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

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May 2013

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

- FDAMA 113 (1997) mandates registry
  - Investigational New Drug application (IND) trials for serious and life-threatening diseases or conditions
- ClinicalTrials.gov launched in February 2000
- Calls for increased transparency of clinical trials
  - Maine State Law; State Attorneys General
  - International Committee of Medical Journal Editors (ICMJE) statement (2004)
- ClinicalTrials.gov accommodates other policies
- FDAAA Section 801 (2007): Expands registry & adds results database

Why the need for a public database?

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

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…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

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

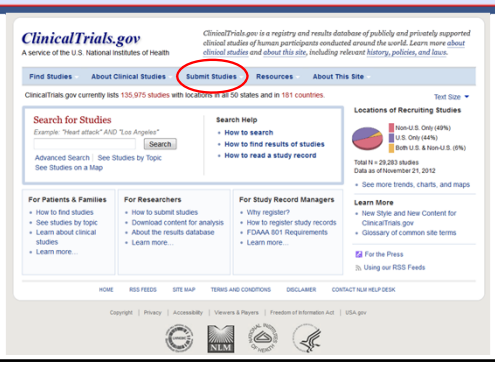
- Applicable Clinical Trials*
  - Interventional studies of drugs, biologics & devices
  - Not Phase 1 (drugs/biologics), not small feasibility (devices)
  - US FDA jurisdiction (e.g., IND/IDE or US site)
  - ACTs initiated on or after 9/27/07 or if initiated after 09/27/07, "ongoing" as of 12/26/07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

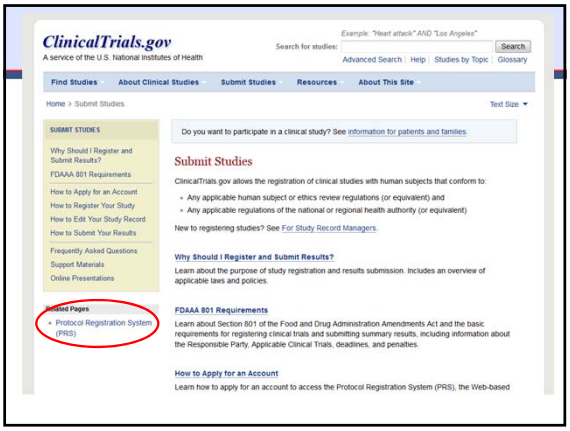
*http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

When do I register and submit results?

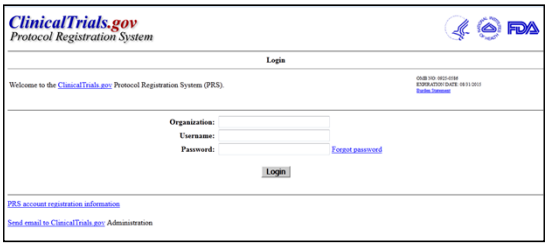
- When to register
  - FDAAA 801: No later than 21 days after the first participant is enrolled
  - ICMJE: before the first participant is enrolled
- When to submit results
  - FDAAA 801: Generally, submission within 12 months of Primary Completion Date (the date that the final subject was examined or 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?

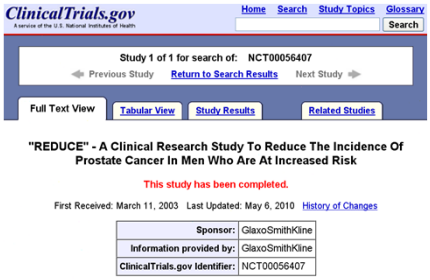




https://register.clinicaltrials.gov



What does it look like?



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 28, 2009

* Required by ClinicalTrials.gov

[*] Conditionally required by ClinicalTrials.gov

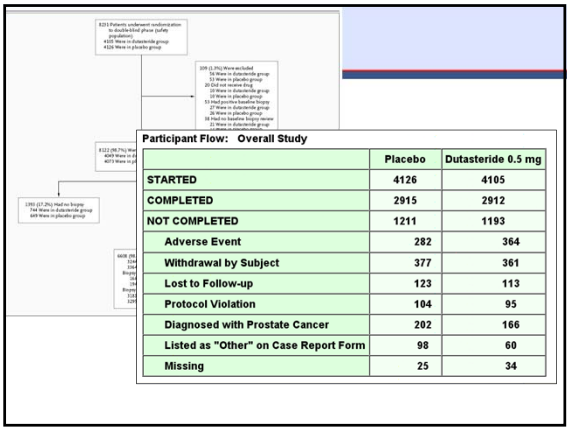
(FDAAA) May be required to comply with US Public Law 110-85, Section 801

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)]



Participant Flow: Overall Study

	Placebo	Dutasteride 0.5 mg
STARTED	4126	4105
COMPLETED	2915	2912
NOT COMPLETED	1211	1193
Adverse Event	282	364
Withdrawal by Subject	377	361
Lost to Follow-up	123	113
Protocol Violation	104	95
Diagnosed with Prostate Cancer	202	166
Listed as "Other" on Case Report Form	98	60
Missing	25	34

What if I have a complicated Participant Flow?

Helpful Hints: The number of Arm/Groups is generally equal to the number of "experiences" to which a participant could be randomized/assigned. (e.g., number of sequences in a crossover, number of interventions in a parallel study, number of doses in a dose escalation, etc.) Although, this can be a little more nuanced if you have multiple randomizations/assignments.

We have some study design examples on ClinicalTrials.gov under
→ Submit Studies
→ Training Materials
→ Results Database Train-the-Trainer Workshop
→ Example Studies for Results Data Entry

OR email us: register@clinicaltrials.gov

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Some Participant Flow Data Elements of Note

Period(s)
Definition: Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported. If only one period, use *Overall Study* for "Period Title."

Milestone(s)
Definition: Specific events or time points in the trial when the numbers of participants are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, STARTED and COMPLETED, within each period.

From ClinicalTrials.gov "Basic Results" Data Elements Definitions (DRAFT)

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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)]

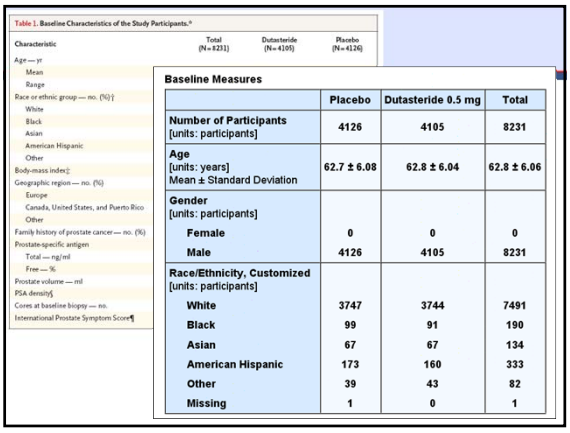


Table 1. Baseline Characteristics of the Study Participants.*

Characteristic	Total (N=8231)	Dutasteride (N=4105)	Placebo (N=4126)
Age — yr			
Mean			
Range			
Race or ethnic group — no. (%)†			
White			
Black			
Asian			
American Hispanic			
Other			
Body-mass index‡			
Geographic region — no. (%)			
Europe			
Canada, United States, and Puerto Rico			
Other			
Family history of prostate cancer — no. (%)			
Prostate-specific antigen			
Total — ng/ml			
Free — %			
Prostate volume — ml			
PSA density§			
Cores at baseline biopsy — no.			
International Prostate Symptom Score¶			

Baseline Measures

	Placebo	Dutasteride 0.5 mg	Total
Number of Participants [units: participants]	4126	4105	8231
Age [units: years] Mean ± Standard Deviation	62.7 ± 6.08	62.8 ± 6.04	62.8 ± 6.06
Gender [units: participants]			
Female	0	0	0
Male	4126	4105	8231
Race/Ethnicity, Customized [units: participants]			
White	3747	3744	7491
Black	99	91	190
Asian	67	67	134
American Hispanic	173	160	333
Other	39	43	82
Missing	1	0	1

Outcome Measure

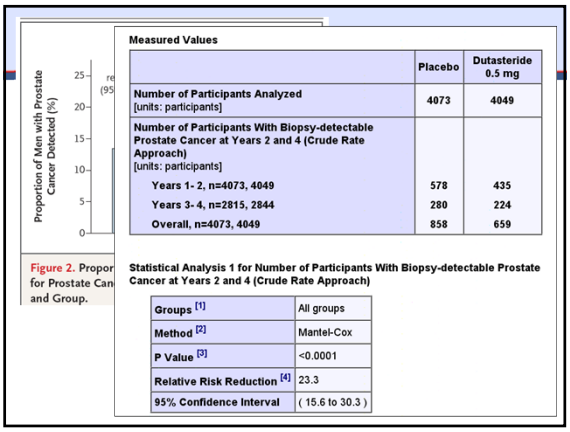
"…a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial…"

[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)]



Measured Values

	Placebo	Dutasteride 0.5 mg
Number of Participants Analyzed [units: participants]	4073	4049
Number of Participants With Biopsy-detectable Prostate Cancer at Years 2 and 4 (Crude Rate Approach) [units: participants]		
Years 1- 2, n=4073, 4049	578	435
Years 3- 4, n=2815, 2844	280	224
Overall, n=4073, 4049	858	659

Statistical Analysis 1 for Number of Participants With Biopsy-detectable Prostate Cancer at Years 2 and 4 (Crude Rate Approach)

Groups [1]	All groups
Method [2]	Mantel-Cox
P Value [3]	<0.0001
Relative Risk Reduction [4]	23.3
95% Confidence Interval	(15.6 to 30.3)

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?*

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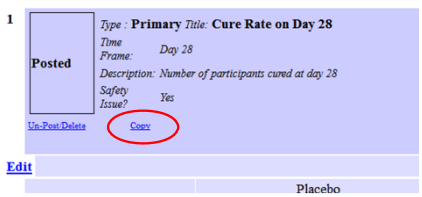
Are there any shortcuts for entering data?

Helpful Hints: You can "Copy" any Outcome Measure, and only edit the data elements that are different.

Sometimes it is possible to use Categories to present multiple "rows" of the same type of data.

We have an XML upload feature, and a separate adverse events upload feature.



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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".

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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)]

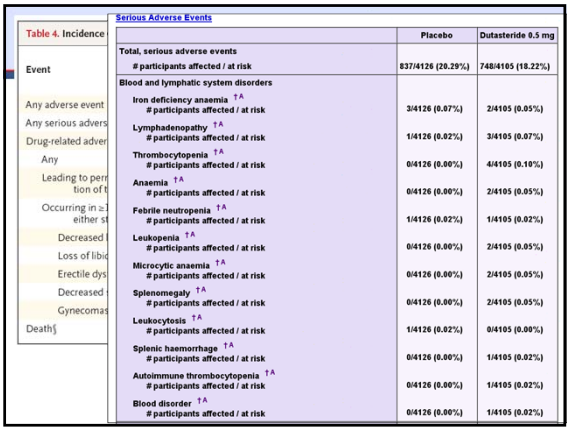


Table 4. Incidence

Event

Any adverse event
Any serious advers
Drug-related adver
Any
Leading to perr tion of t
Occurring in ≥1 either st
Decreased
Loss of libid
Erectile dys
Decreased
Gynecomas
Death‡

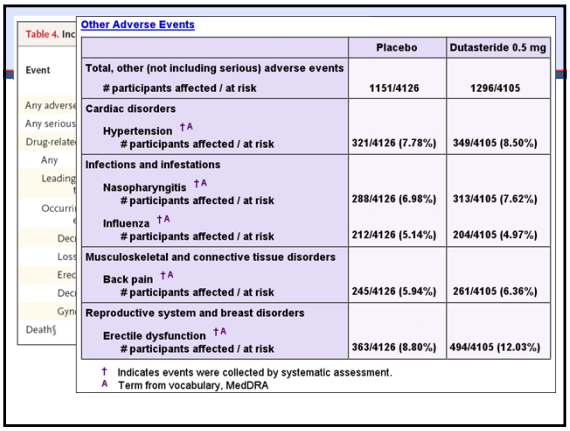
Serious Adverse Events

	Placebo	Dutasteride 0.5 mg
Total, serious adverse events		
# participants affected / at risk	837/4126 (20.29%)	748/4105 (18.22%)
Blood and lymphatic system disorders		
Iron deficiency anaemia †A		
# participants affected / at risk	3/4126 (0.07%)	2/4105 (0.05%)
Lymphadenopathy †A		
# participants affected / at risk	1/4126 (0.02%)	3/4105 (0.07%)
Thrombocytopenia †A		
# participants affected / at risk	0/4126 (0.00%)	4/4105 (0.10%)
Anaemia †A		
# participants affected / at risk	0/4126 (0.00%)	2/4105 (0.05%)
Febrile neutropenia †A		
# participants affected / at risk	1/4126 (0.02%)	1/4105 (0.02%)
Leukopenia †A		
# participants affected / at risk	0/4126 (0.00%)	2/4105 (0.05%)
Microcytic anaemia †A		
# participants affected / at risk	0/4126 (0.00%)	2/4105 (0.05%)
Splenomegaly †A		
# participants affected / at risk	0/4126 (0.00%)	2/4105 (0.05%)
Leukocytosis †A		
# participants affected / at risk	1/4126 (0.02%)	0/4105 (0.00%)
Splenic haemorrhage †A		
# participants affected / at risk	0/4126 (0.00%)	1/4105 (0.02%)
Autoimmune thrombocytopenia †A		
# participants affected / at risk	0/4126 (0.00%)	1/4105 (0.02%)
Blood disorder †A		
# participants affected / at risk	0/4126 (0.00%)	1/4105 (0.02%)

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)]



Other Adverse Events

	Placebo	Dutasteride 0.5 mg
Total, other (not including serious) adverse events # participants affected / at risk	1151/4126	1296/4105
Cardiac disorders		
Hypertension †A # participants affected / at risk	321/4126 (7.78%)	349/4105 (8.50%)
Infections and infestations		
Nasopharyngitis †A # participants affected / at risk	288/4126 (6.98%)	313/4105 (7.62%)
Influenza †A # participants affected / at risk	212/4126 (5.14%)	204/4105 (4.97%)
Musculoskeletal and connective tissue disorders		
Back pain †A # participants affected / at risk	245/4126 (5.94%)	261/4105 (6.36%)
Reproductive system and breast disorders		
Erectile dysfunction †A # participants affected / at risk	363/4126 (8.80%)	494/4105 (12.03%)

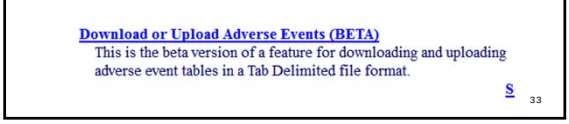
† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA

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 from a tab delimited spreadsheet (this can be organized using Excel), if you explicitly follow the instructions

Link located in "Adverse Event Overview"



Download or Upload Adverse Events (BETA)
This is the beta version of a feature for downloading and uploading adverse event tables in a Tab Delimited file format.

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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)

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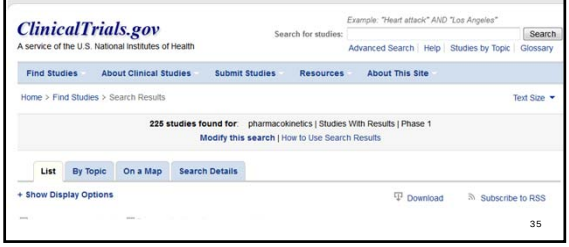
Are there examples available that are similar to my trial design?

Helpful Hint: Do a search on ClinicalTrials.gov!

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



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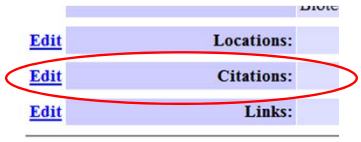
Who is the Audience?

- 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

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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.

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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?)

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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

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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

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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

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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)

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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

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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

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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

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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

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Example 5
Baseline Measure Before QA Review

Baseline Measures

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

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Example 5
Baseline Measure After QA Review

Baseline Measures

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

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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: positive for membrane leakage*]	288

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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

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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)

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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

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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

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Questions?

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