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**

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.

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.
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

<table>
<thead>
<tr>
<th>Field</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>**CAPA # *</td>
<td>Enter a CAPA number.</td>
</tr>
<tr>
<td>**CAPA Topic *</td>
<td>Select the topic that explains the reason for the CAPA. Choices include:</td>
</tr>
<tr>
<td></td>
<td>• Internal Audit</td>
</tr>
<tr>
<td></td>
<td>• Sponsor Audit</td>
</tr>
<tr>
<td></td>
<td>• GCP Issues</td>
</tr>
<tr>
<td></td>
<td>• Suspected Fraud</td>
</tr>
<tr>
<td><strong>Issued Date</strong></td>
<td>(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).</td>
</tr>
<tr>
<td><strong>Target Deadline</strong></td>
<td>Enter the date that you hope to close the CAPA.</td>
</tr>
<tr>
<td><strong>CAPA Status</strong></td>
<td>(read-only) Automatically changes based on actions performed.</td>
</tr>
<tr>
<td><strong>Last Status Date</strong></td>
<td>(read-only) Automatically displays the date of the last status change.</td>
</tr>
<tr>
<td><strong>Resolution Summary</strong></td>
<td>Enter details of the CAPA resolution.</td>
</tr>
<tr>
<td><strong>Closed Date</strong></td>
<td>(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).</td>
</tr>
<tr>
<td><strong>Submitted By Last Name</strong></td>
<td>(read-only) Click the selection icon to select your name when you are submitting the CAPA Letter for approval.</td>
</tr>
<tr>
<td><strong>Submitted To Last Name</strong></td>
<td>(read-only) Click the selection icon to select the name of the person to whom you are submitting the CAPA Letter for approval.</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Field</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Submitted By</strong></td>
<td>Click the selection icon to select your name when you are submitting the CAPA Letter for approval.</td>
</tr>
<tr>
<td><strong>Submitted To</strong></td>
<td>Click the selection icon to select the name of the person to whom you are submitting the CAPA Letter for approval.</td>
</tr>
<tr>
<td><strong>CAPA Status</strong></td>
<td>(read-only) Automatically changes based on actions performed.</td>
</tr>
</tbody>
</table>
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.

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

**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.

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

**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.

- 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).

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**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](mailto:dcriservicedesk@dm.duke.edu).