



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

5<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 two weeks. As of 12pm GMT today, 216 trials on ClinicalTrials.gov are assessed as due to report results. 130 of those have reported results. That is a reporting rate of 60.2%. The potential fines the FDA could have collected is now estimated at \$4,847,411. 86 trials have not reported results. Those trials are listed below.

| Registry ID | Completion Date | Days Late | URL   | Sponsor Name   |
|-------------|-----------------|-----------|---|--|
| NCT02477748 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02477748">https://clinicaltrials.gov/show/NCT02477748</a> | Alcobra Ltd.   |
| NCT02132520 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02132520">https://clinicaltrials.gov/show/NCT02132520</a> | University of Minnesota - Clinical and Translational Science Institute |
| NCT02818556 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02818556">https://clinicaltrials.gov/show/NCT02818556</a> | The Maas Clinic  |
| NCT03296345 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT03296345">https://clinicaltrials.gov/show/NCT03296345</a> | Children's Hospital & Research Center Oakland                          |
| NCT01220687 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT01220687">https://clinicaltrials.gov/show/NCT01220687</a> | University of Oklahoma   |
| NCT01528709 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT01528709">https://clinicaltrials.gov/show/NCT01528709</a> | Boca Raton Regional Hospital   |
| NCT02400164 | 19/01/2017      | 45        | <a href="https://clinicaltrials.gov/show/NCT02400164">https://clinicaltrials.gov/show/NCT02400164</a> | Sequana Medical AG   |
| NCT02093221 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02093221">https://clinicaltrials.gov/show/NCT02093221</a> | Grifols Therapeutics Inc.  |
| NCT01653327 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT01653327">https://clinicaltrials.gov/show/NCT01653327</a> | Dartmouth-Hitchcock Medical Center                                     |
| NCT00777439 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT00777439">https://clinicaltrials.gov/show/NCT00777439</a> | Arnold, George, M.D.   |
| NCT02985736 | 27/01/2017      | 37        | <a href="https://clinicaltrials.gov/show/NCT02985736">https://clinicaltrials.gov/show/NCT02985736</a> | Psoriasis Treatment Center of Central New Jersey                       |
| NCT02004028 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02004028">https://clinicaltrials.gov/show/NCT02004028</a> | Verastem, Inc.   |
| NCT02616302 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02616302">https://clinicaltrials.gov/show/NCT02616302</a> | Takeda   |
| NCT02318368 | 31/01/2017      | 33        | <a href="https://clinicaltrials.gov/show/NCT02318368">https://clinicaltrials.gov/show/NCT02318368</a> | AVEO Pharmaceuticals, Inc.   |

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|-------------|------------|----|---|---|
| NCT02547805 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02547805">https://clinicaltrials.gov/show/NCT02547805</a> | Allena Pharmaceuticals                                |
| NCT01976936 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01976936">https://clinicaltrials.gov/show/NCT01976936</a> | Mitchell S Elkind                                     |
| NCT02947048 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02947048">https://clinicaltrials.gov/show/NCT02947048</a> | F Peter Halas   |
| NCT02449681 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02449681">https://clinicaltrials.gov/show/NCT02449681</a> | Threshold Pharmaceuticals                             |
| NCT02454842 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02454842">https://clinicaltrials.gov/show/NCT02454842</a> | Threshold Pharmaceuticals                             |
| NCT02921386 | 21/01/2017 | 43 | <a href="https://clinicaltrials.gov/show/NCT02921386">https://clinicaltrials.gov/show/NCT02921386</a> | Clarus Therapeutics, Inc.                             |
| NCT02600611 | 30/01/2017 | 34 | <a href="https://clinicaltrials.gov/show/NCT02600611">https://clinicaltrials.gov/show/NCT02600611</a> | Motif Bio   |
| NCT01845740 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01845740">https://clinicaltrials.gov/show/NCT01845740</a> | Immunomedics, Inc.                                    |
| NCT02633969 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02633969">https://clinicaltrials.gov/show/NCT02633969</a> | Iroko Pharmaceuticals, LLC                            |
| NCT02694978 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02694978">https://clinicaltrials.gov/show/NCT02694978</a> | AMAG Pharmaceuticals, Inc.                            |
| NCT02937766 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02937766">https://clinicaltrials.gov/show/NCT02937766</a> | AMAG Pharmaceuticals, Inc.                            |
| NCT02357966 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02357966">https://clinicaltrials.gov/show/NCT02357966</a> | XBiotech, Inc.  |
| NCT01240629 | 02/02/2017 | 31 | <a href="https://clinicaltrials.gov/show/NCT01240629">https://clinicaltrials.gov/show/NCT01240629</a> | University of Southern California                     |
| NCT01711970 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01711970">https://clinicaltrials.gov/show/NCT01711970</a> | Vascular Biogenics Ltd. operating as VBL Therapeutics |
| NCT01272245 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01272245">https://clinicaltrials.gov/show/NCT01272245</a> | M.D. Anderson Cancer Center                           |
| NCT02059265 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02059265">https://clinicaltrials.gov/show/NCT02059265</a> | National Cancer Institute (NCI)                       |
| NCT02820714 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02820714">https://clinicaltrials.gov/show/NCT02820714</a> | Braintree Laboratories                                |
| NCT01313416 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01313416">https://clinicaltrials.gov/show/NCT01313416</a> | Augusta University                                    |
| NCT02623361 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02623361">https://clinicaltrials.gov/show/NCT02623361</a> | University of California, San Francisco               |
| NCT02423330 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02423330">https://clinicaltrials.gov/show/NCT02423330</a> | Rush University Medical Center                        |
| NCT02704689 | 19/01/2017 | 45 | <a href="https://clinicaltrials.gov/show/NCT02704689">https://clinicaltrials.gov/show/NCT02704689</a> | Stryker Spine   |
| NCT02648620 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02648620">https://clinicaltrials.gov/show/NCT02648620</a> | SurModics, Inc.                                       |
| NCT01543776 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01543776">https://clinicaltrials.gov/show/NCT01543776</a> | University of Chicago                                 |
| NCT02821338 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02821338">https://clinicaltrials.gov/show/NCT02821338</a> | Food and Drug Administration (FDA)                    |
| NCT01883648 | 01/02/2017 | 32 | <a href="https://clinicaltrials.gov/show/NCT01883648">https://clinicaltrials.gov/show/NCT01883648</a> | University of South Florida                           |
| NCT01969123 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01969123">https://clinicaltrials.gov/show/NCT01969123</a> | FORUM Pharmaceuticals Inc                             |
| NCT01969136 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01969136">https://clinicaltrials.gov/show/NCT01969136</a> | FORUM Pharmaceuticals Inc                             |
| NCT02431468 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02431468">https://clinicaltrials.gov/show/NCT02431468</a> | Neurotrope Bioscience, Inc.                           |
| NCT02348359 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02348359">https://clinicaltrials.gov/show/NCT02348359</a> | Tyrogenex   |
| NCT02555150 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02555150">https://clinicaltrials.gov/show/NCT02555150</a> | Rhodes Pharmaceuticals, L.P.                          |
| NCT01746043 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01746043">https://clinicaltrials.gov/show/NCT01746043</a> | M.D. Anderson Cancer Center                           |
| NCT02604485 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02604485">https://clinicaltrials.gov/show/NCT02604485</a> | XOMA (US) LLC   |
| NCT02133326 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02133326">https://clinicaltrials.gov/show/NCT02133326</a> | Tufts University School of Dental Medicine            |
| NCT01656187 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT01656187">https://clinicaltrials.gov/show/NCT01656187</a> | University of Texas Southwestern Medical Center       |
| NCT02391545 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02391545">https://clinicaltrials.gov/show/NCT02391545</a> | Verastem, Inc.  |
| NCT02452359 | 21/01/2017 | 43 | <a href="https://clinicaltrials.gov/show/NCT02452359">https://clinicaltrials.gov/show/NCT02452359</a> | Venus Concept   |
| NCT02535065 | 23/01/2017 | 41 | <a href="https://clinicaltrials.gov/show/NCT02535065">https://clinicaltrials.gov/show/NCT02535065</a> | Cook Group Incorporated                               |
| NCT01444742 | 29/01/2017 | 35 | <a href="https://clinicaltrials.gov/show/NCT01444742">https://clinicaltrials.gov/show/NCT01444742</a> | M.D. Anderson Cancer Center                           |
| NCT01846221 | 19/01/2017 | 45 | <a href="https://clinicaltrials.gov/show/NCT01846221">https://clinicaltrials.gov/show/NCT01846221</a> | Columbia University                                   |
| NCT02345369 | 20/01/2017 | 44 | <a href="https://clinicaltrials.gov/show/NCT02345369">https://clinicaltrials.gov/show/NCT02345369</a> | Bassett Healthcare                                    |
| NCT02033876 | 31/01/2017 | 33 | <a href="https://clinicaltrials.gov/show/NCT02033876">https://clinicaltrials.gov/show/NCT02033876</a> | Mayo Clinic   |

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|-------------|------------|----|---|--|
| NCT02797808 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02797808 | University of Minnesota - Clinical and Translational Science Institute |
| NCT02251236 | 18/01/2017 | 46 | https://clinicaltrials.gov/show/NCT02251236 | University of California, San Diego                                    |
| NCT02621593 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02621593 | Lumenis Ltd.   |
| NCT01823705 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01823705 | Medtronic Corporate Technologies and New Ventures                      |
| NCT01985763 | 19/01/2017 | 45 | https://clinicaltrials.gov/show/NCT01985763 | Sofya Pintova  |
| NCT00515281 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT00515281 | University of Chicago  |
| NCT02128646 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02128646 | Michael Moncure, MD  |
| NCT03072732 | 01/02/2017 | 32 | https://clinicaltrials.gov/show/NCT03072732 | Zoll Medical Corporation   |
| NCT01370213 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01370213 | Masonic Cancer Center, University of Minnesota                         |
| NCT01656733 | 02/02/2017 | 31 | https://clinicaltrials.gov/show/NCT01656733 | UConn Health   |
| NCT02809976 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02809976 | Tufts Medical Center   |
| NCT02766907 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02766907 | Tissue Tech Inc.   |
| NCT01192828 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01192828 | University of Colorado, Denver   |
| NCT02335905 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02335905 | Baylor College of Medicine   |
| NCT02197104 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02197104 | Rush University Medical Center   |
| NCT01497860 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01497860 | Eugene Hwang   |
| NCT01213082 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01213082 | University of California, Davis  |
| NCT01875653 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01875653 | Caladrius Biosciences, Inc.  |
| NCT00390325 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT00390325 | National Cancer Institute (NCI)  |
| NCT02780869 | 01/02/2017 | 32 | https://clinicaltrials.gov/show/NCT02780869 | Biom'Up SA   |
| NCT02163057 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02163057 | Inovio Pharmaceuticals   |
| NCT02646566 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02646566 | Acacia Pharma Ltd  |
| NCT02134925 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02134925 | National Cancer Institute (NCI)  |
| NCT02773082 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02773082 | The University of Texas Health Science Center, Houston                 |
| NCT02038972 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02038972 | Florida Hospital   |
| NCT02649062 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02649062 | NGM Biopharmaceuticals, Inc  |
| NCT02086526 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02086526 | Mayo Clinic  |
| NCT01860287 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT01860287 | University of Chicago  |
| NCT02505867 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02505867 | Rami Khayat  |
| NCT02302963 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02302963 | University of Virginia   |
| NCT02542046 | 31/01/2017 | 33 | https://clinicaltrials.gov/show/NCT02542046 | University of California, San Francisco                                |

Yours sincerely

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