



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

12th March 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 three weeks. As of 12pm GMT today, 237 trials on ClinicalTrials.gov are assessed as due to report results. 144 of those have reported results. That is a reporting rate of 60.8%. The potential fines the FDA could have collected is now estimated at \$11,291,344. 93 trials have not reported results. Those trials are listed below.

Registry ID	Completion Date	Days Late	URL	Sponsor Name
NCT02498717	09/02/2017	31	https://clinicaltrials.gov/show/NCT02498717	Florida Hospital
NCT02784613	07/02/2017	33	https://clinicaltrials.gov/show/NCT02784613	Sue Goldstein
NCT02718157	07/02/2017	33	https://clinicaltrials.gov/show/NCT02718157	GenePOC
NCT02556788	07/02/2017	33	https://clinicaltrials.gov/show/NCT02556788	Galderma R&D
NCT01832259	07/02/2017	33	https://clinicaltrials.gov/show/NCT01832259	University of Utah
NCT02034474	06/02/2017	34	https://clinicaltrials.gov/show/NCT02034474	New York State Psychiatric Institute
NCT00217594	06/02/2017	34	https://clinicaltrials.gov/show/NCT00217594	National Heart, Lung, and Blood Institute (NHLBI)
NCT01814813	06/02/2017	34	https://clinicaltrials.gov/show/NCT01814813	Alliance for Clinical Trials in Oncology
NCT02388932	06/02/2017	34	https://clinicaltrials.gov/show/NCT02388932	Case Comprehensive Cancer Center
NCT01692756	05/02/2017	35	https://clinicaltrials.gov/show/NCT01692756	Christian Lattermann
NCT00054756	03/02/2017	37	https://clinicaltrials.gov/show/NCT00054756	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

NCT02103634	03/02/2017	37	https://clinicaltrials.gov/show/NCT02103634	Case Comprehensive Cancer Center
NCT01240629	02/02/2017	38	https://clinicaltrials.gov/show/NCT01240629	University of Southern California
NCT01656733	02/02/2017	38	https://clinicaltrials.gov/show/NCT01656733	UConn Health
NCT01883648	01/02/2017	39	https://clinicaltrials.gov/show/NCT01883648	University of South Florida
NCT02780869	01/02/2017	39	https://clinicaltrials.gov/show/NCT02780869	Biom'Up SA
NCT03072732	01/02/2017	39	https://clinicaltrials.gov/show/NCT03072732	Zoll Medical Corporation
NCT02059265	31/01/2017	40	https://clinicaltrials.gov/show/NCT02059265	National Cancer Institute (NCI)
NCT01656187	31/01/2017	40	https://clinicaltrials.gov/show/NCT01656187	University of Texas Southwestern Medical Center
NCT01543776	31/01/2017	40	https://clinicaltrials.gov/show/NCT01543776	University of Chicago
NCT02505867	31/01/2017	40	https://clinicaltrials.gov/show/NCT02505867	Rami Khayat
NCT02318368	31/01/2017	40	https://clinicaltrials.gov/show/NCT02318368	AVEO Pharmaceuticals, Inc.
NCT02648620	31/01/2017	40	https://clinicaltrials.gov/show/NCT02648620	SurModics, Inc.
NCT02132520	31/01/2017	40	https://clinicaltrials.gov/show/NCT02132520	University of Minnesota - Clinical and Translational Science Institute
NCT02093221	31/01/2017	40	https://clinicaltrials.gov/show/NCT02093221	Grifols Therapeutics Inc.
NCT02133326	31/01/2017	40	https://clinicaltrials.gov/show/NCT02133326	Tufts University School of Dental Medicine
NCT02086526	31/01/2017	40	https://clinicaltrials.gov/show/NCT02086526	Mayo Clinic
NCT01213082	31/01/2017	40	https://clinicaltrials.gov/show/NCT01213082	University of California, Davis
NCT02449681	31/01/2017	40	https://clinicaltrials.gov/show/NCT02449681	Threshold Pharmaceuticals
NCT01192828	31/01/2017	40	https://clinicaltrials.gov/show/NCT01192828	University of Colorado, Denver
NCT02391545	31/01/2017	40	https://clinicaltrials.gov/show/NCT02391545	Verastem, Inc.
NCT01711970	31/01/2017	40	https://clinicaltrials.gov/show/NCT01711970	Vascular Biogenics Ltd. operating as VBL Therapeutics
NCT02128646	31/01/2017	40	https://clinicaltrials.gov/show/NCT02128646	Michael Moncure, MD
NCT02547805	31/01/2017	40	https://clinicaltrials.gov/show/NCT02547805	Allena Pharmaceuticals
NCT02555150	31/01/2017	40	https://clinicaltrials.gov/show/NCT02555150	Rhodes Pharmaceuticals, L.P.
NCT02797808	31/01/2017	40	https://clinicaltrials.gov/show/NCT02797808	University of Minnesota - Clinical and Translational Science Institute
NCT01497860	31/01/2017	40	https://clinicaltrials.gov/show/NCT01497860	Eugene Hwang
NCT01272245	31/01/2017	40	https://clinicaltrials.gov/show/NCT01272245	M.D. Anderson Cancer Center
NCT02542046	31/01/2017	40	https://clinicaltrials.gov/show/NCT02542046	University of California, San Francisco
NCT02335905	31/01/2017	40	https://clinicaltrials.gov/show/NCT02335905	Baylor College of Medicine
NCT02197104	31/01/2017	40	https://clinicaltrials.gov/show/NCT02197104	Rush University Medical Center
NCT02773082	31/01/2017	40	https://clinicaltrials.gov/show/NCT02773082	The University of Texas Health Science Center, Houston
NCT01845740	31/01/2017	40	https://clinicaltrials.gov/show/NCT01845740	Immunomedics, Inc.
NCT02818556	31/01/2017	40	https://clinicaltrials.gov/show/NCT02818556	The Maas Clinic
NCT03296345	31/01/2017	40	https://clinicaltrials.gov/show/NCT03296345	Children's Hospital & Research Center Oakland

NCT02821338	31/01/2017	40	https://clinicaltrials.gov/show/NCT02821338	Food and Drug Administration (FDA)
NCT02621593	31/01/2017	40	https://clinicaltrials.gov/show/NCT02621593	Lumenis Ltd.
NCT02604485	31/01/2017	40	https://clinicaltrials.gov/show/NCT02604485	XOMA (US) LLC
NCT00777439	31/01/2017	40	https://clinicaltrials.gov/show/NCT00777439	Arnold, George, M.D.
NCT01860287	31/01/2017	40	https://clinicaltrials.gov/show/NCT01860287	University of Chicago
NCT02623361	31/01/2017	40	https://clinicaltrials.gov/show/NCT02623361	University of California, San Francisco
NCT02134925	31/01/2017	40	https://clinicaltrials.gov/show/NCT02134925	National Cancer Institute (NCI)
NCT02431468	31/01/2017	40	https://clinicaltrials.gov/show/NCT02431468	Neurotrope Bioscience, Inc.
NCT01969123	31/01/2017	40	https://clinicaltrials.gov/show/NCT01969123	FORUM Pharmaceuticals Inc
NCT01969136	31/01/2017	40	https://clinicaltrials.gov/show/NCT01969136	FORUM Pharmaceuticals Inc
NCT02033876	31/01/2017	40	https://clinicaltrials.gov/show/NCT02033876	Mayo Clinic
NCT00390325	31/01/2017	40	https://clinicaltrials.gov/show/NCT00390325	National Cancer Institute (NCI)
NCT02348359	31/01/2017	40	https://clinicaltrials.gov/show/NCT02348359	Tyrogenex
NCT02423330	31/01/2017	40	https://clinicaltrials.gov/show/NCT02423330	Rush University Medical Center
NCT01370213	31/01/2017	40	https://clinicaltrials.gov/show/NCT01370213	Masonic Cancer Center, University of Minnesota
NCT01746043	31/01/2017	40	https://clinicaltrials.gov/show/NCT01746043	M.D. Anderson Cancer Center
NCT02633969	31/01/2017	40	https://clinicaltrials.gov/show/NCT02633969	Iroko Pharmaceuticals, LLC
NCT02649062	31/01/2017	40	https://clinicaltrials.gov/show/NCT02649062	NGM Biopharmaceuticals, Inc
NCT01823705	31/01/2017	40	https://clinicaltrials.gov/show/NCT01823705	Medtronic Corporate Technologies and New Ventures
NCT02809976	31/01/2017	40	https://clinicaltrials.gov/show/NCT02809976	Tufts Medical Center
NCT01653327	31/01/2017	40	https://clinicaltrials.gov/show/NCT01653327	Dartmouth-Hitchcock Medical Center
NCT02357966	31/01/2017	40	https://clinicaltrials.gov/show/NCT02357966	XBioTech, Inc.
NCT00515281	31/01/2017	40	https://clinicaltrials.gov/show/NCT00515281	University of Chicago
NCT02937766	31/01/2017	40	https://clinicaltrials.gov/show/NCT02937766	AMAG Pharmaceuticals, Inc.
NCT02947048	31/01/2017	40	https://clinicaltrials.gov/show/NCT02947048	F Peter Halas
NCT02694978	31/01/2017	40	https://clinicaltrials.gov/show/NCT02694978	AMAG Pharmaceuticals, Inc.
NCT02820714	31/01/2017	40	https://clinicaltrials.gov/show/NCT02820714	Braintree Laboratories
NCT02302963	31/01/2017	40	https://clinicaltrials.gov/show/NCT02302963	University of Virginia
NCT02454842	31/01/2017	40	https://clinicaltrials.gov/show/NCT02454842	Threshold Pharmaceuticals
NCT02477748	31/01/2017	40	https://clinicaltrials.gov/show/NCT02477748	Alcobra Ltd.
NCT01220687	31/01/2017	40	https://clinicaltrials.gov/show/NCT01220687	University of Oklahoma
NCT01875653	31/01/2017	40	https://clinicaltrials.gov/show/NCT01875653	Caladrius Biosciences, Inc.
NCT02766907	31/01/2017	40	https://clinicaltrials.gov/show/NCT02766907	Tissue Tech Inc.
NCT02646566	31/01/2017	40	https://clinicaltrials.gov/show/NCT02646566	Acacia Pharma Ltd
NCT01313416	31/01/2017	40	https://clinicaltrials.gov/show/NCT01313416	Augusta University
NCT01528709	31/01/2017	40	https://clinicaltrials.gov/show/NCT01528709	Boca Raton Regional Hospital
NCT02004028	31/01/2017	40	https://clinicaltrials.gov/show/NCT02004028	Verastem, Inc.
NCT01976936	31/01/2017	40	https://clinicaltrials.gov/show/NCT01976936	Mitchell S Elkind
NCT02600611	30/01/2017	41	https://clinicaltrials.gov/show/NCT02600611	Motif Bio

NCT01444742	29/01/2017	42	https://clinicaltrials.gov/show/NCT01444742	M.D. Anderson Cancer Center
NCT02985736	27/01/2017	44	https://clinicaltrials.gov/show/NCT02985736	Psoriasis Treatment Center of Central New Jersey
NCT02535065	23/01/2017	48	https://clinicaltrials.gov/show/NCT02535065	Cook Group Incorporated
NCT02452359	21/01/2017	50	https://clinicaltrials.gov/show/NCT02452359	Venus Concept
NCT02345369	20/01/2017	51	https://clinicaltrials.gov/show/NCT02345369	Bassett Healthcare
NCT02704689	19/01/2017	52	https://clinicaltrials.gov/show/NCT02704689	Stryker Spine
NCT02400164	19/01/2017	52	https://clinicaltrials.gov/show/NCT02400164	Sequana Medical AG
NCT01985763	19/01/2017	52	https://clinicaltrials.gov/show/NCT01985763	Sofya Pintova
NCT02251236	18/01/2017	53	https://clinicaltrials.gov/show/NCT02251236	University of California, San Diego

Yours sincerely

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