



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

20th 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 four weeks. As of 12pm GMT today, 268 trials on ClinicalTrials.gov are assessed as due to report results. 173 of those have reported results. That is a reporting rate of 64.6%. The potential fines the FDA could have collected is now estimated at \$19,528,472. 95 trials have not reported results. Those trials are listed below.

| Registry ID | Completion Date | Days Late | URL | Sponsor Name |
|-------------|-----------------|-----------|---|--|
| NCT02129738 | 17/02/2017 | 31 | https://clinicaltrials.gov/show/NCT02129738 | Wellspect HealthCare |
| NCT00524173 | 16/02/2017 | 32 | https://clinicaltrials.gov/show/NCT00524173 | National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) |
| NCT02468336 | 15/02/2017 | 33 | https://clinicaltrials.gov/show/NCT02468336 | Everist Genomics, Inc |
| NCT02660242 | 15/02/2017 | 33 | https://clinicaltrials.gov/show/NCT02660242 | Jaeb Center for Health Research University of California, San Francisco |
| NCT02215161 | 15/02/2017 | 33 | https://clinicaltrials.gov/show/NCT02215161 | Actavis Inc. |
| NCT03294538 | 15/02/2017 | 33 | https://clinicaltrials.gov/show/NCT03294538 | Julie Nangia |
| NCT01986140 | 10/02/2017 | 38 | https://clinicaltrials.gov/show/NCT01986140 | Dr. Reddy's Laboratories Limited |
| NCT02498717 | 09/02/2017 | 39 | https://clinicaltrials.gov/show/NCT02498717 | Florida Hospital |
| NCT02784613 | 07/02/2017 | 41 | https://clinicaltrials.gov/show/NCT02784613 | Sue Goldstein |
| NCT02718157 | 07/02/2017 | 41 | https://clinicaltrials.gov/show/NCT02718157 | GenePOC |
| NCT02556788 | 07/02/2017 | 41 | https://clinicaltrials.gov/show/NCT02556788 | Galderma R&D |
| NCT01832259 | 07/02/2017 | 41 | https://clinicaltrials.gov/show/NCT01832259 | University of Utah |
| NCT00217594 | 06/02/2017 | 42 | https://clinicaltrials.gov/show/NCT00217594 | National Heart, Lung, and Blood Institute (NHLBI) |

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|-------------|------------|----|---|--|
| NCT01814813 | 06/02/2017 | 42 | https://clinicaltrials.gov/show/NCT01814813 | Alliance for Clinical Trials in Oncology |
| NCT02388932 | 06/02/2017 | 42 | https://clinicaltrials.gov/show/NCT02388932 | Case Comprehensive Cancer Center |
| NCT01692756 | 05/02/2017 | 43 | https://clinicaltrials.gov/show/NCT01692756 | Christian Lattermann |
| NCT00054756 | 03/02/2017 | 45 | https://clinicaltrials.gov/show/NCT00054756 | National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) |
| NCT02103634 | 03/02/2017 | 45 | https://clinicaltrials.gov/show/NCT02103634 | Case Comprehensive Cancer Center |
| NCT01240629 | 02/02/2017 | 46 | https://clinicaltrials.gov/show/NCT01240629 | University of Southern California |
| NCT01656733 | 02/02/2017 | 46 | https://clinicaltrials.gov/show/NCT01656733 | UConn Health |
| NCT01883648 | 01/02/2017 | 47 | https://clinicaltrials.gov/show/NCT01883648 | University of South Florida |
| NCT02780869 | 01/02/2017 | 47 | https://clinicaltrials.gov/show/NCT02780869 | Biom'Up SA |
| NCT03072732 | 01/02/2017 | 47 | https://clinicaltrials.gov/show/NCT03072732 | Zoll Medical Corporation |
| NCT02059265 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02059265 | National Cancer Institute (NCI) |
| NCT01656187 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01656187 | University of Texas Southwestern Medical Center |
| NCT01543776 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01543776 | University of Chicago |
| NCT02505867 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02505867 | Rami Khayat |
| NCT02318368 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02318368 | AVEO Pharmaceuticals, Inc. |
| NCT02648620 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02648620 | SurModics, Inc. |
| NCT02132520 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02132520 | University of Minnesota - Clinical and Translational Science Institute |
| NCT02093221 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02093221 | Grifols Therapeutics LLC |
| NCT02133326 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02133326 | Tufts University School of Dental Medicine |
| NCT01213082 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01213082 | University of California, Davis |
| NCT02449681 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02449681 | Threshold Pharmaceuticals |
| NCT01192828 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01192828 | University of Colorado, Denver |
| NCT02391545 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02391545 | Verastem, Inc. |
| NCT01711970 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01711970 | Vascular Biogenics Ltd. operating as VBL Therapeutics |
| NCT02128646 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02128646 | Michael Moncure, MD |
| NCT02547805 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02547805 | Allena Pharmaceuticals |
| NCT02555150 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02555150 | Rhodes Pharmaceuticals, L.P. |
| NCT02797808 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02797808 | University of Minnesota - Clinical and Translational Science Institute |
| NCT01497860 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01497860 | Eugene Hwang |
| NCT01272245 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01272245 | M.D. Anderson Cancer Center |
| NCT02542046 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02542046 | University of California, San Francisco |
| NCT02335905 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02335905 | Baylor College of Medicine |
| NCT02197104 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02197104 | Rush University Medical Center |
| NCT02773082 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02773082 | The University of Texas Health Science Center, Houston |
| NCT01845740 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01845740 | Immunomedics, Inc. |
| NCT02818556 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02818556 | The Maas Clinic |
| NCT03296345 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT03296345 | Children's Hospital & Research Center Oakland |
| NCT02621593 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02621593 | Lumenis Ltd. |

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|-------------|------------|----|---|---|
| NCT02604485 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02604485 | XOMA (US) LLC |
| NCT00777439 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT00777439 | Arnold, George, M.D. |
| NCT01860287 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01860287 | University of Chicago |
| NCT02623361 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02623361 | University of California, San Francisco |
| NCT02431468 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02431468 | Neurotrope Bioscience, Inc. |
| NCT01969123 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01969123 | FORUM Pharmaceuticals Inc |
| NCT01969136 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01969136 | FORUM Pharmaceuticals Inc |
| NCT02033876 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02033876 | Mayo Clinic |
| NCT00390325 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT00390325 | National Cancer Institute (NCI) |
| NCT02348359 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02348359 | Tyrogenex |
| NCT02423330 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02423330 | Rush University Medical Center |
| NCT01370213 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01370213 | Masonic Cancer Center, University of Minnesota |
| NCT01746043 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01746043 | M.D. Anderson Cancer Center |
| NCT02633969 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02633969 | Iroko Pharmaceuticals, LLC |
| NCT02649062 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02649062 | NGM Biopharmaceuticals, Inc |
| NCT01823705 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01823705 | Medtronic Corporate Technologies and New Ventures |
| NCT02809976 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02809976 | Tufts Medical Center |
| NCT01653327 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01653327 | Dartmouth-Hitchcock Medical Center |
| NCT02357966 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02357966 | XBiotech, Inc. |
| NCT00515281 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT00515281 | University of Chicago |
| NCT02937766 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02937766 | AMAG Pharmaceuticals, Inc. |
| NCT02947048 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02947048 | F Peter Halas |
| NCT02694978 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02694978 | AMAG Pharmaceuticals, Inc. |
| NCT02820714 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02820714 | Braintree Laboratories |
| NCT02302963 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02302963 | University of Virginia |
| NCT02454842 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02454842 | Threshold Pharmaceuticals |
| NCT02477748 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02477748 | Alcobra Ltd. |
| NCT01220687 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01220687 | University of Oklahoma |
| NCT01875653 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01875653 | Caladius Biosciences, Inc. |
| NCT02766907 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02766907 | Tissue Tech Inc. |
| NCT02646566 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02646566 | Acacia Pharma Ltd |
| NCT01313416 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01313416 | Augusta University |
| NCT01528709 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01528709 | Boca Raton Regional Hospital |
| NCT02004028 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT02004028 | Verastem, Inc. |
| NCT01976936 | 31/01/2017 | 48 | https://clinicaltrials.gov/show/NCT01976936 | Mitchell S Elkind |
| NCT02600611 | 30/01/2017 | 49 | https://clinicaltrials.gov/show/NCT02600611 | Motif Bio |
| NCT02985736 | 27/01/2017 | 52 | https://clinicaltrials.gov/show/NCT02985736 | Psoriasis Treatment Center of Central New Jersey |
| NCT02535065 | 23/01/2017 | 56 | https://clinicaltrials.gov/show/NCT02535065 | Cook Group Incorporated |
| NCT02345369 | 20/01/2017 | 59 | https://clinicaltrials.gov/show/NCT02345369 | Bassett Healthcare |
| NCT02704689 | 19/01/2017 | 60 | https://clinicaltrials.gov/show/NCT02704689 | Stryker Spine |
| NCT02400164 | 19/01/2017 | 60 | https://clinicaltrials.gov/show/NCT02400164 | Sequana Medical AG |
| NCT01985763 | 19/01/2017 | 60 | https://clinicaltrials.gov/show/NCT01985763 | Sofya Pintova |

Yours sincerely

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