ClinicalTrials.gov "Basic Results" Database

HELPFUL HINTS

1. COMMON STUDY MODELS

a. Parallel Design (*see example, pp 5-11*)
The Protocol Registration System (PRS) defaults generally accommodate simple parallel design studies. The Arms information from the protocol section will be the default column headings for all tables in the results section (e.g., *"Participant Flow: Overall Study" table on p. 6*), although these can be changed, if appropriate (see "b. Crossover Design," below).

b. Crossover Design (*see example, pp. 12-20*)
Crossover studies generally require a few modifications to the default settings. For example, the column headings may not be the same for all tables. The attached example uses the randomized groups as the column headings for Participant Flow (*pp. 12-13*), but uses the overall group as a single column heading for the Baseline Characteristics (*p. 14*), and each separate intervention as column headings for the Outcome Measures (*p.p. 15-18*). In addition, the Participant Flow is divided into three Periods to accurately reflect the different phases of the crossover study (*p. 13*).

c. Diagnostic Accuracy Studies (*see example, pp. 21-29*)
Diagnostic accuracy studies are studies in which the results are generally displayed in a "2 x 2 table," in which columns are displayed as "with disease" and "without disease" based on a reference standard; rows are "test positive" and "test negative" based on the experimental diagnostic test. The system can be used to create 2 x 2 tables, as illustrated in the attached example (*e.g., "Measured Values" table on p. 25*). In addition, the Participant Flow (*p. 21*) and the Baseline Characteristics (*p. 22*) may be reported for one group representing the entire study. Sensitivity (e.g., *"Statistical Analysis 1…Using Threshold A" on p. 23*) and specificity (e.g., *"Statistical Analysis 2…Using Threshold A" on p. 24*) can be entered as statistical analyses, based on each Outcome Measure (e.g., "Diagnostic Test for Disease Using Threshold A"). Separate Outcome Measures, with associated tables, can be defined based on the use of different thresholds (or positivity criteria) in order to display data that would underlie an ROC curve (e.g., *"Threshold B" beginning on p. 24*). The area under the curve can be reported as a statistical analysis after the last relevant 2 x 2 table, as illustrated (e.g., *"Statistical Analysis 3…Using Threshold C" on p. 27*).

2. MEASURES

a. Measure Type

i. Categorical Measures

Most categorical measures will use the number of participants as the unit. (However, it is possible that a different unit, such as the number of knees examined, can be used.) The user can define the number of categories (two or more), and should use the data entry screens to fully characterize the categories and the measures that will be entered. Sometimes a dichotomous category is presented with only one of the two categories displayed (e.g., # improved). It is preferable to report both categories explicitly (e.g., # improved and # not improved). Note that it is possible to have a categorical measure with continuous data in each cell, such as mean age and standard deviation [SD] of participants in each of three baseline diagnostic categories (e.g., *"Diastolic Blood Pressure" and "Systolic Blood Pressure" baseline measures on p. 14*). In this situation, the unit of measurement will typically not be number of participants, but will be whatever units are used for the measurement (e.g., mm Hg for blood pressure).

ii. Continuous Measures

Continuous measures require a measure of central tendency (e.g., mean) and a measure of dispersion/uncertainty (e.g., standard deviation). These must be selected from the pull down menus that are provided in the results section of the PRS. Note that confidence interval and standard error are acceptable measures of dispersion/uncertainty for Outcome Measures, but not for Baseline Measures.

iii. Time to Event Measures

At this time, time to event measures must be represented as either categorical measures (e.g., 5 year survival) or continuous measures (e.g., mean time to death) (e.g., *"Time to Disease X" Outcome Measure on pp. 7*). If desired, a series of categories can be defined to represent time points on a survival curve.

b. Specific Measure Issues

Scales

Outcomes may be evaluated and reported with a specific scale. In order for the measure and the outcome to be easily understood, users should describe the scale in the Outcome Measure Title, Description, and Units of Measure fields (e.g., *"Mean score on the National Library of Medicine (NLM) Pain Scale" Outcome Measure below*).

Specific items to describe include the following:

- Outcome Measure Title: Name of scale (e.g., mean score on NLM Pain Scale)
- Outcome Measure Description:
  - What the scale measures (e.g., severity of pain)
  - Range and direction (e.g., 0 is no pain and 20 is severe pain)
  - Other information as appropriate (e.g., whether the scale is ordinal or continuous).
- Units of Measure: expressed as "units on scale" or "score on scale"

3. STATISTICAL ANALYSES
   Statistical analyses are tied to a specific Outcome Measure. The system allows for the entry of p-values and/or confidence intervals. There is no limit to the number of analyses that can be entered for a given Outcome Measure (e.g., *four statistical analyses are associated with the Primary Outcome Measure on pp. 7-9*). If a p-value is entered, the test used must be specified. Similarly, if a confidence interval is entered, the estimated parameter must be specified. Users are encouraged to use the free text boxes to provide more complete explanations of their analyses.

4. ADVERSE EVENTS
   The Adverse Event module is optional (until Sept 27, 2009). However, if one chooses to use the module, the required data elements must be provided (e.g., *pp. 10-11*). There are separate tables for Serious Adverse Events, and for Other Adverse Events (based on frequency). The same event(s) should not be listed in both tables.

Parallel Design Example

This study has been completed.
Information provided by Test Organization

Study Type:	Interventional
Study Design:	Randomized, Double Blind (Subject, Investigator, Outcomes Assessor), Parallel Assignment
Interventions:	Drug: Drug A Drug: Drug B Drug: Placebo

Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Patients were recruited from the waiting room of ABC Medical Clinic between January 2005 and January 2006

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Patients screened over 3 week period.

Reporting Groups

	Description
Drug A	10mg Drug A administered twice daily
Drug B	20mg Drug B administered twice daily
Placebo	Participants were given a single pill, twice daily.

Participant Flow: Overall Study

	Drug A	Drug B	Placebo
STARTED	50	50	50
COMPLETED	48	49	47
NOT COMPLETED	2	1	3
Lost to Follow-up	1	0	2
Adverse Event	1	1	1

Baseline Characteristics

Reporting Groups

	Description
Drug A	10mg Drug A administered twice daily
Drug B	20mg Drug B administered twice daily
Placebo	Participants were given a single pill, twice daily.
Total	No text entered.

Baseline Measures

	Drug A	Drug B	Placebo	Total
Number of Participants [units: participants]	50	50	50	150
Age [units: participants]				
<=18 years	0	0	0	0
Between 18 and 65 years	50	50	50	150
>=65 years	0	0	0	0
Age [units: years] Mean ± Standard Deviation	41 ± 12	42 ± 11	41 ± 11	41 ± 11
Gender [units: participants]				
Female	25	23	28	76
Male	25	27	22	74

Outcome Measures

1. Primary Outcome Measure: Time to Disease X

Measure Type	Primary
Measure Name	Time to Disease X
Measure Description	No text entered.
Time Frame	24 months
Safety Issue	No

Hide Details

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.
The population analyzed included all patients receiving at least 1 dose of study intervention and at least 1 assessment post-baseline.

Reporting Groups

	Description
Drug A	10mg Drug A administered twice daily
Drug B	20mg Drug B administered twice daily
Placebo	Participants were given a single pill, twice daily.

Measured Values

	Drug A	Drug B	Placebo
Number of Participants [units: Days] Log Mean ± Standard Deviation	50	50	50
Time to Disease X [units: Days] Log Mean ± Standard Deviation	4.94 ± 1.32	5.52 ± 1.28	4.78 ± 1.11

Statistical Analysis 1 for Time to Disease X

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.011

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

Omnibus analysis was performed. Number of observations=150; Root MSE=1.33; R squared = 0.059; Adjusted R squared=0.046

[2] Other relevant information, such as adjustments or degrees of freedom:

No text entered.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

p<0.05 considered significant

Statistical Analysis 2 for Time to Disease X

Groups [1]	Drug A vs. Drug B
Method [2]	t-test, 2 sided
P Value [3]	0.017
Mean Difference (Net) [4]	-0.672
95% Confidence Interval	(-1.224 to -0.119)

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

No text entered.

[2] Other relevant information, such as adjustments or degrees of freedom:

No text entered.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Pairwise comparisons were not corrected for multiple comparisons.

[4] Other relevant estimation information:

Mean difference=Drug A minus Drug B

Statistical Analysis 3 for Time to Disease X

Groups [1]	Drug A vs. Placebo
Method [2]	t-test, 2 sided
P Value [3]	0.825
Mean Difference (Net) [4]	0.059
95% Confidence Interval	(-0.475 to 0.594)

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

No text entered.

[2] Other relevant information, such as adjustments or degrees of freedom:

No text entered.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Not corrected for multiple comparisons.

[4] Other relevant estimation information:

Mean difference is Drug A minus Placebo

Statistical Analysis 4 for Time to Disease X

Groups [1]	Drug B vs. Placebo
Method [2]	t-test, 2 sided
P Value [3]	0.004
Mean Difference (Net) [4]	0.731
95% Confidence Interval	(0.234 to 1.228)

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

No text entered.

[2] Other relevant information, such as adjustments or degrees of freedom:

Not adjusted for multiple comparisons

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

No text entered.

[4] Other relevant estimation information:

Mean difference is Drug B minus Placebo

2. Secondary Outcome Measure: Time to Symptom Y

Measure Type	Secondary
Measure Name	Time to Symptom Y
Measure Description	No text entered.
Time Frame	24 months
Safety Issue	No

Results not yet posted
Anticipated Posting Date: No text entered.

Reported Adverse Events

Reporting Groups

	Description
Drug A	10mg Drug A administered twice daily
Drug B	20mg Drug B administered twice daily
Placebo	Participants were given a single pill, twice daily.

Serious Adverse Events

	Drug A	Drug B	Placebo
Total over all serious adverse events			
number of participants affected	0	0	0

† Indicates events were collected by systematic assessment. All other events were spontaneously reported.

Frequency Threshold for Reporting Other Adverse Events: 5%

Other Adverse Events

	Drug A	Drug B	Placebo
Total over all other adverse events			
number of participants affected	16	4	13
Gastrointestinal disorders			
Nausea †			
number of participants at risk	50	50	50
number of events	4	2	2
number of participants affected	4	2	2

Nervous system disorders			
Headache †			
number of participants at risk	50	50	50
number of events	12	2	11
number of participants affected	12	2	11

† Indicates events were collected by systematic assessment. All other events were spontaneously reported.

More Information

Certain Agreements:

All Principal Investigators **ARE** employed by the organization sponsoring the study.

Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

Results Point of Contact:

Name/Title: Jane Doe
Organization: ABC Health Center
phone: 123-456-7890 ext 123
e-mail: ABC@yahoo.com

Crossover Study Example: Drug A vs. Placebo

This study has been completed.
Information provided by Test Organization

Study Type:	Interventional
Study Design:	Randomized, Double Blind (Subject, Caregiver, Investigator), Placebo Control, Crossover Assignment
Interventions:	Drug: Allopurinol

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 recruited from a specialty clinic at a hospital, in Fictional City, USA between October 2004 and January 2007.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
267 participants recruited; 186 screened, 56 excluded (36 did not meet inclusion criteria and 20 refused participation).

Reporting Groups

	Description
Placebo First	Placebo twice daily in first intervention period and Drug A 25 mg twice daily in second intervention period (after washout period).
Drug A First	Drug A 25 mg twice daily in first intervention period and Placebo twice daily in second intervention period (after washout period).

Participant Flow for 3 periods

Period: First Intervention		
	Placebo First	Drug A First
STARTED	65	65
Received at Least One Dose of Drug	65	64
COMPLETED	65	63
NOT COMPLETED	0	2
neutropenia	0	1
Withdrawal by Subject	0	1

Period: Washout Period of 2 Weeks		
	Placebo First	Drug A First
STARTED	65	63
COMPLETED	63	62
NOT COMPLETED	2	1
Disease relapse	2	1

Period: Second Intervention		
	Placebo First	Drug A First
STARTED	63	62
COMPLETED	60	62
NOT COMPLETED	3	0
Adverse Event	2	0
Lost to Follow-up	1	0

Baseline Characteristics

Reporting Groups

	Description
Entire Study Population	Includes groups randomized to receive placebo first and Drug A first.

Baseline Measures

	Entire Study Population
Number of Participants [units: participants]	130
Age [units: participants]	
<=18 years	0
Between 18 and 65 years	130
>=65 years	0
Age [units: years] Mean ± Standard Deviation	40.3 ± 5.6
Gender, [units: participants]	
Female	60
Male	70
diastolic blood pressure [units: mm Hg] Mean ± Standard Deviation	
At enrollment	82 ± 9.3
Beginning of Placebo treatment	81 ± 9.1
Beginning of Drug A treatment	82 ± 9.2
systolic blood pressure[1] [units: mm Hg] Mean ± Standard Deviation	
At enrollment	138 ± 21.2
Beginning of Placebo treatment	138 ± 18.6
Beginning of Drug A treatment	136 ± 19.7
weight [units: kg] Mean ± Standard Deviation	65 ± 11.2

[1] Measurements were taken at baseline, at beginning of 1st and 2nd intervention periods, and end of 1st and 2nd intervention periods. Yielding baseline measurements for treatment with Placebo and Drug A.

Outcome Measures

1. Primary Outcome Measure: Change in Diastolic Blood Pressure

Measure Type	Primary
Measure Name	Change in Diastolic Blood Pressure
Measure Description	Value at 3 months minus value at baseline.
Time Frame	3 months
Safety Issue	No

Hide Details

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 analysis including only participants who had at least one post-baseline assessment.

Reporting Groups

	Description
Placebo	Placebo administered twice daily in either first intervention period or second intervention period.
Drug A	Drug A 25 mg administered twice daily in either first intervention period or second intervention period.

Measured Values

	Placebo	Drug A
Number of Participants [units: mm Hg] Mean (95% Confidence Interval)	65	65
Change in Diastolic Blood Pressure [units: mm Hg] Mean (95% Confidence Interval)	-2.3 (1.0 to -5.0)	-4.9 (-3.0 to -8.2)

Statistical Analysis 1 for Change in Diastolic Blood Pressure

Groups [1]	All groups
Method [2]	Paired t-test
P Value [3]	<0.04

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

125 patients required to detect 5 mm Hg difference in diastolic BP change, with 90% power. BP parameters not considered independent; 50% covariance assumed. Alpha level of 0.05.

[2] Other relevant information, such as adjustments or degrees of freedom:

No text entered.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Two-sided

2. Primary Outcome Measure: Change in Systolic Blood Pressure

Measure Type	Primary
Measure Name	Change in Systolic Blood Pressure
Measure Description	Value at 3 months minus value at baseline.
Time Frame	3 months
Safety Issue	No

Hide Details

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.
Total number of participants completing period with study intervention.

Reporting Groups

	Description
Placebo	Placebo administered twice daily in either first intervention period or second intervention period.
Drug A	Drug A 25 mg administered twice daily in either first intervention period or second intervention period.

Measured Values

	Placebo	Drug A
Number of Participants [units: mm Hg] Mean (95% Confidence Interval)	62	60
Change in Systolic Blood Pressure [units: mm Hg] Mean (95% Confidence Interval)	-2.1 (0.2 to -4.8)	-7.2 (-5.1 to -9.6)

Statistical Analysis 1 for Change in Systolic Blood Pressure

Groups [1]	All groups
Method [2]	Paired t-test
P Value [3]	0.007

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

125 patients required to detect 5 mm Hg difference in systolic BP change, with 90% power. BP parameters not considered independent; 50% covariance assumed. Alpha level of 0.05.

[2] Other relevant information, such as adjustments or degrees of freedom:

No text entered.

[3] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

Two-sided.

3. Secondary Outcome Measure: Plasma Level of Marker X

Measure Type	Secondary
Measure Name	Plasma Level of Marker X
Measure Description	No text entered.
Time Frame	three months
Safety Issue	No

Results not yet posted
Anticipated Posting Date: No text entered.

4. Secondary Outcome Measure: Change in Weight

Measure Type	Secondary
Measure Name	Change in Weight
Measure Description	
Time Frame	Three months
Safety Issue	No

Results not yet posted
Anticipated Posting Date: No text entered.

Reported Adverse Events

Reporting Groups

	Description
Placebo	Placebo administered twice daily in either first intervention period or second intervention period.
Drug A	Drug A 25 mg administered twice daily in either first intervention period or second intervention period.

Serious Adverse Events

	Placebo	Drug A
Total over all serious adverse events		
number of participants affected	0	1
Blood and lymphatic system disorders		
Neutropenia		
number of participants at risk	65	65
number of events	0	1
number of participants affected	0	1

Frequency Threshold for Reporting Other Adverse Events: 5%

Other Adverse Events

	Placebo	Drug A
Total over all other adverse events		
number of participants affected	5	10
Gastrointestinal disorders		
Nausea †		
number of participants at risk	65	65
number of events	7	12
number of participants affected	5	10

† Indicates events were collected by systematic assessment. All other events were spontaneously reported.

More Information

Certain Agreements:

Principal Investigators (Pis) are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

- [x] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- [ ] Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

Results Point of Contact:

Name/Title: Dr. Clinical Trial
Organization: Clinical Trial University
e-mail: contactme@clinicaltrialuniversity.edu

Diagnostic Test Accuracy Example

This study is ongoing, but not recruiting participants.
Information provided by Test Organization

Study Type:	Interventional
Study Design:	Open Label
Interventions:	Procedure: comparison of screening methods Procedure: computed tomography colonography Procedure: screening colonoscopy

Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
2700 patients were selected from multiple primary care sites across the country and all were healthy at baseline without symptoms of disease.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
100 patients were excluded because they did not properly observe the required pre-diagnostic test routine.

Reporting Groups

	Description
Total Number of Participants	All patients received the reference test (i.e. the gold standard).

Participant Flow: Overall Study

	Total Number of Participants
STARTED	2600
COMPLETED	2500
NOT COMPLETED	100
Protocol Violation	100

Baseline Characteristics

Reporting Groups

	Description
Total Number of Participants	All patients received the reference test (i.e. the gold standard).

Baseline Measures

	Total Number of Participants
Number of Participants [units: participants]	2600
Age [units: participants]	
<=18 years	0
Between 18 and 65 years	2600
>=65 years	0
Age [units: years] Mean ± Standard Deviation	57 ± 6
Gender [units: participants]	
Female	1400
Male	1200
Region of Enrollment [units: participants]	
United States	2600

Outcome Measures

1. Primary Outcome Measure: Diagnostic Test Data for Disease Using Threshold A

Measure Type	Primary
Measure Name	Diagnostic Test Data for Disease Using Threshold A
Measure Description	Disease status was determined by results of reference test.
Time Frame	1 month
Safety Issue	No

Hide Details

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.
Disease status was determined by results of reference test.

Reporting Groups

	Description
Participants With Disease	Disease confirmed by reference test
Participants Without Disease	Absence of disease defined by negative reference test

Measured Values

	Participants With Disease	Participants Without Disease
Number of Participants	450	2050
Diagnostic Test Data for Disease Using Threshold A [units: participants]		
Positive test for disease using threshold A	405	175
Negative test for disease using threshold A	45	1875

Statistical Analysis 1 for Diagnostic Test Data for Disease Using Threshold A

Groups [1]	Participants With Disease
sensitivity [2]	0.78
95% Confidence Interval	(0.71 to 0.85)

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

No text entered.

[2] Other relevant estimation information:

Calculated as proportion of those with disease who had a positive test result.

Statistical Analysis 2 for Diagnostic Test Data for Disease Using Threshold A

Groups [1]	Participants Without Disease
specificity [2]	0.89
95% Confidence Interval	(0.84 to 0.92)

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

No text entered.

[2] Other relevant estimation information:

Specificity was calculated as the proportion of those without disease who had a negative test.

2. Primary Outcome Measure: Diagnostic Test Data for Disease Using Threshold B

Measure Type	Primary
Measure Name	Diagnostic Test Data for Disease Using Threshold B
Measure Description	
Time Frame	1 month
Safety Issue	No

Hide Details

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.
No text entered.

Reporting Groups

	Description
Participants With Disease	Disease confirmed by reference test
Participants Without Disease	Absence of disease defined by negative reference test

Measured Values

	Participants With Disease	Participants Without Disease
Number of Participants	450	2050
Diagnostic Test Data for Disease Using Threshold B [units: participants]		
Positive test for disease using threshold B	400	150
Negative test for disease using threshold B	50	1900

Statistical Analysis 1 for Diagnostic Test Data for Disease Using Threshold B

Groups [1]	Participants With Disease
Sensitivity [2]	0.89
95% Confidence Interval	(0.84 to 0.95)

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

No text entered.

[2] Other relevant estimation information:

No text entered.

Statistical Analysis 2 for Diagnostic Test Data for Disease Using Threshold B

Groups [1]	Participants Without Disease
Specificity [2]	0.93
95% Confidence Interval	(0.87 to 0.99)

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

No text entered.

[2] Other relevant estimation information:

No text entered.

3. Primary Outcome Measure: Diagnostic Test Data for Disease Using Threshold C

Measure Type	Primary
Measure Name	Diagnostic Test Data for Disease Using Threshold C
Measure Description	
Time Frame	1 month
Safety Issue	No

Hide Details

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.
No text entered.

Reporting Groups

	Description
Participants With Disease	Disease confirmed by reference test
Participants Without Disease	Absence of disease defined by negative reference test

Measured Values

	Participants With Disease	Participants Without Disease
Number of Participants	450	2050
Diagnostic Test Data for Disease Using Threshold C [units: participants]		
Positive test for disease using threshold C	380	125
Negative test for disease using threshold C	70	1925

Statistical Analysis 1 for Diagnostic Test Data for Disease Using Threshold C

Groups [1]	Participants With Disease
Sensitivity [2]	0.84
95% Confidence Interval	(0.80 to 0.88)

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

No text entered.

[2] Other relevant estimation information:

No text entered.

Statistical Analysis 2 for Diagnostic Test Data for Disease Using Threshold C

Groups [1]	Participants Without Disease
Specificity [2]	0.94
95% Confidence Interval	(0.89 to 0.99)

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

No text entered.

[2] Other relevant estimation information:

No text entered.

Statistical Analysis 3 for Diagnostic Test Data for Disease Using Threshold C

Groups [1]	All groups
Area Under the Curve [2]	0.91
95% Confidence Interval	(0.89 to 0.95)

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

The Area Under the Curve was estimated based on the sensitivity and specificity measures for each of three thresholds (A, B, and C)

[2] Other relevant estimation information:

No text entered.

Reported Adverse Events

Reporting Groups

	Description
Total Number of Participants	All patients received the reference test (i.e. the gold standard).

Serious Adverse Events

	Total Number of Participants
Total over all serious adverse events number of participants affected	0

Frequency Threshold for Reporting Other Adverse Events: 5%

Other Adverse Events

	Total Number of Participants
Total over all other adverse events number of participants affected	128
Gastrointestinal disorders nausea † number of participants at risk number of events number of participants affected	 2500 130 128

† Indicates events were collected by systematic assessment. All other events were spontaneously reported.

More Information

Certain Agreements:

Principal Investigators (Pis) are **NOT** employed by the organization sponsoring the study.
There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
Only the most experienced technologists participated and were asked to read the test results in this study. Results may not be applicable to those centers without technologists with extensive related experience.

Results Point of Contact:

Name/Title: Dr. Y
Organization: Test Coop
phone: 123-457-9087 ext 1234
e-mail: abc@xyz.inc