Introduction to Abstracting Participating Sites - Include v4.4

Trials are conducted in participating sites. You must provide information about the site itself (organization), the investigator(s), and primary contacts (if a central contact is not provided). Optionally, you can include contact information for a person's title (functional role) rather than a person's name. When you add a participating site to a trial, link (associate) an organization, site, investigator(s), and primary site contact information to it.

Providing a site contact is optional if you provide a central contact instead.

The system assigns investigators and primary contacts a status code that corresponds to the person's/role's curation status.

Information about participating sites can be included in the protocol document or in the Participating Sites document.

How to Abstract Participating Site Information

- 1. Search for the trial of interest. For instructions, refer to Searching for Trials in PA.
- 2. In the search results, click the NCI Trial Identifier link for that trial. The Trial Identification page appears.
- 3. On the **Trial Identification** page, check out the trial. For instructions, refer to Checking In and Checking Out Trials. (This checkout step is optional for Super Abstractors.)
- 4. On the Administrative Data menu, click Participating Sites. The Participating Sites page appears.
- 5. Click Add.

(i)

The Participating Sites page displays three tabbed sections: Participating Site, Investigators, and Contact. The Participating Site tab is displayed by default.

articipating Site Investiga	tors Contact
Participating Site	
Organization Name:*	University of Pennsylvania/Abranson Cancer Center
City:*	Philadelphia
State."	P9.
Country:	USA
ZipPostal Code(US/Canada/Kastralia)	• 19104
Local Trial Identifier:	
Site Recruitment Status:*	Active
Site Recruitment Status Date:*	09/22/2009 🔄 (mmidd(yyy)
Site Recruitment Status Comments:	4. V
	160 characters left
Target Ascrual Nambers	124 Mandatory if Participating alterLead organization is a cancer center

Add/Edit Participating Site- Complete Trial

articipating Site Investig	ators Contact
Participating Site	
Organization Name:*	Click Look Up to choose an organization.
Local Trial Identifier: *	
Site Recruitment Status:*	Select
Site Recruitment Status Date:*	imm/dd/yyyy)
Site Recruitment Status Comments:	
Target Accrual Number:	160 characters left
	Save Cancel

Add/Edit Participating Site - Abbreviated Trial

You must abstract the Participating Site information in the order indicated by the tabbed pages.

6. On the **Participating Site** tab, in the various fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	For Complete Trials (C) For Abbreviated Trials (A)	Description/Instructions
Organi zation Name*	C, A	Click Look Up and follow the instructions in <u>Searching for Organizations</u> . For <i>Complete</i> trials, the City, State, Country, and Zip/Postal Codes fields are populated with the organization information you selected.
Local Trial Identifi er*	C, A	Enter the site trial identifier.
Site Recruit ment Status*	C, A	 a. Optionally, to view the trial's recruitment status history, click History. b. Select the status from the drop-down list. For valid ClinicalTrials.gov recruitment values, refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Expanded Access Statuses. A The system validates all status transitions when you save a trial status record. If you add or update a status transition that does not conform to the rules provided in Trial Status Transitions, the system displays errors and/or warnings. <i>Warnings</i> indicate that fixing the status record is optional; you do not have to resolve the transitions. However, <i>Errors</i> indicate that you must resolve the transitions by correcting trial status records in the Participating Sites Status History window. You can not check in the trial until you correct all status transition errors. For a comprehensive matrix of valid transitions, see Trial and Participating Sites Status Transition Rules.
Site Recruit ment Status Date*	C, A	Enter the date that the status was recorded. The date must be the current date or earlier.
Site Recruit ment Status Comm ents	C, A	Enter one or more comments about the site recruitment status.
Target Accrua I Number	C, A	If the lead organization or participating site is a member of a Cancer Center family of organizations, enter the accrual number.

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Click Save.
 Click the Investigators tab. The Investigators tab displays the trial investigators that may have been added during trial submission or abstraction.

icipating Sites -> Add/Edit Participating Site					
Participating Site	Investigators Co	ontact			
Participating Site Inv	estigators for Example Res	earch Organization			
One item found.1					
Last Name	First Name	Role	Status Code	Set as Site Primary Contact	Delete
Plaster	Stefanie	Principal Investigator	PENDING		٢
(€) Add					

Investigators Tab for a Complete Trial

rticipating Si	cipating Sites -> Add/Edit Participating Site						
Participating Site Investigators Contact							
Participating 2 items found,	y Site Investigators for displaying all items.1	Albert Lea Medical Cen	ter-Mayo Health System				
PO-ID	Last Name	First Name	Role	Status Code	Set as Site Primary Contact	Delete	
2363610	Audet	Isabelle	Principal Investigator	PENDING		٢	
2329559	Bedrosian	Isabelle	Sub Investigator	PENDING		8	
	Add						

Investigators Tab for an Abbreviated Trial

9. Click Add and search for the investigator's name by following the instructions in Searching for Persons.

PO-ID	CTEP-ID	First Name	Middle Name	Last Name	Address	Email	Role Code	Action
2363610	37929	Isabelle	Marie- Marthe	Audet	Warren,MI,USA,48903	lauletigmen com	Principal Investigator	O Select
2329559	37726	Isabelle		Bedrosian	Houston,TX,USA,77030	bedrosian@mdanderson.org	Sub Investigator	O Select

10. When you find the investigator in the search results list, assign the investigator role, either **Principal Investigator** or **Sub Investigator**, and then click **Select**. The person's record you selected appears on the Investigators tab.

Participating	Site Investigators for <i>I</i>	Albert Lea Medical Cen	iter-Mayo Health System			
items found, d	isplaying all items.1					
PO-ID	Last Name	First Name	Role	Status Code	Set as Site Primary Contact	Delete
2262630	Audet	Isabelle	Principal Investigator	PENDING	R.	۵
2329558	Bedrosian	isabelle	Sub Investigator	PENDING	A .	0

11. If you want to indicate that an investigator is the primary contact, click the Set as Site Primary Contact icon next to this investigator's record.



12. Click the **Contact** tab. The Participating Sites page displays the Contact tab.

You must link a Participating Site to the trial before abstracting the site PI and contact information. You can add a contact by providing a person's name (i.e., someone who is associated with the trial itself), or you can add a generic contact (i.e., someone who is associated with the site but not necessarily the trial) by providing a person's title (functional role). You can not provide both types of contacts in the same record.

If you designated a primary investigator as the primary contact (on the Investigators tab), the investigator's name is displayed automatically on the Contact tab.

D-1	- Is December Openation	
Primary Contact for Exam	pie Research Organization	
First Name:*	Stefanie	🔍 Look Up
Middle Name:		
Last Name:	Plaster	
OR		
Generic Contact:		look Up Generic Contact
Phone Number:**		
Email Address:**		
**At least one of Email or	Phone is required.	
Status:		

- On the **Contact** tab, next to the **First Name** field, click **Look Up** and search for the contact person's name by following the instructions in Searchin g for Persons. The person's name you selected appears in the Name fields on the Contact tab.
 In the various fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Phone Number	Enter the contact's primary telephone number (as 123-456-7890), including an extension if provided.
	You must provide either the contact's phone number or email address. You can provide both if the information is available.
Email Address	Type the contact's primary email address.
	You must provide either the contact's phone number or email address. You can provide both if the information is available.
Status	This field is populated by the system after you click Save .
Click Save	

15. Click Save.