

Clinical trial transparency at US universities

Compliance with U.S. law and global best practices

“Lack of transparency in clinical trials harms patients. The timely posting of summary results is an ethical and scientific obligation.”

- [Transparency International and Cochrane](#)

Washington, D.C., and Bristol, UK
25 March 2019

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Executive summary

Obligation to report the results of all trials

Failure to report clinical trial results is not a victimless crime. It has substantial negative consequences for patients, public health and access to medicines. For this reason, there is a universal ethical obligation to report the results of every clinical trial. U.S. law requires universities to post the results of some – but not all – clinical trials onto a public registry within 12 months of trial completion. That law has been fully in force since 18 January 2017, when the Final Rule of the FDA Amendments Act (FDAAA) came into effect. Best practices set out by the World Health Organization require universities to post the results of all clinical trials onto a public registry within 12 months of trial completion.

Scope of this study

This study covers trials run by forty leading U.S. universities that were completed in the year after the Final Rule came into effect. It assesses each university's compliance with U.S. legal reporting requirements since January 2017. In addition, it assesses efforts made by universities during 2015-2017 to clear their backlogs of missing clinical trial results.

Key findings

- Only 15 out of the forty universities assessed are in full compliance with U.S. trial disclosure law, while 25 universities are in violation of the law. There are large variations in individual universities' performance. Some major medical research universities have posted results for less than half of their clinical trials.
- In total, 140 clinical trials run by the 40 universities in our cohort are still missing results on the public registry.
- Many universities have made strong efforts to upload missing results from clinical trials conducted in the past.

Recommendations

- Universities should formally sign up to [the WHO Joint Statement](#) and fully implement its provisions. This entails putting into place policies, processes and systems that ensure that each and every clinical trial they sponsor posts its summary results onto a public registry within 12 months of a trial's primary completion date, including trials not covered by current U.S. law.
- Universities should retrospectively upload missing summary results for trials completed in past years.

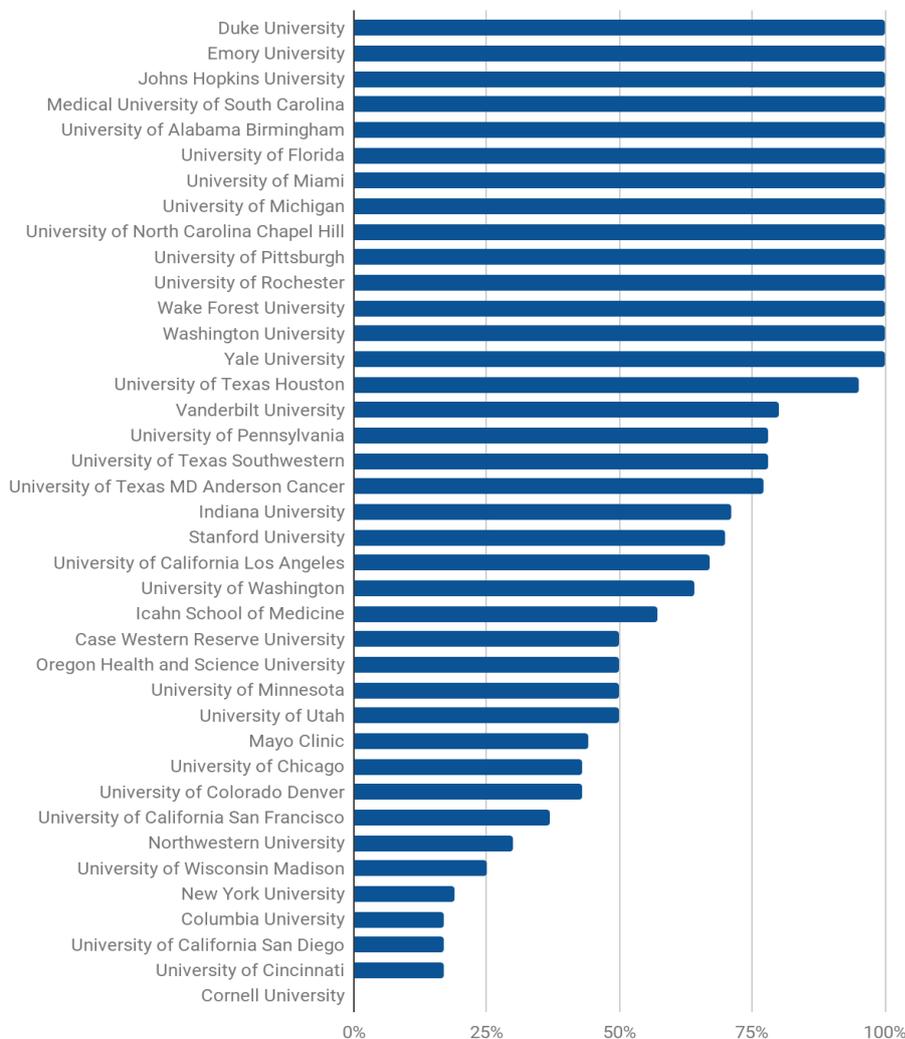
Legal compliance by US universities since 2017

By law, America’s top research universities had to post the results of 450 clinical trials over the course of the past two years. However, 31% of those trials are still missing results on the public registry, in violation of the FDA Amendments Act.

Performance varies strongly between institutions, with 14 universities achieving a reporting rate of 100% and thus full legal compliance. Excepting Baylor University, which has no applicable due trials, all remaining universities are in breach of the FDAAA.

The list of violators includes major trial sponsors. For example, the academic institution sponsoring the most applicable trials, MD Anderson Cancer Center, has only reported 77% of due trials. Mayo Clinic (42%), UC San Francisco (37%), New York University (21%), and Columbia University (17%) perform even worse.

Chart 1: Summary results posted for due clinical trials subject to FDAAA, % by university

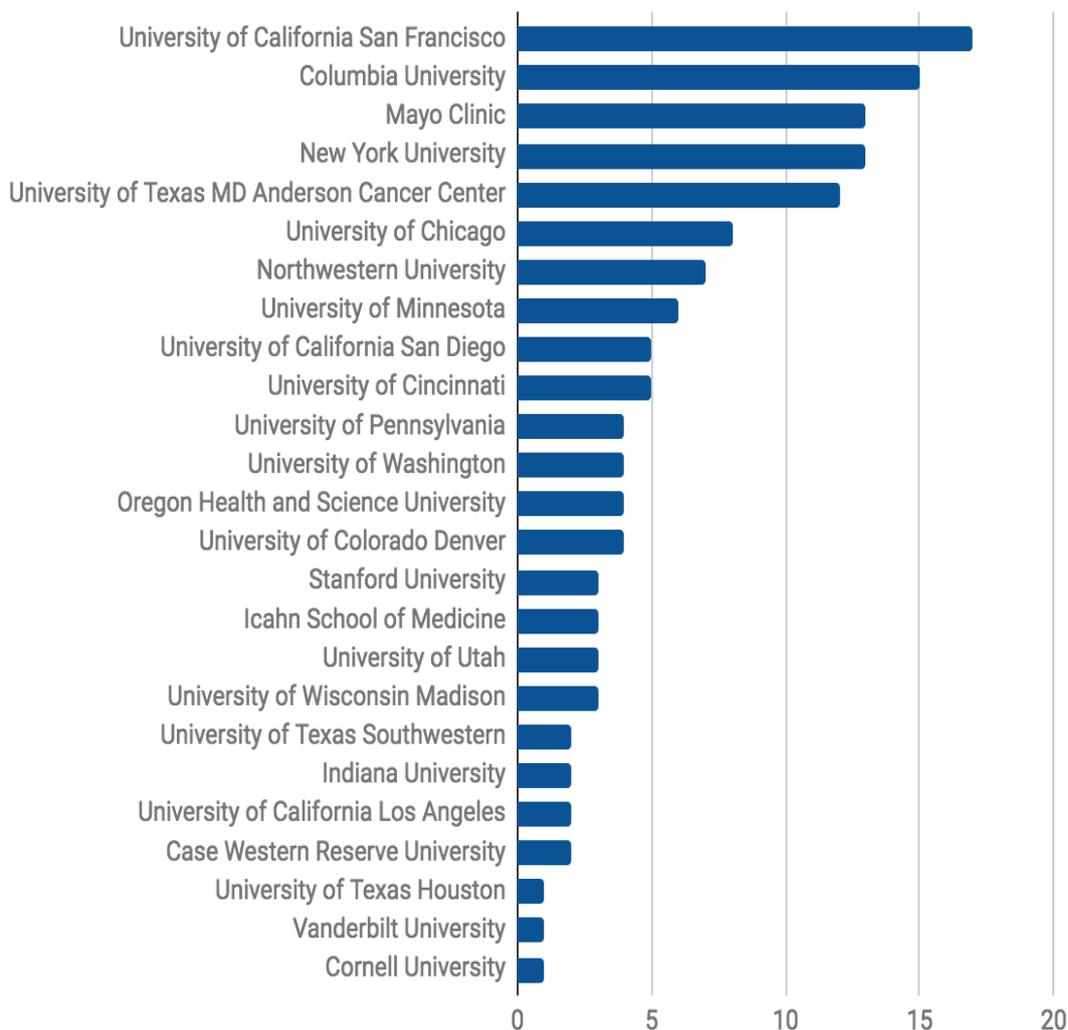


Number of recent clinical trials still missing results

A total of 140 clinical trials that came due since the Final Rule entered into force in January 2017 are still missing results. Five universities are responsible for half of the unreported trials in our cohort: University of California San Francisco (17 trials without results), Columbia (15 trials), Mayo Clinic (13), MD Anderson Cancer Center (12) and Chicago (8).

The chart below shows the number of trials missing results per university.

Chart 2: Clinical trials subject to FDAAA missing summary results, # by university



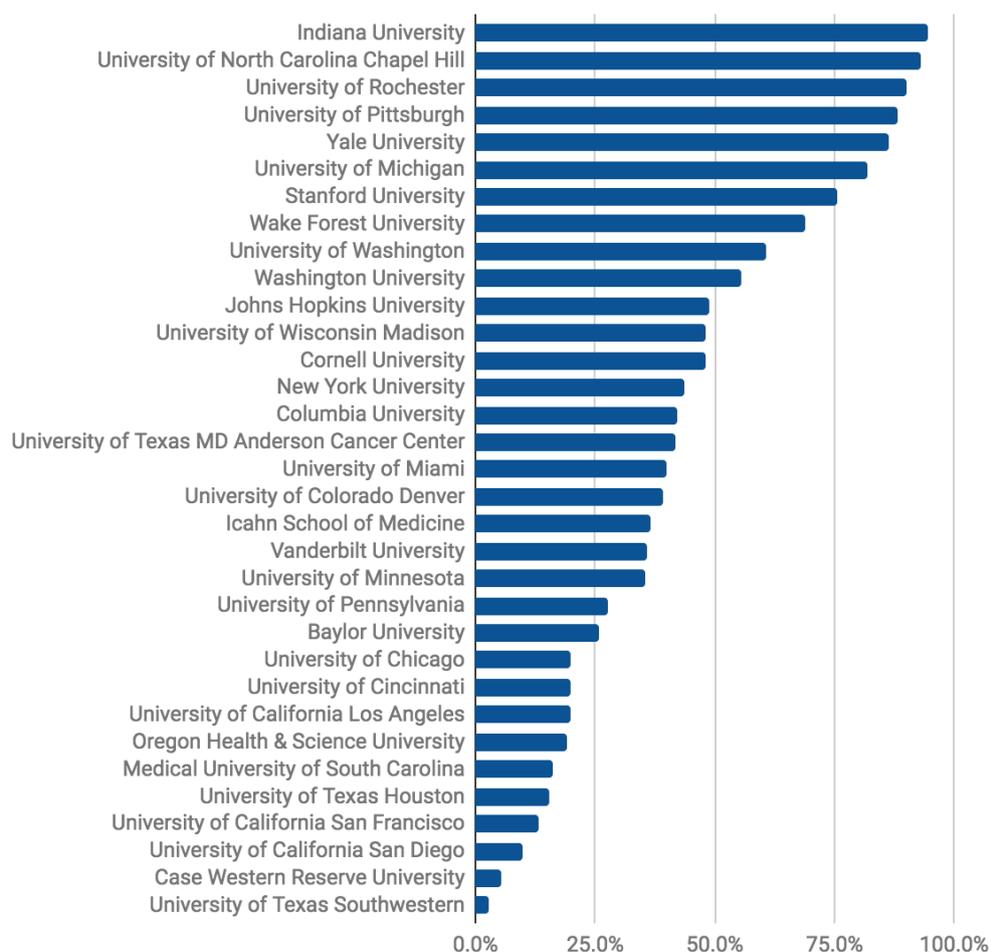
Registry clean-up efforts by US universities 2015-2017

[A 2015 STAT News investigation](#) found that the forty universities in our cohort had failed to post the results of 1,158 trials subject to U.S. law. Following a public outcry, many universities started tackling their backlogs. Follow-up data collected by STAT News in September 2017 showed that universities had posted the results of 512 of these older trials, but 777 trials still remained without results.

The chart below shows that many universities during the course of 2015-2017 put significant effort into retrospectively posting missing results for trials subject to the FDAAA. The universities of Indiana, North Carolina Chapel Hill, Rochester, Pittsburgh and Yale successfully cleared over 85% of their backlogs. Stanford (65 trials), Johns Hopkins (47), and Pittsburgh (45) posted most trial results.

We include this historical data here to highlight and honor the strong positive efforts made by many universities in recent years.

Chart 3: Summary results of clinical trials subject to FDAAA added 2015-2017, % by university



Note: Only universities that had ten or more results missing in 2015 are included in the chart above.

Background

Relevance to public health and clinical practice

A 2017 [report](#) by Transparency International and Cochrane documents that the failure to adequately report trial results has substantial negative consequences:

- Patients are harmed
- Public health agencies cannot make informed decisions
- Public health funds are wasted and research is duplicated
- Medical progress is slowed down
- Shareholders are exposed to substantial risks

Importance of posting results onto trial registries

Traditionally, academic researchers have published the outcomes of clinical trials in academic journals. However, U.S. law and best practices set out by the World Health Organization and other stakeholders focus on posting results onto public trial registries.

There are good reasons for this emphasis on posting trial results onto registries:

- Posting results onto registries accelerates medical progress because the 12-month timeframe permits far more rapid results sharing than the slow academic publication process allows.
- Posting results onto registries minimises the risk of a trial never reporting its results and becoming research waste, which can happen when a principal investigator dies or leaves their post during the prolonged process of submitting an academic paper to a succession of medical journals.
- Research shows that trial results posted on registries typically give a [more comprehensive and accurate picture](#) of patient-relevant trial outcomes than corresponding journal articles do.
- Results posted on registries are easier to locate and are open access.
- Registry reporting facilitates comparison of trial outcomes with a trial's originally stated aims, and thus discourages harmful research malpractices such as the 'silent' suppression, addition, or [switching of selected outcomes, HARKing, and p-hacking](#).

Publication in a journal is not enough

Importantly, according to both U.S. law and World Health Organization standards, publishing trial results in an academic journal is not an acceptable substitute for posting trial results onto public registries. Note that due to the shorter timeframe, posting results onto registries will usually precede academic publication. Medical journal editors have [clearly and explicitly stated](#) that disclosure of results on registries will not be a barrier to subsequent publication in a journal.

U.S. legal framework: Some trials must post results onto the U.S. registry within 12 months

On 18 January 2017, the [Final Rule of the FDA Amendments Act](#) (FDAAA) came into effect. The law requires universities (and other institutions) to post the results of some clinical trials onto the public registry Clinicaltrials.gov within 12 months of their primary completion date.

Universities face a fine of over \$10,000 dollars for every day they fail to post the results of a due clinical trial subject to FDAAA. While the FDA has so far [failed to enforce the law](#), leaving [over two billion dollars in files uncollected](#), it has recently [launched a process](#) that may result in fines finally being collected.

Best practices: All trials must post results onto public registries within 12 months

The Declaration of Helsinki sets out a [universal ethical obligation](#) to report the results of every clinical trial, regardless of whether that trial is covered by current U.S. law.

[WHO best practices](#) require all interventional trials to post their results on every public registry where they were registered within 12 months of their primary completion date.

[Best practices jointly set out by Cochrane and Transparency International](#) also state that “Summary results for all clinical trials should be posted on the registries where they were originally registered within 12 months of study completion.” The two health integrity groups note that retrospectively posting the results of all past trials onto registries “would improve healthcare delivery and government agencies’ decision-making on resource allocations, as well as saving billions of dollars’ worth of medical research from being lost forever.”

Similarly, the trial reporting [benchmark set out by the AllTrials campaign](#) states that “A summary of results (...) should be posted where a trial was registered within one year of completion of a trial.” AllTrials’ over 700 supporter groups include the American Medical Association. Again, this covers all clinical trials.

In addition, a [growing number of medical research funders](#) are now demanding that their grantees post summary results for all clinical trials within 12 months. One of the world’s largest funders, Britain’s MRC, has already started [monitoring grantees’ compliance](#) with this rule. The other [funders who signed the WHO Joint Statement](#) – including Gates Foundation, the Global Alliance, and Wellcome Trust – have also committed to start monitoring grantees’ compliance.

UAEM and TranspáriMED are urging universities to immediately sign up to the WHO-brokered [“Joint statement on public disclosure of results from clinical trials”](#) and fully implement its provisions.

Methodology

Data Collection

The data for charts 1 and 2 on current FDAAA compliance (since the Final Rule came into effect) were manually extracted from the [FDAAA Trials Tracker](#) and are accurate as of 28 February 2019. The FDAAA Trials Tracker’s methodology is [explained here](#). Data for Baylor University is not included in the charts as the university has sponsored no trials flagged as due by the Tracker.

The data for chart 3 was extracted from a larger data set originally [compiled by STAT News](#) that STAT News kindly shared with TranspariMED.

Study Cohort Selection

The study cohort comprises the 40 US universities that had sponsored the largest number of clinical trials subject to FDAAA as of September 2017, based on data [compiled by STAT News](#).

Limitations

To the best of our knowledge, nobody has so far found a trial that was incorrectly flagged as overdue by the FDAAA Trials Tracker. However, the tracker relies on data from Clinicaltrials.gov, which [sometimes does not give sufficient information](#) to allow users to unambiguously determine whether a trial is subject to the law.

In some cases, several different units within one university have assumed legal responsibility for reporting clinical trial results. In keeping with the FDAAA Trials Tracker methodology, we only included trials for which the university itself assumed responsibility, based on searches using the university names as provided in the charts and data table. Hence, we included only the 16 “[Johns Hopkins University](#)” trials, while excluding the 10 “[Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins](#)” trials, and the single “[Johns Hopkins Bloomberg School of Public Health](#)” trial.

In a few instances, the STAT News data set (represented in chart 3) mistakenly identified trials as overdue, but the data set remains the most accurate assessment possible as of September 2017. See STAT’s [Editor’s Note](#) for more details.

About UAEM and TranspáriMED

[Universities Allied for Essential Medicines](#) (UAEM) is a global movement of students organizing on their campuses and beyond to ensure that publicly funded medicines are accessible and affordable for all, regardless of income. UAEM believes that universities and publicly funded research institutions will be part of the solution to the global access to medicines crisis.

[TranspáriMED](#) is a global initiative that develops and promotes policy solutions to the problem of evidence distortion in medical research.

Authorship

Dr Till Bruckner, founder of TranspáriMED, acted as the lead author and extracted the FDAAA compliance data (from the FDAAA Trials Tracker by EBM Data Lab) and the 2015-2017 clean-up data (from the data set collated by STAT News). UAEM also extracted the data separately for comparison.

The UAEM student team was led by Navya Dasari, Mehreen Qureshi and Jackie Xu and supported by Gabriela Arima, John Deng, Chloë Hogg, Zahra Ahmed and Neelu Paleti, who developed the microsite, infographics and charts in conjunction with Signals. Merith Basey, Executive Director for UAEM North America managed the overall project and provided editorial oversight.

ANNEX: Data table

The data in the table below was manually extracted from the FDAAA Trials Tracker on 28th February 2019.

UNIVERSITY	DUE TRIALS	REPORTED	UNREPORTED	% REPORTED	LINK
Baylor University	0	0	0	N/A	N/A
Case Western Reserve University	4	2	2	50	https://fdaaa.trialstracker.net/sponsor/case-western-reserve-university/
Columbia University	18	3	15	17	https://fdaaa.trialstracker.net/sponsor/columbia-university/
Cornell University	1	0	1	0	https://fdaaa.trialstracker.net/sponsor/cornell-university/
Duke University	15	15	0	100	https://fdaaa.trialstracker.net/sponsor/duke-university/
Emory University	19	19	0	100	https://fdaaa.trialstracker.net/sponsor/emory-university/
Icahn School of Medicine	7	4	3	57	https://fdaaa.trialstracker.net/sponsor/icahn-school-of-medicine-at-mount-sinai/
Indiana University	7	5	2	71	https://fdaaa.trialstracker.net/sponsor/indiana-university/
Johns Hopkins University	16	16	0	100	https://fdaaa.trialstracker.net/sponsor/johns-hopkins-university/
Mayo Clinic	23	10	13	44	https://fdaaa.trialstracker.net/sponsor/mayo-clinic/
Medical University of South Carolina	5	5	0	100	https://fdaaa.trialstracker.net/sponsor/medical-university-of-south-carolina/
New York University	16	3	13	19	https://fdaaa.trialstracker.net/sponsor/new-york-university-school-of-medicine/
Northwestern University	10	3	7	30	https://fdaaa.trialstracker.net/sponsor/northwestern-university/
Oregon Health and Science University	8	4	4	50	https://fdaaa.trialstracker.net/sponsor/oregon-health-and-science-university/
Stanford University	10	7	3	70	https://fdaaa.trialstracker.net/sponsor/stanford-university/
University of Alabama Birmingham	10	10	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-alabama-at-birmingham/
University of California Los Angeles	6	4	2	67	https://fdaaa.trialstracker.net/sponsor/university-of-california-los-angeles/
University of California San Diego	6	1	5	17	https://fdaaa.trialstracker.net/sponsor/university-of-california-san-diego/
University of California San Francisco	27	10	17	37	https://fdaaa.trialstracker.net/sponsor/university-of-california-san-francisco/
University of Chicago	14	6	8	43	https://fdaaa.trialstracker.net/sponsor/university-of-chicago/

University of Cincinnati	6	1	5	17	https://fdaaa.trialstracker.net/sponsor/university-of-cincinnati/
University of Colorado Denver	7	3	4	43	https://fdaaa.trialstracker.net/sponsor/university-of-colorado-denver/
University of Florida	1	1	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-florida/
University of Miami	2	2	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-miami/
University of Michigan	9	9	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-michigan/
University of Minnesota	12	6	6	50	https://fdaaa.trialstracker.net/sponsor/university-of-minnesota-clinical-and-translational-science-institute/
University of North Carolina Chapel Hill	24	24	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-north-carolina-chapel-hill/
University of Pennsylvania	18	14	4	78	https://fdaaa.trialstracker.net/sponsor/university-of-pennsylvania/
University of Pittsburgh	1	1	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-pittsburgh/
University of Rochester	4	4	0	100	https://fdaaa.trialstracker.net/sponsor/university-of-rochester/
University of Texas Houston	20	19	1	95	https://fdaaa.trialstracker.net/sponsor/the-university-of-texas-health-science-center-houston/
University of Texas MD Anderson Cancer Center	52	40	12	77	https://fdaaa.trialstracker.net/sponsor/md-anderson-cancer-center/
University of Texas Southwestern	9	7	2	78	https://fdaaa.trialstracker.net/sponsor/university-of-texas-southwestern-medical-center/
University of Utah	6	3	3	50	https://fdaaa.trialstracker.net/sponsor/university-of-utah/
University of Washington	11	7	4	64	https://fdaaa.trialstracker.net/sponsor/university-of-washington/
University of Wisconsin Madison	4	1	3	25	https://fdaaa.trialstracker.net/sponsor/university-of-wisconsin-madison/
Vanderbilt University	5	4	1	80	https://fdaaa.trialstracker.net/sponsor/vanderbilt-university/
Wake Forest University	15	15	0	100	https://fdaaa.trialstracker.net/sponsor/wake-forest-university-health-sciences/
Washington University	15	15	0	100	https://fdaaa.trialstracker.net/sponsor/washington-university-school-of-medicine/
Yale University	7	7	0	100	https://fdaaa.trialstracker.net/sponsor/yale-university/
Total	450	310	140	Avg 69%	