The CTMS has been upgraded to version 3.16.1. This bulletin summarizes the key features and enhancements in this software release.

New Fields for Internal Personnel View

On the **Protocol Internal Personnel** view tab (located on the **Protocols** screen tab), there are several new columns:

- **User ID** - To assist in maintaining protocol access
- **Employee Type** - Indicates employee category (*Employee*, *Contractor*, *Partner*, etc.)
- **Employee Experience** - Fields to track employee's experience (*DCRI Start Date, Functional Group, Nursing Experience*, etc.)

  Note: These fields are obtained through the *CTMS Access Form*, are read-only, and do not show by default. To add them, click the menu icon ⚙ and then select **Columns Displayed**.

Review Level Displayed on Site Visit Record

Approved Date	Review Level
3/27/2018	2

On the **Site Visit** view tab, the **Review Level**, which is entered by the Trip Report approver during the approval process, is now displayed after the **Approved Date** field.

New Trip Report Approver Fields

Trip Report Approvers (*Approvers*) will be able to provide information to assist in tracking CRA performance.

Sign Approval

Review Level:
TR Quality Score:
TR Review Time:
Network ID: STUDENT13
Password:

By entering your Network ID and Password and clicking 'OK', you are certifying that this is the legally binding equivalent of your traditional handwritten signature.

OK   Cancel
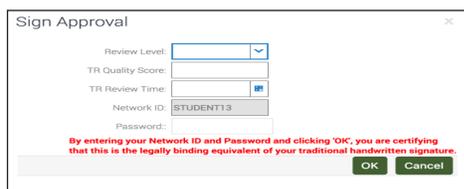
Approvers will be able to enter the following information upon approval of a Trip Report:

- **TR Quality Score**
- **TR Review Time**

More Info

Expense Report Submitted:		Expense Report Approved:		Trip Report Sent To Sponsor:		Trip Report Completed:	
Exp Rpt Submit By FN:		Exp Rpt Appr By FN:		Follow-up Letter Sent:		Review Level: 1	
Exp Rpt Submit By LN:		Exp Rpt Appr By LN:					
Actual Subjects Monitored:		Travel Time:		Time On Site:		Planning/Reporting Time:	
TR Quality Score: 30		TR Review Time: 45		OSM Survey-PI:		OSM Survey-SC:	
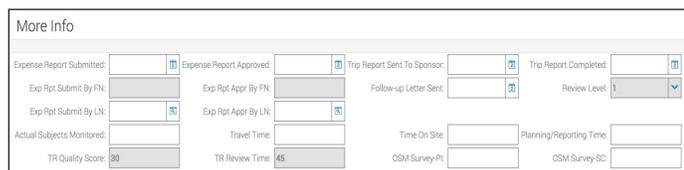
In addition, Approvers will see the following fields on the site visit's **More Info** area (found by scrolling down below a site visit record) that assist in tracking CRA performance:

- **TR Quality Score** - displays data entered upon approval and is read only
- **TR Review Time** - displays data entered upon approval and is read only
- **OSM Survey-PI** - on-site monitoring survey input received from PI
- **OSM Survey-SC** - on-site monitoring survey input received from SC

Invalid Email Format No Longer Allowed

When entering email address details, the CTMS will no longer allow an invalid format.

New CAPA Functionality

New functionality has been added to provide the ability to track **Site** *Corrective And Preventive Action Plan* (CAPA) information.

To start a CAPA record:

1. On the **Site Management** screen tab, locate and select the site to which you want to add a CAPA record.
2. Click the **CAPAs** view tab (you may need to click the drop-down arrow to the right or below the view tabs to locate it).
3. Click the **Add** button.

tters   Conversation Log   CAPAs

+   🗑   🔍   ⚙   No Records
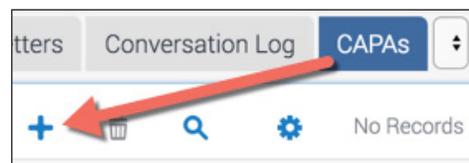
4. Use the following table as a guideline for completing the CAPA record. Fields marked with an asterisk are required.

   Note: Some of these fields are only available on the list view, but most can also be accessed on the form, which you will access by clicking the **CAPA Topic** blue hyperlink.

Field	Guidelines
CAPA # *	Enter a CAPA number.
CAPA Topic *	Select the topic that explains the reason for the CAPA. Choices include: • Internal Audit • Sponsor Audit • GCP Issues • Suspected Fraud
Issued Date	(read-only) Automatically displays the date the CAPA letter was last approved. If the approved CAPA letter is deleted by a clinical administrator, the Issued Date is also deleted (or it is changed to the most recently approved CAPA letter date, if one exists).
Target Deadline	Enter the date that you hope to close the CAPA.
CAPA Status	(read-only) Automatically changes based on actions performed.
Last Status Date	(read-only) Automatically displays the date of the last status change.
Resolution Summary	Enter details of the CAPA resolution.
Closed Date	(read-only) Automatically displays the date the CAPA Closure Letter was approved. If the approved CAPA Closure letter is deleted by a clinical administrator, the Closed Date is also deleted (or it is changed to the most recently approved CAPA Closure letter date, if one exists).
Submitted By Last Name	(read-only) Click the selection icon to select your name when you are submitting the CAPA Letter for approval.
Submitted To Last Name	(read-only) Click the selection icon to select the name of the person to whom you are submitting the CAPA Letter for approval.

Field	Guidelines
CAPA Sent Date	Enter the date when the CAPA letter was sent.
Follow Up Sent Date	Enter the date when the Follow-up Letter was sent.
Closure Sent Date	Enter the date when the Closure Letter was sent.
PI Signed Date	Enter the date when the PI signed the CAPA document.
PI Sig Rcvd Date	Enter the date when the PI signature was received.
Assigned To	Automatically populated with the user ID of the person who entered the record. Click the selection icon to assign to another person.

To add CAPA details:

1   Click the **CAPA Topic** blue hyperlink to drill into the CAPA details.
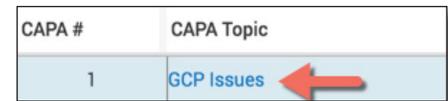
The CAPA details page appears.
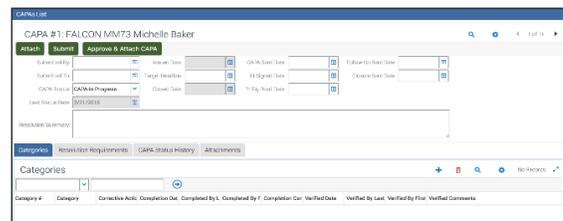
2   Use the following table as a guideline for completing the CAPA record.

Field	Guidelines
Submitted By	Click the selection icon to select your name when you are submitting the CAPA Letter for approval.
Submitted To	Click the selection icon to select the name of the person to whom you are submitting the CAPA Letter for approval.
CAPA Status	(read-only) Automatically changes based on actions performed.

Field	Guidelines
Last Status Date	(read-only) Automatically displays the date of the last status change.
Issued Date	(read-only) Automatically displays the date the CAPA letter was last approved. If the approved CAPA letter is deleted by a clinical administrator, the Issued Date is also deleted (or it is changed to the most recently approved CAPA letter date, if one exists).
Target Deadline	Enter the date that you hope to close the CAPA.
Closed Date	(read-only) Automatically displays the date the CAPA Closure Letter was approved. If the approved CAPA Closure letter is deleted by a clinical administrator, the Closed Date is also deleted (or it is changed to the most recently approved CAPA Closure letter date, if one exists).
CAPA Sent Date	Enter the date when the CAPA letter was sent.
PI Signed Date	Enter the date when the PI signed the CAPA document.
PI Sig Rcvd Date	Enter the date when the PI signature was received.
Follow Up Sent Date	Enter the date when the Follow-up Letter was sent.
Closure Sent Date	Enter the date when the Closure Letter was sent.
Resolution Summary	Enter details of the CAPA resolution.

To add CAPA Categories:
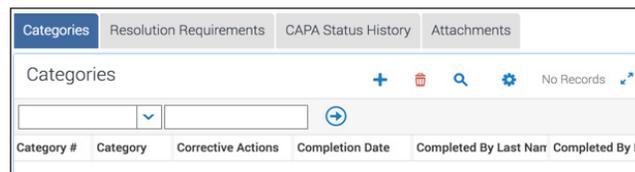
1 Click the **Categories** tab.
2 Click the **Add** button. ✚
3 Use the following table as a guideline for completing the record. Fields marked with an asterisk are required.

Field	Guidelines
Category # *	Enter a category number. This field becomes read-only when the CAPA is approved.
Category *	Click the selection icon to select a CAPA category. This field becomes read-only when the CAPA is approved.
Corrective Actions	Enter corrective actions. This field becomes read-only when the CAPA is approved.
Completion Date	Enter a completion date.
Completed By Last Name	Click the selection icon to select who completed the category.
Completion Comments	Enter completion comments.
Verified Date	Enter the date the category was verified.
Verified By Last Name	Click the selection icon to select who verified the category.
Verified Comments	Enter verification comments.
Category Instructions	(read-only) Provides instructions for the CAPA Letter. This field is hidden by default. To add it, click the menu icon ⚙ and then select **Columns Displayed**.

Note: You cannot add or delete Category records after the CAPA is approved.

To add CAPA Issues:

4 On the **Categories** tab, scroll down to the **Issues** area.

5 Click the **Add** button. ✚

6 Use the following table as a guideline for completing the record. Fields marked with an asterisk are required.

Field	Guidelines
Issue # *	Enter an issue number. This field becomes read-only when the CAPA is approved.
Issue *	Enter issue details. This field becomes read-only when the CAPA is approved.
Corrective Actions	Enter corrective actions. This field becomes read-only when the CAPA is approved.
Completion Date	Enter a completion date.
Completed By Last Name	Click the selection icon to select who completed the CAPA.
Completion Comments	Enter completion comments.
Verified Date	Enter the date the issue was verified.
Verified By Last Name	Click the selection icon to select who verified the issue.
Verified Comments	Enter verification comments.

Note: You cannot add or delete Issue records after the CAPA is approved.

To add CAPA Resolution Requirements:

Click the **Resolution Requirements** tab, and enter the details, about the CAPA resolution requirements. This field becomes read-only when the CAPA is approved.

To view CAPA Status History:
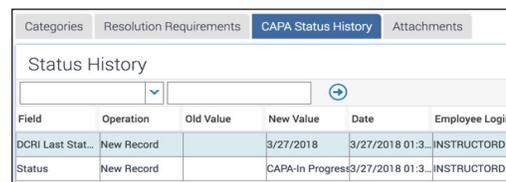
Click the **CAPA Status History** tab. This tab is read-only and displays the history of statuses for this CAPA.

To attach/view the CAPA Letter:
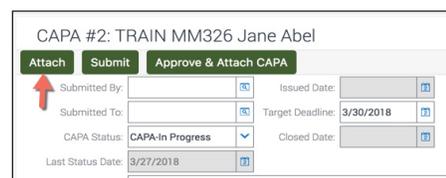
1 Click the **Attach** button at the top of the screen. This attaches the CAPA Letter to the **Attachments** tab.

2 Click the **Attachments** tab.

3 Click the **Attachment Name** blue hyperlink to open the letter.

The letter uses a pre-defined template to merge in the data you have added.

To submit and approve the CAPA Letter:
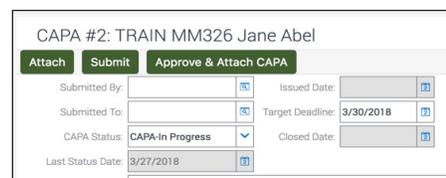
1 Click the selection icon in the **Submitted By** field. Select your name.

2 Click the selection icon in the **Submitted To** field. Select the person to whom you are submitting your letter for approval.

3 Click **Submit**.

4 Enter your DCRI network password, and click **OK**.

An email is automatically generated and sent to the person in the **Submitted To** field, and the **CAPA Status** changes to *CAPA-Submitted*.

5 When the approver is ready to approve the letter, they will simply click the **Approve & Attach CAPA** button, enter their DCRI password, and click **OK**.

- The approved letter regenerates with any changes that were made since the letter was submitted

- The approved letter is automatically signed electronically.

- The PDF version of the letter is attached to the **Attachments** tab.

- An email is automatically generated and sent to the person in the **Submitted By** field.

- The **CAPA Status** changes to *CAPA-Approved*.

Note: You cannot delete the PDF version.

To submit and approve a CAPA Follow-up Letter:
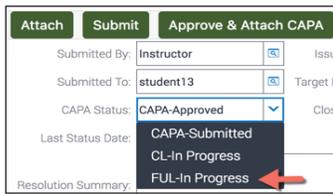
1 Change the **CAPA Status** to *FUL-In Progress*.

2 Click **Attach**.

The CAPA Follow-up Letter is added to the **Attachments** tab and will include updates to Category and Issue statuses.

3 When you are ready to *submit* the Follow-up Letter for approval, follow steps 1-4 in the ***To submit and approve the CAPA Letter*** section of this bulletin.

4 To *approve* a Follow-up Letter:

a Go to the **Attachments** view tab.

b Click on the record to highlight the Follow-up Letter

c Click **Approve FUL/CL**, enter your DCRI password, and click **OK**.

- The PDF version of the letter is attached. The **Attachment Type** field indicates the type of letter. You cannot delete the PDF version.

- The **CAPA Status** field changes to *FUL-Approved*.

If another Follow-up Letter must be sent, you can change the **CAPA Status** back to *FUL-In Progress*, and follow the procedure above.

To upload supporting documentation:

To upload the *PI Signature* documentation, and any other supporting files, click the **New File** button on the **Attachments** tab.

To submit and approve a Closure Letter:

1 Change the **CAPA Status** to *CL-In Progress*.

2 Click **Attach**.

The CAPA Closure Letter is added to the **Attachments** tab and will include updates to Category and Issue statuses.

3 When you are ready to *submit* the letter for approval, follow steps 1-4 in the ***To submit and approve the CAPA Letter*** section of this bulletin.

4 To *approve* a Closure Letter:

a Go to the **Attachments** view tab.

b Click on the record to highlight the Closure Letter

c Click **Approve FUL/CL**, enter your DCRI password, and click **OK**.

- The PDF version of the letter is attached. The **Attachment Type** field indicates the type of letter. You cannot delete the PDF version.

- The **CAPA Status** field changes to *CL-Approved*.

- The **Closed Date** field automatically displays the date that the Closure Letter was approved. When there is a date in this field, all fields in the CAPA record become read-only, except for **CAPA Status** and **Closure Sent Date**. In addition, all fields on the Categories and Issues sections become read-only.

Other areas to view CAPA information:

- On the **Site Management** screen tab *list* view, you can add the **Open CAPA** and **Total # CAPAs** columns by clicking the **Menu** icon ⚙ and selecting **Columns Displayed**.

- On the site's *form* view, you will see **Open CAPA** at the top of the form. If there are open CAPAs for this site, the word "yes" will appear in red. If not, the word "no" appears in black.

  Open CAPA **Yes**

- The **CAPAs** screen tab allows you to view:
  - ◊ **CAPAs (All My Sites)** - View all the CAPAs for sites to which you are assigned. Click the **CAPA Topic** blue hyperlink to drill into the CAPA details.
  - ◊ **CAPAs (All Sites)** - View CAPAs for all sites. Click the **CAPA Topic** blue hyperlink to drill into the CAPA details.

- On the **Accounts** screen tab, you can view a list of all CAPAs that have been associated to that account by clicking on the **CAPAs** view tab. Click the **CAPA Topic** blue hyperlink to drill into the CAPA details.

- On the **Contacts** screen tab, you can view a list of all CAPAs that have been associated to that contact by clicking on the **CAPAs** view tab. Click the **CAPA Topic** blue hyperlink to drill into the CAPA details.

- On the **Home** tab, you can view/access CAPAs in the new **My Open CAPAs** area. To enable this view, on the **Home** tab click **Edit Layout**, click the *check mark* icon to the right of "My Open CAPAs," and then click **Done**.

Note: Samples of the CAPA letters will be made available on the **CTMS Learning Center** (https://dcri.org/ctms-learning-center).

Getting Help

CTMS documentation, additional training and resources can be found on the **CTMS Learning Center** (https://dcri.org/ctms-learning-center).

If you have additional questions or issues that you would like to discuss with CTMS support representatives, please email your requests to the **DCRI Service Desk** (dcriservicedesk@dm.duke.edu).