







		Login			
Welcome to the <u>ClinicalTrials gov</u> Protocol Registration System (PRS).				OMB NO: 0910-0459 EXPIRATION DATE: 11/30/2007 Eurolen Statement	
	Organization: User Name: Password:		Forgot password		
		Login			

PRS account registration information

Send email to ClinicalTrials.gov Administration









Main Menu

Important Information on U.S. Public Law 110-85 Dec 12,2007

Protocol Records

Create

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Check my records

 $\underline{\text{Undelete}}$

User Account

Change password PRS Administrator(s)

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What's New Dec 18, 2007

User's Guide

Data Element Definitions

FDAMA 113 Requirements

Session

Logout







Create New Protocol Record

Especially for multi-site trials, data submitters must coordinate with all of their partners such that trial information is submitted only once to ClinicalTrials.gov.

All studies submitted to ClinicalTrials.gov must have approval from a human subjects review board, such as an Institutional Review Board, ethics committee or equivalent group.

Unique Protocol ID: *	123456789	
Brief Title: *	FDA Amendments Act of 2007, Title VIII, Screenshots	
Continue Cancel	* Required fields	



Continue

Quit







Fitle Oversight Sponsor Summary	Status Design Interventions Conditions Eligibility Locations Citations Links	
Citle: FDA Amendments Act of 2007,	Title VIII, Screenshots	ID: 123456789
Unique Protocol ID: *	Enter sponsoring organization's unique identifier. 123456789	
Brief Title: * (Special characters)	Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer FDA Amendments Act of 2007, Title VIII, Screenshots	
Acronym:	If there is an acronym or abbreviation used to identify this study, enter it here.	
Official Title:	Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic	: Adenocarcinoma of the Prostate
Secondary ID's: * (One ID per line)	Include ISRCTN, NIH grant or contract numbers.	
Study Type: *	○ Interventional ○ Observational ○ Expanded Access About expanded access records	
FDA Regulated Intervention? *	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations. —Select− ▼	
IND/IDE Protocol? *	Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigation (IDE). —Select─ ▼	nal New Drug (IND) Application or Investigational Device Exemption









Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Provide information for the human subjects review board, such as an Institutional Review Board (IRB), ethics committee or equivalent group, that is responsible for the review and monitoring of this protocol. For studies involving multiple review boards, provide information only for a single board.

Board Approval: *	If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date in mm/dd/yyyy format. Please send a signed board approval letter to ClinicalTrials.gov (address and instructions). Status: —Select— Approval Number:
Board Name: *	
Board Affiliation: *	
Board Contact: * (Not made public)	NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov. Business Phone: Business Email: Business Address:
Data Monitoring Committee?	Has a group been appointed to monitor safety and scientific integrity of the study? —Select─ ▼
Oversight Authorities: * (One per line)	Enter, in English, country followed by organization name. [List of oversight authorities] Examples: United States: Food and Drug Administration Germany: Federal Institute for Drugs and Medicinal Devices
Continue Quit	* Required fields



Quit

Continue







Title Oversight Sponsor Summary	Status Design Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007,	Title VIII, Screenshots	ID: 123456789
Sponsor: *	Test Organization	
Collaborators: (One per line)	Include all additional funding sources. Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).	
Responsible Party: *	Sponsor or principal investigator, as defined in US Public Law 110-85, Title VI If responsible party is an organization enter the contact person by Name/Official Title: If responsible party is an individual enter organizational affiliation. Organization: Contact information will not be made public. Phone: Extension: Email:	



Quit

Continue







	status Design Interventions Conditions Eligibility Locations Citations Links	
Citle: FDA Amendments Act of 2007, Titl	e VIII, Screenshots	ID: 123456789
Brief Summary: * (Formatting tips)	Use lay language. Include a statement of the study hypothesis.	
Detailed Description: (Formatting tips)	Provide a more extensive description, if desired. Avoid duplication of information to be recorded elsewhere, such as eligibility criteria or outcome measures.	



Continue

Quit







Title Oversight Sponsor Summary Status Design	Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Title VIII, Scre	enshots	ID: 123456789
Record Verification Date: *	-Select- ▼ Year:	
Overall Recruitment Status: *	-Select- ✓	
Why Study Stopped:	For suspended, terminated or withdrawn studies, briefly explain why the study was stopped.	
Key Trial Dates		
Study Start Date: *	-Select- ✓ Year:	
Study Completion Date:	-Select- ▼ Year: Type: -Select- ▼	
Primary Completion Date: *	Final data collection date for primary outcome measure. -Select- Year: Type: -Select- Y	









Title Oversight Sponsor Summary Status Design Interventions Conditions	Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Title VIII, Screenshots		ID: 123456789
NOTE: These attributes apply to an "Interventional" study. If desired,	change the study type to "Observational".	
Primary Purpose: *	-Select- ✓	
Study Phase: *	-Select- ▼	
Intervention Model: *	Formerly referred to as Study Design or Assignment. -Select-	
Number of Arms: *		
Masking: *	—Select— ✓ Masked Roles: □ Subject □ Caregiver □ Investigator □ Outcomes Assessor	
Allocation: *	-Select- ▼	
Control:	Control is being phased out. Specify study arms instead. -Select-	
Study Endpoint Classification:	-Select- ▼	
Enrollment: *	Number of Subjects: Type: -Select- V	
Continue Quit * Requir	ed fields	



Continue

Quit







	Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Title VⅢ, Scre	enshots enshots	ID: 123456789
NOTE: These attributes apply to an "Obser	vational" study. If desired, change the study type to "Interventional".	
Observational Study Model: *	Formerly referred to as Study Design. -Select-	
Time Perspective: *	-Select- ▼	
Biospecimen Retention: *	-Select- ✓	
Biospecimen Description: *	May be left blank if no biospecimens are to be retained.	
Enrollment: *	Number of Subjects: Type: -Select- •	
Number of Groups/Cohorts: *		



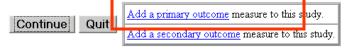






Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Provide the primary and key secondary outcome measures associated with the protocol, along with the associated time frames.



Primary Outcome Measure

Primary Outcomes:

There is no primary outcome measure specified for this study.

Key Secondary Outcome Measures

Secondary Outcomes:

There are no secondary outcome measures specified for this study.

^{*} Required









Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Primary Outcome Measure	
Outcome Measure: *	Enter only one distinct outcome measure.
Time Frame: *	
Safety Issue? *	Does this outcome measure assess a safety issue? —Select— ▼
Continue Quit	* Required fields



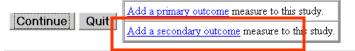






Title: FDA Amendments Act of 2007, Title VIII, Screenshots ID: 123456789

Provide the primary and key secondary outcome measures associated with the protocol, along with the associated time frames.



Primary Outcome Measure

Primary Outcomes:	There is no primary outcome measure specified for this study.
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Key Secondary Outcome Measures

Secondary Outcomes:	There are no secondary outcome measures specified for this study.
---------------------	---

^{*} Required









Title Oversight Sponsor Summary Status **Design** Interventions Conditions Eligibility Locations Citations Links

Title: FDA Amendments Act of 2007, Title VIII, Screenshots

D: 123456789

	Secondary Outcome Measure	
Outcome Measure: *	Enter only one distinct outcome measure.	
Time Frame: *		
Safety Issue? *	Does this outcome measure assess a safety issue? —Select─ ▼	
Continue Quit	* Required fields	









Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Specify the arms, if any, and their associated interventions (Specifying Study Arms).



Study Arms

Arm: *

There are no arms currently listed for this study.

Interventions

Interventions: * There are no Interventions currently listed for this study.

ERROR: At least one Intervention must be specified for an Interventional study.









	sign Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Title VI	II, Screenshots	ID: 123456789
Arm Number or Label: *	Examples: A, 2, III	
Arm Type: *	-Select- ▼	
Arm Description:		
Continue Quit	* Required fields	









Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Specify the arms, if any, and their associated interventions (Specifying Study Arms).



Study Arms

Arm: *

There are no arms currently listed for this study.

Interventions

Interventions: *

There are no Interventions currently listed for this study.

ERROR: At least one Intervention must be specified for an Interventional study.



Quit

Continue







	n Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Title VIII,	Screenshots	ID: 123456789
Intervention Type: *	-Select- ▼	
Intervention Name: *	Use the generic name if it has been established.	
Intervention Description: *	Key details, e.g., for drugs include dosage form, dosage, frequency and duration.	
Other Names: (One per line)	Include brand names, serial numbers and code names, if applicable. If there are no other names for the intervention, enter "n/a".	









Title: FDA Amendments Act of 2007, Title VIII, Screenshots		ID: 123456789
Specify the primary condition or disease being studied, or the primary	nary focus of the study.	
Conditions are checked against the National Library of Medicine' <u>Search MeSH</u> for a specific condition term.	s Medical Subject Headings (MeSH).	
	Enter only condition or focus (no numbers, dashes, bullets, etc.), one per line.	

Conditions or Focus of Study: * (Enter 1 to 5 items)	
<u>Keywords:</u>	Enter only Keywords (no numbers, dashes, bullets, etc.), one per line.

Continue Quit * Required fields



Continue

Quit







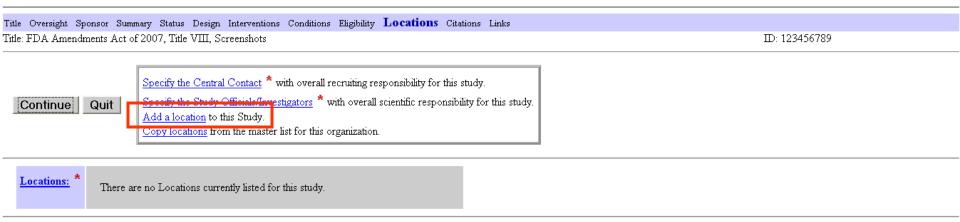
Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links			
Title: FDA Amendments Act of 2007, Title V	III, Screenshots	ID: 123456789	
Study Population Description: *			
Sampling Method: *	-Select- ▼		
Eligibility Criteria: * (Special characters)	For best results use the preferred format. Inclusion Criteria: Exclusion Criteria: -		
Gender: *	-Select- ▼		
Age Limits: *	Minimum:		
Accepts Healthy Volunteers? *	-Select- ▼		

















litle Oversight Sponsor Summary Statu	s Design Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Tit	le VIII, Screenshots	ID: 123456789
Facility: * (Special characters)	Name: City: State/Province: Postal Code: Country:	
Recruitment Status: *	Location recruitment status is required when Overall Status is "Recruiting". If Overall Status is anything other than Recruiting, location status is not displayed on one of the status is not displayed on the status i	ClinicalTrials.gov.
Facility Contact: *	Facility contact is required for locations that are recruiting, but may be ommitted if a Great First: MI:	Central Contact is provided for the trial.
Facility Contact Backup:	First: MI: Last: Degree: Phone: Ext. Email:	
Continue Cancel	* Required	











Continue

Quit

Specify the Central Contact * with overall recruiting responsibility for this study.

Specify the Study Officials/Investigators * with overall scientific responsibility for this study.

Add a location to this Study.

Copy locations from the master list for this organization.

Locations: *

There are no Locations currently listed for this study.



Quit

Continue





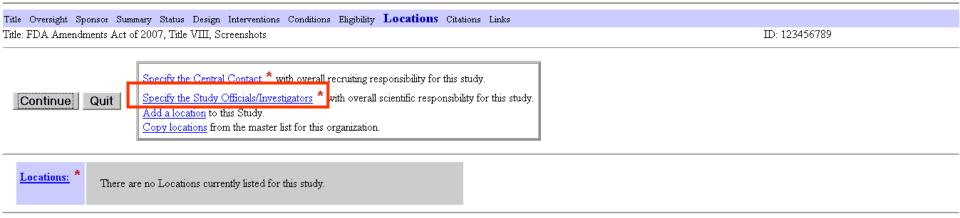


Title Oversight Sponsor Summary Status D		igibility Locat	tions Citations Links		
itle: FDA Amendments Act of 2007, Title V.	Ⅲ, Screenshots				ID: 123456789
-	erson with overall recruitment resp provided for all recruiting locations		The state of the s		
Central Contact: *	First: Phone:	MI: Ext:	Last: Email:	Degree:	
Central Contact Backup:	First: Phone:	MI: Ext:	Last: Email:	Degree:	

















Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Study officials, including the principal investigator, are the persons responsible for the overall scientific leadership of the protocol.

ОК

Add a Study Official to this study.

Study Officials:

There are no Study Officials currently listed for this study.

• NOTE: Study Official is required by the WHO and ICMJE.









Title Oversight Sponsor Summary Status De	esign Interventions Conditions Eligibility Locations Citations Links	
Title: FDA Amendments Act of 2007, Title VI	II, Screenshots	ID: 123456789
Study Official's Name:	First:	
Official's Role:	-Select- ▼	
Organizational Affiliation:		
OK Cancel	* Required fields	









Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Provide Citations of publications related to the protocol, background or results.

Continue

Quit

Add a Citation to this study, if applicable.

Citations:

There are no Citations currently listed for this study.



OK Cancel







itle Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links					
Title: FDA Amendments Act of 2007, Title VIII, Screenshots		ID: 123456789			
Provide the unique PubMed Identifier (PMID) for the citation. Search for a citation in MEDLINE, using the PubMed browser.					
MEDLINE Identifier:	Enter PubMed Identifier (PMID)				
Results Reference?	Does the publication report on results of this study? —Select— •				
If the publication was not found in MEDLINE, enter the citation text.					









Title: FDA Amendments Act of 2007, Title VIII, Screenshots

Use this screen to provide pointers to web pages directly relevant to the protocol. Provide up to 5 suggested links.

Continue

Quit

Add a Link to a related web page to this study, if applicable.

Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

Links:

There are no Links to related web pages currently listed for this study.



Cancel

OK







itle Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links				
Ettle: FDA Amendments Act of 2007, Title VIII, Screenshots				
<u>URL:</u>	http://			
Description:				









Protocol Record Completed

Title: FDA Amendments Act of 2007, Title VIII, Screenshots

ID: 123456789

You have reached the last data entry screen. Proceed to the next screen (Edit Protocol) to review the entire record.

Note that the data that you have entered are automatically validated by the system. Messages describing problems of varying severity (Errors, Alerts, or Notes) are included on the Edit Protocol screen, beneath the relevant fields. Review each message and take the appropriate action.

Once the record is ready for review by your administrator, click on the "Complete" link near the top of the Edit Protocol Record screen to mark the record as completed. Your administrator must then "Approve" and "Release" the record, in order for the record to be submitted for final Quality Assurance review and publication on the ClinicalTrials.gov web site.

