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 (*pp. 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 a 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*).

d. Studies with Pharmacokinetic Outcome Measures (Bioequivalence Studies)
Bioequivalence and other study types include Outcome Measures to assess the pharmacokinetics of an intervention. The system can accommodate pharmacokinetic outcome measures and specific examples are provided (*pp. 30-*

35). The Outcome Measure should be fully spelled out and any relevant description should be provided in the Outcome Measure Description. Generally, plasma blood samples are taken at regular time points to assess pharmacokinetics and the Time Frame data element should accurately reflect these time points. Many bioequivalence studies use a cross-over study design and it is recommended that the Crossover Design example (*pp.12-20*) be reviewed, if it applies.

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., number improved). It is preferable to report both categories explicitly (e.g., number improved and number not improved). Note that it is possible to have a categorical measure with continuous data in each cell, such as mean blood pressure 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 are selected from the pull down menus that are provided in the results section of the PRS. Note that confidence interval and standard error are 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 Progression" Outcome Measure on p. 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 a scale," "scores on a scale," or "points on a 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) involving the same participants 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
Participants 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
Participants 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.

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 Progression

Measure Type	Primary
Measure Name	Time to Disease Progression
Measure Description	Disease progression was defined as >25% loss in hearing compared to baseline.
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 participants 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 Analyzed [units: Participants]	50	50	50
Time to Disease Progression [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 Progression

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 mean squared error (RMSE)=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 Progression

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 Progression

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 Progression

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	
Time Frame	36 months
Safety Issue	No

Results not yet posted
Anticipated Posting Date: May 2010.

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.

Time Frame	24 months
Additional Description	A validated questionnaire was used to assess adverse events every 3 months.

Serious Adverse Events

	Drug A	Drug B	Placebo
Total # participants affected/at risk	0/50	0/50	0/50

Other Adverse Events
Frequency Threshold Above which Other Adverse Events are Reported: 5%

	Drug A	Drug B	Placebo
Total # participants affected/at risk	16/50	4/50	13/50
Gastrointestinal disorders			
Nausea †			
# participants affected/at risk	4/50 (8%)	2/50 (4%)	2/50 (4%)
# events	4	2	2
Nervous system disorders			
Headache †			
# participants affected/at risk	12/50 (24%)	2/50 (4%)	11/50 (22%)
number of events	12	2	11

† Indicates events were collected by systematic assessment

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, then Drug A	Placebo twice daily in first intervention period and Drug A 25 mg twice daily in second intervention period (after washout period).
Drug A First, then Placebo	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, then Drug A	Drug A First, then Placebo
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, then Drug A	Drug A First, then Placebo
STARTED	65	63
COMPLETED	63	62
NOT COMPLETED	2	1
Disease relapse	2	1

Period: Second Intervention		
	Placebo First, then Drug A	Drug A First, then Placebo
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 from Baseline in Diastolic Blood Pressure at 3 Months

Measure Type	Primary
Measure Name	Change from Baseline in Diastolic Blood Pressure at 3 Months
Measure Description	Value at 3 months minus value at baseline.
Time Frame	Baseline and 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 Analyzed [units: Participants]	127	127
Change in Diastolic Blood Pressure [units: mm Hg] Mean (95% Confidence Interval)	-2.3 (-5.0to 1.0)	-4.9 (-8.2 to -3.0)

Statistical Analysis 1 for Change from Baseline in Diastolic Blood Pressure at 3 Months

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 participants 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 from Baseline in Systolic Blood Pressure at 3 Months

Measure Type	Primary
Measure Name	Change in Systolic Blood Pressure
Measure Description	Value at 3 months minus value at baseline.
Time Frame	Baseline and 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 Analyzed [units: Participants]	127	127
Change in Systolic Blood Pressure [units: mm Hg] Mean (95% Confidence Interval)	-2.1 (-4.8 to 0.2)	-7.2 (-9.6 to -5.1)

Statistical Analysis 1 for Change from Baseline in Systolic Blood Pressure at 3 Months

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 participants 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	
Time Frame	Baseline and 3 months
Safety Issue	No

Results not yet posted
Anticipated Posting Date: May 2010

4. Secondary Outcome Measure: Change from baseline in Weight at 3 Months

Measure Type	Secondary
Measure Name	Change in Weight
Measure Description	
Time Frame	Baseline and 3 months
Safety Issue	No

Results not yet posted
Anticipated Posting Date: May 2010

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.

Time Frame	3 months
Additional Description	

Serious Adverse Events

	Placebo	Drug A
Total # participants affected/at risk	0/127	1/127
Blood and lymphatic system disorders		
Neutropenia‡		
# participants affected/at risk	0/127 (0%)	1/127 (0.79%)
# events	0	1

‡ Indicates events were collected by non-systematic methods.

Other Adverse Events

Frequency Threshold Above which Other Adverse Events are Reported: 5%

	Placebo	Drug A
Total # participants affected/at risk	5/127	10/127
Gastrointestinal disorders		
Nausea ‡		
# participants affected/at risk	5/127 (3.94%)	10/127 (7.87%)
# events	7	12

‡ Indicates events were collected by non-systematic methods.

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:
☑ 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 has been completed.
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 participants 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 participants were excluded because they did not properly observe the required pre-diagnostic test routine.

Reporting Groups

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

Participant Flow: Overall Study

	Reference Test
STARTED	2600
COMPLETED	2500
NOT COMPLETED	100
Protocol Violation	100

Baseline Characteristics

Reporting Groups

	Description
Total Number of Participants	All participants who 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.
No text entered.

Reporting Groups

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

Measured Values

	Participants With Disease	Participants Without Disease
Number of Participants Analyzed [units: Participants]	450	2050
Diagnostic Test Data for Disease Using Threshold A [units: participants]		
Positive diagnostic test for disease using threshold A	405	175
Negative diagnostic 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]	0.90
95% Confidence Interval	(0.87 to 0.93)

[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. 91
95% Confidence Interval	(0.90 to 0.93)

[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	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.
No text entered.

Reporting Groups

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

Measured Values

	Participants With Disease	Participants Without Disease
Number of Participants Analyzed [units: Participants]	450	2050
Diagnostic Test Data for Disease Using Threshold B [units: participants]		
Positive diagnostic test for disease using threshold B	400	150
Negative diagnostic 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	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.
No text entered.

Reporting Groups

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

Measured Values

	Participants With Disease	Participants Without Disease
Number of Participants Analyzed [units: Participants]	450	2050
Diagnostic Test Data for Disease Using Threshold C [units: participants]		
Positive diagnostic test for disease using threshold C	380	125
Negative diagnostic 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 participants received the reference test (i.e. the gold standard).

Serious Adverse Events

	Total Number of Participants
Total # participants affected/at risk	0/2500

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Total Number of Participants
Total # participants affected/at risk	128/2500
Gastrointestinal disorders	
nausea	
# participants affected/at risk	128/2500 (5.12%)
# events	130

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

Pharmacokinetic Outcome Measures (Bioequivalence Study) Example

This study has been completed.
Information provided by Test Organization

Outcome Measures

1. Primary Outcome Measure: Maximum Observed Plasma Concentration (Cmax)

Measure Type	Primary
Measure Name	Maximum Observed Plasma Concentration (Cmax)
Measure Description	
Time Frame	0, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours post-dose
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.
Each participant received reference and test drug and is, therefore, included in the analysis population for both the reference and test drug.

Measured Values

	Reference Drug 150 mg	Test Drug 150 mg
Number of Participants [units: Participants]	14	14
Maximum Observed Plasma Concentration (Cmax) [units: mcg/mL] Mean ± Standard Deviation	3.64 ± 0.79	3.75 ± 0.75

Statistical Analysis 1 for Maximum Observed Plasma Concentration (Cmax)

Groups [1]	Reference Drug 150 mg, Test Drug 150 mg
Method [2]	ANOVA
P-Value [3]	0.087975
Other Estimated Parameter [Ratio of Cmax values] [4]	103.02
90% Confidence Interval	(101.06 to 105.45)

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

No text entered

[2] 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.

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

No text entered.

[4] Other relevant estimation information:

Ratio of Cmax values = Test drug 150mg/Reference drug 150mg

2. Primary Outcome Measure: Time to Reach Maximum Observed Plasma Concentration (Tmax)

Measure Type	Primary
Measure Name	Time to Reach Maximum Observed Plasma Concentration (Tmax)
Measure Description	
Time Frame	0, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours post-dose
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.
Each participant received reference and test drug and is, therefore, included in the analysis population for both the reference and test drug.

Measured Values

	Reference Drug 150 mg	Test Drug 150 mg
Number of Participants [units: Participants]	14	14
Time to Reach Maximum Observed Plasma Concentration (Tmax) [units: hours] Mean ± Standard Deviation	2.96 ± 1.00	2.79 ± 1.26

3. Primary Outcome Measure: Area Under the Curve From Time Zero to Last Quantifiable Concentration [AUC (0-t)]

Measure Type	Primary
Measure Name	Area Under the Curve From Time Zero to Last Quantifiable Concentration [AUC (0-t)]
Measure Description	AUC (0-t)= Area under the plasma concentration versus time curve from time zero (pre-dose) to time of last quantifiable concentration (0-t)
Time Frame	0, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours post-dose
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.
Each participant received reference and test drug and is, therefore, included in the analysis population for both the reference and test drug.

Measured Values

	Reference Drug 150 mg	Test Drug 150 mg
Number of Participants	14	14
Area Under the Curve From Time Zero to Last Quantifiable Concentration [AUC (0-t)] [units: mcg*h/mL] Mean ± Standard Deviation	135.72 ± 29.52	137.30 ± 31.94

Statistical Analysis 1 for Area Under the Curve From Time Zero to Last Quantifiable Concentration [AUC (0-t)]

Groups [1]	Reference Drug 150 mg, Test Drug 150 mg
Method [2]	ANOVA
P-Value [3]	0.715861
Other Estimated Parameter [Ratio of AUC(0-t) values] [4]	101.16
90% Confidence Interval	(97.11 to 104.69)

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

No text entered

[2] 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.

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

No text entered.

[4] Other relevant estimation information:

Ratio of AUC(0-t) values = Test Drug 150mg/Reference Drug 150mg

4. Primary Outcome Measure: Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)]

Measure Type	Primary
Measure Name	Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)]
Measure Description	AUC (0 - ∞)= Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time (0 - ∞). It is obtained from AUC (0 - t) plus AUC (t - ∞).
Time Frame	0, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours post-dose
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.
Each participant received reference and test drug and is, therefore, included in the analysis population for both the reference and test drug.

Measured Values

	Reference Drug 150 mg	Test Drug 150 mg
Number of Participants [units: Participants]	14	14
Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)] [units: mcg*h/mL] Mean ± Standard Deviation	153.33 ± 35.96	154.45 ± 36.81

Statistical Analysis 1 for Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)]

Groups [1]	Reference Drug 150 mg, Test Drug 150 mg
Method [2]	ANOVA
P-Value [3]	0.784755
Other Estimated Parameter [Ratio of AUC (0 - ∞) values] [4]	100.73
90% Confidence Interval	(97.96 to 103.36)

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

No text entered

[2] 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.

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

No text entered.

[4] Other relevant estimation information:

Ratio of AUC (0 - ∞) values = Test Drug 150mg/Reference Drug 150mg

5. Primary Outcome Measure: Plasma Decay Half-Life (t1/2)

Measure Type	Primary
Measure Name	Plasma Decay Half-Life (t1/2)
Measure Description	Plasma decay half-life is the time measured for the plasma concentration to decrease by one half.
Time Frame	0, 1, 2, 3, 4, 6, 8, 12, 24, 48, 72, 96 hours post-dose
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.
Each participant received reference and test drug and is, therefore, included in the analysis population for both the reference and test drug.

Measured Values

	Reference Drug 150 mg	Test Drug 150 mg
Number of Participants [units: Participants]	14	14
Plasma Decay Half-Life (t1/2) [units: hours] Least Squares Mean ± Standard Deviation	29.99 ± 4.84	29.99 ± 4.34