Stem Cell Research Oversight (SCRO)

Regulatory Services for Clinical Trials

ClinicalTrials.gov, FDA INDs and IDEs

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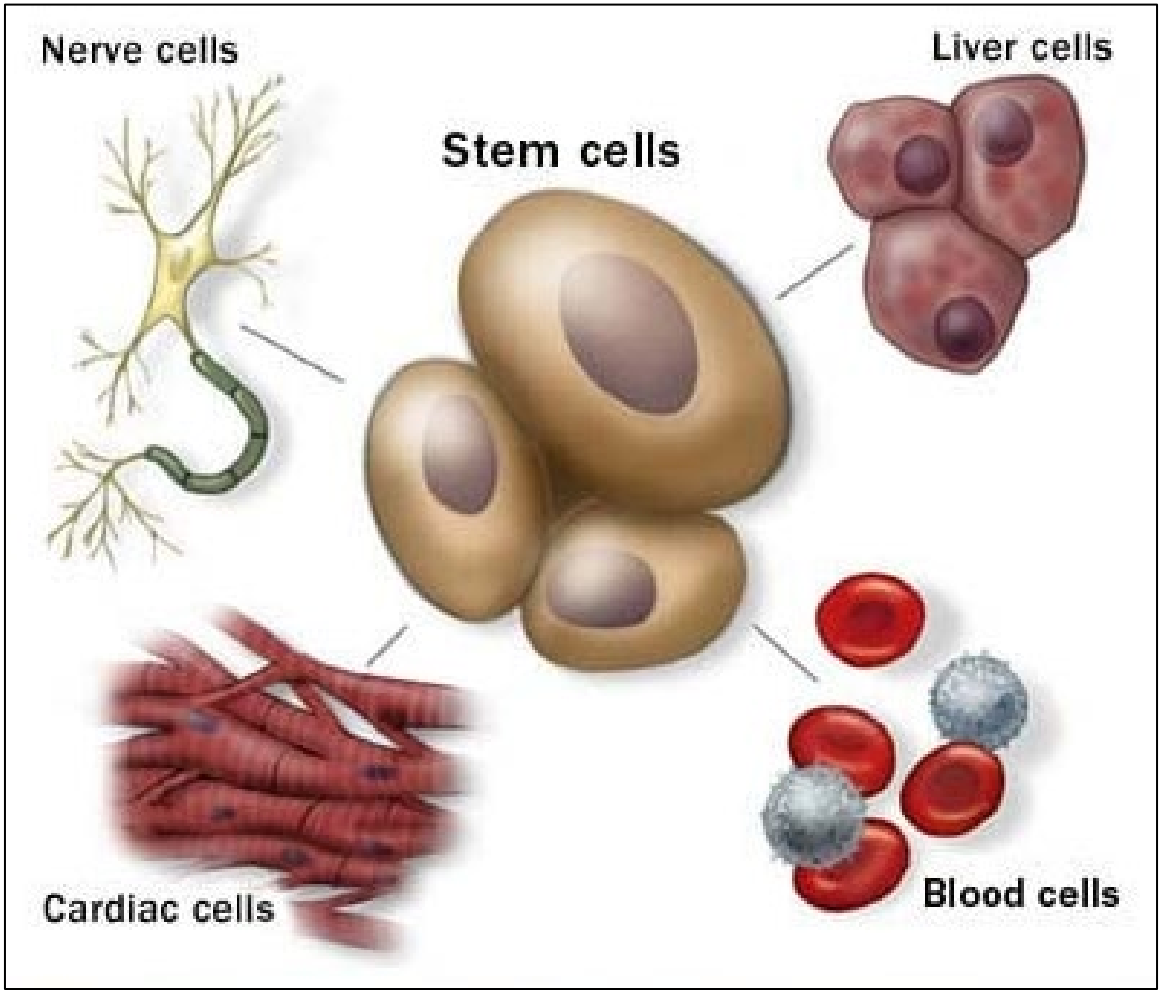
Clinical Trials Resource Center (CTRC)

The University of Texas Health Science Center at Houston

Stem Cell Research Oversight (SCRO)

Stem cells are the body's raw materials — cells from which all other cells with specialized functions are generated



From https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117

There are many different types of stem cells.

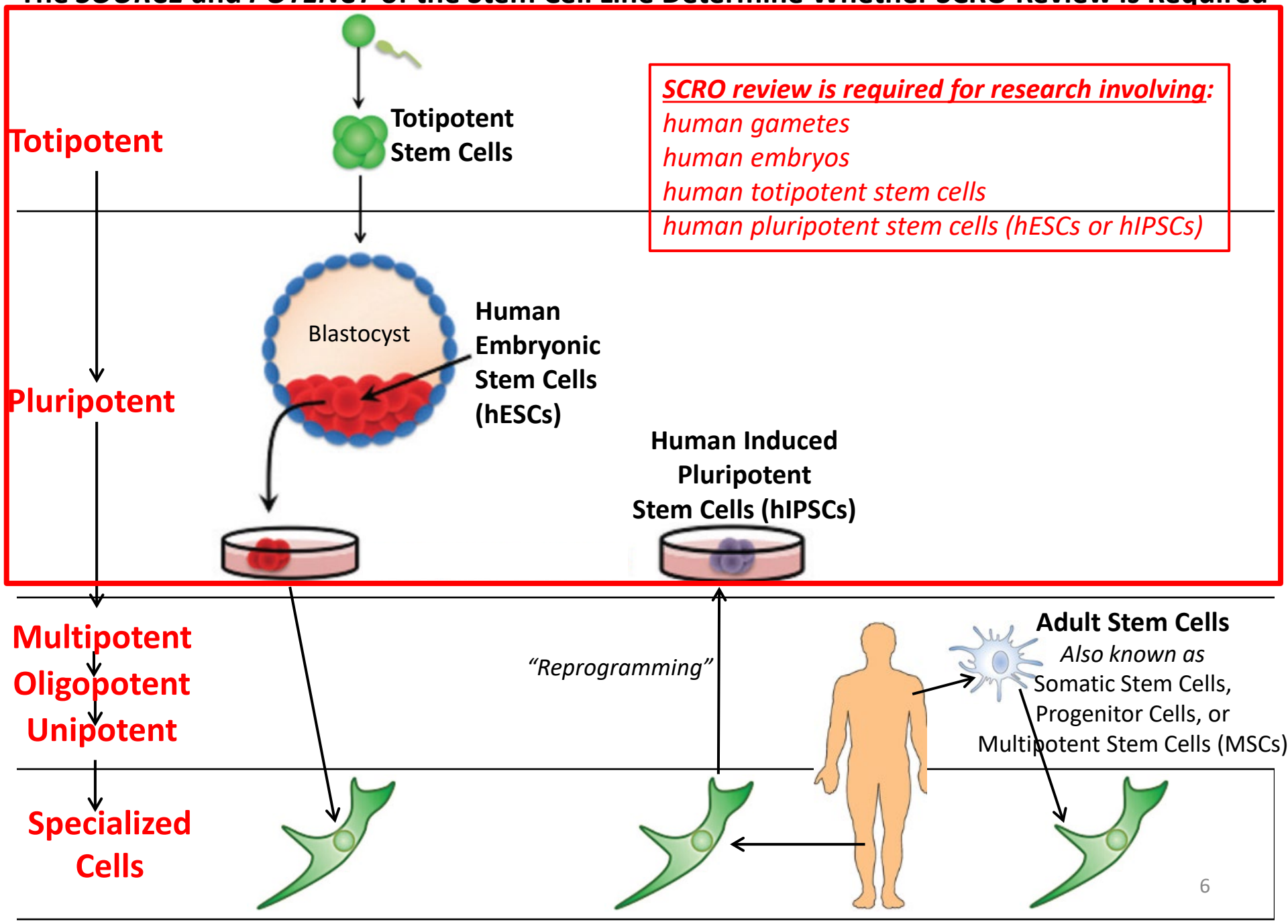
SCRO Committee review is only required for certain human stem cell types.

HOOP 200 – Review of Research

H. Human Stem Cell Research Oversight (SCRO) Committee

All research involving human embryonic stem cells (hESCs) or human induced pluripotent stem cells (hIPSCs) conducted at the university by its employees and/or involving use of its facilities or resources must be reviewed and approved by the Human Stem Cell Research Oversight (SCRO) Committee before it is initiated. Some research involving hESCs or hIPSCs may require additional approval by the AWC, IBC and/or CPHS. For more information on the application process, please contact the SCRO office at scro@uth.tmc.edu.

The *SOURCE* and *POTENCY* of the Stem Cell Line Determine Whether SCRO Review is Required



SCRO Review is Required for Research Involving the Following (or their Derivatives)

	Generation for Research Purposes	Research Use
human embryonic stem cells (hESCs)	**YES**	**YES**
human induced pluripotent stem cells (hIPSCs)	*No*	**YES**
human totipotent stem cells	**YES**	**YES**
human gametes	**YES**	**YES**
human embryos	**YES**	**YES**
human adult stem cells (non-neural)	*N/A*	*No*
human neural stem cells, of any source	*depends on source*	**YES**

Reach out to Elizabeth Gendel to discuss whether SCRO review is required for your project.
Elizabeth.M.Gendel@uth.tmc.edu

To Avoid Delays in Release of Grant Funds:

- Ensure Review and Approval (R&A) Form Submitted to SPA Correctly Indicates Stem Cell Involvement and Correctly Indicates Stem Cell Types
- Ensure Project is Submitted to SCRO Well Before Grant Funding is Received

R&A Form within UTSTART

INSTITUTIONAL COMPLIANCE

Yes ☐ No ☑ * Does project involve human subjects (or material or data from human subjects)?

Yes ☑ No ☐ * Does project involve stem cells?

* type(s):
embryonic ☐ iPSC ☐ adult ☐

Yes ☐ No ☑ * Does project involve vertebrate animals?

Yes ☐ No ☑ * Does project involve biological agents, infectious agents, or recombinant or synthetic nucleic acid?

Yes ☐ No ☑ * Does project involve radioactive materials?

Yes ☐ No ☑ * Does project involve toxic or physically dangerous chemicals or carbon or silica based nanochemistry?

Stem Cell Research Oversight (SCRO) Website

https://inside.uth.edu/scro/

- SCRO Application
- Document “SCRO Policy and Procedures”
- Document “Guidelines for SCRO Review”

Levels of SCRO Review and Timelines

- **Expedited Review** **(about 1 week turnaround time)**
  - *In vitro* work with hESC lines that are approved by NIH or previously approved by UTHealth SCRO
  - *In vitro* work with hIPSC lines
  - Introduction of hESCs (NIH- or UTHealth SCRO-approved) or hIPSCs to animals if:
    - *Cells are transplanted to postnatal animals and there is no likelihood of contributing to the central nervous system or germ line (e.g., the development of a teratoma to evaluate pluripotency).*
- **Full Committee Review** **(about 2-week to 2-month turnaround time, but new technology or new ethical issues may take longer)**
  - Generation of brain organoids
  - Transplantation of hESCs or hIPSCs to animals if:
    - *There is a likelihood of transplanted cells contributing to the central nervous system or germ line.*
  - Transplantation of hESCs or hIPSCs to humans
  - Any work with hESCs that are not NIH approved or previously approved by UTHealth SCRO
    - Lines listed on NIH Registry are eligible for use in NIH-supported research: https://grants.nih.gov/stem_cells/registry/current.htm
  - Derivation of hESCs
  - Creation of embryos, gametes, or totipotent cells

Stem Cell Research Oversight (SCRO) Contact Information

- *SCRO Office*
  - SCRO@uth.tmc.edu
  - *(*713) 500-3587

- *Elizabeth Gendel*
  - Elizabeth.M.Gendel@uth.tmc.edu
  - (713) 500-3587

Regulatory Services for Clinical Trials

FDA INDs and IDEs

ClinicalTrials.gov

Regulatory Services for Clinical Trials

- **IRB submissions (full board) are reviewed to determine:**
  - If a study must be registered at ClinicalTrials.gov
  - If a study of a drug, biological product, or device might need to receive FDA approval before it begins *(that is, if an IND or IDE is needed)*

- **Either the Clinical Trials Resource Center (CTRC) or CPHS will notify your study team if any of the above are required**

- **CTRC can assist with:**
  - ClinicalTrials.gov Registration, Updates, and Results Entry
  - Preparation and Submission of Application to FDA for Approval to Study an Investigational Drug or Device *(that is, an IND or IDE application),* and Preparation of Subsequent IND and IDE Reports

FDA INDs and IDEs

An IND or IDE Application Must be Submitted to FDA for Certain Clinical Studies

- An **Investigational New Drug (IND)** application must be submitted to FDA for certain studies involving drugs or biologic products

- An **Investigational Device Exemption (IDE)** application must be submitted to FDA for certain studies involving medical devices

Elizabeth Gendel and Jessica Martinez of CTRC Assist with Submissions to FDA

Clinical Trials Resource Center (CTRC) - clinicaltrials@uth.tmc.edu
Elizabeth Gendel - 713-500-3587, Elizabeth.M.Gendel@uth.tmc.edu
Jessica Martinez - 713-500-3551, Jessica.L.Martinez@uth.tmc.edu

FDA INDs and IDEs
Helpful Tip

- **To avoid delays with study start-up, consider ASAP whether your study involves something FDA views as a "drug" or "device" and whether an IND or IDE might be required**
  - If a product is given to or applied to humans, and the study aims to look at the effect of that product on study participants re: "*diagnosis, cure, mitigation, treatment, or prevention of disease*" or "*affect [on] the structure or any function of the body*,"
    - then FDA may consider that product to meet the definition of "drug," "biologic," or "medical device." If so, then an IND or IDE application might be required.
  - Some examples that may come as a surprise:
    - Products not sold as "drugs" but used as "drugs" [i.e., Supplements, Vitamins, Human Tissue Products]
    - Products not sold as "medical devices" but used as "medical devices" [i.e., Virtual Reality Headsets]
    - Software, Algorithms, Artificial Intelligence, or Mobile Apps used as "medical devices" [i.e., Diagnostic Algorithms]

Contact Elizabeth Gendel for guidance - Elizabeth.M.Gendel@uth.tmc.edu - (713) 500-3587

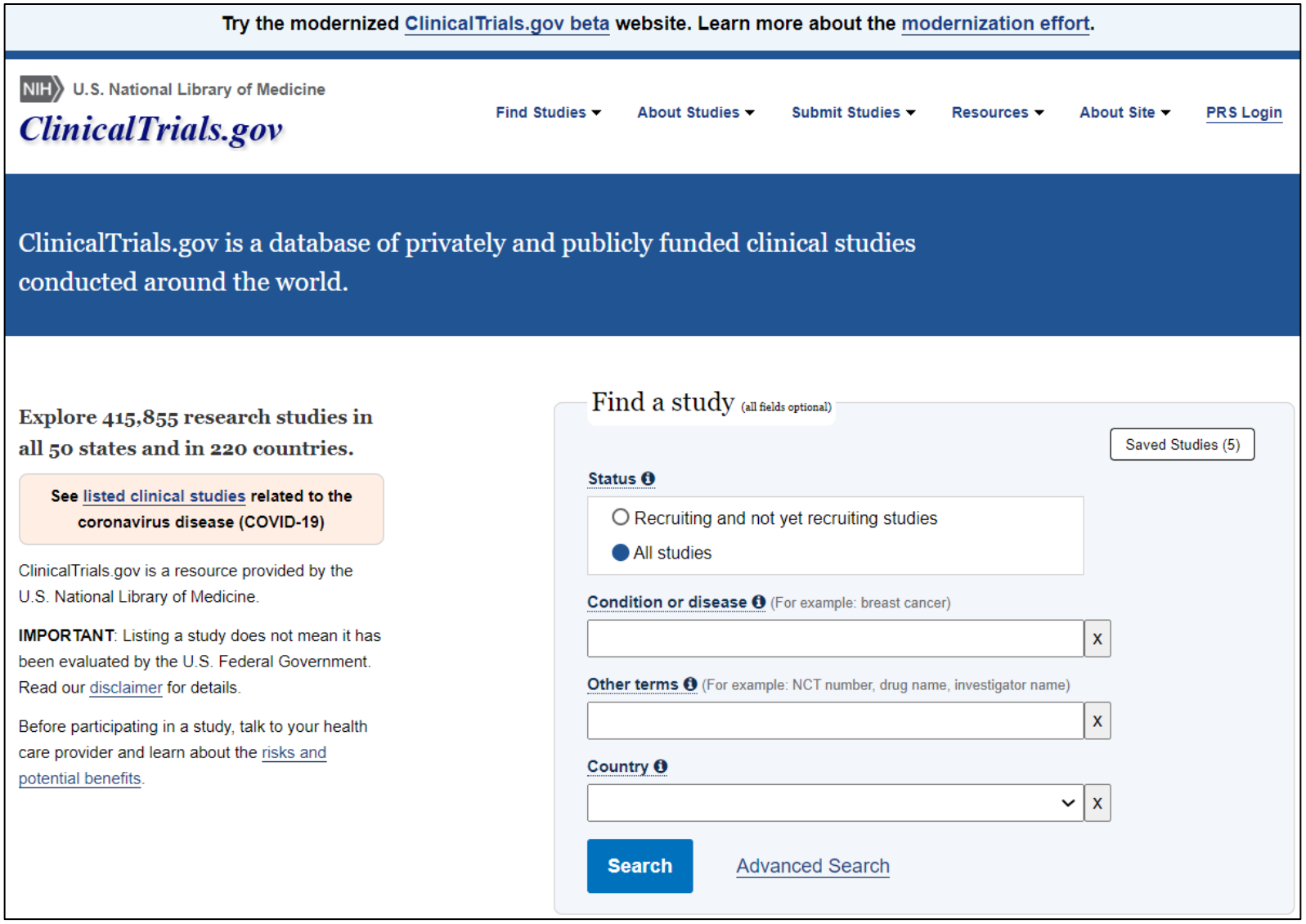
FDA INDs and IDEs
Reporting

- **For studies conducted under an FDA IND or IDE held by the UTHealth PI, the UTHealth PI is responsible for submitting various reports to FDA, per the regulations:**
  - Annual Reports
  - Safety Reports
  - Protocol Amendments
  - Changes to Investigators
  - Changes to the Study Product
  - New Pharmacology-Toxicology or New Clinical Information
  - Withdrawal of the IND or IDE

There are specific requirements for what to submit and how to submit to FDA, with major differences between submissions for INDs (drugs) and IDEs (devices).
Elizabeth Gendel and Jessica Martinez of CTRC Can Assist

ClinicalTrials.gov

ClinicalTrials.gov is a Public Database of Clinical Trials



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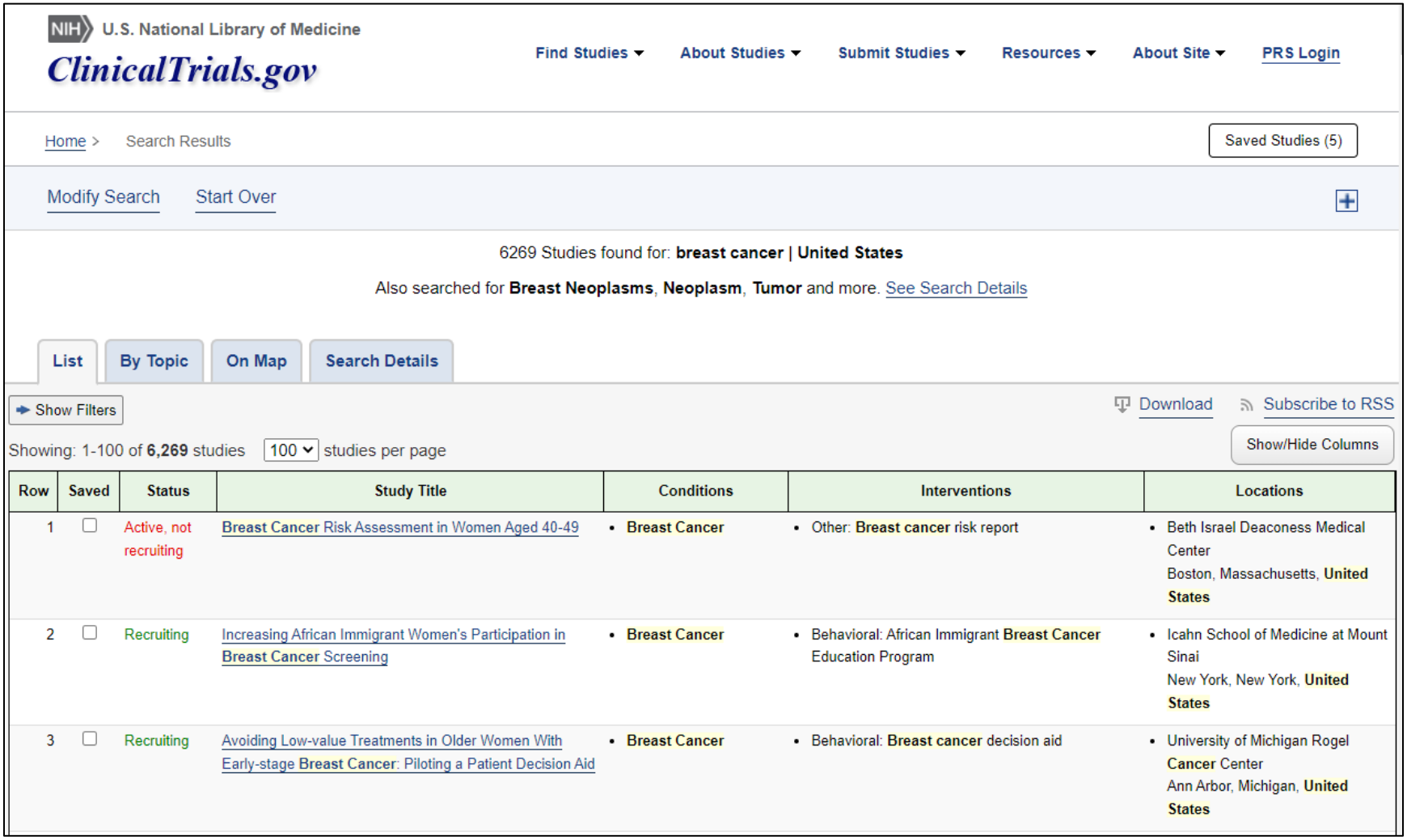

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site | PRS Login

Home > Search Results

Saved Studies (5)

Modify Search | Start Over

6269 Studies found for: **breast cancer | United States**

Also searched for **Breast Neoplasms**, **Neoplasm**, **Tumor** and more. See Search Details

List | By Topic | On Map | Search Details

Show Filters

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Showing: 1-100 of **6,269** studies 100 studies per page

Show/Hide Columns

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Active, not recruiting	Breast Cancer Risk Assessment in Women Aged 40-49	• **Breast Cancer**	• Other: **Breast cancer** risk report	• Beth Israel Deaconess Medical Center Boston, Massachusetts, **United States**
2	☐	Recruiting	Increasing African Immigrant Women's Participation in **Breast Cancer** Screening	• **Breast Cancer**	• Behavioral: African Immigrant **Breast Cancer** Education Program	• Icahn School of Medicine at Mount Sinai New York, New York, **United States**
3	☐	Recruiting	Avoiding Low-value Treatments in Older Women With Early-stage **Breast Cancer**: Piloting a Patient Decision Aid	• **Breast Cancer**	• Behavioral: **Breast cancer** decision aid	• University of Michigan Rogel **Cancer** Center Ann Arbor, Michigan, **United States**

Once a Trial is Registered, it is Assigned an NCT

NCT # stands for National Clinical Trial #

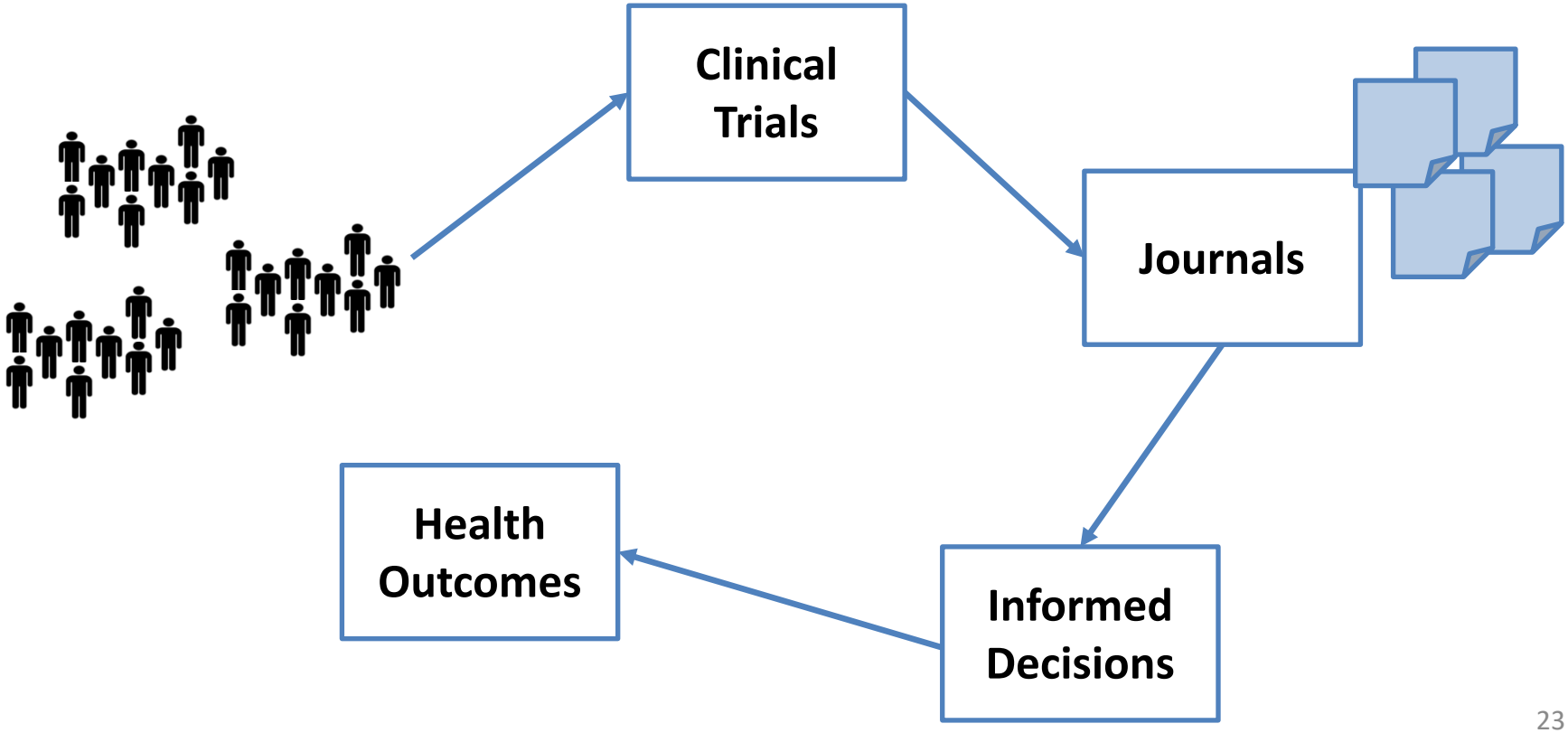
NCT00000000

ClinicalTrials.gov Record Life Cycle

- **REGISTER**
  - *before enrollment begins*
- **UPDATE RECORD**
  - *At least once per year until data collection is completed*
- **ENTER RESULTS**
  - *1 year after the date that last piece of primary outcome data was collected*

Why Register and Report Results? Public Benefits

- Contribute research results to medical knowledge
- Support evidence-based medical decision making
- Fulfill ethical obligations to participants
- Reduce publication and reporting biases



Why Register and Report Results at ClinicalTrials.gov?

- It's the **law**! *enforceable by fines*
- **NIH** funding can be terminated or withheld
- It can affect the ability to publish in a medical **journals**
  - ICMJE = International Committee of Medical Journal Editors
- An NCT # is required by **CMS** for claims for research-related procedures
- **To Avoid Public Shaming** for Late Results: https://fdaaa.trialstracker.net/
- Required per UTHealth's **HOOP 186**
- Can serve as a **recruiting** tool

FDA Penalties for Late ClinicalTrials.gov Results

- FDA fines of **$14,262** plus **$14,262 per day thereafter**
- FDA performs inspections of ClinicalTrials.gov records

FDA Sends Noncompliance Letters to "Responsible Party"

1. **FDA Pre-Notice of Noncompliance Letter**
   - 30 days to correct
   - Not publicly identified in ClinicalTrials.gov

2. **FDA Notice of Noncompliance Letter**
   - 30 days to correct
   - Publicly identified in ClinicalTrials.gov
     - Correction or penalty noted in ClinicalTrials.gov
   - Letter publicly posted on FDA website

3. **Monetary Enforcement by FDA**
   - Up to **$14,262** per day
   - Noted in ClinicalTrials.gov

FDA Website Lists All People Who've Received a Pre-Notice:
https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/pre-notices-potential-noncompliance

FDA Website Lists All People Who've Received a Notice or Monetary Penalty:
https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions#:~:text=FDA%20has%20the%20authority%20to,or%20misleading%20clinical%20trial%20information

FDA Website Lists Names of People/Companies Who Have Received Letters or Penalties

ClinicalTrials.gov - Notices of Noncompliance and Civil Money Penalty Actions

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Federal law requires responsible parties to submit registration and summary results information to the ClinicalTrials.gov data bank for certain applicable clinical trials. The law also requires a submitter of certain applications/submissions to FDA certify that all the above-referenced requirements have been met for applicable clinical trials referenced in such applications/submissions. FDA has the authority to issue a Notice of Noncompliance to a responsible party for failure to comply with certain requirements, including:

- Failing to submit required clinical trial information
- Submitting false or misleading clinical trial information

FDA also has the authority to issue a Notice of Noncompliance to a submitter who has failed to submit or knowingly submitted a false certification to FDA.

FDA has authority to assess civil money penalties for these violations. If a responsible party does not take adequate corrective action within 30 days after receiving a Notice of Noncompliance regarding failure to submit required information, that responsible party may be subject to additional civil money penalties.

FDA will take into consideration any corrective action that is taken by a responsible party after receiving a Notice of Noncompliance when considering civil money penalties. See Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank and 21 CFR part 17 for more information.

Notices of Noncompliance

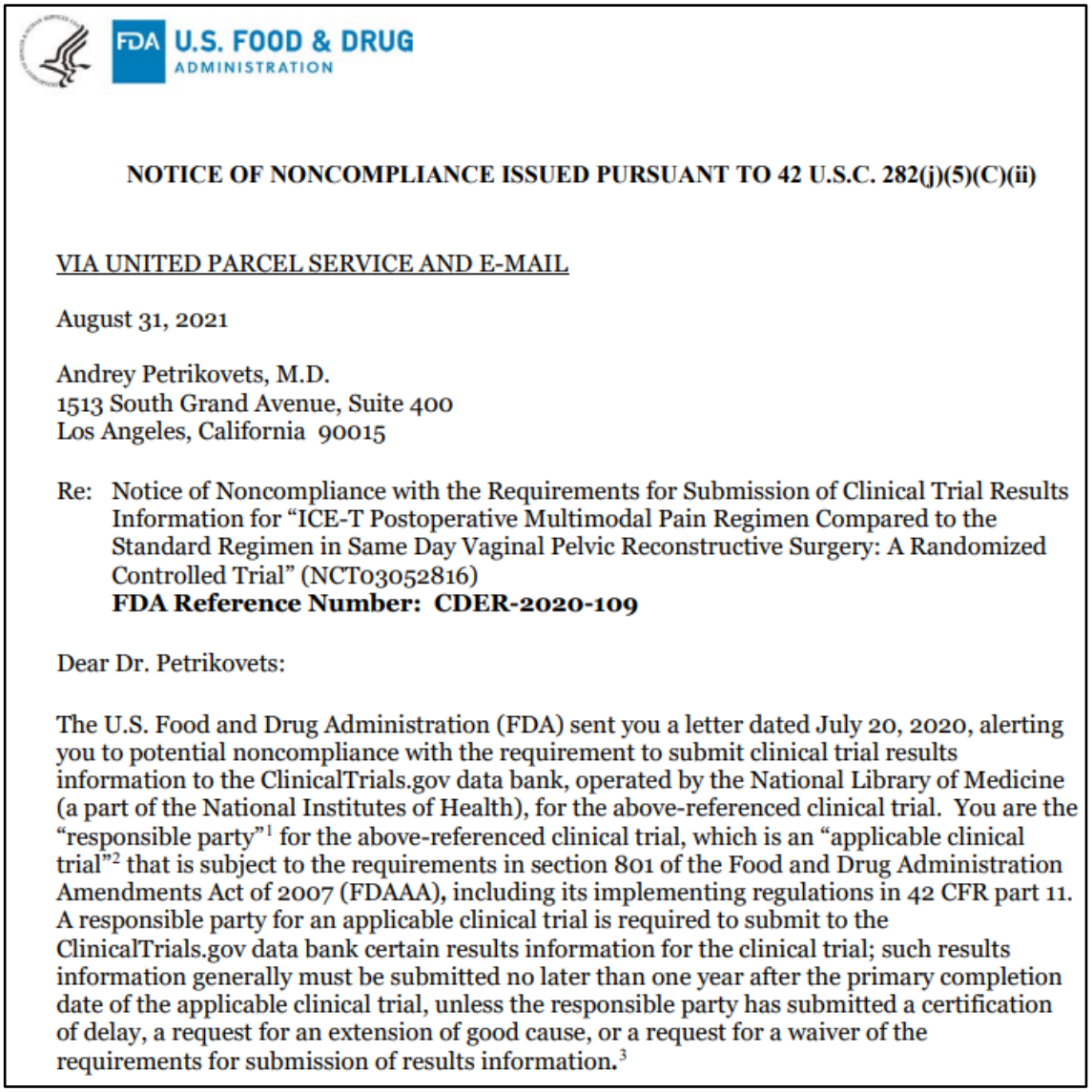
The table below lists the Notices of Noncompliance sent by FDA and the amount of civil money penalties assessed, if any, for each responsible party or submitter listed.

Responsible Party/Submitter	NCT Number	Notice of Noncompliance	Response Letter (if any)	Civil Money Penalty Amount (if any)
Ocugen	NCT03785340	4/15/2022	08/01/2022	
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021	12/20/2021	
Accuitis Inc.	NCT03064438	7/26/2021	05/26/2022	
Acceleron Pharma, Inc.	NCT01727336	4/27/2021	12/13/2021	

Notices and Monetary Penalties:
https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions#:~:text=FDA%20has%20the%20authority%20to,or%20misleading%20clinical%20trial%20information

Pre-Notices:
https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/pre-notices-potential-noncompliance

On 8/31/21, FDA Issued the First **Notice of Noncompliance** ***to an Individual Investigator***



FDA U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF NONCOMPLIANCE ISSUED PURSUANT TO 42 U.S.C. 282(j)(5)(C)(ii)

VIA UNITED PARCEL SERVICE AND E-MAIL

August 31, 2021

Andrey Petrikovets, M.D.
1513 South Grand Avenue, Suite 400
Los Angeles, California 90015

Re: Notice of Noncompliance with the Requirements for Submission of Clinical Trial Results Information for "ICE-T Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Same Day Vaginal Pelvic Reconstructive Surgery: A Randomized Controlled Trial" (NCT03052816)
FDA Reference Number: CDER-2020-109

Dear Dr. Petrikovets:

The U.S. Food and Drug Administration (FDA) sent you a letter dated July 20, 2020, alerting you to potential noncompliance with the requirement to submit clinical trial results information to the ClinicalTrials.gov data bank, operated by the National Library of Medicine (a part of the National Institutes of Health), for the above-referenced clinical trial. You are the "responsible party"[1] for the above-referenced clinical trial, which is an "applicable clinical trial"[2] that is subject to the requirements in section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), including its implementing regulations in 42 CFR part 11. A responsible party for an applicable clinical trial is required to submit to the ClinicalTrials.gov data bank certain results information for the clinical trial; such results information generally must be submitted no later than one year after the primary completion date of the applicable clinical trial, unless the responsible party has submitted a certification of delay, a request for an extension of good cause, or a request for a waiver of the requirements for submission of results information.[3]

Link to FDA Letter

Link to STAT article

Link to all Notices of Noncompliance

Effects on Federal Funding

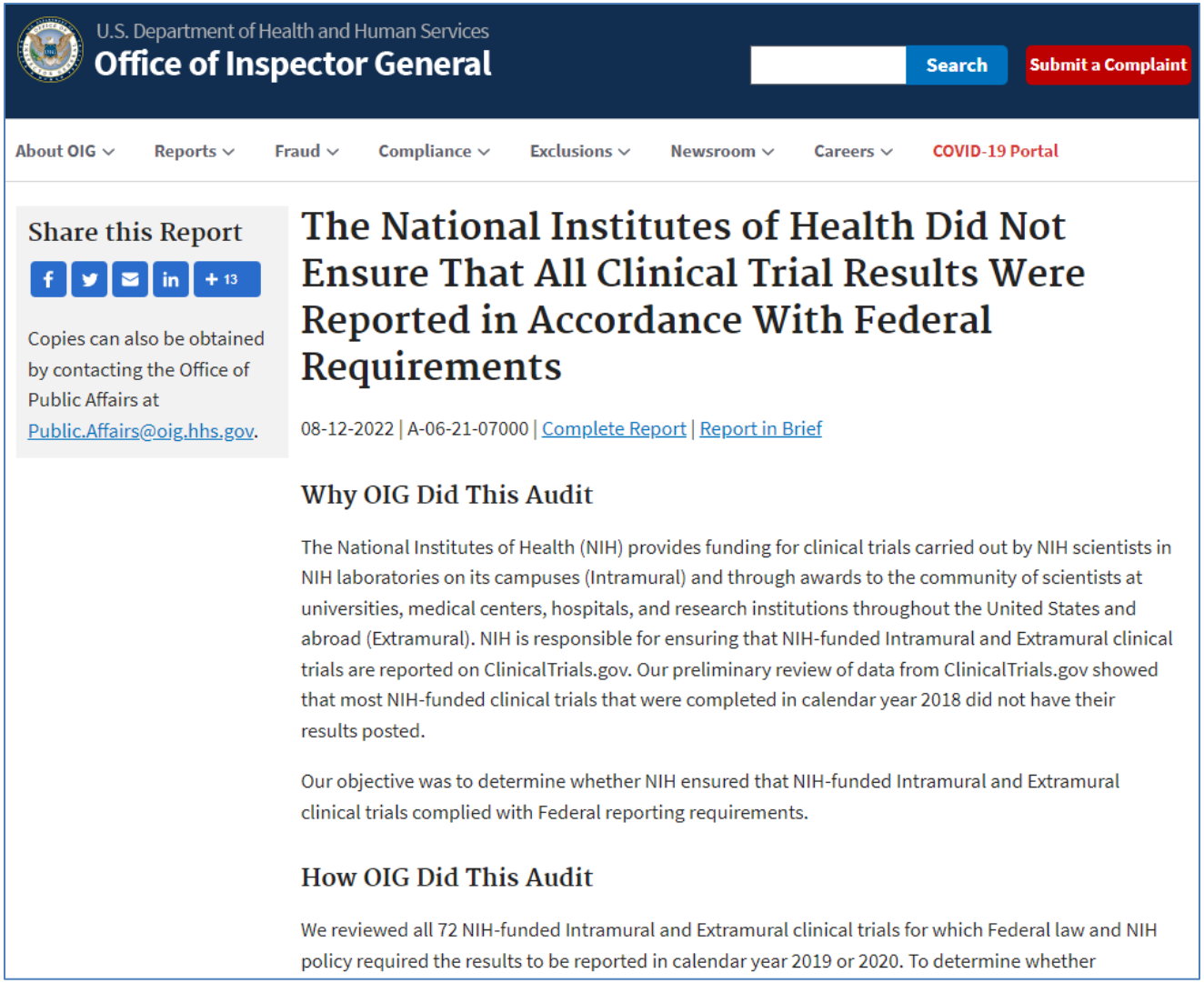
- Federal grant funding can be withheld
- Suspension or termination of NIH funding
- May affect future NIH funding decisions
- Enforcement by NIH at the institutional level

  "NIH will withhold clinical trial funding to grantee institutions if the agency is unable to verify adequate registration and results reporting from all trials funded at that institution."

  JAMA: Toward a New Era of Trust and Transparency in Clinical Trials - Kathy Hudson, Michael Lauer, Francis Collins

  http://jamanetwork.com/journals/jama/fullarticle/2553888?guestAccessKey=554e0981-9434-45f2-b122-d0e673cd1182

OIG Audited NIH Performance



U.S. Department of Health and Human Services
Office of Inspector General

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Copies can also be obtained by contacting the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance With Federal Requirements

08-12-2022 | A-06-21-07000 | Complete Report | Report in Brief

Why OIG Did This Audit

The National Institutes of Health (NIH) provides funding for clinical trials carried out by NIH scientists in NIH laboratories on its campuses (Intramural) and through awards to the community of scientists at universities, medical centers, hospitals, and research institutions throughout the United States and abroad (Extramural). NIH is responsible for ensuring that NIH-funded Intramural and Extramural clinical trials are reported on ClinicalTrials.gov. Our preliminary review of data from ClinicalTrials.gov showed that most NIH-funded clinical trials that were completed in calendar year 2018 did not have their results posted.

Our objective was to determine whether NIH ensured that NIH-funded Intramural and Extramural clinical trials complied with Federal reporting requirements.

How OIG Did This Audit

We reviewed all 72 NIH-funded Intramural and Extramural clinical trials for which Federal law and NIH policy required the results to be reported in calendar year 2019 or 2020. To determine whether

https://oig.hhs.gov/oas/reports/region6/62107000.asp

OIG Report on NIH performance

What OIG Recommends and NIH Comments

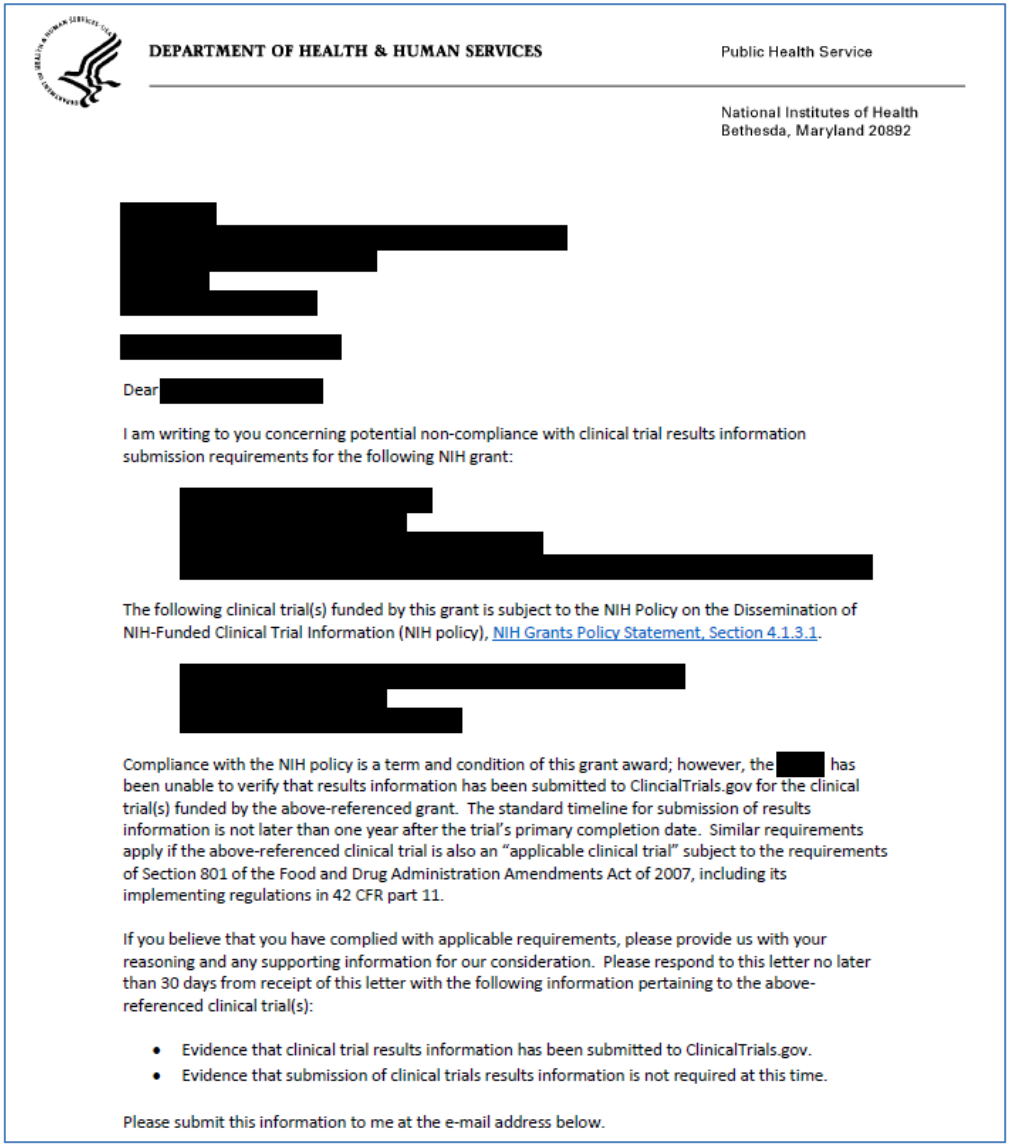
We recommend that NIH (1) improve its procedures to ensure that responsible parties of NIH-funded clinical trials comply with requirements to submit results to ClinicalTrials.gov in a timely manner, (2) take enforcement actions against responsible parties that are late in submitting trial results or do not submit results, and (3) work with the responsible parties to understand their challenges related to ClinicalTrials.gov and implement procedures to address the challenges.

In written comments on our draft report, NIH concurred with our recommendations and described the actions it has taken or plans to take to address them. For example, NIH stated it has begun to implement improvements to its internal procedures and activities to enhance its ability to take compliance action against responsible parties out of compliance.

https://oig.hhs.gov/oas/reports/region6/62107000.asp

Recent NIH Actions to Enhance Compliance

NIH is Sending Letters to Institutions' Sponsored Projects Offices



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

[redacted]

Dear [redacted]

I am writing to you concerning potential non-compliance with clinical trial results information submission requirements for the following NIH grant:

[redacted]

The following clinical trial(s) funded by this grant is subject to the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NIH policy), NIH Grants Policy Statement, Section 4.1.3.1.

[redacted]

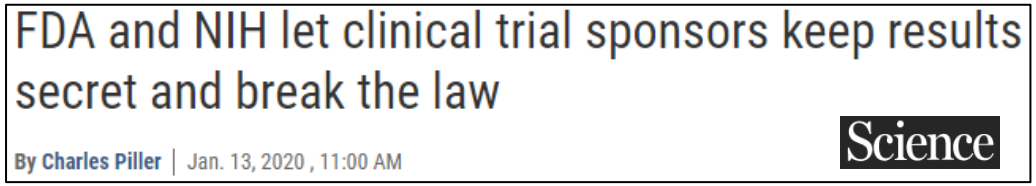
Compliance with the NIH policy is a term and condition of this grant award; however, the [redacted] has been unable to verify that results information has been submitted to ClincialTrials.gov for the clinical trial(s) funded by the above-referenced grant. The standard timeline for submission of results information is not later than one year after the trial's primary completion date. Similar requirements apply if the above-referenced clinical trial is also an "applicable clinical trial" subject to the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007, including its implementing regulations in 42 CFR part 11.

If you believe that you have complied with applicable requirements, please provide us with your reasoning and any supporting information for our consideration. Please respond to this letter no later than 30 days from receipt of this letter with the following information pertaining to the above-referenced clinical trial(s):

- Evidence that clinical trial results information has been submitted to ClinicalTrials.gov.
- Evidence that submission of clinical trials results information is not required at this time.

Please submit this information to me at the e-mail address below.

Steady Stream of Public Shaming


FDA and NIH let clinical trial sponsors keep results secret and break the law

By Charles Piller | Jan. 13, 2020 , 11:00 AM

Science


The New York Times

OPINION

Biden Made a Promise to Scientists. He Can Still Keep It.

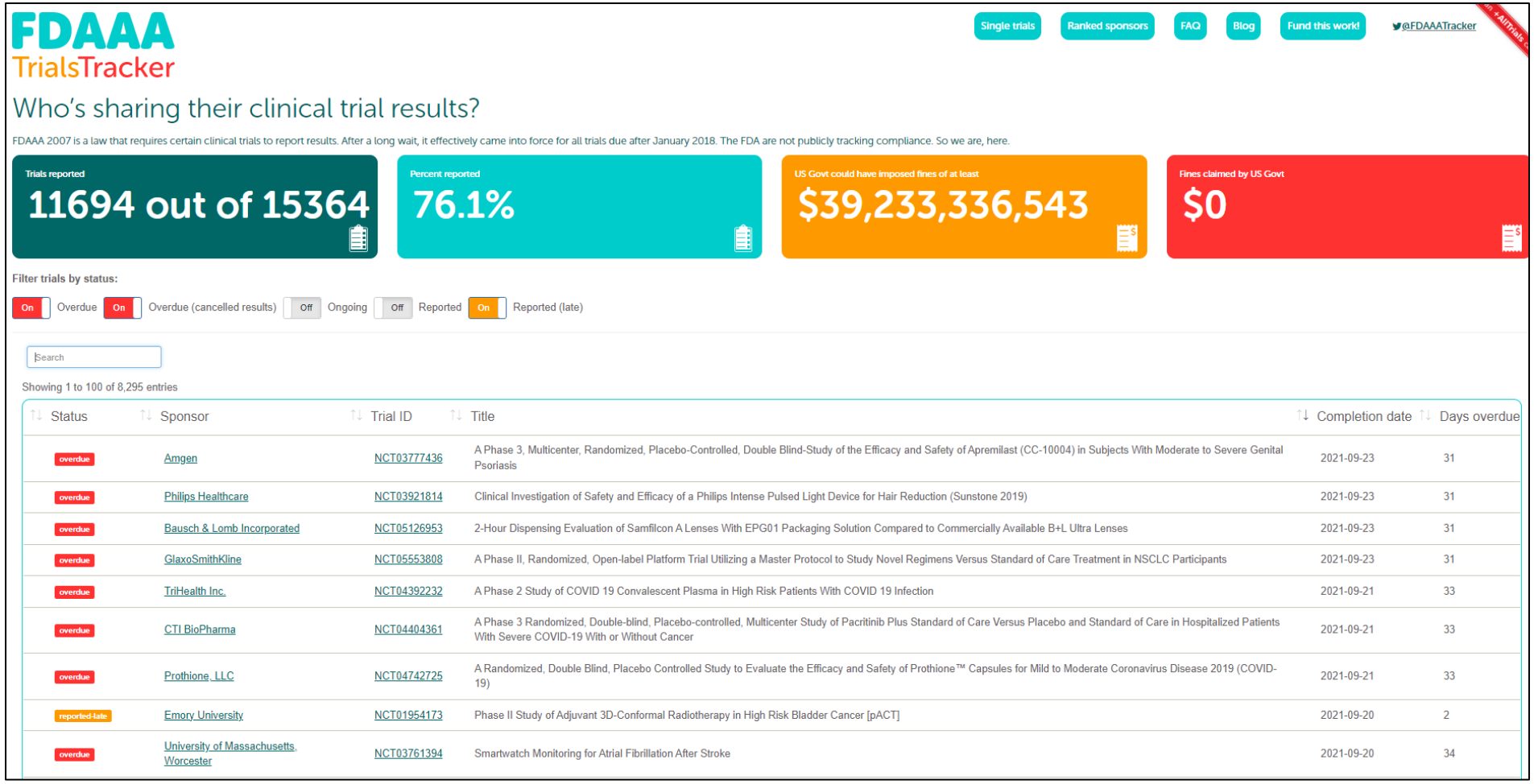
Researchers who receive federal help consistently fail to report their results to the public. The government should hold them accountable.

April 8, 2021

- Robert Califf et al., NEJM report (2015)
- Charles Piller, STAT report (2015)
- Harlan Krumholz, BMJ report (2016)
- Ben Goldacre, first TrialsTracker report (2016)
- Charles Piller/Talia Bronshtein, STAT report (2018)
- Holly Fernandez Lynch, STAT editorial (2018)
- Ben Goldacre of University of Oxford, FDAAA TrialsTracker site launched (2018)
  - Open letter to FDA
  - BMJ unreported trial of the week
- TranspariMED and UAEM report (2019)
  - Nature report on TranspariMED/UAEM findings (2019)
- John P.A. Ioannidis of Stanford, Annals of Internal Medicine report (2019)
  - Harlan Krumholz of Yale, Annals of Internal Medicine editorial (2019)
- Charles Piller, Science report (2020)
- Charles Piller, NY Times editorial (2021)
- TranspariMED and UAEM report #2 (2021)
- Reshma Ramachandran, JAMA report (2021)

Public Shaming Website for Late Results

https://fdaaa.trialstracker.net/



FDAAA TrialsTracker

Single trials | Ranked sponsors | FAQ | Blog | Fund this work! | @FDAAATracker

Who's sharing their clinical trial results?

FDAAA 2007 is a law that requires certain clinical trials to report results. After a long wait, it effectively came into force for all trials due after January 2018. The FDA are not publicly tracking compliance. So we are, here.

Trials reported	Percent reported	US Govt could have imposed fines of at least	Fines claimed by US Govt
11694 out of 15364	76.1%	$39,233,336,543	$0

Filter trials by status:

On Overdue | On Overdue (cancelled results) | Off Ongoing | Off Reported | On Reported (late)

Search

Showing 1 to 100 of 8,295 entries

Status	Sponsor	Trial ID	Title	Completion date	Days overdue
overdue	Amgen	NCT03777436	A Phase 3, Multicenter, Randomized, Placebo-Controlled, Double Blind-Study of the Efficacy and Safety of Apremilast (CC-10004) in Subjects With Moderate to Severe Genital Psoriasis	2021-09-23	31
overdue	Philips Healthcare	NCT03921814	Clinical Investigation of Safety and Efficacy of a Philips Intense Pulsed Light Device for Hair Reduction (Sunstone 2019)	2021-09-23	31
overdue	Bausch & Lomb Incorporated	NCT05126953	2-Hour Dispensing Evaluation of Samfilcon A Lenses With EPG01 Packaging Solution Compared to Commercially Available B+L Ultra Lenses	2021-09-23	31
overdue	GlaxoSmithKline	NCT05553808	A Phase II, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants	2021-09-23	31
overdue	TriHealth Inc.	NCT04392232	A Phase 2 Study of COVID 19 Convalescent Plasma in High Risk Patients With COVID 19 Infection	2021-09-21	33
overdue	CTI BioPharma	NCT04404361	A Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Study of Pacritinib Plus Standard of Care Versus Placebo and Standard of Care in Hospitalized Patients With Severe COVID-19 With or Without Cancer	2021-09-21	33
overdue	Prothione, LLC	NCT04742725	A Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Prothione™ Capsules for Mild to Moderate Coronavirus Disease 2019 (COVID-19)	2021-09-21	33
reported-late	Emory University	NCT01954173	Phase II Study of Adjuvant 3D-Conformal Radiotherapy in High Risk Bladder Cancer [pACT]	2021-09-20	2
overdue	University of Massachusetts, Worcester	NCT03761394	Smartwatch Monitoring for Atrial Fibrillation After Stroke	2021-09-20	34

UTHealth's ClinicalTrials.gov Policy and Procedures

https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm

PURPOSE:

- Ensure Compliance with Law and NIH Policy
- Avoid Consequences of Non-Compliance
  - *FDA Letters of Non-Compliance and Fines*
  - *Loss of NIH and other federal funding*
  - *Inability to publish in ICMJE journal*
  - *Public shaming*
  - *CMS consequences (an NCT # is required by CMS for claims for research-related procedures)*

UTHealth's ClinicalTrials.gov Policy and Procedures

https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm

- **Policy**
  - What needs to happen, by who, and by when
  - Responsibilities of UTHealth PIs
- **Procedures**
  - How responsibilities will be met
  - How CTRC can help
  - How noncompliance will be handled

The Clinical Trials Resource Center (CTRC) Assists with ClinicalTrials.gov

CTRC - clinicaltrials@uth.tmc.edu

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Find Guidance on the CTRC ClinicalTrials.gov website:

https://www.uth.edu/ctrc/regulatory/clinicaltrials.gov-registration.htm

ClinicalTrials.gov Process at UTHealth

- **During initial IRB review, Elizabeth Gendel reviews studies that go to the full-board IRB to determine if the study must be registered at ClinicalTrials.gov**
  - *Note that expedited studies are not reviewed, but be aware that some expedited studies must be registered*
- **Shwetha Pazhoor notifies study teams if a full-board study must be registered, and provides assistance**
- **Jessica Martinez reaches out about updates, and provides assistance**
- **Jessica Martinez and Elizabeth Gendel reach out about results entry, and provide assistance**

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THANK YOU!

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