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OMB NO: 0910-0459
EXPIRATION DATE: 01/31/2011
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Select Protocol Record - Edit

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Sort by Protocol ID	ClinicalTrials.gov ID	Sort by Brief Title	Sort by Owner	Sort by Updater	Sort by Updated	Record Status
Edit	11110000	Study of Investigational New Device for Heart Disease			12/08/2008 12:47	Completed
Edit	PL110-85	Food and Drug Administration Amendments Act of 2007, Title VIII (RESULTS)			12/08/2008 12:47	In Progress

[Main Menu](#)

Results: **Pre-fill Results from Protocol**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Results are required only after the study is Complete. Click Cancel if you are not ready to report results.

The protocol information shown below will be copied into the results section of the record. Please review the information carefully. If the information is not correct, cancel and edit the protocol record. For each protocol arm an Arm/Group will be created in the results section.

Protocol Arm Label and Description	<p>You may use the data entry system to modify the arms/groups. If modified, changes may need to be made in both protocol and results sections.</p> <p>Combo</p> <p>Drug X = Drug Y + Drug Z</p> <p>Placebo</p>
Protocol Primary Outcome Measures	<p>For each protocol primary outcome measure, a primary outcome measure will be created in the results section. You may use the data entry system to modify the primary outcome measures.</p> <ul style="list-style-type: none"> Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI [Within the first 30 days (plus or minus 3 days) after surgery] ; Safety Issue? Yes
Protocol Secondary Outcome Measure	<p>For each protocol secondary outcome, a secondary outcome measure will be created in the results section. You may use the data entry system to modify the secondary outcome measures.</p> <p>Protocol has no secondary outcomes.</p>

Create Results section of record PL110-85?

OK Cancel

Results: [Overview](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

[Edit](#)

Results Point of Contact: Name/Official Title:
Organization:
Phone:
Email:

- STOP ERROR : Neither Phone nor Email was entered for results point of contact.**
- STOP ERROR : Results point of contact Organization has not been entered.**
- STOP ERROR : Results point of contact Name/Official Title has not been entered.**

[Edit](#)

Certain Agreements: [Relationship of Principal Investigator and Sponsor not specified.]

- STOP ERROR : The Certain Agreement question about PI employment has not been answered.**

[Edit](#)

Participant Flow: Trial Period: Overall Study

- STOP ERROR : Number of participants to Complete Period not entered**
- STOP ERROR : Number of participants to Complete Period not entered**
- STOP ERROR : Number of participants to Start Period not entered**
- STOP ERROR : Number of participants to Start Period not entered**

Baseline Characteristics: [Post Baseline Characteristics](#)
Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted.

- STOP ERROR : Baseline measures have not been entered.**

[Edit](#)

Outcome Measures: Primary Outcome(s):
 Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI [Within the first 30 days (plus or minus 3 days) after surgery] Units: <>
Secondary Outcome(s):
None

- STOP ERROR : At least one primary outcome measure must post result data.**

[Edit](#)

Limitations and Caveats:

Adverse Events: [Post Adverse Events](#)



Results: **Edit Point of Contact**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Name or Official Title: * Enter the results point of contact by name or official title.

Medical Director

Organization Name: * PharmEx

Phone: * 402-352-2121

ext.

Email: * MDirector@PharmEx.com

OK

Cancel

Results: **Overview**

Title: Food and Drug Administration Amendments Act of 2007, Title V... ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

[Edit](#)

Results Point of Contact:	Name/Official Title: Medical Director
	Organization: PharmEx
	Phone: 402-352-2121
	Email: MDirector@PharmEx.com

[Edit](#)

Certain Agreements:	[Relationship of Principal Investigator and Sponsor not specified.]
----------------------------	---

STOP ERROR : The Certain Agreement question about PI employment has not been answered.

[Edit](#)

Participant Flow:	Trial Period: Overall Study
--------------------------	-----------------------------

- STOP ERROR : Number of participants to Start Period not entered**
- STOP ERROR : Number of participants to Start Period not entered**
- STOP ERROR : Number of participants to Complete Period not entered**
- STOP ERROR : Number of participants to Complete Period not entered**

Baseline Characteristics: [Post Baseline Characteristics](#)
Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted.

STOP ERROR : Baseline measures have not been entered.

[Edit](#)

Outcome Measures:	Primary Outcome(s): <input type="text" value="Not Posted"/> Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI [Within the first 30 days (plus or minus 3 days) after surgery] Units: <>
	Secondary Outcome(s): None

STOP ERROR : At least one primary outcome measure must post result data.

[Edit](#)

Limitations and Caveats:	
---------------------------------	--

Adverse Events: [Post Adverse Events](#)



Results: [Edit Certain Agreements](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V... ID: PL110-85

Restrictions on PI after Trial is Completed*

*Other than an agreement solely to comply with applicable provisions of law protecting the privacy of human participants.

<p>Are all PIs Employees of Sponsor?*</p>	<p>If all principal investigators are employees of the sponsor, select "Yes" and skip the remaining questions.</p> <p><input type="text" value="Yes"/></p>
<p>Results Disclosure Restriction on PI(s)?</p>	<p>If there is an agreement between the sponsor (or its agent) and any non-employee PI(s) that restricts the PI's rights to discuss or publish trial results after the trial is completed, select "Yes" and select a "Restriction Type." Trial completion is defined as the final date on which data were collected (see Study Completion Date definition).</p> <p>If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes" and answer the remaining question.</p> <p><input type="text" value="-- Please Select --"/></p> <p>If "No", skip the following question.</p>
<p>PI Disclosure Restriction Type:</p>	<p>Indicate which type of restriction applies. If there are varying agreements with multiple PIs, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period).</p> <ul style="list-style-type: none"><input checked="" type="radio"/> None Selected<input type="radio"/> 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 from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.<input type="radio"/> 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 from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.<input type="radio"/> Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. <p>If the restriction type is "Other disclosure agreement ...", please describe the agreement.</p> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>

Results: [Overview](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

Edit	Results Point of Contact:	Name/Official Title: Medical Director Organization: PharmEx Phone: 402-352-2121 Email: MDirector@PharmEx.com
Edit	Certain Agreements:	All Principal Investigators ARE employed by the organization sponsoring the study.
Edit	Participant Flow:	Trial Period: Overall Study STOP ERROR : Number of participants to Complete Period not entered STOP ERROR : Number of participants to Complete Period not entered STOP ERROR : Number of participants to Start Period not entered STOP ERROR : Number of participants to Start Period not entered
	Baseline Characteristics:	Post Baseline Characteristics Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted. STOP ERROR : Baseline measures have not been entered.
Edit	Outcome Measures:	Primary Outcome(s): <input type="text" value="Not Posted"/> Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI [Within the first 30 days (plus or minus 3 days) after surgery] Units: <> Secondary Outcome(s): None STOP ERROR : At least one primary outcome measure must post result data.
Edit	Limitations and Caveats:	
	Adverse Events:	Post Adverse Events

Results: **Participant Flow**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

Edit	Recruitment Details:	
	Pre-assignment Details:	

[Create Period](#)

[Add Arm/Group](#)

Periods		Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Overall Study Modify/Delete	STARTED		
	COMPLETED		
	Not Completed: (=Started - Completed)	unknown (Calculated)	unknown (Calculated)

Started Milestone Messages:

-  **ERROR : Number of participants to Start Period not entered**
-  **ERROR : Number of participants to Start Period not entered**

Completed Milestone Messages:

-  **ERROR : Number of participants to Complete Period not entered**
-  **ERROR : Number of participants to Complete Period not entered**

Results:Participant Flow: **Edit Pre-assignment Description**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Recruitment Please enter key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context.
Details:

Pre-assignment Please describe any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups.
Details:

OK

Cancel

Results:Participant Flow:Period: **Edit Milestone Data**

Title: Food and Drug Administration Amendments Act of 2007, Title V... ID: PL110-85

Please enter the number of participants for each milestone and any related comments

<u>Overall Study</u>	Combo	Placebo
<u>STARTED</u>	Number: <input type="text" value="250"/> *	Number: <input type="text" value="260"/> *
	Comments: <input type="text"/>	Comments: <input type="text"/>
<u>COMPLETED</u>	Number: <input type="text" value="240"/> *	Number: <input type="text" value="250"/> *
	Comments: <input type="text"/>	Comments: <input type="text"/>

Results: **Participant Flow**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

Edit	Recruitment Details:	
	Pre-assignment Details:	

Create Period

[Add Arm/Group](#)

Periods		Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit	Overall Study Modify/Delete		
	STARTED		
	COMPLETED		
	Not Completed: <i>(=Started - Completed)</i>	unknown <i>(Calculated)</i>	unknown <i>(Calculated)</i>

Started Milestone Messages:

-  **ERROR : Number of participants to Start Period not entered**
-  **ERROR : Number of participants to Start Period not entered**

Completed Milestone Messages:

-  **ERROR : Number of participants to Complete Period not entered**
-  **ERROR : Number of participants to Complete Period not entered**

Results:Participant Flow: **Add Period**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

When a trial has more than one period, none of the period titles should be "Overall Study"

Period Title: *

New Period Title: *

OK

Cancel

Results: **Participant Flow**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

Edit	Recruitment Details:	
	Pre-assignment Details:	

[Create Period](#)

[Add Arm/Group](#)

Periods		Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit	Overall Study Modify/Delete		
	STARTED		
	COMPLETED		
	Not Completed: <i>(=Started - Completed)</i>	unknown <i>(Calculated)</i>	unknown <i>(Calculated)</i>

Started Milestone Messages:

-  **ERROR : Number of participants to Start Period not entered**
-  **ERROR : Number of participants to Start Period not entered**

Completed Milestone Messages:

-  **ERROR : Number of participants to Complete Period not entered**
-  **ERROR : Number of participants to Complete Period not entered**

Results:Participant Flow: **Add Participant Flow Arm/Group**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Arm/Group Title: *

Arm/Group Description:

Modify Similar Arm/Groups: Also add similar group in: **Baseline Characteristics**

Yes, add similar groups No, add only this group

OK

Cancel

Results:Participant Flow: **Period**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Participant Flow](#)

[Add Milestone](#)

Edit	Overall Study	Combo	Placebo
	STARTED	250	260
	COMPLETED	240	250
	Not Completed: (=Started - Completed)	10 (Calculated)	10 (Calculated)

[Add Reason for Not Completed](#)

No Reasons for Not Completed

Results:Participant Flow:Period: **Add Reason Not Completed**

Title: Food and Drug Administration Amendments Act of 2007, Title V... ID: PL110-85

<u>Reason Not Completed:</u> *	-- Please Select --
<u>Other Reason:</u>	-- Please Select --
	Adverse Event
	Death
	Lack of Efficacy
	Lost to Follow-up
	Physician Decision
	Pregnancy
	Protocol Violation
	Withdrawal by Subject
	Other

OK Cancel

is selected as Reason Not Completed.

Results:Participant Flow:Period: **Edit Reason Not Completed Data**

Title: Food and Drug Administration Amendments Act of 2007, Title V... ID: PL110-85

Please enter the number of participants to drop or withdraw due to each reason. Include each participant only once. The sum across all reasons in a group should equal the total not completed for the group.

<u>Overall Study</u>	Combo	Placebo
	Number Participants	Number Participants
Total Not Completed	10 <i>(Calculated=Started - Completed Milestone)</i>	10 <i>(Calculated=Started - Completed Milestone)</i>
Adverse Event	<input type="text" value="5"/> *	<input type="text" value="6"/> *
Lost to Follow-up	<input type="text" value="5"/> *	<input type="text" value="4"/> *

Results: [Overview](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

Edit	Results Point of Contact:	Name/Official Title: Medical Director Organization: PharmEx Phone: 402-352-2121 Email: MDirector@PharmEx.com
Edit	Certain Agreements:	All Principal Investigators ARE employed by the organization sponsoring the study.
Edit	Participant Flow:	Trial Period: Overall Study
Edit	Baseline Characteristics:	Post Baseline Characteristics Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted.
Edit		<p>STOP ERROR : Baseline measures have not been entered.</p>
Edit	Outcome Measures:	Primary Outcome(s): <input type="text" value="Not Posted"/> Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI [Within the first 30 days (plus or minus 3 days) after surgery] Units: <> Secondary Outcome(s): None
Edit		<p>STOP ERROR : At least one primary outcome measure must post result data.</p>
Edit	Limitations and Caveats:	
Edit	Adverse Events:	Post Adverse Events

Results: **Baseline Overview**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

	Add Baseline Measure	Add Arm/Group	
		Total	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete
			Placebo Modify/Delete
Edit	Overall Number of Baseline Participants	510 <i>(Calculated)</i>	250

Age Categorical <i>Units: participants</i> Modify/Delete			
		<i>Total</i>	<i>Combo</i>
	<i>Number participants</i>	<i>(Calculated)</i>	
<=18 years		<>	<>
Between 18 and 65 years		<>	<>
>=65 years		<>	<>

[Edit](#)

Results:Baseline Overview:Baseline Measure: [Edit Measure Category Data](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Age Categorical

<u>Age Categorical</u> *	Total	Combo	Placebo
	Number	Number	Number
<=18 years <i>Units: participants</i>	<i>Total will be sum of all groups.</i>	<input type="text" value="100"/>	<input type="text" value="100"/>
Between 18 and 65 years <i>Units: participants</i>	<i>Total will be sum of all groups.</i>	<input type="text" value="100"/>	<input type="text" value="110"/>
>=65 years <i>Units: participants</i>	<i>Total will be sum of all groups.</i>	<input type="text" value="50"/>	<input type="text" value="50"/>

Results: **Baseline Overview**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

Add Baseline Measure

[Add Arm/Group](#)

	Total	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Overall Number of Baseline Participants	510 (Calculated)	250	260

Age Categorical Units: participants

[Modify/Delete](#)

		<i>Total</i>	<i>Combo</i>	<i>Placebo</i>
Edit				
<=18 years	Number participants	200 (Calculated)	100	100
Between 18 and 65 years	Number participants	210 (Calculated)	100	110
>=65 years	Number participants	100 (Calculated)	50	50

Results:Baseline Overview: **Add Baseline Measure**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Baseline Measure Title: *

Study-Specific Baseline Measure Title: If the Baseline Measure Title is "Study-Specific", please enter a brief descriptive name for the measure.

Baseline Measure Description: Additional information such as details about the collection method or participant population, if different from Overall
Number of Baseline Participants.

Measure Type: *

Measure of Dispersion: * Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.

Unit of Measure: * If the Measure Type is "Number", the Unit of Measure is typically "participants".

Results: [Overview](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

Edit	Results Point of Contact:	Name/Official Title: Medical Director Organization: PharmEx Phone: 402-352-2121 Email: MDirector@PharmEx.com
Edit	Certain Agreements:	All Principal Investigators ARE employed by the organization sponsoring the study.
Edit	Participant Flow:	Trial Period: Overall Study
Edit	Baseline Characteristics:	Age Categorical Gender, Male/Female
Edit	Outcome Measures:	Primary Outcome(s): <input type="text" value="Not Posted"/> Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI [Within the first 30 days (plus or minus 3 days) after surgery] Units: <> Secondary Outcome(s): None
ERROR : At least one primary outcome measure must post result data.		
Edit	Limitations and Caveats:	
	Adverse Events:	Post Adverse Events

Results: Outcome Overview: **Edit Outcome Measure**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

<u>Outcome Measure Type</u> *	Primary
<u>Outcome Measure Reporting Status</u> *	Indicate whether posting results data for this outcome measure. At least one outcome in each record must be "Posted". Posted
<u>Anticipated Posting Date</u>	If the Reporting Status is "Not Posted", please enter a month and 4 digit year for the anticipated posting date. Month: -- Please Select -- Year:
<u>Outcome Measure Title</u> *	Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI
<u>Outcome Measure Time Frame</u> *	Within the first 30 days (plus or minus 3 days) after su
<u>Outcome Measure Description</u>	
<u>Safety Issue</u> (FDAAA)	Is this outcome measure assessing a safety issue? Yes
<u>Measure Type</u> *	Number
<u>Measure of Dispersion</u> *	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types. Not Applicable
<u>Unit of Measure</u> *	If the Measure Type is "Number", the Unit of Measure is typically "participants". participants

Results:Outcome Overview: **Outcome Measure**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Outcome Overview](#)

Posted

Primary Outcome: Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI ; Units: participants [Within the first 30 days (plus or minus 3 days) after surgery]

[Add Arm/Group](#)

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Number of Participants Analyzed	240	250
Analysis Population Description		

[Create Categories](#)

Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Combo	Placebo
Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI	Number	Number
Edit <i>Units: participants</i>	ERROR : A measure value has not been entered.	ERROR : A measure value has not been entered.

[Add Statistical Analysis](#)

Results: Outcome Overview: Outcome Measure: **Edit Participants Analyzed**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Posted

Primary Outcome: Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI ; Units: participants [Within the first 30 days (plus or minus 3 days) after surgery]

Please enter the number of participants analyzed for this specific outcome measure.

	Combo	Placebo
<u>Number of Participants Analyzed:</u>*	<input type="text" value="240"/>	<input type="text" value="250"/>
<u>Analysis Population Description:</u>	Please explain how the number of participants for analysis was determined. Indicate whether the analysis was per protocol, intention to treat (ITT), or another method. Also provide relevant details such as imputation technique (e.g., Last Observation Carried Forward (LOCF)), as appropriate. <input type="text"/>	

OK

Cancel

Results:Outcome Overview: **Outcome Measure**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Outcome Overview](#)

Posted

Primary Outcome: Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI ; Units: participants [Within the first 30 days (plus or minus 3 days) after surgery]

[Add Arm/Group](#)

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Number of Participants Analyzed	240	250
Analysis Population Description		

[Create Categories](#)

Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Combo	Placebo
Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI	Number	Number
Edit <i>Units: participants</i>	ERROR : A measure value has not been entered.	ERROR : A measure value has not been entered.

[Add Statistical Analysis](#)

Results:Outcome Overview:Outcome Measure: [Edit Measure Category Data](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Posted

Primary Outcome: Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI ; Units: participants [Within the first 30 days (plus or minus 3 days) after surgery]

Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI *	Combo	Placebo
<i>Units: participants</i>	Number <input type="text" value="25"/>	Number <input type="text" value="15"/>

OK

Cancel

Results: Outcome Overview: **Outcome Measure**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Outcome Overview](#)

Posted

Primary Outcome: Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI ; Units: participants [Within the first 30 days (plus or minus 3 days) after surgery]

[Add Arm/Group](#)

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Number of Participants Analyzed	240	250
Analysis Population Description		

[Create Categories](#)

Create Categories if you wish to report categorical data (e.g., low, medium, or high).

	Combo	Placebo
Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI	Number	Number
Edit <i>Units: participants</i>	25	15

[Add Statistical Analysis](#)

There are no statistical analyses.

Results:Outcome Overview:Outcome Measure: [Edit Outcome Statistical Analysis](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Posted

Primary Outcome: Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI ; Units: participants [Within the first 30 days (plus or minus 3 days) after surgery]

[Statistical Analysis Overview:](#)

Comparison Group Selection: *

Generally, at least 2 groups should be checked. Check all groups for an "omnibus" analysis.

Combo Placebo

Please provide additional details about the analysis, such as null hypothesis and power calculation.

[Statistical Test of Hypothesis:](#)

Is this a non-inferiority or equivalence analysis? *

If yes, please describe details of power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters.

P-Value: (e.g. <0.01)

If desired, provide additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance.

Statistical Test of Hypothesis:

Method: ANCOVA If other, please specify:

Describe any other relevant information, such as adjustments or degrees of freedom.

When the confidence interval is entered, all 3 confidence interval fields (% , lower, and upper limits) must be entered. Also, when a confidence interval is entered, an Estimated Value and type must be entered. If the confidence interval is one-sided, also provide the Estimated Value in either the Lower Limit or Upper Limit.

% **Confidence Interval:** to

Estimated Value:

What parameter did you estimate(e.g., Odds Ratio)?

If other, please specify:

Parameter Dispersion Type:

Describe any other relevant estimation information, including the direction of the comparison (e.g., describe which Arm/Group represents the numerator and denominator for relative risk).

Method of Estimation:

OK

Cancel

Delete

Results: [Overview](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

Edit	Results Point of Contact:	Name/Official Title: Medical Director Organization: PharmEx Phone: 402-352-2121 Email: MDirector@PharmEx.com
Edit	Certain Agreements:	All Principal Investigators ARE employed by the organization sponsoring the study.
Edit	Participant Flow:	Trial Period: Overall Study
Edit	Baseline Characteristics:	Age Categorical Gender, Male/Female
Edit	Outcome Measures:	Primary Outcome(s): <input type="checkbox"/> Posted Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI <i>[Within the first 30 days (plus or minus 3 days) after surgery] Units: participants</i> Secondary Outcome(s): None
Edit	Limitations and Caveats:	
	Adverse Events:	Post Adverse Events

Results: **Edit Limitations and Caveats**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Overall Limitations and If appropriate, please describe limitations of the trial.

Caveats: Examples: Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.

OK

Cancel

Results: [Overview](#)

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Edit Protocol](#) [Delete Results](#)

Edit	Results Point of Contact:	Name/Official Title: Organization: Phone: Email:	Medical Director PharmEx 402-352-2121 MDirector@PharmEx.com
Edit	Certain Agreements:	All Principal Investigators ARE employed by the organization sponsoring the study.	
Edit	Participant Flow:	Trial Period:	Overall Study
Edit	Baseline Characteristics:	Age Categorical Gender, Male/Female	
Edit	Outcome Measures:	Primary Outcome(s): <input type="text" value="Posted"/>	Evidence of clinically definite ischemic stroke focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI <i>[Within the first 30 days (plus or minus 3 days) after surgery]</i> Units: participants
		Secondary Outcome(s): None	
Edit	Limitations and Caveats:		
	Adverse Events:	Post Adverse Events	

Results: **Adverse Events**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

[Delete Adverse Event Report](#) You may delete the entire Adverse Events section from the reported Results. Adverse event reporting is not required at this time.

[Add Arm/Group](#)

Add Serious Adverse Event List all Serious Adverse Events.

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit	Total # Affected by any Serious Adverse Event	

[Add Other Adverse Event](#) List all Other (Not Including Serious) Adverse Events which occur above the reporting threshold.

Edit	Frequency Threshold for reporting Other Adverse Event	< %
	Combo	Placebo
Edit	Total # Affected by any Other Adverse Event	

Results: Adverse Events: **Add Serious Adverse Event**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

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Adverse Event Term:*

Source Vocabulary Name:

Please enter the name and version for the term's source vocabulary, if any, (e.g., MeSH 2007, SNOMED CT 2007, ICD9CM_2007, MedDRA 10.0).

Organ System:*

- Please Select -

Assessment Type:*

- Please Select -

OK

Cancel

Results: **Adverse Events**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

[Delete Adverse Event Report](#) You may delete the entire Adverse Events section from the reported Results. Adverse event reporting is not required at this time.

[Add Arm/Group](#)

[Add Serious Adverse Event](#) List all Serious Adverse Events.

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Total # Affected by any Serious Adverse Event	◇	◇

[Add Other Adverse Event](#) List all Other (Not Including Serious) Adverse Events which occur above the reporting threshold.

Edit Frequency Threshold for reporting Other Adverse Event	◇ %	
	Combo	Placebo
Edit Total # Affected by any Other Adverse Event	◇	◇

Results: Adverse Events: **Edit Serious Adverse Event Data**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

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Please enter the number of participants affected or at risk as integers. Also, if available, enter the number of events as integers.

Serious Adverse Event(s)	Combo <i>Drug X = Drug Y + Drug Z</i>			Placebo		
	# Affected *	# Events	# Participants at Risk *	# Affected *	# Events	# Participants at Risk *
Total # Affected by any Serious Adverse Event*	<input type="text" value="50"/>			<input type="text" value="60"/>		
Heart Attack <i>Systematic Assessment</i>	<input type="text" value="50"/>	<input type="text" value="57"/>	<input type="text" value="250"/>	<input type="text" value="60"/>	<input type="text" value="62"/>	<input type="text" value="260"/>

Results: **Adverse Events**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

[Delete Adverse Event Report](#) You may delete the entire Adverse Events section from the reported Results. Adverse event reporting is not required at this time.

[Add Arm/Group](#)

[Add Serious Adverse Event](#) List all Serious Adverse Events.

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Total # Affected by any Serious Adverse Event	50	60
Heart Attack <i>Cardiac disorders</i> <i>Systematic Assessment</i> Modify/Delete	50 Affected (57 Events) out of 250 At Risk:	60 Affected (62 Events) out of 260 At Risk:

[Add Other Adverse Event](#) List all Other (Not Including Serious) Adverse Events which occur above the reporting threshold.

Edit Frequency Threshold for reporting Other Adverse Event	< %	
	Combo	Placebo
Edit Total # Affected by any Other Adverse Event	< ERROR : The total number affected has not been entered.	< ERROR : The total number affected has not been entered.

Results: **Adverse Events**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

[Results Overview](#)

[Delete Adverse Event Report](#) You may delete the entire Adverse Events section from the reported Results. Adverse event reporting is not required at this time.

[Add Arm/Group](#)

[Add Serious Adverse Event](#) List all Serious Adverse Events.

	Combo <i>Drug X = Drug Y + Drug Z</i> Modify/Delete	Placebo Modify/Delete
Edit Total # Affected by any Serious Adverse Event	50	60
Heart Attack <i>Cardiac disorders Systematic Assessment</i> Modify/Delete	50 Affected (57 Events) out of 250 At Risk:	60 Affected (62 Events) out of 260 At Risk:

[Add Other Adverse Event](#) List all Other (Not Including Serious) Adverse Events which occur above the reporting threshold.

Edit Frequency Threshold for reporting Other Adverse Event	5 %	
	Combo	Placebo
Edit Total # Affected by any Other Adverse Event	50	60
Allergy <i>Immune system disorders Spontaneous Report</i> Modify/Delete	50 Affected (78 Events) out of 250 At Risk:	60 Affected (89 Events) out of 260 At Risk:

Results: Adverse Events: **Edit Other (Not Including Serious) Adverse Event Data**

Title: Food and Drug Administration Amendments Act of 2007, Title V...

ID: PL110-85

Please enter the number of participants affected or at risk as integers. Also, if available, enter the number of events as integers.

<u>Other Adverse Event(s)</u>	Combo <i>Drug X = Drug Y + Drug Z</i>	Placebo				
Total # Affected by any Other Adverse Event*	<input type="text" value="50"/>	<input type="text" value="60"/>				
	# Affected *	# Events	# Participants at Risk *	# Affected *	# Events	# Participants at Risk *
Allergy <i>Spontaneous Report</i>	<input type="text" value="50"/>	<input type="text" value="78"/>	<input type="text" value="250"/>	<input type="text" value="60"/>	<input type="text" value="89"/>	<input type="text" value="260"/>

OK **Cancel**