Events

The eTMF will update when trials encounter events such as when:

- An amendment is made to the protocol
- A mistake is detected in how a question was answered in a wizard
- A regulation changes requiring the need to collect a new document in a country for each new PI
- A site is cancelled/terminated
- A natural disaster at an investigator site causes you to be unable to collect some documents

Each eTMF is customized to support your specific business processes.

When to Use Study Events vs. Create Expected Study Item

Executing a Study Event is a response to an occurrence or change to the trial that requires a standard set of documents. Add Study Item is used to add individual documents that were not anticipated or that were added due to changes in regulations, sponsor requirements, etc.

How to Execute Study Events

To add item(s) to a study list based upon the occurrence of an event, use the following steps:

- Navigate to the <u>Study Home Page</u> for the study for which an event has happened.
- 2. Select Actions -> Execute Event
- 3. The Execute Event screen is displayed.

TMF Add From Event					
Ve Create Placeholders					
Event:					
Event Date:	Database Change				
Description:	New Vendor (Study Level)				
	New Vendor (Country Level)				
	New Vendor (Site Level)				
Instructions:	Protocol Deviation				
	Protocol Amendment				
	Revision: Case Report Form (unrelated to protocol amendment)				
	Revision: Informed Consent (unrelated to protocol amendment)				
Add From Event	Safety Event: Other				
Selected ID	Safety Event: Pregnancy				
	Safety Event: SAE				
	Safety Event: SUSAR				
	Study Termination				
	Unplanned Blind Breaking				
	Unplanned Interim Analysis				

4. Select an Event from the drop-down list of events. The description, instructions, and list of items are updated based upon the event selected.

You should review the instructions to see if any other actions must be taken or considered.

IMF Add From	Event				
🖓 Create Place	eholders	🖏 Close			
Event:		New Vendor (Country Level)			•
Event Date	:				
Description:		A new vendor is needed at the Country level.			
Instruction	IS:	Determine which study items will be needed for t country(ies).	he specific vendor. Ch	noose the applicat	le
Add From E	Event				
Selected	ID	Document Type	Process Group	Level	
	109.05	Third Parties Confidentiality Agreement (Countr	Third Parties	Country	
	109.11	Third Parties Contractual Agreement (Country	Third Parties	Country	
	109.02	Third Parties Qualification and Compliance (Co	Third Parties	Country	
	109.14	Third Parties Roles and Responsibilities Matrix	Third Parties	Country	

5. Enter an Event Date.

This will be used with an offset to calculate a Due Date for the items that are added.

- 6. Review the items that are listed. Remove any placeholders that do not need to be created by unchecking the 'Selected' checkbox.
- When the correct set of items are selected/deselected based upon the event and the study, click Create Placeholders.
- 8. If the event being added creates s at the Site or Country level, the Country/Site selection screen will allow you to specify which Countries and Sites get the new placeholders created by your event.

Events can add placeholders to Ongoing sites as well as to the template for new sites.

If you select any of the "All New Sites" options here, then all new sites created in that selection will include the Placeholders created by this event.

TMF Add Study Item: Country/Site Selection							
Create Placeholders							
One or more selected placeholders are country or site level. For which countries or sites are the selected placeholders relevant?							
Select sites:	Available 8245 (CANADA)-ONGOING 8657 (CANADA)-ONGOING 1003 (MEXICO)-ONGOING 1110 (MEXICO)-ONGOING 1110 (MEXICO)-ONGOING 4444 (SOUTH AFRICA)-ONGOING 6078 (UNITED KINGDOM)-ONGOING All New Sites All New Sites (CANADA) All New Sites (MEXICO)	Selected					

The "Add From Event" screen allows you to duplicate any placeholders in your event if necessary.