CTMS Frequently Asked Questions

Question/Issue	Answer/Resolution
Where are the most current versions of the CTMSR and CTMS Access Request forms located?	These forms can be found in either: a) Home Tab in CTMS under Helpful Links b) Under Forms and Instructions section of the CTMS Learning Center
Are CTMS Trip Reports 21 CFR Part 11 compliant?	CTMS uses electronic signature for Submission and Approval of Trip Reports, meeting the requirements for being Part 11 compliant.
What is the correct way to change a PI at a site?	Click on the Site Management Screen tab, query for the Site. Within the main site record (NOT on the Site Contact view tab), click on the selection icon for the PI Last Name field, then query for and select the new PI's contact record; click OK. Click on the Site Contact view tab & you will see the new PI record showing the current date in the Start Date field. To see the previous PI's record, on the Site Contact view tab, change the display from Active Only to All. The record will include the End Date. Both the End Date for the previous PI and the Start Date for the new PI can be changed if needed. *Review the CBT for changing PI.*
I need to know the last date a PI had a monitoring visit. How do I find this?	In order to see this date, a site must be created in your Protocol for the PI in question. On the list view for that site there's a column "Last PI/Account Visit". If the PI, in combination with the Account used for your site, has had a visit tracked in CTMS, there will be a date in this field. However, it will only show the date of the last visit, not the visit type or for which study. Contact the DCRI Service Desk to obtain that information.
Can custom letter templates be used in CTMS for confirmation and follow-up letters?	Yes. Submit a CTMSR, and the letter template to DCRI Service Desk.

Question/Issue	Answer/Resolution
Can a Protocol specific Checklist Activities Template be added to CTMS	Yes. Submit a CTMSR, and the Checklist Activities template to DCRI Service Desk. It is the responsibility of the PL to ensure compliance with the appropriate SOP for trip reports.
Can a new Region be added to an existing Protocol and assign existing sites to that new Region?	New Regions can be requested by submitting a CTMSR to the DCRI Service Desk. It is the User's responsibility to change the Region assignment to the new region for any existing sites.
Is there a way to close open follow-up items without creating the next site visit?	Follow-up items can be closed at the Site Visit Screen tab, Site Visit Follow-Up link.
Why is the Row ID required on the CTMSR for requests to delete or change data?	Each record in CTMS has a unique Row ID. This ID is used to identify the EXACT record to which the request refers eliminating any question about what data should be deleted/changed.
If I no longer work on a protocol, what is the process for removing my access?	The PL, LCRA or CTM submits a CTMS Access request form to the DCRI Service Desk, providing the end date for your Role on the protocol and requesting removal of your access to that protocol.
Is there a way to see in CTMS a Contact's previous trial experience?	On the Contacts Screen tab, query for the Contact and click on the Protocol Experience View tab. This will display information for all Protocols in which the contact has participated.
Is a Trip Report Approver allowed to correct errors on a submitted trip report?	No. The TR Approver may not correct any errors on a trip report submitted for their approval. The internal comments field is used to notify the CRA of corrections that need to be made. The TR Approver updates the TR Status to "Not Approved". This will notify the CRA who can make any corrections needed and resubmit the report for approval.

CTMS Frequently Asked Questions

Question/Issue	Answer/Resolution
A Study Coordinator no longer works on my protocol and her role is given an end date. The same Study Coordinator has returned to work on my protocol and CTMS will not allow me to add her. Why?	CTMS will not allow the same Site Contact with the Same Role at one site, regardless if the role has been given an end date. If a contact leaves and then returns go to the Site Contact View tab, change the view from Active Only to All and remove the end date. It's advised that you do not change the original start date. Use the Comments field on the main site form to document the date the contact stopped working at the site, and the date the contact returned.
Can CTMS training be done remotely or does the person have to attend an on-site class?	All CTMS classes are offered for remote attendance. On site attendance is not required.
Where can I find training dates for CTMS classes?	Go to the IT Training intranet page - http://dcrihome.dcri.duke.edu/functional-groups/itt/it-training/it-training-calendar/month. The current month displays, and can be changed to show future months.
As a CRA in a time zone other than Eastern, why is the date and time for my e-Signature information different on my PDF trip report than in the trip report window in CTMS?	e-Signature information displays in the User's time zone in the Trip Report window in CTMS. The PDF of the Trip Report always displays the e-Signature date and time in Eastern time (EST or EDT).
My protocol is using the functionality to notify a vendor to ship a Starter box. A Starter Box was requested to be sent to a site that has multiple Study Coordinators and it was sent to the wrong one. Why?	When using the functionality to communicate with a Vendor, to avoid this situation, the Study Coordinator who is to receive the supplies, must be only Site Contact with the Role of Study Coordinator. The Role of Co-Coordinator should be used for all other Study Coordinators.

CTMS Frequently Asked Questions

Question/Issue	Answer/Resolution
I need to make changes to a trip report but the checklist activities items are locked and I cannot enter data. What do I need to do to allow edits?	For a Trip Report that has not been Approved, the checklist activities become locked for editing in two ways. The Trip Report Status is Submitted OR the Trip Report has been Exported (by clicking the Export Button). If the status is Submitted, you may Recall the Trip Report, change the status to In Progress, and the fields will be editable. If the Trip Report has been Exported, you will need to Import the Trip Report before the fields will become editable.
If DCRI is not negotiating contracts, is any additional training required to track Contract Send and Contract Executed dates	No additional training is required to tract Contract Sent and Contract Executed dates on the Milestones tab in CTMS.