Overview

On August 15, 2022 a CTMS to eTMF Integration occurred, making automatic transfer of essential records and data from CTMS to PhlexTMF a reality. This QRC outlines new features and benefits for project teams that choose to synchronize their projects from CTMS to PhlexTMF.

How Does the Integration Affect Me?

If your project has sites in both CTMS and PhlexTMF (Phlex), it is eligible to take advantage of the CTMS to Phlex Integration. You can choose to synchronize (sync) your project from CTMS to Phlex, so that changes made in CTMS are automatically pushed to Phlex. Benefits of syncing your project include:

- Consistency between systems:
    - **Sponsor**, **Program** (**Network** in CTMS), and **Protocol Name** will be identical.
    - Changes in certain parameters in CTMS—**Site Name** (PI changes), **Site Status** (Active vs. Closed), and certain **Milestones** (e.g. Activated for Enrollment, Close-Out Pack Sent)—are pushed to Phlex.
- Automated upload of essential Trip Report documents to their appropriate TMF reference locations in Phlex.
- Help in ensuring regulatory compliance.
- Improvement in audit and inspection readiness.
- Automation of many Phlex activities, including most Site Management Role (SMR) activities:

CTMS Activity	If project is NOT synced, Phlex activities are…	If project is synced, Phlex activities are…
Create Project	Manual	Automated
Create New Site	Manual	Automated
PI or Site # change	Manual	Mostly Automated A PI change may require moving certain documents manually.
Add Interested or Active Status	Manual	Automated
Add Interested Stop Status	Manual	Automated
Add Closed Status	Manual	Automated
Close Site	Manual	Automated **Note:** Project teams should verify that all site documents have been uploaded in Phlex before closing the site in CTMS.
Update Certain Milestones	Manual	Automated
Close Project	Manual	Manual

How CTMS Site Status & Milestone Changes Sync to Phlex

After syncing your project, you no longer have to manually add sites, change site statuses, or update site level milestones in Phlex. Adding or changing site statuses and certain milestones in CTMS, automatically triggers activity in Phlex.

> **IMPORTANT:** Though site level milestones are automated, trial and country level milestones are not.
> Even after your project is synced, trial and country level milestones still need to be manually updated in Phlex.

| *Action taken in CTMS*	*Site Activity in Phlex*	*Milestone Activity in Phlex*
*Set site **Status** to **Entered** or **Approached***	N/A	N/A
*Set site **Status** to **Interested***	Site is created and set to **Active** status.	N/A
*Set site **Status** to **Interested Stop***	Site is set to **Closed** status, **(NS)**, i.e. Not Selected, is appended to the Site Name. Notation "Site not selected; CTMS status is Interested Stop" is added.	N/A
*Set site **Status** to **Active***	If site is not in Phlex, site is created. If site is not at Active status, site is set to **Active** status.	Milestone **S01-Site Selected** is set to CTMS status change Date
*Set site Status to **Active Stop***	N/A	N/A
*Add **Activated for Enrollment** Milestone*	N/A	**S02-Ready to Enroll** is set to CTMS Milestone Date
*Add **First Subject Randomized** Milestone*	N/A	**S03-First Patient First Visit** is set to CTMS Milestone Date
*Add **Close-Out Pack Sent** Milestone*	N/A	**S04-Site Close Out** is set to CTMS Milestone Date
*Set site **Status** to **Closed***	Site is set to **Closed** status. Notation "Site is Closed" added to site.	**S04-Site Close Out** is set to CTMS status change Date
*Change **Site #***	Site name is changed.	N/A
*Change **PI First Name** and/or **Last Name***	Site name is changed.	N/A

Important Considerations for Existing Projects

If the same site existed in both CTMS and Phlex prior to syncing, the site name in Phlex will be changed to include the **Site #**, **PI Last Name**, and **PI First Name** fields from CTMS. If the Phlex Status does not match up with the CTMS Status, the Phlex Status will be changed as indicated above. Milestones will not populate until a site status change is made in CTMS.

How to know if a Site has Synced

A new **Phlex Site ID** column was added to the CTMS **Site Management** List to help you identify which sites have been synced. A site will not have a **Phlex Site ID** unless it has been synced. To add **Phlex Site ID** to your default Site Management List:

1 In CTMS **Site Management**, click the **Sites Menu** icon.
2 In the drop-down menu, select **Columns Displayed**.
   The **Columns Displayed** prompt opens.
3 In **Available Columns** scroll down to find **Phlex Site ID**, and then select it.
4 Next to **Selected Columns**, click the right arrow icon to add the new column to your list.
   Tip: In Selected Columns, select **Phlex Site ID** and use the Up and Down arrows to change its position.
5 Click **Save**.
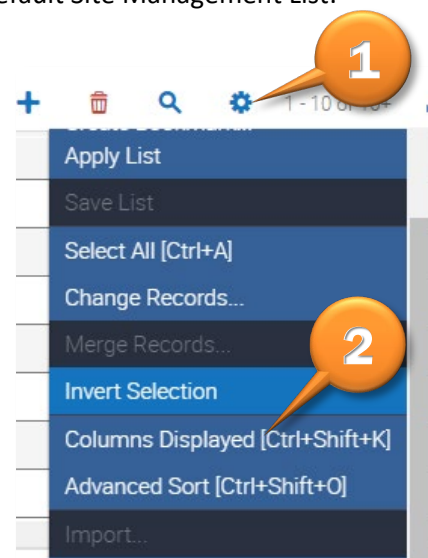
Other helpful columns include **Phlex Site Name** (how the site name appears in Phlex), **Phlex Sponsor Name** and **Phlex Program Name** (the Sponsor and Program your Protocol falls under in Phlex), and **Row ID** (useful when discussing a particular site with CTMS Support).

## About Essential Site Visit Documents

What are "Essential Site Visit Documents"

Essential Site Visit Documents include the 63 unique **Confirmation Letters**, **Follow-Up Letters**, and **Visit Reports** associated with each of the 11 CTMS Visit Types. A full List of Essential Site Visit Documents is available on the PhlexTMF Learning Center.

- Site Initiation (SIV)
- Site Selection (SSV)
- Site Selection/Initiation (SSV/SIV)
- Periodic Monitoring (PMV)
- Remote (REMV)

- Periodic Monitoring/Close-Out (PMV/COV)
- Site Close-Out (COV)
- Booster (BOV)
- Other
- Unblinded

How Documents get from CTMS to Phlex

The Integration automated the renaming and uploading of Essential Site Visit Documents to Phlex. This automation was incorporated into the normal CTMS workflow (as shown below) so that you don't have to change how you work.

Note: CTMS uploads only Essential Site Visit Documents to Phlex. All other documents have to be uploaded manually.
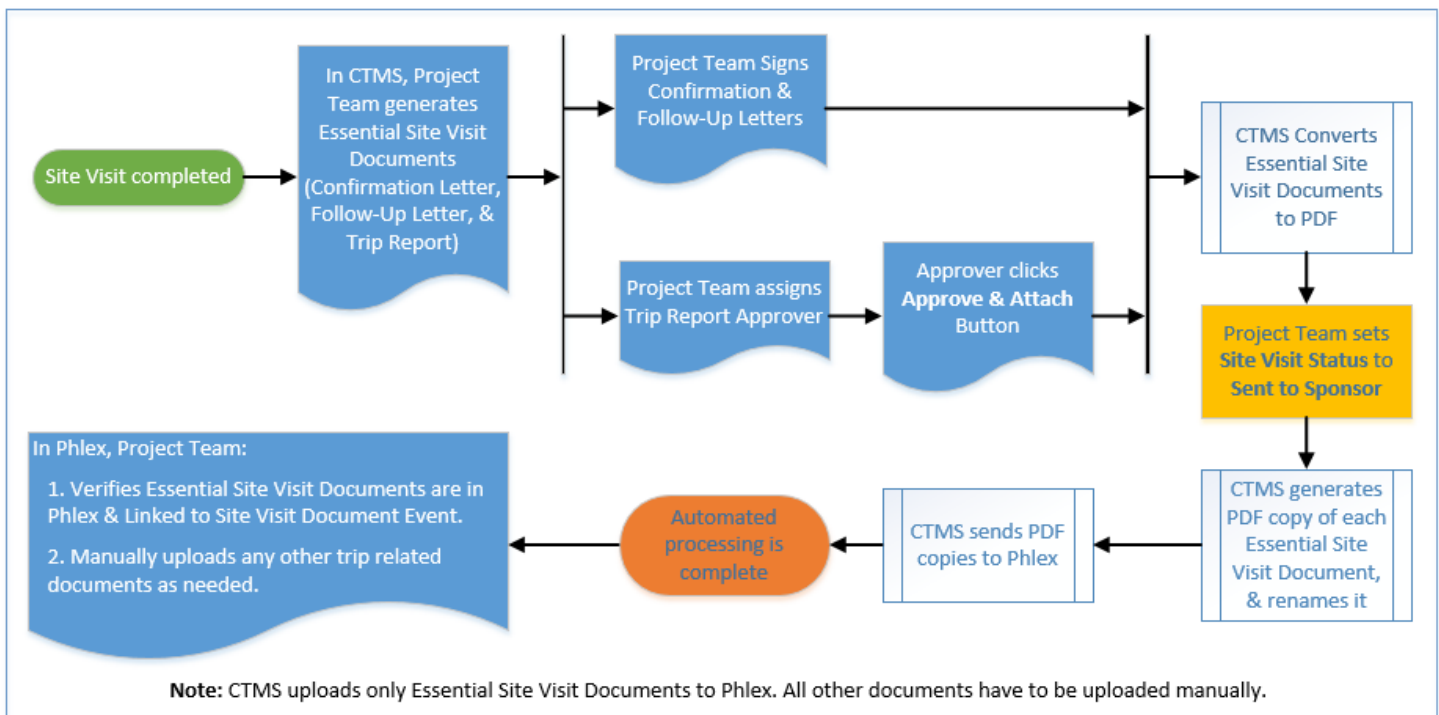
As shown in the diagram, changing the **Site Visit Status** to **Sent to Sponsor** triggers automated processing. The PDFs are renamed following the convention below. Note that UB is short for unblinded, and is included only in unblinded documents.

<Site#>_<PI Last Name>_<Visit Type Abbreviation>_<Document Type Abbreviation>_UB_<Actual Visit Date>

CTMS follows a mapping file to determine where the document belongs in your project's TMF based on CTMS Document Type and Visit Type. For a detailed list of how all 63 documents are mapped, see the *Essential Site Visit Documents* list.

The example below illustrates how Essential Site Visit Documents are renamed, and where they are uploaded in the TMF. The example is of a **Site Initiation Visit (SIV)** at site **007 – Reddy, Shamantha** on **11-11-2021**. When the Project Team changes the **Site Visit Status** to **Sent to Sponsor**, the documents are processed as follows:

Document Type	Renamed To	Uploaded to Phlex Artifact >> Sub-Artifact
Confirmation Letter	007_Reddy_SIV_CL_2021-11-11	05.03.01 - Trial Initiation Monitoring Report >> Trial Initiation Monitoring Confirmation letter.
Follow Up Letter	007_Reddy_SIV_FL_2021-11-11	05.03.01 - Trial Initiation Monitoring Report >> Trial Initiation Monitoring Follow-up letter.
SIV (Trip) Report	007_Reddy_SIV_TR_2021-11-11	05.03.01 - Trial Initiation Monitoring Report >> Trial Initiation Monitoring Report

How to Track Essential Site Visit Documents

Two new Site Level Event Types have been created in Phlex to help track Essential Site Visit Documents. These Event Types are Raised when a new site is created in a project that has been synced.

New Event Type	Comment
Site Visit Document Event	Added automatically when a new site is synced to Phlex.
Unblinded Site Visit Document Event	If your project uses Unblinded Site Documents, added automatically when a new site is synced to Phlex.

The Site Visit Document Events have been designed to stand out in a Site's Event List. As shown below, Event Names begin with the word **Visit**, and the Status column icons display zeros.

> **Tip:** Click on **Event Name** to sort by that column, and group your automated Events together.

It is important to note that these new events do not replace the Site Level Events that are currently in use.

- SMRs must continue to raise and monitor **PI**, **Sub-I**, and **Other Site Personnel** events.

- The **Site Document Event** will include only non-trip related site documents.

  Note: Documents related to site visits will be included in the new **Site Visit Document Event**, or **Unblinded Site Visit Document Event**.

- **Sites that were in Phlex prior to syncing your project will <u>not</u> get a Site Visit Document Event**. Instead, the existing Site Document Event will be used to track all site related documents (including Essential Site Visit Documents).

Getting Help

For more guidance on the PhlexTMF system, visit the eTMF Learning Center on DCRI Pulse at: https://dcrihome.dcri.org/IT/Pages/LearningCenters/etmf.aspx.

If you have questions or comments about the content of this quick reference card (QRC), please email brad.conant@duke.edu. If you experience any technical problems working with the PhlexTMF system, please open a Service-Now ticket through the Fix IT tool, or contact the DHTS Service Desk directly at 919.684.2243.