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

26th February 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 one week. As of 12pm GMT today, 128 trials on ClinicalTrials.gov are assessed as due to report results. 114 of those have reported results. That is a reporting rate of 89.1%. The potential fines the FDA could have collected is now estimated at $1,052,779. 14 trials have not reported results. Those trials are listed below.

Registry ID	Completion Date	Days Late	URL	Sponsor Name
NCT02400164	19/01/2017	38	https://clinicaltrials.gov/show/NCT02400164	Sequana Medical AG
NCT02921386	21/01/2017	36	https://clinicaltrials.gov/show/NCT02921386	Clarus Therapeutics, Inc.
NCT02704689	19/01/2017	38	https://clinicaltrials.gov/show/NCT02704689	Stryker Spine
NCT02547129	23/01/2017	34	https://clinicaltrials.gov/show/NCT02547129	Mayo Clinic
NCT02401412	20/01/2017	37	https://clinicaltrials.gov/show/NCT02401412	Hollister Incorporated
NCT02452359	21/01/2017	36	https://clinicaltrials.gov/show/NCT02452359	Venus Concept
NCT02535065	23/01/2017	34	https://clinicaltrials.gov/show/NCT02535065	Cook Group Incorporated
NCT01846221	19/01/2017	38	https://clinicaltrials.gov/show/NCT01846221	Columbia University
NCT02730598	20/01/2017	37	https://clinicaltrials.gov/show/NCT02730598	University of Kansas Medical Center
NCT02345369	20/01/2017	37	https://clinicaltrials.gov/show/NCT02345369	Bassett Healthcare
NCT02251236	18/01/2017	39	https://clinicaltrials.gov/show/NCT02251236	University of California, San Diego
NCT01985763	19/01/2017	38	https://clinicaltrials.gov/show/NCT01985763	Sofya Pintova
NCT02410551	20/01/2017	37	https://clinicaltrials.gov/show/NCT02410551	M.D. Anderson Cancer Center
NCT02995018	25/01/2017	32	https://clinicaltrials.gov/show/NCT02995018	Bayer

We were concerned to see the FDA quoted by the BBC as stating: "It is often not possible to determine which parties may be non-compliant based solely on the information in the record that is publicly posted on clinicaltrials.gov". We took great care to ensure that we could say which trials are required to report under the law. We use the Final Rule and documentation from ClinicalTrials.gov including the PRS Guide, “Checklist for Evaluating Whether a Clinical Trial or

Study is an Applicable Clinical Trial (ACT)," "Protocol Registration Data Element Definitions," and information on the Final Rule from both ClinicalTrials.gov and the FDA. In a small number of cases, we have had to work around the decision made by FDA / ClinicalTrials.gov to withhold certain information needed to ascertain whether a trial is covered by FDAAA. We have taken a conservative approach to work around this, dropping studies from the list of due trials if the lack of transparency from FDA / ClinicalTrials.gov makes it impossible to ascertain whether a trial is covered by FDAAA.

All the methods and assumptions for this tool are described in detail in the accompanying preprint paper, which is openly accessible online[1] and includes an appendix of correspondence with ClinicalTrials.gov staff. We openly welcome feedback. If after review you feel this methodology is incorrectly identifying overdue trials, please do offer explicit feedback as to why this is the case. The intent of the FDAAA is to increase accountability: this accountability cannot be achieved if information is withheld by FDA / ClinicalTrials.gov on which trials are due; and it cannot be achieved if the FDA makes vague and unsubstantiated public statements that spread uncertainty about reporting rates.

Good progress has been made on trials transparency, during the three decades since non-reporting was first well documented, but there is still much to be done. We will continue to call for the FDA to use the full range of legal recourse at your disposal to ensure all trials are reported.

Dr Síle Lane, the AllTrials Campaign www.alltrials.net
Dr Ben Goldacre, EBM DataLab, University of Oxford.

[1] https://www.biorxiv.org/content/biorxiv/early/2018/02/20/266452.full.pdf