NCT02809976	31/01/2017	75	https://clinicaltrials.gov/show/NCT02809976	Tufts Medical Center
NCT01653327	31/01/2017	75	https://clinicaltrials.gov/show/NCT01653327	Dartmouth-Hitchcock Medical Center
NCT02357966	31/01/2017	75	https://clinicaltrials.gov/show/NCT02357966	XBioTech, Inc.
NCT00515281	31/01/2017	75	https://clinicaltrials.gov/show/NCT00515281	University of Chicago
NCT02937766	31/01/2017	75	https://clinicaltrials.gov/show/NCT02937766	AMAG Pharmaceuticals, Inc.
NCT02947048	31/01/2017	75	https://clinicaltrials.gov/show/NCT02947048	F Peter Halas
NCT02820714	31/01/2017	75	https://clinicaltrials.gov/show/NCT02820714	Braintree Laboratories
NCT02302963	31/01/2017	75	https://clinicaltrials.gov/show/NCT02302963	University of Virginia
NCT02454842	31/01/2017	75	https://clinicaltrials.gov/show/NCT02454842	Threshold Pharmaceuticals
NCT02477748	31/01/2017	75	https://clinicaltrials.gov/show/NCT02477748	Alcobra Ltd.
NCT01220687	31/01/2017	75	https://clinicaltrials.gov/show/NCT01220687	University of Oklahoma
NCT01875653	31/01/2017	75	https://clinicaltrials.gov/show/NCT01875653	Caladrius Biosciences, Inc.
NCT02766907	31/01/2017	75	https://clinicaltrials.gov/show/NCT02766907	Tissue Tech Inc.
NCT02646566	31/01/2017	75	https://clinicaltrials.gov/show/NCT02646566	Acacia Pharma Ltd
NCT01313416	31/01/2017	75	https://clinicaltrials.gov/show/NCT01313416	Augusta University
NCT01528709	31/01/2017	75	https://clinicaltrials.gov/show/NCT01528709	Boca Raton Regional Hospital
NCT02345369	20/01/2017	86	https://clinicaltrials.gov/show/NCT02345369	Bassett Healthcare
NCT01985763	19/01/2017	87	https://clinicaltrials.gov/show/NCT01985763	Sofya Pintova
NCT02251236	18/01/2017	88	https://clinicaltrials.gov/show/NCT02251236	University of California, San Diego

Yours sincerely

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