The CTMS has been upgraded to version 3.15.1. This bulletin summarizes the key features and enhancements in this software release.

Future Date Limitation Added

The following functionality has been added to prevent incorrect date entry:

- You cannot enter a *future* subject **Enrollment Date** or **Screening Date** when manually entering subjects.
- You cannot add a *future* **Activity Date** on the **Conversation Log** tab.
- You cannot add a *future* **PD Date** on the **Protocol Deviation** tab.

New Visit Types Available for Metrics Tracking

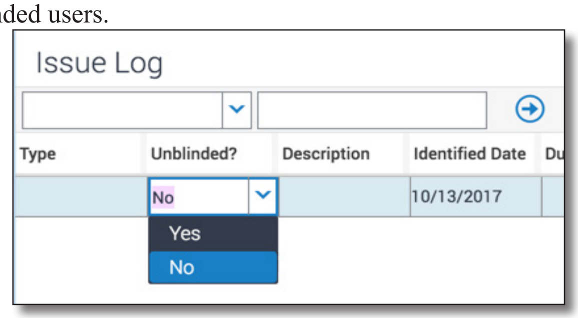
When setting up a new protocol, you can now track trip report completion metrics for the new **Visit Types** that were added in the 3.10.1 upgrade. The visit types include:

- *SSV/SIV*
- *PMV/COV*
- *Other*
- *Other1*
- *Remote*
- *Unblinded*

Note: If you would like to begin tracking these visit types, submit a *CTMS Request (CTMSR)* form to the **DCRI Service Desk**.

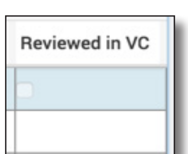
Unblinded Field on Issue Log

On a site's **Issue Log** tab, you can now indicate whether a record is *Blinded* or *Unblinded*. Unblinded records can only be viewed by Unblinded users.



Ability to Check Contact's Visual Compliance

On the **Protocols** screen tab's **Site Contact** view tab, a check mark appears in the new **Reviewed in VC** field to indicate it has been viewed by the CTMS Support team for *Visual Compliance* (VC). This field is read-only. You can click the contact's last name link to view details about the contact.



New Editable Fields

New Account and Contact fields were added with the 3.14.1.upgrade. CTMS users may now edit and request Global Database changes to these fields. The fields that are now editable include the following.

Accounts Tab:

- Health System
- EHR Outpatient
- EHR Hospital
- EHR National

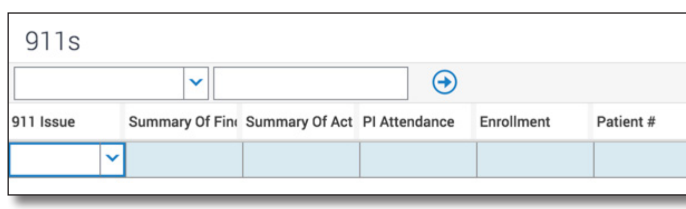
Contacts Tab (Physician Profile form area):

- PI Experience Since
- Sub I Experience Since
- SC Experience Since
- Clinical Background
- Employed By
- Research Availability
- Networks

New "911s" Tab Being Piloted by MegaTrials

On the **Site Management** screen tab, there is a new **911s** view tab. This tab allows you to track items that need *immediate* attention, as opposed to the regular items tracked on the **Issue Log** view tab.

Note: You cannot copy or delete these records.



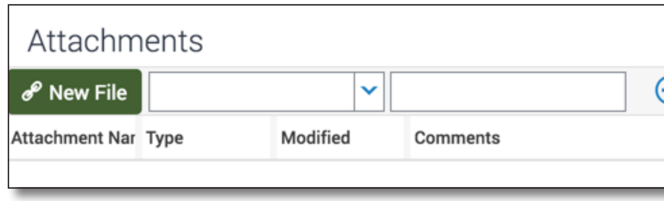
To add a 911s record:

1. Click the **Site Management** screen tab.
2. Click the **911s** view tab (you may need to click the drop-down to the far right of the view tabs to locate this tab
3. Click the + button.

4 Use the following table as a guideline for completing the new record. Items marked with an asterisk are required.

Field	Description
911 Issue *	Select an issue from the drop-down list.
Summary of Findings	Free text field for entering a summary of findings.
Summary of Action Plan	Free text field for entering a summary of the action plan.
PI Attendance	Select an option from the drop-down list.
Enrollment	Indicate the number of enrolled subjects at the site.
Patient #	If applicable, enter the patient's number.
Visit Name	If applicable, enter the visit's name.
Identified Date	Indicate the date the issue was identified. Defaults to today's date.
Detected By	Select an option from the drop-down list. • SDR (Source Data Review) • SDV (Source Data Verification) • Site Self-Reported • Other
Guiding Principle	Select an option from the drop-down list.
SDR/SDV Action	Enter details about the SDR or SDV action.
Identified By Role	Select the role from the drop-down list.
Identified By Name	Enter the name of the person who identified the issue.
Sponsor Notified Date	Enter the date the sponsor was notified of the issue.
Leadership Notified Date	Enter the date when leadership was notified of the issue.

5 If needed, you can add related attachments by scrolling down to the **Attachments** applet and clicking **New File**.



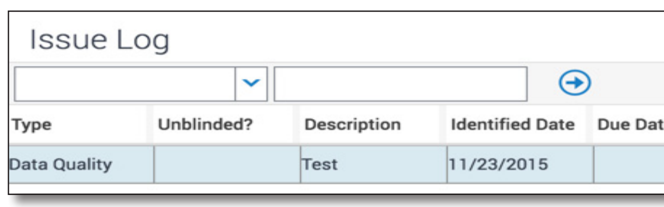
Tip: You can drag-and-drop attachments to this applet area. You can also drag emails to a file location, like your K:/T: drive folder, and then drag that file to this applet area.

New Issue Log Fields for SONAR Report

The SONAR report is being piloted by the MegaTrials group for tracking issues that need attention. New fields have been added to the **Site Management** screen tab's **Issue Log** view tab, to be printed on the new SONAR report.

Note: The new fields do not appear by default, and must be added by clicking the button, selecting **Columns Displayed**, and adding the fields.

Note: For the Clinical Operations teams, the form view of the **Issue Log** record still shows the original fields only.



To enter information in the new Issue Log fields

Field	Description
Severity	Select *Major* or *Minor* from the drop-down list.
Guiding Principle	Select an option from the drop-down list.
Identified By Role	Select the role from the drop-down list.
Enrollment	Indicate the number of enrolled subjects at the site.

Field	Description
Action Status	**1** Click the selection icon. **2** Click the + button. **3** Check the **Current** check box. **4** Select an **Action Status** from the drop-down list. **5** Enter an **Action Date** (defaults to today's date). **6** Enter **Action Comments**. **7** Click **OK**.
Action Date	Automatically populated when you complete the Action Status field.
Action Com-ments	Automatically populated when you complete the Action Status field.
SDR/SDV Action	Enter details about the SDR or SDV action.
CAPA Issued	Select *Yes* or *No* from the drop-down list.
CAPA Issued Date	Enter the date the CAPA was issued.
Sponsor Notified Date	Enter the date the sponsor was notified.
Natl Coord Notified Date	Enter the date the national coordinator was notified.
Documentation Location	Enter information regarding where supporting documentation is located.
Show on SONAR	Check the box to include this record on the SONAR report.
Patient #	If applicable, enter the patient's number.

Getting Help

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