



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

26<sup>th</sup> 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 five weeks. As of 12pm GMT today, 282 trials on ClinicalTrials.gov are assessed as due to report results. 189 of those have reported results. That is a reporting rate of 67%. The potential fines the FDA could have collected is now estimated at \$25,440,231. 93 trials have not reported results. Those trials are listed below.

Registry ID	Completion Date	Days Late	URL	Sponsor Name
NCT02511431	23/02/2017	31	<a href="https://clinicaltrials.gov/show/NCT02511431">https://clinicaltrials.gov/show/NCT02511431</a>	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
NCT02189629	23/02/2017	31	<a href="https://clinicaltrials.gov/show/NCT02189629">https://clinicaltrials.gov/show/NCT02189629</a>	Galderma R&D
NCT01548690	23/02/2017	31	<a href="https://clinicaltrials.gov/show/NCT01548690">https://clinicaltrials.gov/show/NCT01548690</a>	William Lee
NCT02047604	23/02/2017	31	<a href="https://clinicaltrials.gov/show/NCT02047604">https://clinicaltrials.gov/show/NCT02047604</a>	Valeant Pharmaceuticals International, Inc.
NCT02210325	22/02/2017	32	<a href="https://clinicaltrials.gov/show/NCT02210325">https://clinicaltrials.gov/show/NCT02210325</a>	Cempra Inc
NCT02129738	17/02/2017	37	<a href="https://clinicaltrials.gov/show/NCT02129738">https://clinicaltrials.gov/show/NCT02129738</a>	Wellspect HealthCare
NCT02468336	15/02/2017	39	<a href="https://clinicaltrials.gov/show/NCT02468336">https://clinicaltrials.gov/show/NCT02468336</a>	Everist Genomics, Inc
NCT02660242	15/02/2017	39	<a href="https://clinicaltrials.gov/show/NCT02660242">https://clinicaltrials.gov/show/NCT02660242</a>	Jaeb Center for Health Research
NCT02215161	15/02/2017	39	<a href="https://clinicaltrials.gov/show/NCT02215161">https://clinicaltrials.gov/show/NCT02215161</a>	University of California, San Francisco
NCT03294538	15/02/2017	39	<a href="https://clinicaltrials.gov/show/NCT03294538">https://clinicaltrials.gov/show/NCT03294538</a>	Actavis Inc.
NCT01986140	10/02/2017	44	<a href="https://clinicaltrials.gov/show/NCT01986140">https://clinicaltrials.gov/show/NCT01986140</a>	Julie Nangia
NCT02498717	09/02/2017	45	<a href="https://clinicaltrials.gov/show/NCT02498717">https://clinicaltrials.gov/show/NCT02498717</a>	Florida Hospital
NCT02784613	07/02/2017	47	<a href="https://clinicaltrials.gov/show/NCT02784613">https://clinicaltrials.gov/show/NCT02784613</a>	Sue Goldstein

NCT02718157	07/02/2017	47	<a href="https://clinicaltrials.gov/show/NCT02718157">https://clinicaltrials.gov/show/NCT02718157</a>	GenePOC
NCT02556788	07/02/2017	47	<a href="https://clinicaltrials.gov/show/NCT02556788">https://clinicaltrials.gov/show/NCT02556788</a>	Galderma R&D
NCT01832259	07/02/2017	47	<a href="https://clinicaltrials.gov/show/NCT01832259">https://clinicaltrials.gov/show/NCT01832259</a>	University of Utah
NCT00217594	06/02/2017	48	<a href="https://clinicaltrials.gov/show/NCT00217594">https://clinicaltrials.gov/show/NCT00217594</a>	National Heart, Lung, and Blood Institute (NHLBI)
NCT01814813	06/02/2017	48	<a href="https://clinicaltrials.gov/show/NCT01814813">https://clinicaltrials.gov/show/NCT01814813</a>	Alliance for Clinical Trials in Oncology
NCT02388932	06/02/2017	48	<a href="https://clinicaltrials.gov/show/NCT02388932">https://clinicaltrials.gov/show/NCT02388932</a>	Case Comprehensive Cancer Center
NCT01692756	05/02/2017	49	<a href="https://clinicaltrials.gov/show/NCT01692756">https://clinicaltrials.gov/show/NCT01692756</a>	Christian Lattermann
NCT00054756	03/02/2017	51	<a href="https://clinicaltrials.gov/show/NCT00054756">https://clinicaltrials.gov/show/NCT00054756</a>	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
NCT02103634	03/02/2017	51	<a href="https://clinicaltrials.gov/show/NCT02103634">https://clinicaltrials.gov/show/NCT02103634</a>	Case Comprehensive Cancer Center
NCT01240629	02/02/2017	52	<a href="https://clinicaltrials.gov/show/NCT01240629">https://clinicaltrials.gov/show/NCT01240629</a>	University of Southern California
NCT01883648	01/02/2017	53	<a href="https://clinicaltrials.gov/show/NCT01883648">https://clinicaltrials.gov/show/NCT01883648</a>	University of South Florida
NCT02780869	01/02/2017	53	<a href="https://clinicaltrials.gov/show/NCT02780869">https://clinicaltrials.gov/show/NCT02780869</a>	Biom'Up SA
NCT03072732	01/02/2017	53	<a href="https://clinicaltrials.gov/show/NCT03072732">https://clinicaltrials.gov/show/NCT03072732</a>	Zoll Medical Corporation
NCT02059265	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02059265">https://clinicaltrials.gov/show/NCT02059265</a>	National Cancer Institute (NCI)
NCT01656187	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01656187">https://clinicaltrials.gov/show/NCT01656187</a>	University of Texas Southwestern Medical Center
NCT01543776	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01543776">https://clinicaltrials.gov/show/NCT01543776</a>	University of Chicago
NCT02505867	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02505867">https://clinicaltrials.gov/show/NCT02505867</a>	Rami Khayat
NCT02318368	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02318368">https://clinicaltrials.gov/show/NCT02318368</a>	AVEO Pharmaceuticals, Inc.
NCT02648620	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02648620">https://clinicaltrials.gov/show/NCT02648620</a>	SurModics, Inc.
NCT02132520	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02132520">https://clinicaltrials.gov/show/NCT02132520</a>	University of Minnesota - Clinical and Translational Science Institute
NCT02093221	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02093221">https://clinicaltrials.gov/show/NCT02093221</a>	Grifols Therapeutics LLC
NCT02133326	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02133326">https://clinicaltrials.gov/show/NCT02133326</a>	Tufts University School of Dental Medicine
NCT01213082	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01213082">https://clinicaltrials.gov/show/NCT01213082</a>	University of California, Davis
NCT02449681	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02449681">https://clinicaltrials.gov/show/NCT02449681</a>	Threshold Pharmaceuticals
NCT01192828	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01192828">https://clinicaltrials.gov/show/NCT01192828</a>	University of Colorado, Denver
NCT02391545	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02391545">https://clinicaltrials.gov/show/NCT02391545</a>	Verastem, Inc.
NCT01711970	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01711970">https://clinicaltrials.gov/show/NCT01711970</a>	Vascular Biogenics Ltd. operating as VBL Therapeutics
NCT02128646	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02128646">https://clinicaltrials.gov/show/NCT02128646</a>	Michael Moncure, MD
NCT02547805	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02547805">https://clinicaltrials.gov/show/NCT02547805</a>	Allena Pharmaceuticals
NCT02555150	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02555150">https://clinicaltrials.gov/show/NCT02555150</a>	Rhodes Pharmaceuticals, L.P.
NCT02797808	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02797808">https://clinicaltrials.gov/show/NCT02797808</a>	University of Minnesota - Clinical and Translational Science Institute
NCT01497860	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01497860">https://clinicaltrials.gov/show/NCT01497860</a>	Eugene Hwang
NCT02542046	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02542046">https://clinicaltrials.gov/show/NCT02542046</a>	University of California, San Francisco

NCT02335905	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02335905">https://clinicaltrials.gov/show/NCT02335905</a>	Baylor College of Medicine
NCT02197104	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02197104">https://clinicaltrials.gov/show/NCT02197104</a>	Rush University Medical Center
NCT02773082	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02773082">https://clinicaltrials.gov/show/NCT02773082</a>	The University of Texas Health Science Center, Houston
NCT01845740	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01845740">https://clinicaltrials.gov/show/NCT01845740</a>	Immunomedics, Inc.
NCT02818556	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02818556">https://clinicaltrials.gov/show/NCT02818556</a>	The Maas Clinic
NCT03296345	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT03296345">https://clinicaltrials.gov/show/NCT03296345</a>	Children's Hospital & Research Center Oakland
NCT02621593	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02621593">https://clinicaltrials.gov/show/NCT02621593</a>	Lumenis Ltd.
NCT02604485	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02604485">https://clinicaltrials.gov/show/NCT02604485</a>	XOMA (US) LLC
NCT00777439	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT00777439">https://clinicaltrials.gov/show/NCT00777439</a>	Arnold, George, M.D.
NCT01860287	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01860287">https://clinicaltrials.gov/show/NCT01860287</a>	University of Chicago
NCT02431468	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02431468">https://clinicaltrials.gov/show/NCT02431468</a>	Neurotrope Bioscience, Inc.
NCT01969123	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01969123">https://clinicaltrials.gov/show/NCT01969123</a>	FORUM Pharmaceuticals Inc
NCT01969136	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01969136">https://clinicaltrials.gov/show/NCT01969136</a>	FORUM Pharmaceuticals Inc
NCT02033876	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02033876">https://clinicaltrials.gov/show/NCT02033876</a>	Mayo Clinic
NCT00390325	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT00390325">https://clinicaltrials.gov/show/NCT00390325</a>	National Cancer Institute (NCI)
NCT02348359	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02348359">https://clinicaltrials.gov/show/NCT02348359</a>	Tyrogenex
NCT02423330	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02423330">https://clinicaltrials.gov/show/NCT02423330</a>	Rush University Medical Center
NCT01370213	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01370213">https://clinicaltrials.gov/show/NCT01370213</a>	Masonic Cancer Center, University of Minnesota
NCT01746043	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01746043">https://clinicaltrials.gov/show/NCT01746043</a>	M.D. Anderson Cancer Center
NCT02633969	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02633969">https://clinicaltrials.gov/show/NCT02633969</a>	Iroko Pharmaceuticals, LLC
NCT02649062	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02649062">https://clinicaltrials.gov/show/NCT02649062</a>	NGM Biopharmaceuticals, Inc
NCT01823705	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01823705">https://clinicaltrials.gov/show/NCT01823705</a>	Medtronic Corporate Technologies and New Ventures
NCT02809976	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02809976">https://clinicaltrials.gov/show/NCT02809976</a>	Tufts Medical Center
NCT01653327	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01653327">https://clinicaltrials.gov/show/NCT01653327</a>	Dartmouth-Hitchcock Medical Center
NCT02357966	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02357966">https://clinicaltrials.gov/show/NCT02357966</a>	XBiotech, Inc.
NCT00515281	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT00515281">https://clinicaltrials.gov/show/NCT00515281</a>	University of Chicago
NCT02937766	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02937766">https://clinicaltrials.gov/show/NCT02937766</a>	AMAG Pharmaceuticals, Inc.
NCT02947048	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02947048">https://clinicaltrials.gov/show/NCT02947048</a>	F Peter Halas
NCT02694978	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02694978">https://clinicaltrials.gov/show/NCT02694978</a>	AMAG Pharmaceuticals, Inc.
NCT02820714	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02820714">https://clinicaltrials.gov/show/NCT02820714</a>	Braintree Laboratories
NCT02302963	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02302963">https://clinicaltrials.gov/show/NCT02302963</a>	University of Virginia
NCT02454842	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02454842">https://clinicaltrials.gov/show/NCT02454842</a>	Threshold Pharmaceuticals
NCT02477748	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02477748">https://clinicaltrials.gov/show/NCT02477748</a>	Alcobra Ltd.
NCT01220687	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01220687">https://clinicaltrials.gov/show/NCT01220687</a>	University of Oklahoma
NCT01875653	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01875653">https://clinicaltrials.gov/show/NCT01875653</a>	Caladrius Biosciences, Inc.
NCT02766907	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02766907">https://clinicaltrials.gov/show/NCT02766907</a>	Tissue Tech Inc.

NCT02646566	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02646566">https://clinicaltrials.gov/show/NCT02646566</a>	Acacia Pharma Ltd
NCT01313416	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01313416">https://clinicaltrials.gov/show/NCT01313416</a>	Augusta University
NCT01528709	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01528709">https://clinicaltrials.gov/show/NCT01528709</a>	Boca Raton Regional Hospital
NCT02004028	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT02004028">https://clinicaltrials.gov/show/NCT02004028</a>	Verastem, Inc.
NCT01976936	31/01/2017	54	<a href="https://clinicaltrials.gov/show/NCT01976936">https://clinicaltrials.gov/show/NCT01976936</a>	Mitchell S Elkind
NCT02985736	27/01/2017	58	<a href="https://clinicaltrials.gov/show/NCT02985736">https://clinicaltrials.gov/show/NCT02985736</a>	Psoriasis Treatment Center of Central New Jersey
NCT02535065	23/01/2017	62	<a href="https://clinicaltrials.gov/show/NCT02535065">https://clinicaltrials.gov/show/NCT02535065</a>	Cook Group Incorporated
NCT02345369	20/01/2017	65	<a href="https://clinicaltrials.gov/show/NCT02345369">https://clinicaltrials.gov/show/NCT02345369</a>	Bassett Healthcare
NCT02400164	19/01/2017	66	<a href="https://clinicaltrials.gov/show/NCT02400164">https://clinicaltrials.gov/show/NCT02400164</a>	Sequana Medical AG
NCT01985763	19/01/2017	66	<a href="https://clinicaltrials.gov/show/NCT01985763">https://clinicaltrials.gov/show/NCT01985763</a>	Sofya Pintova
NCT02251236	18/01/2017	67	<a href="https://clinicaltrials.gov/show/NCT02251236">https://clinicaltrials.gov/show/NCT02251236</a>	University of California, San Diego

Yours sincerely

Ben Goldacre & Sile Lane, [www.alltrials.net](http://www.alltrials.net)