ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Login

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

OMB NO: 0910-0459
EXPIRATION DATE: 01/31/2011
Burden Statement

Organization:

User Name:

Password: Forgot password

Login

PRS account registration information

Send email to ClinicalTrials.gov Administration

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Important Information on U.S. Public Law 110-85 Feb 5, 2008
About Results Data Entry...

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Select Protocol Record - Edit

Main Menu

	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

Edit Protocol Record

Next Action: Complete Tip: Remember to update Record Verification Date when reviewing or updating a protocol record.

Record Status: **In Progress** | Completed | Approved | Released

Owned by: **Last updated:** 12/08/2008 12:47

Initial release: [not yet released]

Edit		
Edit	**Comments:**	None

Edit		
Edit	**Unique Protocol ID:**	PL110-85
	Secondary IDs:	
	ClinicalTrials.gov ID:	
	Brief Title:	Food and Drug Administration Amendments Act of 2007, Title VIII (RESULTS)
	Official Title:	Food and Drug Administration Amendments Act of 2007, Title VIII, Results Database Screen Shots
	Study Type:	Interventional
	FDA Regulated Intervention?	No
	IND/IDE Protocol?	No

For completed studies: Enter Results About Results Data Entry... Delayed Results Posting...

Edit		
Edit	**Sponsor:**	Test Organization
	Collaborators:	
	Responsible Party:	Name/Official Title: Name Organization: Org Phone: Phone Ext: Email:

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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	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. Combo Drug X = Drug Y + Drug Z Placebo
Protocol Primary Outcome Measures	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. • 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	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. Protocol has no secondary outcomes.

Create Results section of record PL110-85?

OK Cancel

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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): 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

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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

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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.]
		ERROR : The Certain Agreement question about PI employment has not been answered.
Edit	**Participant Flow:**	Trial Period: Overall Study
		ERROR : Number of participants to Start Period not entered **ERROR : Number of participants to Start Period not entered** **ERROR : Number of participants to Complete Period not entered** **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.
		ERROR : Baseline measures have not been entered.
Edit	**Outcome Measures:**	Primary Outcome(s): 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:: **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.

Are all PIs Employees of Sponsor?*	If all principal investigators are employees of the sponsor, select "Yes" and skip the remaining questions. Yes
Results Disclosure Restriction on PI(s)?	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). 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. -- Please Select -- If "No", skip the following question.
PI Disclosure Restriction Type:	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). (•) None Selected ( ) 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. ( ) 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. ( ) Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. If the restriction type is "Other disclosure agreement ...", please describe the agreement.

OK Cancel

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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
		ERROR : Number of participants to Complete Period not entered **ERROR : Number of participants to Complete Period not entered** **ERROR : Number of participants to Start Period not entered** **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.
		ERROR : Baseline measures have not been entered.
Edit	**Outcome Measures:**	Primary Outcome(s): 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: **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 *Drug X = Drug Y + Drug Z* 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 Details:	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.
Pre-assignment Details:	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.

OK Cancel

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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

Overall Study	Combo	Placebo
STARTED	Number: 250 *	Number: 260 *
	Comments	Comments
COMPLETED	Number: 240 *	Number: 250 *
	Comments	Comments

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 *Drug X = Drug Y + Drug Z* 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

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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:*	Overall Study
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 *Drug X = Drug Y + Drug Z* 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

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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

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

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

Reason Not Completed: * -- Please Select --

Other Reason: s selected as Reason Not Completed.

OK Cancel

-- Please Select --
Adverse Event
Death
Lack of Efficacy
Lost to Follow-up
Physician Decision
Pregnancy
Protocol Violation
Withdrawal by Subject
Other

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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.

Overall Study	Combo	Placebo
	Number Participants	Number Participants
Total Not Completed	10 *(Calculated=Started - Completed Milestone)*	10 *(Calculated=Started - Completed Milestone)*
Adverse Event	5 *	6 *
Lost to Follow-up	5 *	4 *

OK Cancel

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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
	Baseline Characteristics:	Post Baseline Characteristics Note: Region of Enrollment will be pre-filled from protocol locations when Baseline Characteristics are first posted.
		ERROR : Baseline measures have not been entered.
Edit	**Outcome Measures:**	Primary Outcome(s): 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: **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 *Drug X = Drug Y + Drug Z* Modify/Delete	Placebo Modify/Delete
Edit	**Overall Number of Baseline Participants**	510 *(Calculated)*	250	260

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

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

Age Categorical *	Total	Combo	Placebo
	Number	Number	Number
<=18 years *Units: participants*	*Total will be sum of all groups.*	100	100
Between 18 and 65 years *Units: participants*	*Total will be sum of all groups.*	100	110
>=65 years *Units: participants*	*Total will be sum of all groups.*	50	50

OK Cancel

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 *Drug X = Drug Y + Drug Z* Modify/Delete	Placebo Modify/Delete
Edit	**Overall Number of Baseline Participants**	510 *(Calculated)*	250	260

	Age Categorical *Units: participants* Modify/Delete			
Edit		*Total*	*Combo*	*Placebo*
	<=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*

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

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

Baseline Measure Title:*	-- Please Select --
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:*	-- Please Select --
Measure of Dispersion:*	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types. -- Please Select --
Unit of Measure:*	If the Measure Type is "Number", the Unit of Measure is typically "participants".

OK Cancel

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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): 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

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

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

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

OK Cancel

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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 *Drug X = Drug Y + Drug Z* 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	*Units: participants*	ERROR : A measure value has not been entered.	ERROR : A measure value has not been entered.

Add Statistical Analysis

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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
Number of Participants Analyzed:*	240	250
Analysis Population Description:	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.	

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 *Drug X = Drug Y + Drug Z* 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	*Units: participants*	ERROR : A measure value has not been entered.	ERROR : A measure value has not been entered.

Add Statistical Analysis

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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
	Number	Number
Units: participants	25	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 *Drug X = Drug Y + Drug Z* 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	*Units: participants*	25	15

Add Statistical Analysis

There are no statistical analyses.

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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.

Is this a non-inferiority or equivalence analysis? * No

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

Statistical Test of Hypothesis:

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

Method of Estimation:

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.

95 **% Confidence Interval:** **to**

Estimated Value:

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

If other, please specify:

Parameter Dispersion Type: – Please Select –

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).

OK Cancel Delete

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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): 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: participants* Secondary Outcome(s): None
Edit	**Limitations and Caveats:**	
	Adverse Events:	Post Adverse Events

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Results: **Edit Limitations and Caveats**

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

Overall Limitations and Caveats:	If appropriate, please describe limitations of the trial. Examples: Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.

OK Cancel

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Send message to PRS

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): 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: participants* Secondary Outcome(s): None
Edit	**Limitations and Caveats:**	
	Adverse Events:	Post Adverse Events

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Protocol Registration System

Send message to PRS

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 *Drug X = Drug Y + Drug Z* 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**	<>	<>

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

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

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 *Drug X = Drug Y + Drug Z* 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**	<>	<>

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Protocol Registration System

Send message to PRS

Results:Adverse Events: **Edit 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.

Serious Adverse Event(s)	Combo *Drug X = Drug Y + Drug Z*			Placebo		
Total # Affected by any Serious Adverse Event*	50			60		
	# Affected *	# Events	# Participants at Risk *	# Affected *	# Events	# Participants at Risk *
Heart Attack *Systematic Assessment*	50	57	250	60	62	260

OK Cancel

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

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 *Drug X = Drug Y + Drug Z* Modify/Delete	Placebo Modify/Delete
Edit	**Total # Affected by any Serious Adverse Event**	50	60
	Heart Attack *Cardiac disorders* *Systematic Assessment* 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.**

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

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 *Drug X = Drug Y + Drug Z* Modify/Delete	Placebo Modify/Delete
Edit	**Total # Affected by any Serious Adverse Event**	50	60
	Heart Attack *Cardiac disorders* *Systematic Assessment* 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 *Immune system disorders* *Spontaneous Report* Modify/Delete	50 *Affected* (78 *Events*) *out of* 250 *At Risk:*	60 *Affected* (89 *Events*) *out of* 260 *At Risk:*

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

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.

Other Adverse Event(s)	Combo *Drug X = Drug Y + Drug Z*			Placebo		
Total # Affected by any Other Adverse Event*	50			60		
	# Affected *	# Events	# Participants at Risk *	# Affected *	# Events	# Participants at Risk *
Allergy *Spontaneous Report*	50	78	250	60	89	260

OK Cancel