ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Submitting Results to ClinicalTrials.gov
(including some Practical Helpful Hints)

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Disclaimer!

In this presentation, I may paraphrase or talk about FDAAA 801, but this is not meant to be legal advice and should not be interpreted as such. Information about FDAMA 113 and FDAAA 801 can be found on ClinicalTrials.gov and legal council should be sought from other appropriate sources.

ClinicalTrials.gov Background

ClinicalTrials.gov Brief Timeline

- Jan 1997: FDAMA Section 113 mandates creation of a registry
- Feb 2000: ClinicalTrials.gov launched
- ClinicalTrials.gov accommodates other policies
  - International Committee of Medical Journal Editors (ICMJE) statement (2004)
  - WHO International Clinical Trials Registry Platform (ICTRP)
- Sept 2007: FDAAA Section 801 expands registry & adds results database requirements
- Sept 2008: ClinicalTrials.gov Basic Results database launched
  - Sept 2009: Serious and Other Adverse Events required

Why the need for a public database?

- Give patients access to information about clinical trials
- Reduce/eliminate publication bias
- Publically acknowledge all pre-specified outcome measures
- Publically display any changes made to a trial protocol that could affect the interpretation of the findings
  - e.g., changes to pre-specified outcome measures

Why should trials register and report results?

- Human Subjects and Public Health Benefits
  - Allows potential participants to find studies
  - Access to trial results influences medical decisions
  - Assists ethical review boards and others to evaluate studies (e.g., harms, benefits, redundancy)
  - Promote fulfillment of ethical responsibility to human volunteers – all research contributes to medical knowledge
- Scientific Research Integrity
  - Increasing transparency creates trust in research enterprise
  - Disclosure of protocol changes allows for contextualized interpretation of results
  - Keeping the existence of trials and their results hidden impedes scientific progress
  - Promotes more efficient allocation of resources

…and did we mention?

- FDAAA 801 enforcement provisions
  - Notices of non-compliance
  - Civil monetary penalties up to $10,000/day
  - Withholding of NIH grant funds
- the ability to publish research
  - ICMJE policy

Registering and Submitting Results to ClinicalTrials.gov

Which studies? Who is supposed to register and submit results?

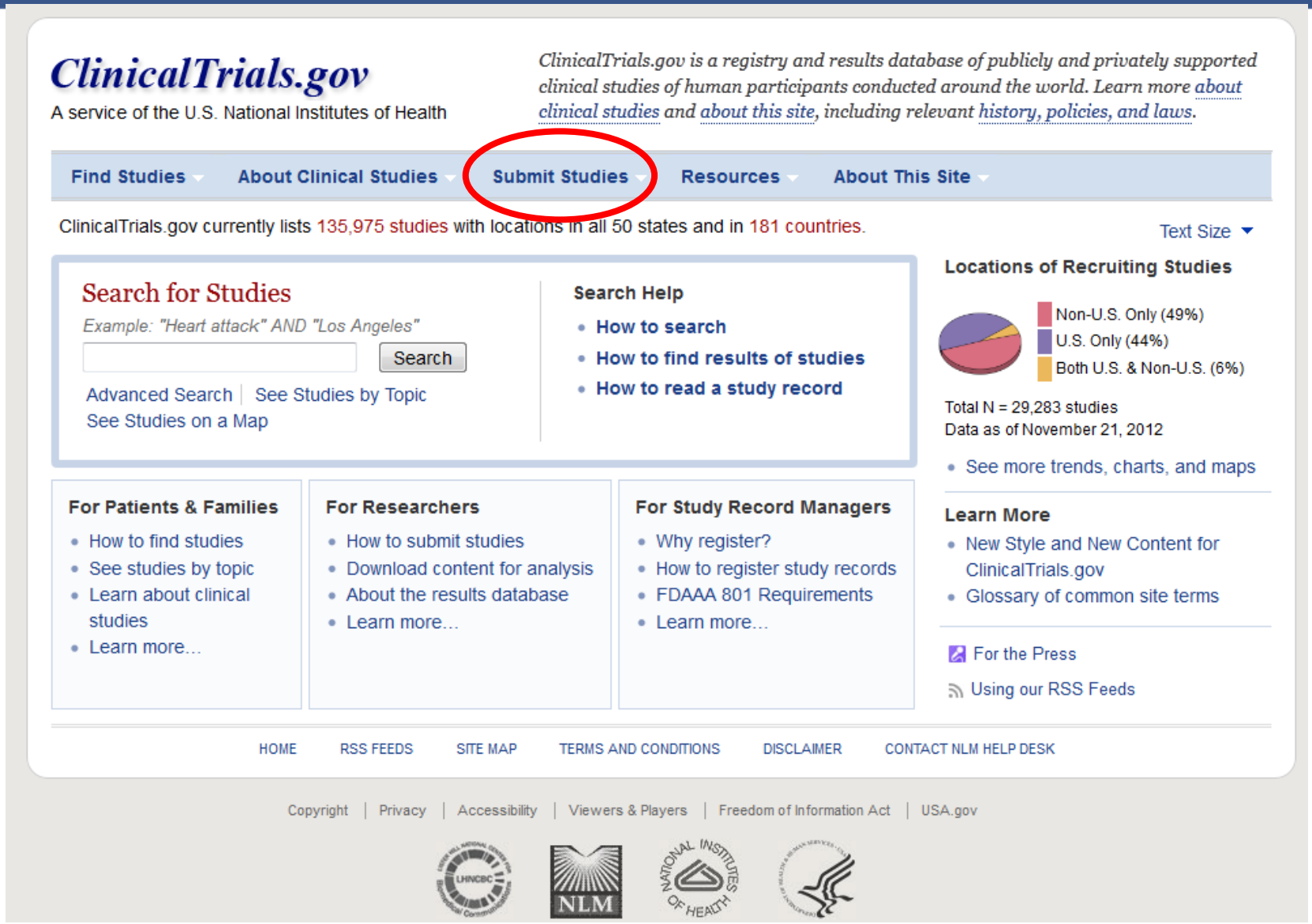
- Applicable Clinical Trials*
  - Interventional studies of drugs, biologics & devices
  - Not Phase 1 (drugs/biologics), not small feasibility (devices)
  - US FDA jurisdiction (e.g., IND/IDE or US site)
  - ACTs initiated on or after 9/27/07 or if initiated after 09/27/07, “ongoing” as of 12/26/07
- Responsible Party*
  - Sponsor [only one per trial]
  - Sponsor may designate the Principal Investigator (PI) [only one per trial]

*http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

When do I register and submit results?

- When to register
  - FDAAA 801: No later than 21 days after the first participant is enrolled
  - ICMJE: before the first participant is enrolled
- When to submit results
  - FDAAA 801: Generally, submission within 12 months of Primary Completion Date (the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome) or use official mechanisms for Delayed Submission of Results

How do I register and submit results?



SUBMIT STUDIES

Why Should I Register and Submit Results?
FDAAA 801 Requirements

How to Apply for an Account
How to Register Your Study
How to Edit Your Study Record
How to Submit Your Results

Frequently Asked Questions
Support Materials
Online Presentations

Related Pages
- Protocol Registration System (PRS)

Do you want to participate in a clinical study? See information for patients and families.

Submit Studies

ClinicalTrials.gov allows the registration of clinical studies with human subjects that conform to:

- Any applicable human subject or ethics review regulations (or equivalent) and
- Any applicable regulations of the national or regional health authority (or equivalent)

New to registering studies? See For Study Record Managers.

Why Should I Register and Submit Results?

Learn about the purpose of study registration and results submission. Includes an overview of applicable laws and policies.

FDAAA 801 Requirements

Learn about Section 801 of the Food and Drug Administration Amendments Act and the basic requirements for registering clinical trials and submitting summary results, including information about the Responsible Party, Applicable Clinical Trials, deadlines, and penalties.

How to Apply for an Account

Learn how to apply for an account to access the Protocol Registration System (PRS), the Web-based

https://register.clinicaltrials.gov

ClinicalTrials.gov
Protocol Registration System

Login

Welcome to the ClinicalTrials.gov Protocol Registration System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
Burden Statement

Organization:
Username:
Password: Forgot password

Login

PRS account registration information

Send email to ClinicalTrials.gov Administration

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

What does it look like?

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **8 of 231** for: Studies With Results | massachusetts general
◂ Previous Study | Return to List | Next Study ▸

Early Intervention for Children at Risk for Anxiety

This study has been completed.

Sponsor:
Massachusetts General Hospital

Collaborator:
National Institute of Mental Health (NIMH)

Information provided by:
Massachusetts General Hospital

ClinicalTrials.gov Identifier:
NCT00865306

First received: March 17, 2009
Last updated: September 22, 2010
Last verified: September 2010
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

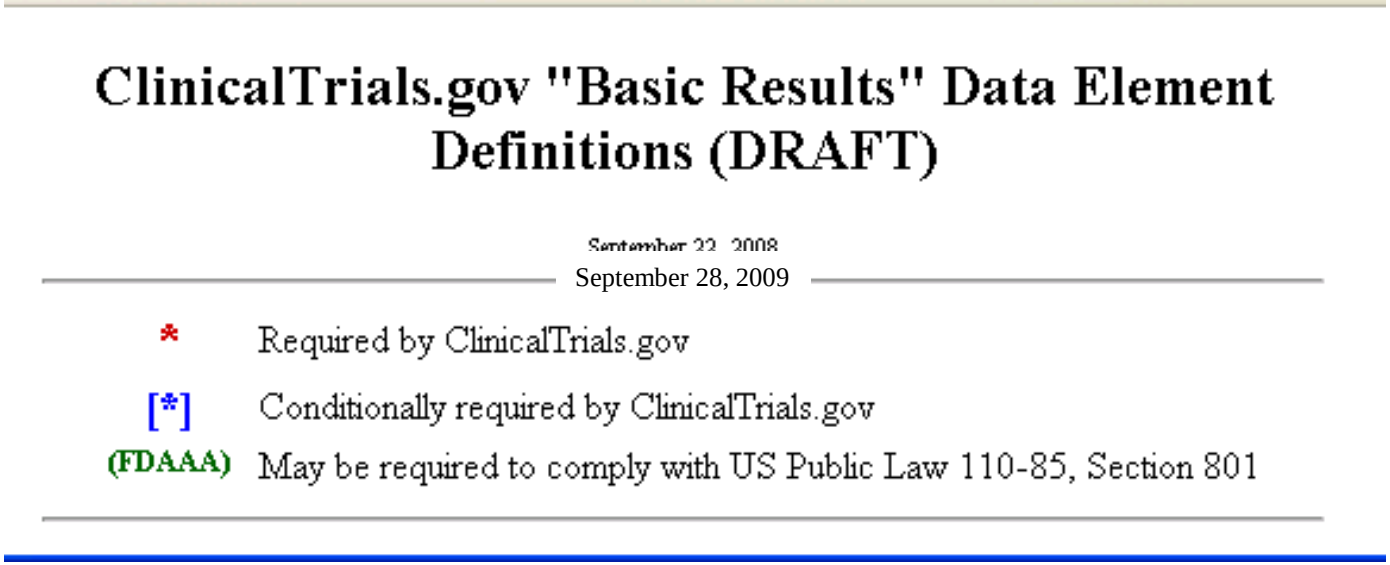
What results do I submit?

- Participant Flow
- Baseline and Demographic Characteristics
- Outcome Measures
- Adverse Events (summary data)
- Other Information
  - "Certain Agreements" related to *Restrictions on Results Disclosure*
  - Overall Limitations and Caveats
  - Results Point of Contact

Helpful Hint: Use the **Simple Results Templates** (On ClinicalTrials.gov, under Submit Studies, Support Materials) to organize your information before starting PRS data entry

Basic Results: Data Elements

http://prsinfo.clinicaltrials.gov/results_definitions.html



ClinicalTrials.gov "Basic Results" Data Element Definitions (DRAFT)

~~September 22, 2008~~
September 28, 2009

*	Required by ClinicalTrials.gov
[*]	Conditionally required by ClinicalTrials.gov
(FDAAA)	May be required to comply with US Public Law 110-85, Section 801

Go to ClinicalTrials.gov

→ Submit Studies

→ Support Materials

→ Protocol Registration System (PRS) Information

→ Data Element Definitions

Participant Flow

"A table ..., including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any."

[Sec. 282(j)(3)(C)(i)]

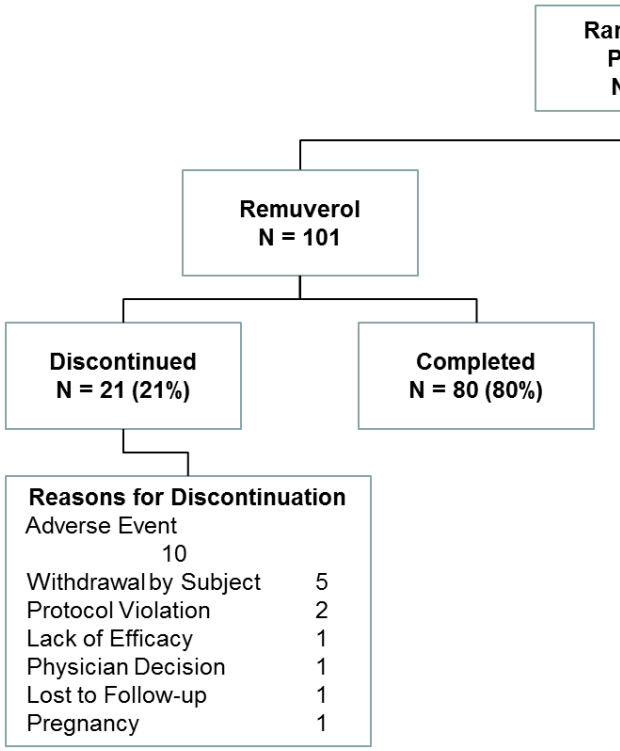


Figure 1. Enrollment, Randomization, and

Participant Flow

Recruitment Details -- *Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations:*

Participants were recruited based on physician referral at 3 academic medical centers between February 2010 and January 2011. The first participant was enrolled in March 2010, and the last participant was enrolled in December 2010.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Overall Study

	Remuverol	Placebo
STARTED	101	99
Per Protocol Population Week 12	98	95
Per Protocol Population Week 24	76	81
COMPLETED	80	81
Not Completed	**21**	**18**
Adverse Event	10	8
Withdrawal by Subject	5	4
Protocol Violation	2	2
Lack of Efficacy	1	1
Physician Decision	1	1
Lost to Follow-up	1	2
Pregnancy	1	0

What if I have a complicated Participant Flow?

Helpful Hints:

- Each Arm/Group is a unique “experience” a participant could have had as they progressed through the study. (e.g., the sequences in a crossover, the interventions in a parallel study, the doses in a dose escalation, etc.) The number of Arm/Groups is generally equal to the number of “paths” a participant can take from Enrollment to Completion in a CONSORT flow diagram.
- Some study design examples on ClinicalTrials.gov. Go to:
  - → Submit Studies
  - → Training Materials
  - → Results Database Train-the-Trainer Workshop
  - → Example Studies for Results Data Entry
- Email us: register@clinicaltrials.gov

Some Participant Flow Data Elements of Note

Period(s)

- Each Period = a distinct stage of the study.
- # Periods = # times that participants changed their assigned interventions and/or the manner in which they were receiving an intervention (e.g., Double Blind to Open Label Periods). *Note: most studies only need one Period.*

Milestone(s)

- Each Milestone (row) = a key point in the study (Started, Completed)
- “Started” is typically initial assignment/randomization of participants
- Additional Milestones are used for important events (e.g., Received at least one intervention dose) and/or analysis populations (e.g., Safety Analysis Population) within the study.
- “Completed” is how many of the participants in that column finished the period
- “Not Completed” is calculated automatically (Started minus Completed)

Baseline Measures

"A table of the demographic and baseline data collected overall and for each arm of the clinical trial…"

[Sec. 282(j)(3)(C)(i)]

Table 1. Baseline Demographics and Disease C

CHARACTERISTIC
Age, years, mean (SD)
Sex, n (%)
Female
Ethnicity, n (%)
African
Caucasian
Hispanic
Native American
Region of Enrollment, n (%)
United States
Canada
Mexico
QTF Classification of Spinal Disorder*
Class 0, n (%) – *no pain*
Class 1, n (%) – *pain without radiation*
Class 2, n (%) - *pain with proximal extremity radiation*
Body Mass Index (BMI), kg/m2, mean (SD)

Baseline Measures

	Remuverol	Placebo	Total
Number of Participants	101	99	**200**
Age, Continuous *[units: years]* *Mean ± Standard Deviation*	34.78 ± 9.72	35.34 ± 10.71	**34.98 ± 9.89**
Gender, Male/Female *[units: participants]*			
Female	60	63	**123**
Male	41	36	77
Race/Ethnicity, Customized *[units: participants]*			
African	5	4	**9**
Caucasian	90	90	**180**
Hispanic	5	4	**9**
Native American	1	1	**2**
Region of Enrollment *[units: participants]*			
United States	44	47	**91**
Canada	35	35	**70**
Mexico	22	17	**39**
Study Specific Measure [Quebec Task Force Classification of Spinal Disorders] [1] *[units: participants]*			
Class 0 (no pain)	16	14	**30**
Class 1 (pain without radiation)	73	68	**141**
Class 2 (pain with proximal extremity radiation)	12	17	**29**
Study Specific Measure [Body Mass Index] *[units: kg/m^2]* *Mean ± Standard Deviation*	26.65 ± 4.50	27.41 ± 4.72	**26.91 ± 4.55**

Outcome Measure

"…a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial…"

[Sec. 282(j)(3)(C)(ii)]

Statistical Analysis

"…a table of values for each of the primary and secondary outcome measures…, including the results of scientifically appropriate tests of the statistical significance of such outcome measures."

[Sec. 282(j)(3)(C)(ii)]

Table 2: Mean Change f
with Condition A

MEASURE	N
Change in SPS-11 Score: Baseline to Week 24	101

* Mixed Models Analysis

Table 3: SPS-11 Pain Re

	RE
TIME FRAME	N
Week 12	98
Week 24	76
	RE
Week 24	76

* Fisher Exact

1. Primary Outcome Measure:

Measure Title	**Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24**
Measure Description	SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score - Baseline score)
Time Frame	Baseline and Week 24
Safety Issue?	No

Analysis Population Description -- *Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate:*

Intent to treat population (all participants who received at least one dose of intervention). Last observation carried forward (LOCF) imputation method.

Reporting Groups

	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Measured Values

	Remuverol	**Placebo**
Number of Participants Analyzed	101	99
Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24 *[units: units on a scale]* Mean ± Standard Error	-3.84 ± 0.61	-2.08 ± 0.51

Statistical Analysis 1 for Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24

Groups	Remuverol, Placebo
Method	Mixed Models Analysis
P-Value	0.002

Additional details about the analysis, such as null hypothesis and power calculation:

It was calculated that 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test ($\alpha = 0.05$). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.

Which Outcome Measures are required?

Per FDAAA 801: Collected data for all Primary and Secondary Outcome Measures are required to be reported for an Applicable Clinical Trial whether or not the trial was terminated

Helpful Hint: You can include an “Other Pre-specified” Outcome Measure Type in Registration and/or Results, and you can include a “Post-hoc” Outcome Measure Type in Results.

Specific Example: *What if a publication includes other Outcome Measures or analyses that were not pre-specified?*

What if specific data are not calculable or not available for a field in the data table?

Helpful Hint: It is possible to insert NA into a numerical data field to indicate that data are Not Available. When you use this feature, you will need to provide a rationale regarding *why* data are not available in the free text box.

Specific Example: *If median was not reached in a "Median Time-to-Event" Outcome Measure. The rationale would be, "Not enough participants experienced the event"*

What do I submit in Outcome Measure data tables if I didn't collect any Outcome data?

Helpful Hint: Include 0 Participants Analyzed with a valid explanation in the Analysis Population Description to indicate why data were not collected.

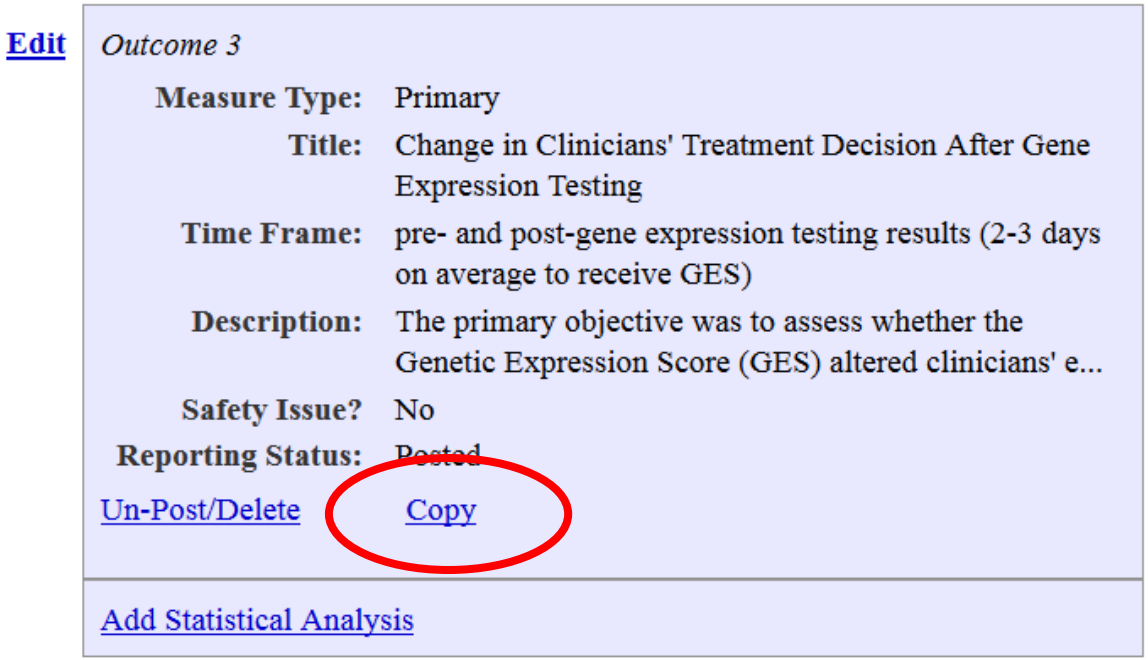
Specific Example: *If the Primary Outcome Measure was pre-specified to be measured at 4 months, but the study was terminated before any participant completed 4 months, then the Primary Outcome Data would not have been collected.*

NOTE! *Any data that actually were collected should be summarized and submitted whether or not a study was terminated. 0 Participants Analyzed should only be used if data were NOT COLLECTED.*

Are there any shortcuts for entering data?

Helpful Hints:

- "Copy" an Outcome Measure, and only edit the data elements that are different.
- You can use Categories to present multiple "rows" of the same type of data.
- XML upload feature for Results



Are Statistical Analyses Required?

Per FDAAA 801: If the trial is an Applicable Clinical Trial, then you should submit “the results of scientifically appropriate tests of the statistical significance of,” Primary and Secondary Outcome Measures

Note: We do not review for compliance! We will post a record without statistical analysis sections, but this is not a determination of compliance or even “good practice”.

Serious Adverse Events

"A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial."

[Sec. 282(j)(3)(I)(iii)(I)]

Frequent Adverse Events

"A table of anticipated and unanticipated adverse events that are not included in the [Serious Adverse Events] table … that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial."

[Sec. 282(j)(3)(I)(iii)(II)]

Reporting Groups

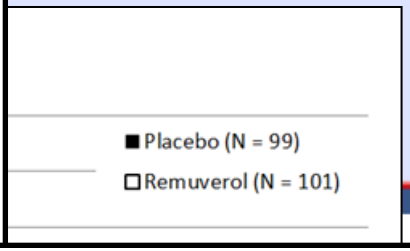
	Description
Remuverol	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.
Placebo	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

Time Frame	
Additional Description	

Serious Adverse Events

	Remuverol	Placeb
Total # participants affected/at risk	**4/101 (3.96%)**	**0/99 (0**
Blood and lymphatic system disorders		
Anemia Iron Deficiency † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0
Idiopathic Thrombocytopenic Purpura † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0
Immune system disorders		
Viral Meningitis † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0
Skin and subcutaneous tissue disorders		
Psoriasis † A		
# participants affected/at risk	1/101 (0.99%)	0/99 (0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)



Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 1%

	Remuverol	Placebo
Total # participants affected/at risk	**98/101 (97.03%)**	**46/99 (46.46%)**
Ear and labyrinth disorders		
Earache † A		
# participants affected/at risk	35/101 (34.65%)	7/99 (7.07%)
Endocrine disorders		
Hypothyroidism † A		
# participants affected/at risk	27/101 (26.73%)	25/99 (25.25%)
Eye disorders		
Conjunctivitis † A		
# participants affected/at risk	13/101 (12.87%)	4/99 (4.04%)
Gastrointestinal disorders		
Nausea † A		
# participants affected/at risk	12/101 (11.88%)	7/99 (7.07%)
Stomachache † A		
# participants affected/at risk	10/101 (9.9%)	2/99 (2.02%)
Vomiting † A		
# participants affected/at risk	10/101 (9.9%)	3/99 (3.03%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (12.0)

Why is organ system required?

FDAAA 801 says that both the Serious and Other (Non-Serious) Adverse Events tables should be "grouped by organ system"

Helpful hint: You can upload Adverse Events in a spreadsheet (Excel or general tab delimited) by following the step-by-step instructions

How can I provide more contextual information for adverse events?

Helpful Hint: Use the Additional Description free text for the Adverse Event Module and/or Adverse Event Term to provide more information.

Specific Example: *How do I convey adverse event severity and attribution?*

Time Frame	Duration of study plus follow-up, approximately 2 years total
Additional Description	Safety population includes all participants who received at least one dose. All adverse events are included whether or not they were attributed to the study intervention.

Serious Adverse Events

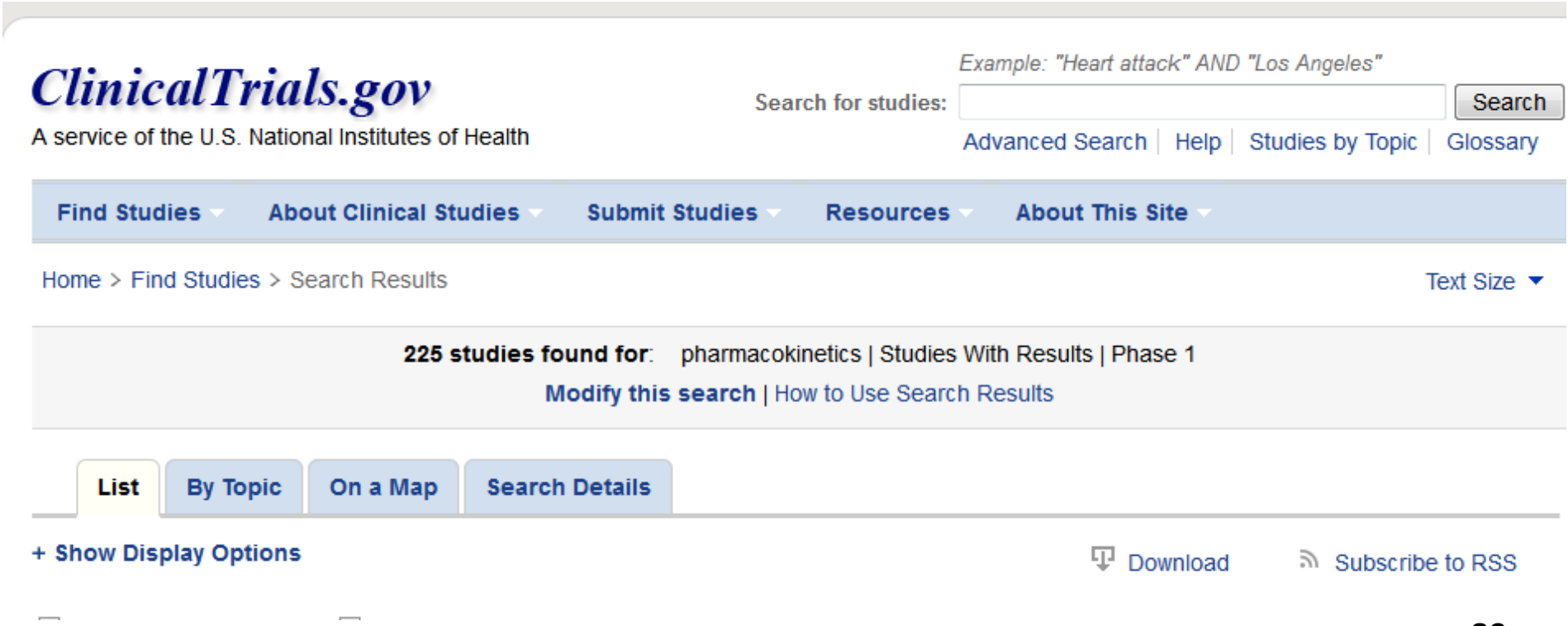
	Placebo	Hypertena
Total # participants affected/at risk	**0/23 (0%)**	**1/24 (4.17%)**
Vascular disorders		
Hypertension [1]		
# participants affected/at risk	0/23 (0%)	1/24 (4.17%)

[1] Grade 3 (SBP ≥ 180 mmHg or DBP ≥ 110 mmHg)

Are there examples available that are similar to my trial design?

Helpful Hint: Do a search on ClinicalTrials.gov!

Specific Example: *How do I report a Phase I Study with Pharmacokinetic Outcome Measures?*



Who is the Audience?

PI and Clinical Research Team

Other Medical Researchers in same field

Other Medical Researchers in other fields

General Readers of the medical literature

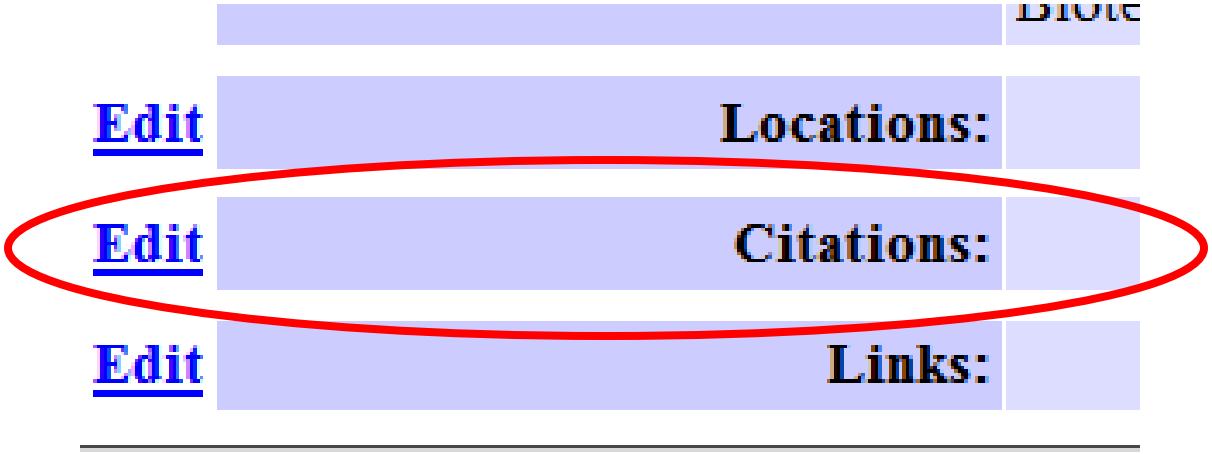
Science Writers

Lay Public (readers of consumer health literature)

Helpful Hint: From the “Edit Protocol Record” screen, use the “Preview” link to see the public view in its entirety.

How can I link to manuscript(s) with Results for more info?

Located in “Edit Protocol Record” screen:



→ Click “Edit” next to Citations
→ Click “Add” a Citation
→ Search for the manuscript, enter the PMID, or manually enter the citation text
→ Select “Yes” from the “Results Reference” drop down menu

NOTE! This can be done in addition to but NOT in lieu of entering data into PRS

How can I provide disclaimers or caveats for the submitted data?

Helpful Hint: Use the free text fields to provide contextual information, particularly the Limitations and Caveats data element.

Specific Example: *What if my study was terminated and I am reporting for transparency, but know that the data are not significant?*

Limitations and Caveats -- *Limitations of the study, such as early termination leading to small numbers of subjects analyzed and technical problems with measurement leading to unreliable or uninterpretable data:*

> Study was terminated due to lack of funding before power analysis target accrual was met. Results are reported for transparency only, and should not be used to extrapolate significant conclusions.

Protocol and Results Review

- Protocol and results must be clear and informative
- Review focuses on:
  - Logic and internal consistency
  - Apparent validity
  - Meaningful entries
  - Formatting
- Note: Review is NOT “peer review” and is NOT a determination of compliance

Results QA Review

(i.e., What kinds of things are we trying to prevent in QA Review?)

Example 1
Participant Flow and Outcome Measure Before QA Review

Participant Flow

Reporting Groups

	Description
A. High Intensive Exercise	High intensive exercise
B. Low-intensive Exercise	Low-to-moderate intensive supervised walks

Overall Study

	A. High Intensive Exercise	B. Low-intensive Exercise
STARTED	34	33
COMPLETED	29	29
Not Completed	**5**	**4**
Lost to Follow-Up	5	4

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Physical Function**
Measure Description	Six-minute walk test
Time Frame	15 weeks
Safety Issue?	No

Reporting Groups

	Description
Exercise	

Measured Values

	Exercise
Number of Participants Analyzed	58
Physical Function [*units: meter*] Mean ± Standard Deviation	37.7 ± 41.8

Example 1
Outcome Measure After QA Review

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Six-minute Walk Test**
Measure Description	Patient is instructed to walk as fast as she can. The distance covered during 6 minutes is documented.
Time Frame	15 weeks
Safety Issue?	No

Reporting Groups

	Description
Arm A. Exercise	The intervention group participated in Nordic walking
Arm B. Active Comparator	The active comparison group participated in low-intensive walks.

Measured Values

	Arm A. Exercise	**Arm B. Active Comparator**
Number of Participants Analyzed	29	29
Six-minute Walk Test [*units: meter*] Mean ± Standard Deviation	37.7 ± 41.8	8.6 ± 42.2

Example 2
Outcome Measure Before QA Review

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Change in Biomarkers of Breast Cancer and Cancer Progression**
Measure Description	
Time Frame	Typically 4-6 weeks
Safety Issue?	No

Reporting Groups

	Description
Group 1	

Measured Values

	Group 1
Number of Participants Analyzed	32
Change in Biomarkers of Breast Cancer and Cancer Progression [*units: participants*]	19

Example 2
Outcome Measure After QA Review

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Change in Serum VEGF in Breast Cancer**
Measure Description	Change in serum VEGF from baseline to post treatment with polyphenon E.
Time Frame	Baseline and 4 to 6 weeks
Safety Issue?	No

Reporting Groups

	Description
ECGC and Breast Cancer	Single arm for a phase II study of EGCG extract and breast cancer. Subjects are asked to take 4 polyphenol E (200mg) capsules daily with a meal for the duration of the study. Biomarkers are measured at baseline and then again at presurgery, the end point for the study.

Measured Values

	ECGC and Breast Cancer
Number of Participants Analyzed	58
Change in Serum VEGF in Breast Cancer [*units: pg/ml*] Median (Inter-Quartile Range)	270 (-142.5 to 581.25)

Example 3
Outcome Measure Before QA Review

- **Outcome Measures**

1. Primary Outcome Measure:

Measure Title	**Compare the Change in Hemoglobin A1c and the Proportion of Patients Achieving A1C < 7%**
Measure Description	A1C and the proportion of patients achiving A1C < 7% will be measured at baseline and after 12 and 24 weeks of treatment.
Time Frame	24 weeks
Safety Issue?	Yes

Reporting Groups

	Description
Sitagliptin	add sitagliptin100mg/d to pre-study OADs
Pioglitazone	add pioglitazone 30mg/d to pre-study OADs

Measured Values

	Sitagliptin	**Pioglitazone**
Number of Participants Analyzed	60	59
Compare the Change in Hemoglobin A1c and the Proportion of Patients Achieving A1C < 7% [*units: participants %*] Least Squares Mean ± Standard Error	-0.71 ± 0.12	-0.94 ± 0.12

Example 3
Outcome Measure After QA Review

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Mean Change in Glycosylated Hemoglobin (A1C)**
Measure Description	A1C change from baseline to 24 weeks
Time Frame	24 weeks
Safety Issue?	Yes

Reporting Groups

	Description
Sitagliptin	add sitagliptin100mg/d to pre-study OADs
Pioglitazone	add pioglitazone 30mg/d to pre-study OADs

Measured Values

	Sitagliptin	**Pioglitazone**
Number of Participants Analyzed	60	59
Mean Change in Glycosylated Hemoglobin (A1C) [*units: percentage of Hb*] Least Squares Mean ± Standard Error	-0.71 ± 0.12	-0.94 ± 0.12

Example 4
Outcome Measure Before QA Review

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Adherence (MMAS and Pharmacy Refill Data)**
Measure Description	
Time Frame	Q 4 Months
Safety Issue?	No

Reporting Groups

	Description
Intervention	UC Home Automated Telemanagement
Control	Best Available Care

Measured Values

	Intervention	**Control**
Number of Participants Analyzed	25	22
Adherence (MMAS and Pharmacy Refill Data) [*units: percent*]	57	67

Example 4
Outcome Measure After QA Review

Outcome Measures

3. Primary Outcome Measure:

Measure Title	**Percentage of Participants Adherent to Therapy**
Measure Description	Adherence was assessed using the Morisky Medication Adherence Score, a 4 item survey in which participants self-report medication-taking behavior. Each question that is answered with a No receives a score of 1. The possible scoring range is therefore 0 to 4. Higher scores correlate with better medical adherence. For the purpose of evaluating percent of participants adherent to therapy, the variable was dichotomized to "Adherent" or "Non-adherent". Any response of Yes to one of the 4 items was scored as "Non-Adherent".
Time Frame	12 Months
Safety Issue?	No

Reporting Groups

	Description
Intervention	UC Home Automated Telemanagement
Control	Best Available Care

Measured Values

	Intervention	**Control**
Number of Participants Analyzed	25	22
Percentage of Participants Adherent to Therapy [*units: Percentage of Participants*]	57	67

Example 5
Baseline Measure Before QA Review

Baseline Measures

	Women Pregnant
Age Continuous *[units: years]* *Mean ± Standard Deviation*	288 ± .01

Example 5
Baseline Measure After QA Review

Baseline Measures

	Women Pregnant
Age Continuous *[units: years]* *Mean ± Standard Deviation*	27.26 ± 5.81

Example 5
Outcome Measure Before QA Review

Outcome Measures

1. Primary Outcome Measure:

Measure Title	**Women Pregnant**
Measure Description	Healthy pregnant women between 15 or greater weeks gestation reporting with signs or symptoms of rupture of membranes.
Time Frame	1 weeks
Safety Issue?	No

Reporting Groups

	Description
Women Pregnant	Healthy pregnant women between 15 or greater weeks gestation reporting with signs or symptoms of rupture of membranes.

Measured Values

	Women Pregnant
Number of Participants Analyzed	285
Women Pregnant [*units: positve for membrane leakage*]	288

Example 5
Outcome Measure After QA Review

Measure Title	**Pregnant Women Positive and Negative for Membrane Rupture Measured Via Clinical Assessment, Chart Review and ROM Plus**
Measure Description	Patients underwent two assessments to determine positive or negative membrane rupture status: (1) Standard clinical assessment using fluid leaking from the cervical os, or two of the following; pooling, positive nitrazine test, or ferning and (2) A new combination immunoassay ROM Plus containing a combination of monoclonal and polyclonal antibodies to Placental Protein 12 (PP12) and Alpha-fetoprotein (AFP). Then, membrane rupture status was determined by chart review for reference based on a post delivery patient chart review by an experienced physician blinded to ROM Plus results.
Time Frame	1 week

	Description
Pregnant Women (Clinical Assessment vs. Chart Review)	This study was a multi-center prospective observational study performed in patients presenting with signs or symptoms of rupture of amniotic membranes. Initial evaluation included the standard clinical assessment for rupture of membranes. The clinical diagnosis of rupture of membranes was confirmed on review of the medical chart records following delivery.
Pregnant Women (ROM Plus vs. Chart Review)	This study was a multi-center prospective observational study performed in patients presenting with signs or symptoms of rupture of amniotic membranes. Initial evaluation included the new combination immunoassay ROM Plus containing a combination of monoclonal and polyclonal antibodies to Placental Protein 12 (PP12) and Alpha-fetoprotein (AFP). The clinical diagnosis of rupture of membranes was confirmed on review of the medical chart records following delivery.

	Pregnant Women (Clinical Assessment vs. Chart Review)	**Pregnant Women (ROM Plus vs. Chart Review)**
Number of Participants Analyzed	285	285
Pregnant Women Positive and Negative for Membrane Rupture Measured Via Clinical Assessment, Chart Review and ROM Plus [*units: participants*]		
True Negative Membrane Rupture	95	88
True Positive Membrane Rupture	160	187
False Negative Membrane Rupture	2	9
False Positive Membrane Rupture	28	1

Example 6
Outcome Measure Before QA Review

Measure Title	**The Assayed Absolute Immune Cells Count(CD3, CD4, and CD8 + T Cells Numbers)**
Measure Description	The "Arm 1" participant's blood samples were analyzed. The study was depended on one test method and equipment to ensure the T- Lymphocyte enumeration. Unexpected results were repeated before convince the efficacy of the 0.200 mg drug dose. HIV patient's pre/post CD+ T cell status were evaluated. The Surrogate Markers", the assayed absolute CD+ T cells numbers on participants were measured.
Time Frame	"24 weeks"
Safety Issue?	No

Reporting Groups

	Description
"Kallunk Oxide"	The "Arm 1" participants were received one drug that is a combination of a traditional alternative (CAM) medicine as "Kallunk oxide", locally sourced minerals (alloyed) which has calcinated/or oxide form molecules and powder of a herb's seed, naturally occurring a herb's seed, was also used as a carrier of Kallunk oxide molecules. The Botanical name of the drug carrier is "Piper longum". The number of participants who were received a daily regimen of 0.200 mg "Kallunk oxide. The powder form medicine is added to 1/2 cup hotter water (an adjuvant). The Kallunk oxide safe dose 0.200 mg was studied. Dosage form: Powder form sample size product 500 mg (0.200 mg + 499.800 mg) was administered. Frequency of administration: Once daily dose on 5 days treatment as one course.

Measured Values

	"Kallunk Oxide"
Number of Participants Analyzed	40
The Assayed Absolute Immune Cells Count(CD3, CD4, and CD8 + T Cells Numbers) [*units: "Participants"*] Mean (95% Confidence Interval)	38 (1 to 40)

Example 6
Outcome Measure After QA Review

Measure Title	**CD3+ T Cell Change**
Measure Description	Number of participants with blood samples was analyzed. The earlier baseline absolute CD3+ T cell count and the later absolute CD3+ T cell count were measured. The CD3+ T cell change levels between the earlier time point and the later time point was evaluated. The change was calculated as the later time point minus the earlier time point i.e., the 6 months minus the baseline. A mean increase of CD3+ T cell count from Baseline to 6 months was measured. Flow Cytometry laboratory analysis was performed.
Time Frame	Baseline and 6 months
Safety Issue?	No

Reporting Groups

	Description
"Kallunk Oxide"	Number of participants with received a daily regimen of Kallunk oxide(Immunotherapy) + Long Pepper", that is a combination of a traditional alternative medicine(Complementary and Alternative Medicine CAM). The participants were received the drug for once daily dose in 5 days treatment. The powder form 0.200 mg dosage was administered. Drug was assigned to 0.200 mg Kallunk oxide molecules with 499.800 mg antidote. This antidote was used as a carrier of Kallunk oxide molecules. The Botanical name of the antidote is "Piper Longum".

Measured Values

	"Kallunk Oxide"
Number of Participants Analyzed	40
CD3+ T Cell Change [*units: "Cells/mm^3"*] Mean ± Standard Deviation	175 ± 30

Example 7
Baseline Measure Before QA Review

Baseline Measures

	[redacted]	[redacted]	Total
Number of Participants	6	14	**20**
Age, Customized *[units: years]* *Mean ± Standard Deviation*	32.5 ± 12.4	31.4 ± 11.7	**31.7 ± 11.3**
number of adverse events			
Gender, Male/Female *[units: participants]*			
Female	0	1	**1**
Male	6	13	**19**
Region of Enrollment *[units: participants]*	6	14	**20**
United States			

Where can I get information?

www.clinicaltrials.gov

- General info about Submitting studies:
  http://clinicaltrials.gov/ct2/manage-recs

Where do I send questions?

register@clinicaltrials.gov

Questions?

National Library of Medicine & Lister Hill Center for Biomedical Communications
Bethesda, MD