Introduction to Abstracting Participating Sites - Include v4.5

Trials are conducted in participating sites. Information about the site (organization), investigator(s), and primary contacts (if a central contact is not provided) must be abstracted. Information about participating sites can be included in the protocol document or in the Participating Sites document.

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

Abstracting Participating Site Information

- 1. Search for the trial of interest. For instructions, refer to Searching for Trials in PA.
- 2. In the search results, select the NCI Trial Identifier link for the desired trial. This will open the Trial Identification page.
- 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, select Participating Sites.

ADMINISTRATIVE DATA
General Trial Details
NCI Specific Information
Regulatory Information
Trial Status
Trial Funding
Participating Sites
Collaborators
Trial Related Documents

5. On the Participating Sites page, select Add.

Participating Sites
Nothing found to display.
(Add

The Participating Sites page displays three tabbed sections: Participating Site, Investigators, and Contact.

Participating Site Inve	stigators	Contact				
Participating Site						
T untoiputing one						
Organization Name:*					Click Look Up to choose an organization.	🔍 Look Up
City:*						
State:*						
Country:*			<u>ا</u>			
Zip/Postal Code(US/Canada/Australia).*						
Zip/Postal Code(US/Canada/Au	stralia):					
Local Trial Identifier:						
Site Recruitment Status:*	Selec	t		0		
Site Recruitment Status Date:*		💽 (mm/dd/	(yyyy)			
Site Recruitment Status Comm	ents:			1		
			,			
	100 1	cters left		2		

Add/Edit Participating Site- Complete Trial

Participating Site Invest	igators Contact		
Participating Site			
Organization Name:*		Click Look Up to choose an organization.	🔍 Look Up
Local Trial Identifier: *	<u>≜</u>		
Site Recruitment Status:*	Select	\$	
Site Recruitment Status Date:*	📰 (mm/dd/yyyy)		
Site Recruitment Status Comment	s:		
	160 characters left		

Add/Edit Participating Site - Abbreviated Trial 6. See the following table for reference on the **Participating Site** fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Organi zation Name*	Select Look Up and follow the instructions in Searching for Organizations. For <i>Complete</i> trials, the City, State, Country, and Zip /Postal Codes fields are populated when an organization is selected.
Local Trial Identifi er*	Enter the site trial identifier.
Site Recruit ment	Select the status from the drop-down list. Refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Expanded Access Statuses for additional details regarding
Status*	CTRP validates all status transitions when a trial status record is saved. If a status transition is added or updated which does not conform to the rules provided in Trial Status Transitions, CTRP displays errors and/or warnings. <i>Warnings</i> indicate that correcting the transition in the trial status record is optional. However, <i>Errors</i> indicate that correcting the transition in the trial status record is not updated in the Participating Sites Status History window. The trial cannot be checked in until all status transition errors have been resolved. For a comprehensive matrix of valid transitions, see Trial and Participating Sites Status Transition Rules.
Site Recruit ment Status Date*	Enter the date that the status was recorded. The date must be the current date or earlier.
Site Recruit ment Status Comm ents Select Say	Enter one or more comments about the site recruitment status.

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

Participatin	g Site Investig	gators Contact				
Participating	Site Investigators for	r Albert Lea Medical Cer	iter-Mayo Health System			
2 items found,	displaying all items.1					
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		

9. Select 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	laudet@man.com	Principal Investigator	Select
2329558	37726	Isabelle		Betrosian	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 investigator selected will be added to the Investigators tab.

Participatin	ig Site Inve	estigators	Contact				
	Participating Site Investigators for Albert Lea Medical Center-Mayo Health System						
2 items found,	displaying all items	5.1					
PO-ID	Last Name	Fi	rst Name	Role	Status Code	Set as Site Primary Contact	Delete
2363610	Audet	160	stelle	Principal Investigator	PENDING	R .	۵
2329558	Bedrosian	last of the second s	abella	Sub Investigator	PENDING		8
				S Add			

11. To indicate that an investigator is the primary contact, select the Set as Site Primary Contact icon next to this investigator's record.

12. Select the **Contact** tab.

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A Participating Site must be linked to the trial before abstracting the site PI and contact information. A contact can be added by providing a person's name (i.e., someone who is associated with the trial itself), or a generic contact can be added (i.e., someone who is associated with the site but not necessarily the trial) by providing a person's title (functional role). Both types of contacts can not be added in the same record. An abstraction cannot be completed if a primary contact is not assigned.

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

articipating Site	Investigators Conta		
Primary Contact for May	yo Clinic		
First Name:*	Alyssa	🔍 Look Up	
Middle Name:			
Last Name:	Jones	E	
OR			
Generic Contact:		look Up Generic Contact	
Phone Number:**			
Email Address:**	m@abc.com		
**Enter either the contact	ct's phone number or email add	ress. You can provide both if the information is available.	
Status:	PENDING		

- 13. On the **Contact** tab, next to the **First Name** field, select **Look Up** and search for the contact person's name by following the instructions in Search ing for Persons.
- 14. 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.
	*Either the contact's phone number or email address are required. Both can be provided.
Email Address*	Type the contact's primary email address.
	*Either the contact's phone number or email address are required. Both can be provided.
Status	CTRP populated after the record is saved.

15. Select Save.