

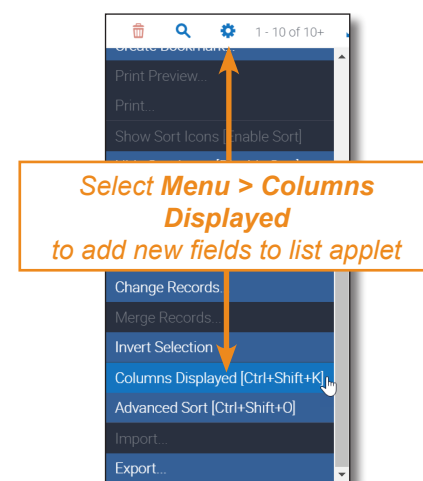
The CTMS has been upgraded to version 5.0.
This bulletin summarizes the key features and enhancements in this software release.

New Customizable Fields Available on Site Management and Site Visits tabs

- 20 new fields are available to be customized *per protocol* - this means that each protocol team can identify how each field will be used in the protocol's Data Entry Guideline (DEG) document:
 - 4 check box fields (*User Check 1-4*)
 - 4 date fields (*User Date 1-4*)
 - 4 pick fields (*User Pick 1-4*): these can be configured to show lists of values customized *per protocol* - to customize these fields, see the **Requesting Customized Pick Field List of Values Configuration** section on **page 3**
 - 4 number fields (*User Num 1-4*)
 - 4 text fields (*User Text 1-4*)
- The new fields are available via **Menu**  **> Columns Displayed**
- The **User Fields** form applet at the bottom of the window also displays these new fields
 - On the **Site Management** screen tab, these fields will always be editable
 - On the **Site Visits** view tab, when the **Trip Report Status** is *Approved* or *Sent to Sponsor*, these new fields will be locked along with all other fields on the *list* applet, but they will remain editable in the **User Fields** form applet

User Fields							
User Check 1: ☐	User Check 2: ☐	User Check 3: ☐	User Check 4: ☐				
User Date 1:	User Date 2:	User Date 3:	User Date 4:				
User Pick 1:	User Pick 2:	User Pick 3:	User Pick 4:				
User Num 1:	User Num 2:	User Num 3:	User Num 4:				
User Text 1:	User Text 2:	User Text 3:	User Text 4:				

New fields display on **User Fields** form applet at bottom of screen/view



New Fields Available on Protocol Deviation Tabs

New fields are available on both the *Site's Protocol Deviation* view tab and the *Trip Report's Protocol Deviation* view tab

- 2 new Protocol Deviation (PD) fields:
 - PD Status** - pick list with universal values to be used based on your protocol's Data Entry Guideline (DEG) instructions
 - PD Completion Date** - to document the date that the protocol deviation has been resolved
- 20 new fields to be customized *per protocol* and outlined in the protocol's Data Entry Guideline (DEG) document:
 - 4 check box fields (*User Check 1-4*)
 - 4 date fields (*User Date 1-4*)
 - 4 pick fields (*User Pick 1-4*): these can be configured to show lists of values customized *per protocol* - to customize these fields, see the **Requesting Customized Pick Field List of Values Configuration** section on **page 3**
 - 4 number fields (*User Num 1-4*)
 - 4 text fields (*User Text 1-4*)
- The new fields are available via **Menu**  **> Columns Displayed**
- The **User Fields** form applet at the bottom of the window also displays these new fields
 - On the *Site's Protocol Deviation* view tab (which displays records entered at both the *Site* and *Trip Report* levels) the new fields will be editable only when the **Entry Location** is *Site*
 - On the *Trip Report's Protocol Deviation* view tab, when the **Trip Report Status** is *Approved* or *Sent to Sponsor*, these new fields will be locked along with all other fields on the *list* applet, but they will remain editable in the **User Fields** form applet

PD Status	PD Completion Date

Site's Protocol Deviation View Tab

Entry Location
Site
Trip Report

New “Provided to Sponsor Date” Field on Site Visits View Tab

The new **Provided to Sponsor Date** field is available to be added to the **Site Visits** view tab via **Menu** ⚙️ > **Columns Displayed**

Provided to Sponsor Date	
10/17/2023	

- Can be used to indicate the date when documentation is provided to the sponsor outside of the eTMF for specific requests (e.g., review, audit)
- Not connected to the Trip Report’s *Sent to Sponsor Status*, or the **Trip Report Sent to Sponsor** date field
- When the corresponding Trip Report’s **Status** is *Approved* or *Sent to Sponsor*, this new field will be locked along with all other fields on the **Site Visit** *list* applet, but it will remain editable in the **More Info** *form* applet

New “ClinTrials.gov #” Field on the Protocols and Site Management Screen Tabs

The new **ClinTrials.gov #** field displays (if applicable) the study number from the *clinicaltrials.gov* website

ClinTrials.gov #

- For *new* projects, this number will be a field on the **CTMS Protocol Setup Requirements Form**
- The number can also be added *after start-up* by submitting a **CTMSR**
- On the **Protocols** screen tab, the field displays by default
- On the **Site Management** screen tab, the field is available to be added via **Menu** ⚙️ > **Columns Displayed**

New Way to Track Site Statuses - Must Use the Status Field

While always available as an optional method, updating the Site’s **Status** field is now the **only** way to track statuses

► To track a new Site status:

- 1 On the **Site Management** screen tab, search for and locate your Site
- 2 In either the list or form applet, go to the Site’s **Status** field, and click its *selection icon* to open the **Site Status** window
- 3 Click the **plus sign** to start a new record
- 4 Check the **Current** check box
- 5 Select a new **Status** (and **Sub-Status**, if applicable)
- 6 Enter a **Date**
- 7 Enter a **Comment** (optional)
- 8 Click **OK**

Status:	Interested	
---------	------------	--

Current	Status	Sub-Status	Date	Comment
☐	Entered		10/17/2...	
☒	Active		10/17/2...	
☐	Interested		10/17/2...	

- The Site’s **Status History** view tab is now *read-only*
- The reason for this change is due to a quality issue affecting automatic syncing with PhlexTMF

ISF Word Document No Longer Automatically Attached

The **Investigator Study File (ISF)** document will no longer *automatically* appear on the Trip Report’s **Attachments** tab. Previously, for protocols *not* using the **ISF** tab, this Word document automatically appeared to allow study teams to complete the form, as needed.

Should you need to use the ISF Word document, you will find it on the [CTMS Learning Center](#), under **Forms & Instructions** and on the [CTMS Home](#) tab under **Helpful Links**.

INVESTIGATOR'S STUDY FILE INVENTORY				
Site ID: _____	Investigator: _____			
Date(s) Assessed: _____	Protocol Number: _____			
ESSENTIAL DOCUMENTS YES = All versions of the following essential documents are present	Yes	No	N/A	Comments
1. Signed Confidentiality agreement (or equivalent)	☐	☐	☐	Date of signature: _____
2. Certificate of Confidentiality	☐	☐	☐	Date of signature: _____
3. Curriculum Vitae (or biographical sketch) for Principal Investigator	☐	☐	☐	List Name(s): _____
- Medical license (or equivalent)	☐	☐	☐	
4. Curriculum Vitae (or biographical sketch) for Sub-Investigator(s) and/or other site personnel	☐	☐	☐	
- Medical license (or equivalent)	☐	☐	☐	
5. Signed Investigator Statement (FDA 1572 or equivalent)	☐	☐	☐	Date of Signature: _____
6. Approved protocol and amendment(s) (including signed signature sheets)	☐	☐	☐	Date of Signature: _____
Protocol Version: _____				
Amendment(s): _____				

Requesting Customized Pick Field List of Values Configuration

To customize the list of values for the configurable **Pick** fields (*User Pick 1-4*), your study's leadership must submit a **CTMS Request (CTMSR)** via the **Request for CTMS** form:

CTMS Learning Center

Forms and Instructions

- [Request for CTMS \(to request CTMS support\)](#)
- [Access for External Users \(PDF\)](#)
- [Protocol Setup Requirements Form \(.docx\)](#)
- [Protocol Setup Instructions \(PDF\)](#)
- [External Account Request Instructions \(PDF\)](#)
- [DEG: Data Entry Guideline Template \(.docx\)](#)
- [DEG: CTMS DEG Review Checklist \(PDF\)](#)
- [CTMS Access Form \(.docx\)](#)
- [CTMSR: CTMS Request Form \(.xlsx\)](#)
- [CTMSR: Instructions \(PDF\)](#)

- Go to the [CTMS Learning Center](https://dcric.org/ctms-learning-center/) (<https://dcric.org/ctms-learning-center/>)
- Under **Forms and Instructions**, click [CTMSR: CTMS Request Form](#)
 - Complete the **CTMSR Overview** tab, checking the check box for *Protocol Configuration - Change - Complete Tab 6*
 - Go to the **Protocol Config Change - 6** tab, and add your field configuration details
 - If you are not an approver (project leadership), obtain approval via email

2a - CTMSR Overview Tab

2b - CTMSR Protocol Config Change-6 Tab

- On the [CTMS Learning Center](https://dcric.org/ctms-learning-center/) (<https://dcric.org/ctms-learning-center/>), under **Forms and Instructions**, click [Request for CTMS \(to request CTMS support\)](#)

This will launch the *Request for CTMS* form within ServiceNow

- Complete the form
- Attach the **CTMSR** with your field configuration details
- If you are not an approver (project leadership), attach a PDF version of the approval email, as well
- Click **Request Now**

3 b-c

3d

Getting Help

- If you have questions or comments about the content of this QRC, please email [Technology Training](#).
- If you experience any technical problems working with the CTMS that you are unable to resolve, visit the [CTMS Learning Center](#) or submit a [Request for CTMS](#) ticket via ServiceNow.