

# Clinical Trials Transparency Campaign: An Advocacy Guide for UAEM Chapters

## Introduction

Clinical trial transparency is key to accelerating medical progress, ensuring drug safety and efficacy, and improving access to essential medicines today. Universities undertake a large portion of all clinical research done in the United States, and it is becoming increasingly important for each university to follow the principle of transparency in doing so. At the very least, universities must abide by the FDA Amendments Act of 2007 (FDAAA), which legally mandates institutions to report results from a subset of clinical trials within one year of the study's completion. UAEM chapters should aim to increase clinical trial transparency at their universities, and our new report and microsite are intended as a tool for chapters to use as they raise awareness and put pressure on university leadership.

## What This Guide Is For

This guide is for all UAEM chapters to use as they push for increased clinical trial transparency at their university, ideally getting their university to be fully compliant under the FDAAA Of 2007. For more information regarding clinical trial transparency and its significance, please refer to the [Clinical Trial Transparency Fact Sheet](#).

## Microsite

As part of the transparency campaign, UAEM will launch a new [microsite](#) and report promoting clinical trial transparency at the university level. The microsite evaluates the 40 US universities sponsoring the largest number of clinical trials on their commitment to transparency. **If your university is one of these 40, the microsite will be an especially important tool for your chapter!** The microsite communicates the significance of this campaign to a wider, general audience, making it easier for you to advocate for transparency as you speak with students, professors, and university officials.

*\*\*Note: If your university is not included in our report, you can still access the data from the [FDAAA Trials Tracker](#), which gives detailed information about the reporting status of clinical trial sponsors and institutions. This data has been scraped directly from [clinicaltrials.gov](#), the national database where trials are to be reported. You can also contact the UAEM transparency campaign team if you would like more assistance on gathering reporting data for your institution. See below for more details.*

## Getting Strategic on Campus

Rallying for any cause is often made easier with a strategic plan of action. Consider your university's climate and make a plan of action for increasing clinical trial transparency!

### Step 1: Analyzing the University

Here are a few sample questions to ask about your university:

- Is clinical research conducted at your university?
- Is your university evaluated in the UAEM report?
- If you search your university on the [AllTrials Trial Tracker](#), do you see any overdue results?
- Who at your university is responsible for ensuring that clinical trial results are reported? Is there someone with the title of PRS Administrator?
- Are clinical trials divided by department and school at your university? (ie. Are clinical trials at the university and medical school managed and funded separately?)
- How does your university market itself publicly?
- Is there a governing body or department overlooking all research studies?
- What are the existing guidelines to begin a clinical trial research study here?
- How often are researchers mandated to report and update their results?
- Who are the major funders of research done here? Public or private funding?
- What are the key student societies or organisations who you might ally with for change?
- Who is/are the key individual(s) for implementing better transparency measures?

Researching the answers to such questions online can be a great way to get started. However, you will most likely need to engage relevant faculty and administrators when conducting this initial background research.

Once you have the needed background tools and knowledge, teaming up with other campus organizations can be an effective means of capturing the attention of the student body. At the very least, connecting with different student groups may lead you to better resources and contacts needed to plan this transparency campaign at your university.

### Step 2: Planning

Once you have an understanding of your environment, you are ready to make your plan.

Try and make the plan **SMART**: Specific (be exact), Measurable (how will you know you have achieved things?), Achievable (is it realistic?), Relevant (is it meaningful?), and Time-bound (everything should have a deadline!). How will you get your university to commit to clinical trial transparency?

### Step 3: Action

This is where each chapter can implement specific activities and programs to engage your respective student bodies and university leadership. Be creative, and use the microsite as a tool!

### Form Alliances

First, identify faculty or student groups (health care clubs and activist groups are a good bet) who might be interested in clinical trial transparency. Your new allies can help you approach university leadership and raise awareness. Working with research centers, public policy or global health groups, and academic departments on campus can help you find more faculty support.

### Make Your Ask: Meet with University Leadership

Once you identify the university official who can change the university's transparency policies, arrange a meeting with them. Use the microsite as a tool to explain the university's relative success or failure when it comes to transparency. Finally, make your ask! How can they commit to clinical trial transparency? ***Push for administration to make a plan to achieve 100% reporting rate and emphasize that this is groundbreaking, important, and good press for the university.***

Achieving 100% reporting rate may take different steps depending on where your university stands at present. Try to understand the existing structures that dictate clinical research and reporting before meeting with university leadership in order to have a more informed discussion. Some first steps that you can advise university leadership to take can include hiring staff to handle registration and reporting responsibilities, conducting research trainings on reporting requirements, developing infrastructure and data protocols for results reporting, and sending periodic reminders to researchers about reporting timelines and duties. Depending on your university, such changes might be able to be integrated into the institution's existing research administration and support networks. You can also encourage administrators at your university to become part of the Clinical Trial Registration and Results Reporting taskforce - a voluntary organization that aims to facilitate some of the above-mentioned changes that promote better transparency in results reporting.

By rallying support on campus and arranging meetings with different university officials (president, dean, research department heads, professors, etc.), you can negotiate arrangements with your university to encourage compliance with the FDAAA's legal provisions - and the WHO's ethical guidelines on clinical trial results reporting.

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### Sample Email

Dear \_\_\_\_\_,



My name is \_\_\_\_\_, and I am a student at \_\_\_\_\_ university and a member of Universities Allied for Essential Medicines (UAEM), a student-led organization committed to ensuring that publicly funded medicines and medical innovations are affordable and accessible. UAEM believes that universities must be part of the solution to the current access to medicines crisis, and that students and faculty are uniquely positioned to push for transformative change, starting on their campuses.

I am writing today to discuss \_\_\_\_\_ university's performance on UAEM's recent report analyzing clinical trials transparency at US universities. \_\_\_\_\_ university has reported \_\_\_\_\_% of clinical trials that are due for reporting. This falls short of the university's legal responsibility to report 100% of clinical trial results that are subject to the FDA Amendments Act (FDAAA) of 2007. This legislation requires summaries of clinical trial results to be made publicly available on ClinicalTrials.gov within one year of each study's completion, and failure to comply can result in monetary penalties and the withholding of future grant funds.

As students, researchers, and advocates for the progression of equitable research at our university, we would love for the chance to meet with you to discuss strategies to improve the school's reporting rates.

Clinical trial transparency is critical to accelerating medical progress, improving understanding of drug safety and efficacy, and reducing fraud and bias, thereby increasing access to innovative medicines. We invite you to collaborate with UAEM to further promote these goals. We hope you will recognize the significance and urgency of this campaign, especially amidst the current COVID-19 pandemic, where the efficacy of treatments and vaccines is constantly being debated.

We hope this will serve as an opportunity for our university to abide by their mission to establish a more transparent biomedical research and development system that better serves patients.

Sincerely,

\_\_\_\_\_

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If meetings take a long time to schedule or seem to go nowhere, don't lose hope! Instead...

## **Grab Their Attention: Creative Action Ideas**

Creative actions can help you rally support on campus, especially if university officials are withholding or reluctant to make change. Here are some ideas to get you started!

### **Remote Actions**

### Class Speech

Talk to your professors, especially those teaching classes relevant to health policy and global health, for permission to address the class briefly before a lecture. You can give a short spiel about UAEM and the transparency campaign, and suggest a small action item for the class: email you afterwards to get involved, visit the website, sign a petition to the university, etc.

- What You Need
  - A friendly professor

### Online Speaker Panel Event

Coordinate with other allies and student organizations on campus to plan a panel event with speakers who are local advocates for access to medicines and clinical trials transparency. Publicize the event amongst faculty, students, and other communities on campus to raise awareness about the issue and your school's reporting status.

- What You Need
  - Speakers who are willing to talk about the issue of transparency (reach out to the UAEM North America coordinating committee for ideas on who to invite!)
  - Social media flyers and posts to publicize the event
  - Zoom!

### **In-Person Actions** (Remember to practice social distancing!)

#### Window Washing

Window washing is a creative play on the idea of “transparency” that can attract attention on campus, so choose your target wisely. This would involve washing windows at the university, so you can make a point about transparency in a way that doesn't cause damage. Do you want to wash the windows of the office of the president, or the technology transfer office? Either way, play up the spectacle, take pictures, and make sure passersby know what's going on.

- What You Need
  - Buckets of soapy water/access to a tap
  - Sponges
  - Something to dry the window
  - Posters, signs, or another means of making the transparency message clear
  - Equipment to film or photograph the event

- Important Considerations
  - People might be worried about causing damage: be careful by using soft sponges, and move to other windows if someone is worried.
  - If it's too cold to get wet: try to pick a day that's not too cold, or take turns and wear gloves in-between.
  - This probably would require more manpower than some of the other stunts.

### The Black Box

Decorate a black box with question marks. Make holes in the walls of the box and place signs, such as arrows, telling spectators to look inside the holes. Inside the box you can place messages relating to transparency, with the whole stunt aiming to educate people on clinical trials transparency.

- What You Need
  - A cardboard box that can be painted black
  - Black paint
  - A way to cut holes in the box
  - Paper with messages about transparency on them
  - Somewhere you can display the box to a wide audience
  - Equipment to film or photograph the event
- Important Considerations
  - People may not go and look in the box without the encouragement of others being there: try to have someone to encourage people to look and answer questions about transparency.
  - Can people read the messages inside the box? A light may be required or enough holes to let light in.

### The Fog Machine

Place a fog machine in front of a poster about clinical trial transparency, so any spectators have to look past the fog to examine the poster. The fog is a dramatic way to draw attention to the issue while playing on the idea of transparency.

- What You Need
  - A fog machine **(N.B. UAEM will not reimburse the costs of this)**.
  - Some people/posters to explain the issue of transparency to any interested passersby
  - Equipment to film or photograph the event.

- Important Considerations
  - Could cause people to steer clear of the area: try and have someone there to engage in conversation and explain why you are there!
  - Expense of a fog machine: perhaps someone works in clubs or events and can lend theirs for cheap?

### The Torn Poster

Make a poster advocating for clinical trial transparency, with a large piece torn out of the middle. The hole in the middle should function as a frame you can use to take pictures of students for a photo campaign.

- What You Need
  - A poster with a piece torn out, or a piece you have to unfurl to see the person behind.
  - A camera to take pictures of people to post to social media.
- Important Considerations
  - Consent for people having their pictures taken to post on any webpages or social media.

### The Instagram Frame

A frame that is made with a cardboard or poster window. The frame would then be designed like an 'Instagram post,' with messages relating to transparency on the bottom. You can even make a selection of frames with different messages. Find students to take pictures for a photo campaign.

- What You Need
  - A poster decorated to look like an Instagram frame, with a square cut out of the centre.
  - 'Frosted' plastic to stick over the centre hole to blur out whoever is standing behind--but it shouldn't completely obscure them.
  - A camera to take pictures of people holding the frame to post to social media.
- Important Considerations
  - Consent for people having their pictures taken to post on any webpages or social media.

### Chalking

Chalking is a good way to get the name of UAEM and the transparency campaign to be familiar all over campus!

- What You Need
  - Chalk!
  - Spaces you can chalk on that a lot of students will see.
- Important Considerations
  - Because not a lot of information can be communicated, and it's difficult to know who is personally engaging with the slogans, it's best to use chalking as a way to draw attention to a specific event or to the transparency website once it's launched.

### Flyering/Posters/Stickers

Flyers are best when they're bold, eye-catching, and focus on the problem we're trying to address. You can include the transparency microsite URL in order to draw more traffic to the site.

- What You Need
  - Printed flyers
  - UAEM will be providing additional, high-quality materials for students to use in marketing!
- Important Considerations
  - Hang flyers on university bulletin boards, on sidewalks, and even in the departments of researchers and people involved in clinical trials (we aren't only trying to reach students).

### Class Speech

Talk to your professors, especially those teaching classes relevant to health policy and global health, for permission to address the class briefly before a lecture. You can give a short spiel about UAEM and the transparency campaign, and suggest a small action item for the class: come up to you afterwards to get involved, visit the website, sign a petition to the university, etc.

Fake proposals are a UAEM classic ([check out this video for a perfect example of how to pull it off](#)) and are sure to keep your classmates talking long after class is over! This is a super fun and exciting tactic, and whatever you do, make sure to film it!

- What You Need
  - A friendly professor
  - A ring box, a fake "pill," and two people (*if doing a fake proposal*)
  - Equipment to film
- Important Considerations

- For best results with a fake proposal, pick a large lecture class. Otherwise, the size of the class doesn't matter!

### Tabling

Setting up a booth at events or public spaces can be a good way to raise awareness of the campaign with students who might otherwise never hear about it.

- What You Need
  - A table
  - A UAEM or Transparency poster
  - A laptop to display the microsite--invite people to play around with the graphs!
- Important Considerations
  - This is most useful at club fairs and other events that call for a booth, but it never hurts to pick a spot on campus with a large amount of foot traffic and see whose attention you get!

### **Raising More Awareness: Campus and Local Media**

- Connect with your university's student newspaper or popular media outlet and find out how to obtain coverage for UAEM and the transparency campaign launch. Listed below are a few ideas to start.
  - On-campus outlets
    - Student radio
    - Student newspapers
    - Relevant campus email lists
  - Off-campus press (local and national level)
    - Newspapers
    - Television stations
- ***If you attend one of the forty universities covered in the microsite, getting campus and local coverage is extremely important. Reach out if you need any support in doing so!***
- Use social media outlets (especially in collaboration with other student-led groups) to spread the word on the campaign launch and available UAEM resources.
- You want as many students as possible to be aware of the issue and to join you in putting pressure on the university!

### Sample Tweets

Tweet
More than half of all university clinical trials are never published. [ <i>Your university</i>

<p><i>name</i>] publishes [X] %. @uaem @youruniversitytwitterhandle</p> <p>[Link report]</p> <p>#transparency #access2meds</p>
<p>Publishing of negative results helps notify doctors of the safety and efficacy of drugs. So why isn't #transparency a priority? #access2meds</p>
<p>Full reporting of clinical trials results is an important component of a transparent approach to R&amp;D, which must also include transparency in funding, pricing, and licensing. #access2meds @uaem</p>
<p>University mission statements often highlight their commitment to the public good. To fulfill that commitment, universities need to make their clinical trials transparent. #access2meds @uaem</p>
<p>The public should be able to trust our academic institutions. Public disclosure of clinical trial results is a critical part of that. #access2meds @uaem @youruniversitytwitterhandle</p>
<p>Transparency helps to cut research spending by avoiding duplicate studies. Shouldn't this be enough incentive for universities to introduce transparency in research? #access2meds @uaem @youruniversitytwitterhandle</p>
<p>We performed a study and found 101 clinical trials recently run by the 40 US universities in our cohort with unpublished results. This is a serious hindrance to scientific progress in the US and worldwide. #transparency #access2meds @uaem @youruniversitytwitterhandle</p>
<p>Transparency is key to ensuring safe, effective medicines, especially during a global pandemic. #access2meds @uaem</p>

## Following up

- Staying in touch and acknowledging the involved university contacts and other key players can be essential in executing future activism projects. If necessary, continue pressing university officials to make a commitment.
- It would also be helpful to encourage student body engagement through periodic programs, meetings, and more.

Are there ways you can hold your university accountable? Some ideas might be:

- Asking the university about the long-term plan to mandate clinical trial transparency can incite more sustainable changes.

- Publishing reports or updates about the university in local or student newspapers.
- Getting involved in a report card project of your university.

## Need help?

If your chapter campaign is ever stuck or if you need advice on how to make change at your university, contact:

- Neelu Paleti ([paletin9@sas.upenn.edu](mailto:paletin9@sas.upenn.edu))
- Defne Yorgancioglu ([defne.yorgancioglu@duke.edu](mailto:defne.yorgancioglu@duke.edu))
- Merith Basey ([merith@essentialmedicine.org](mailto:merith@essentialmedicine.org))

## Further Reading

### Recent Media Coverage on Clinical Trials Transparency

- [COVID-19 lesson: New FDA chief, when chosen, must crack down on clinical trial transparency](#), The Baltimore Sun, 2021
- [NYU and Yale Collaboration Leads to Ruling that Will Reveal Decade of Undisclosed Clinical Trial Data](#), NYU Law, 2020
- [Transparency Advocates Win Victory for Public Access to Clinical Trial Data](#), Yale Law, 2020
- [Some Covid-19 trial sponsors never posted other study results in an EU database. Will they hide data again?](#), STAT News, 2020
- [Many leading universities are still failing to report clinical trial results](#), STAT News, 2019
- [Top US institutes still aren't reporting clinical-trial results on time](#), Nature, 2019

### UAEM Resources

The UAEM website ([uaem.org](http://uaem.org)) has more information about our movement.

If you want academic articles to use as evidence in your campaign, [UAEM Evidence](#) is a great source for relevant papers.

The UAEM Report Cards may provide detailed information about the performance of other universities in licensing and other activities. Find out more here: <http://globalhealthgrades.org/>

### Allies of the Transparency Campaign movement:

- WHO: <http://www.who.int/ictrp/en/>
- AllTrials: <http://www.alltrials.net/>
- ResIn: <http://researchinvestments.org/>
- University Student Unions & Medical Societies
- Researchers & Academics

### **Existing Guidelines for Transparency:**

- International Committee of Medical Journal Editors (ICMJE) requirement for trial registration (2005)
- World Health Organization (WHO) trial registration policy (2006)
- Food and Drug Administration (FDA) Amendments Act requiring summary results posting (2007)
- EMA [policy](#) on publication of clinical data for medicinal products for human use (2014)
- Yale [lawsuit](#) against FDA, NIH, HHS leads to mandate on retrospective reporting

### **External activism resources**

The Centre for Applied Non-violent Action and Strategies (CANVAS) have published a Core Curriculum on activism, giving detailed information about making strategy and organising. Pages 86-95 Focus on Strategy and pages 110-119 focus on messaging.

[http://canvas3.cervinistrategies.com/wp-content/uploads/2015/08/CANVAS-Core-Curriculum\\_EN.pdf](http://canvas3.cervinistrategies.com/wp-content/uploads/2015/08/CANVAS-Core-Curriculum_EN.pdf)

The website Beautiful Trouble contains loads and loads of material for inspiration. This includes different tactics, different theoretical principles, and different case studies from around the world.

<http://beautifultrouble.org/> and <http://explore.beautifultrouble.org/#-1:00000>

The website Beautiful Rising has lots of different tactics, theories, methodologies, case studies, and principles for you to draw from. <https://beautifulrising.org/>

### **Analysis**

The Change Agency has an easy to use power-mapping guide available for free download, as part of their Political Analysis toolkit.

<http://www.thechangeagency.org/campaigners-toolkit/training-resources/political-analysis/>.

Beautiful Rising have examples of analysis such as [power-mapping](#), [Pillars of Power](#), and [Narrative Power Analysis](#) to help you understand your university environment.

Pillars of Support/Power Theory is another way of analysing your environment. A useful download is available here <http://turningtide.org.uk/toolkit/pillars-of-power/> which you can use to guide your chapter through the process.