

MATCHBox Protocol Application User Guide

Revision 1

December 16, 2022

Document Information

Revision Information for the MATCHBox Protocol Application User Guide

Revision History

#	Date	By	Description
1	08-Dec-2022	Lela Makbul	Created initial version.

File Location: <https://wiki.nci.nih.gov/display/CDISC/PMI+Committee>

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1. Background

The status information about the cohorts for the precision medicine treatment protocols needs to be communicated to MATCHBox for the appropriate treatment regimen assignment. Cohort information is managed by the lead National Clinical Trials Network (NCTN) group outside of OPEN and each group has its own workflow for closing and reopening a cohort or cohort-stratum combination. Some groups manage the statuses in their databases while others have a manual process for monitoring the statuses.

An automated and semi-automated process was created to provide the cohort and stratum status information to MATCHBox in real time.

A new service was created to allow Groups to push the cohort and strata data into the Protocol application from an external database.

In addition, some group users have the ability to manually update specific data in Cohorts and Strata tables within the Protocol application. This user guide provides instructions to the groups on how to navigate MATCHBox tables within the Protocol application and update data when applicable.

For more information, please contact the CTSU Help Desk (phone: 1-888-823-5923; email: ctscontact@westat.com).

2. Navigating MATCHBox Information within Protocol Application

2.1 Updating Strata, Cohort Status and Accrual target

After accessing the Protocol application (<https://protocol.ctsu.org/login>) and selecting the appropriate study from the Browser screen, group users will land on the *Details* Module.

On the bottom side of this module, the MATCHBox Information box, Cohorts and Strata for Cohorts will be displayed. The group user can click on the Cohort row to review the Cohort/Stratum combination, as illustrated in Figure 1.

MATCHBox data is only displayed if the study is mapped to MATCHBox, and if the Treatment Flag is selected as Yes (this information is saved in the Protocol Details section of the Details Module).

Figure 1: MATCHBox Information, Cohort and Strata

Group users are able to manually update the Strata or Cohort status if certain conditions are met. In addition, group users can update the Accrual Target. Refer to Table 1 to review when Cohorts or Strata statuses and target accrual can be updated.

Groups do not have the ability to manually *add* new Cohorts or Strata.

Table 2 provides a description for each Cohort/Strata status.

Table 1: Cohort/Strata Table Updates

Protocol Status	Cohort or Strata Status	Cohort/Strata Table (Status and Accrual Target)
In Review	Ready	Not editable
Approved	Ready	Not editable
Approval on hold status	Ready	Not editable

Navigating MATCHBox Information within Protocol Application

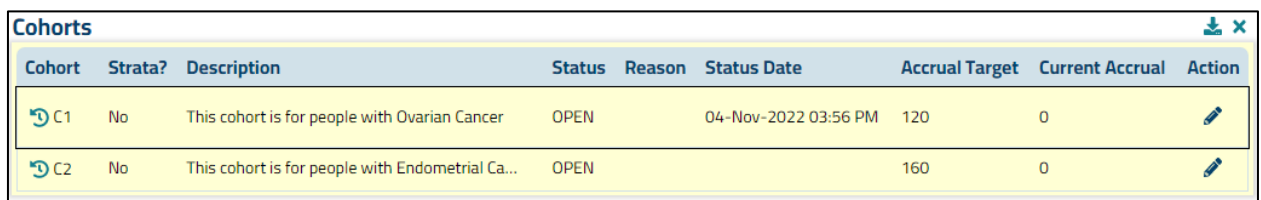
Protocol Status	Cohort or Strata Status	Cohort/Strata Table (Status and Accrual Target)
Active	Open, Suspended	Editable
Active	Closed	Not editable
Temporarily Closed to Accrual	Open, Suspended, Closed	Not editable
Temporarily Closed to Accrual & Treatment	Open, Suspended, Closed	Not editable
Closed	Closed	Not editable

Table 2: Cohort/Strata Status Description

Cohort/Strata Status	Status Description
Ready	The cohort and/or strata information from MATCHBox is in the Protocol application but the trial is not active yet.
Open	The protocol is active and the cohort and/or strata are active.
Closed	An individual cohort or strata is no longer available for patient enrollment. This is a terminal status.
Suspended	An individual cohort or strata is temporarily unavailable. The status may be changed back to Open. Other cohorts or strata may still be open for enrollment.

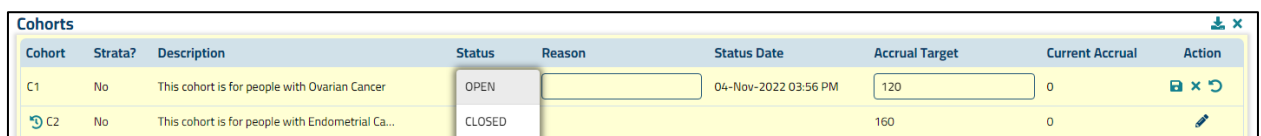
To update the Cohorts status:

- Click on the edit/pencil icon above the Cohorts table. This step will prompt the Action column to appear, as illustrated in Figure 2.
- Under the Action column, select the pencil icon again on the line to edit. Then select the appropriate Status from the Status column, as shown in Figure 3. If applicable, add the accrual number to the Accrual Target column. Then click on the save icon to save the data.



Cohort	Strata?	Description	Status	Reason	Status Date	Accrual Target	Current Accrual	Action
C1	No	This cohort is for people with Ovarian Cancer	OPEN		04-Nov-2022 03:56 PM	120	0	
C2	No	This cohort is for people with Endometrial Ca...	OPEN			160	0	

Figure 2: Updating Cohorts Status and Accrual Target – Action Column



Cohort	Strata?	Description	Status	Reason	Status Date	Accrual Target	Current Accrual	Action
C1	No	This cohort is for people with Ovarian Cancer	OPEN		04-Nov-2022 03:56 PM	120	0	
C2	No	This cohort is for people with Endometrial Ca...	CLOSED			160	0	

Figure 3: Updating Cohorts Status and Accrual Target – Saving Changes

Navigating MATCHBox Information within Protocol Application

2.2 Reviewing Change History

By clicking on the History icon, groups can review the Change History log which shows changes made to the Cohort or Strata table.

The Cohort or Strata Change History table shows status changes (both old and new status), accrual target update, status change date, and the name of the user who made the change.

Examples of the Cohort and Strata Change History are shown in Figure 4 and Figure 5.

Click for History

Cohort	Stratum	Description	Status	Reason	Status Date	Accrual Target	Current Accrual
C1	Yes	This cohort excludes participants who: * Have ...	OPEN		25-Aug-2022 04:35 PM	66	0
C2	Yes	This cohort is for participants that have experi...	OPEN		25-Aug-2022 04:35 PM	45	0

Strata for Cohort C1

Stratum	Description	Status	Reason	Status Date	Accrual Target	Current Accrual
S1	This stratum is for people with pancreatic can...	OPEN		25-Aug-2022 04:35 PM		0
S2	This stratum is for people with all other cance...	OPEN		25-Aug-2022 04:35 PM		0

Cohort Change History- Cohort C1

Change Date	From Status	To Status	Reason	Accrual Target Update	Changed By
25-Aug-2022	READY	OPEN			Whitefield Phoebe
25-Aug-2022	READY	READY			Whitefield Phoebe
25-Aug-2022		READY	66		CTSUESYS
25-Aug-2022	READY	READY			Whitefield Phoebe

Pop up box with change history for cohort

Close

Figure 4: Cohort Change History Example

Navigating MATCHBox Information within Protocol Application

The screenshot shows the 'Strata for Cohort C1' section with a table of strata. A callout box points to a download icon with the text 'Click for History'. Below the table, a 'Stratum Change History - Cohort C1, Stratum S1' pop-up box is shown, containing a table of changes. A second callout box points to the pop-up with the text 'Pop up box with change history for cohort/stratum'.

Stratum	Description	Status	Reason	Status Date	Accrual Target	Current Accrual
S1	This stratum is for people with pancreatic can...	OPEN		25-Aug-2022 04:35 PM		0
S2	This stratum is for people with all other cance...	OPEN		25-Aug-2022 04:35 PM		0

Change Date	From Status	To Status	Reason	Accrual Target Update	Changed By
25-Aug-2022	READY	OPEN			Whitefield Phoebe
25-Aug-2022		READY			Whitefield Phoebe

Figure 5: Strata Change History Example

2.3 Exporting Strata/Cohort Data

Groups are able to export both Cohort and Strata data. To export the data, click on the download icon, as shown in Figure 6, and then select the appropriate format. The data can be exported in both Excel and PDF Format, as illustrated in Figure 7.

The screenshot shows the 'Cohorts' table with a download icon in the top right corner.

Cohort	Strata?	Description	Status	Reason	Status Date	Accrual Target	Current Accrual
C1	No	This cohort is for people with Ovarian Cancer	OPEN	updated1	04-Nov-2022 03:56 PM	120	0
C2	No	This cohort is for people with Endometrial Ca...	OPEN			160	0

Figure 6: Download Icon in Cohorts and Strata Tables

The screenshot shows two versions of the cohort data: an Excel spreadsheet and a PDF document. The Excel spreadsheet has columns for Cohort, Strata?, Description, Status, Reason, Status Date, Accrual Target, and Current Accrual. The PDF document is a headered table with the same columns and data.

Cohort	Strata?	Description	Status	Reason	Status Date	Accrual Target	Current Accrual
C1	undefined	This cohort is for people with Ovarian Cancer	OPEN		04-Nov-2022 03:56 PM	120	0
C2	undefined	This cohort is for people with Endometrial Cancer	OPEN			160	0

Figure 7: Exported Cohort and Strata data in Excel and PDF Format