Using AutoEncoder 5.0

Table of Contents

Revision History

Revision	Description of Change	Author	Effective Date
1.0	New document	Lorrie Tate	23-APR-2018

PREFACE

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2.0 Intended Audience

The prime users for AutoEncoder are Medical Coders. Other users include Data Managers and Monitors who require the ability to access, evaluate, and apply coding from industry dictionaries.

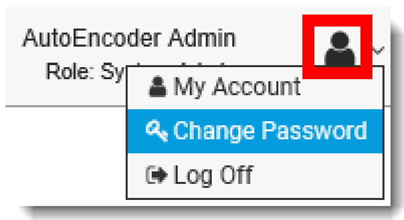
3.0 Manual Conventions

After each instruction, feedback is provided as necessary (i.e., if a window displays or a specific action occurs).

Bolded text highlights certain screenshots or indicates a user action, such as clicking selecting an option. In screenshots, user actions are outlined in red boxes or circles.

Example:

1. Click the **User** Account icon on the top right of the AutoEncoder status bar.



2. Select **Change Password** from the drop-down list.
3. Enter the **Old Password, New Password**. (Refer to Password Rules when entering the new password.)
4. Enter the new password in the **Confirm Password** field.
5. Click on the **Change Password** button to save the new password. A confirmation message displays at the top of the Login page and an email is sent to you, indicating that the password was successfully changed.

4.0 Getting Started

After logging into AutoEncoder refer to the Autoencoder Workflow to determine your tasks according to your user/role.

To get acquainted with the AutoEncoder interface, see AutoEncoder Interface.

LOG IN/LOG OFF

4.1 Log In

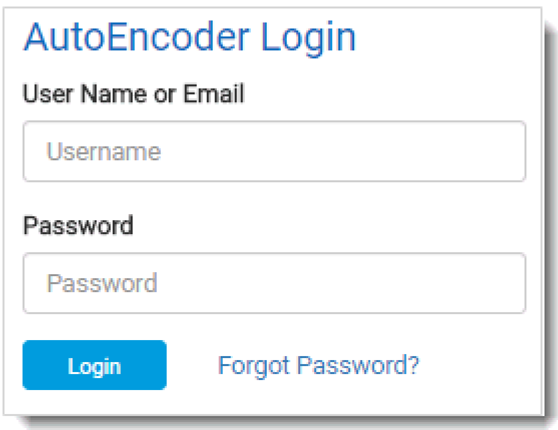
The initial installation includes a single System User/System Admin (Administrator) named "AecAdmin" (not case-sensitive)". Then you may then create other user accounts, which may be System Users/System Admins or Regular Users. (See Edit Add a User for more information.)

Note: If you get locked out for exceeding the allowed number of incorrect login attempts, you must contact the trial administrator to have your password reset immediately. Otherwise, you cannot log in until an hour passes.

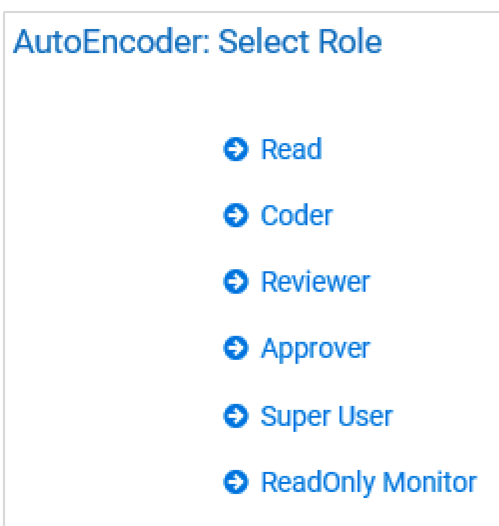
To log in:

1. Start a web browser application, such as IE 11, Firefox, or Chrome.
2. Enter the appropriate URL for AutoEncoder. The URL is set up when AutoEncoder is first installed.

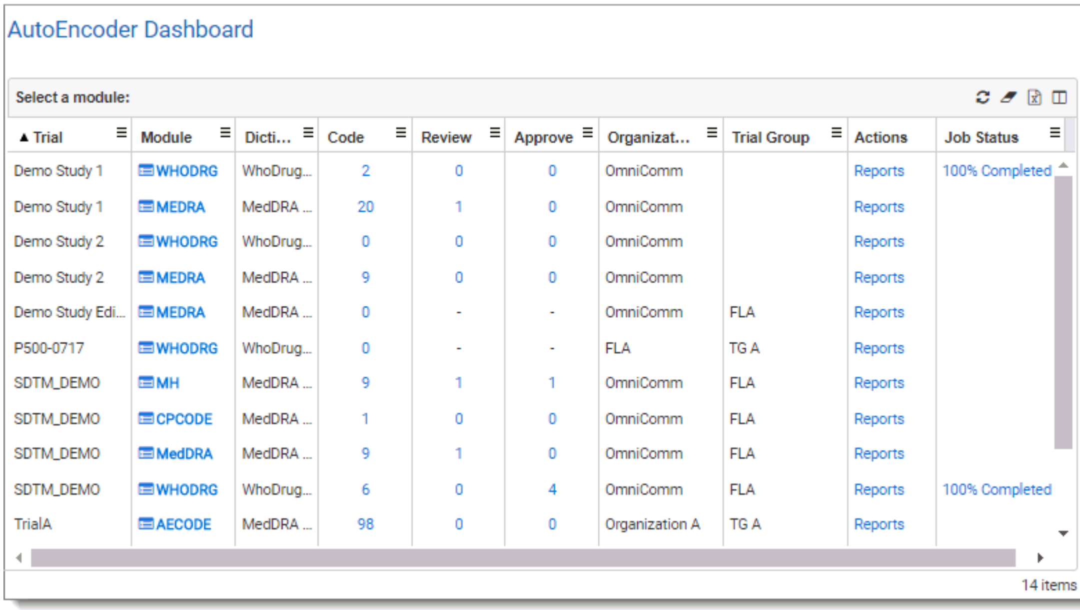
   The Log in page displays.



3. Enter your User Name/Email address and Password and click the **Login** button.
4. If you were assigned multiple roles, click on a role in the Select Role page.



The Dashboard displays.



▲ Trial	Module	Dicti...	Code	Review	Approve	Organizat...	Trial Group	Actions	Job Status
Demo Study 1	WHODRG	WhoDrug...	2	0	0	OmniComm		Reports	100% Completed
Demo Study 1	MEDRA	MedDRA ...	20	1	0	OmniComm		Reports	
Demo Study 2	WHODRG	WhoDrug...	0	0	0	OmniComm		Reports	
Demo Study 2	MEDRA	MedDRA ...	9	0	0	OmniComm		Reports	
Demo Study Edi...	MEDRA	MedDRA ...	0	-	-	OmniComm	FLA	Reports	
P500-0717	WHODRG	WhoDrug...	0	-	-	FLA	TG A	Reports	
SDTM_DEMO	MH	MedDRA ...	9	1	1	OmniComm	FLA	Reports	
SDTM_DEMO	CPCODE	MedDRA ...	1	0	0	OmniComm	FLA	Reports	
SDTM_DEMO	MedDRA	MedDRA ...	9	1	0	OmniComm	FLA	Reports	
SDTM_DEMO	WHODRG	WhoDrug...	6	0	4	OmniComm	FLA	Reports	100% Completed
TrialA	AECODE	MedDRA ...	98	0	0	Organization A	TG A	Reports	

Note: If the user role has no access to the data on the page, no rows/data display. However when navigating from the Coding and Transmission Queue pages, the Dashboard displays the relevant data.

5. Refer to Use the Dashboard for Coding to get started with AutoEncoder.

4.2 Change Password

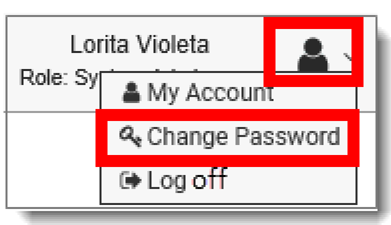
For security purposes, it may be necessary to change your password. There are two ways to change your password:

- Change your password manually through the User Account Manager
- Wait until the system prompts you for a new password when it expires. Once your password expiration is near, a warning displays after login. The system gives you the option to change it immediately, or sometime before the password expiration (the default setting is 5 days, which may be configured to another setting).

Note: If your password becomes locked, reset your password using the **Forgot Password** link on the login page. (See Retrieve a Forgotten Password for instructions.)

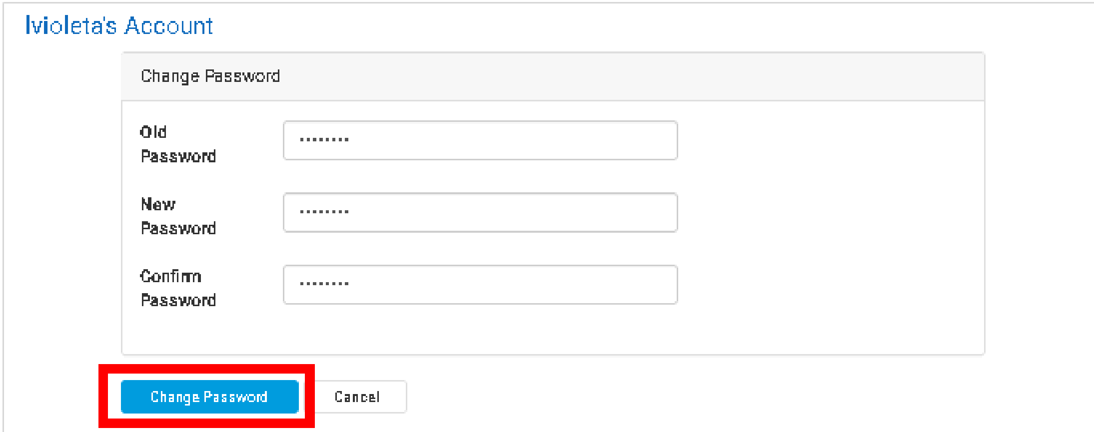
To change your password:

1. Click the **User Account** icon on the top right of the AutoEncoder status bar.



2. Select **Change Password** from the drop-down list.

The Change Password dialog displays.



3. Enter the **Old Password** and **New Password**. (Refer to Password Rules when entering the new password.)
4. Enter the new password in the **Confirm Password** field.
5. Click on the **Change Password** button to save the new password. A confirmation message displays at the top of the Login page and an email is sent to you, indicating that the password was successfully changed.
6. Click the **Cancel** button to return to the Login page.

Note: If you do not use the link your password remains the same. If you did not request your password be reset, please contact your administrator.

4.2.1 Password Rules

The following password rules apply (these settings are configurable):

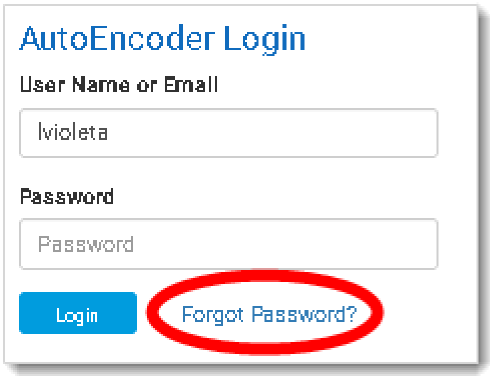
- Must have at least 1 uppercase letter
- Must have at least 1 lowercase letter
- Must have at least 1 numeric character
- Password length is must be 8 characters
- Must have at least 1 special character
- Password expiration is 90 days
- Password Warning message displays on the Dashboard on login starting 5 days prior to the expiration: "Your password will expire in {5} days. Please change it as soon as possible."

4.2.2 Retrieve a Forgotten Password

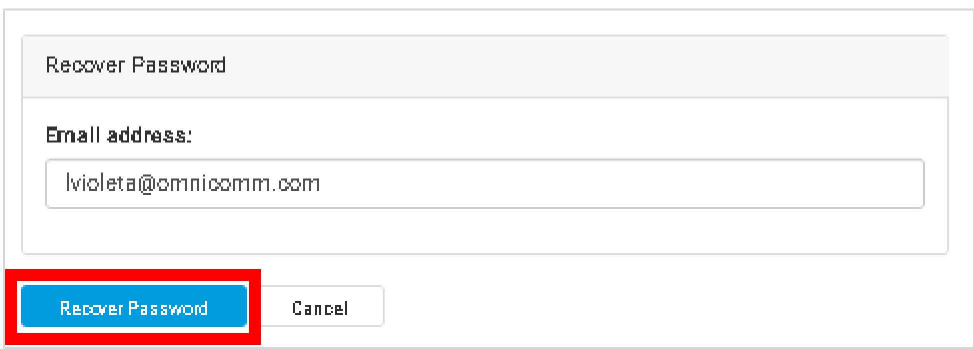
When retrieving a forgotten password, a temporary password is sent to your email address.

To retrieve a forgotten password:

1. Click the **Forgot Password** link on the Login page.



The Recover Password dialog displays.



2. Enter your email address and click the **Recover Password** button. The Login page re-displays and you receive two notification emails: A notification with a reset password link and a notification with a temporary password.
3. Enter your **User Name** and the temporary **Password** in the Login page. (The password can only be used once and you must change it as soon as possible.)
4. Enter the required information in the Change Password dialog. (Refer to Change Password for guidance.)

4.2.3 Password Notifications

Temporary password notifications are sent when a:

- New user is created
- System User/System Admin clicks the Reset Password link on the Users page to reset a user's password
- User clicks the **Forgot Password** link on the Login page

The system sends an email notification with a newly generated temporary password to the user. The password is valid for the configured password expiration (default is 90 days). This password is a one-time use password and must be changed after the user logs in.

Users are not forced to change the password on login. If the user does not change the password after login, they will not be able to log in again.

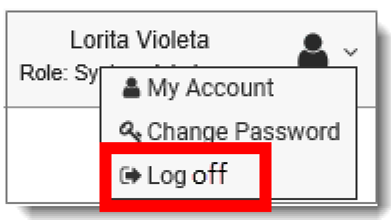
The user can click on the **Forgot Password** link on the login page or the System User/System Admin can click on the **Reset Password** link for that user to reset the user's password.

4.2.4 Log Off

You can log off from the User Account drop-down menu.

To log off:

1. Click the **User Account** icon on the top right of the AutoEncoder status bar.



2. Select **Log Off** from the drop-down list.

USING AUTOENCODER

5.0 About AutoEncoder

Most data entered into EDC (Electronic Data Capture) is entered as free text but must be coded against standard medical dictionaries. Commonly coded clinical data includes AE (Adverse Event) verbatim terms, medical history, physical conditions and procedures, and medications.

To start using AutoEncoder, refer to AutoEncoder Workflow.

6.0 AutoEncoder Workflow

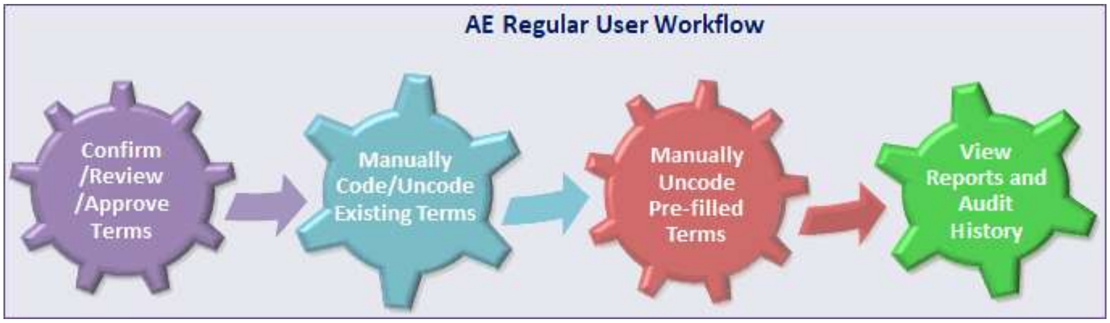
This section provides AutoEncoder workflow diagram and steps.

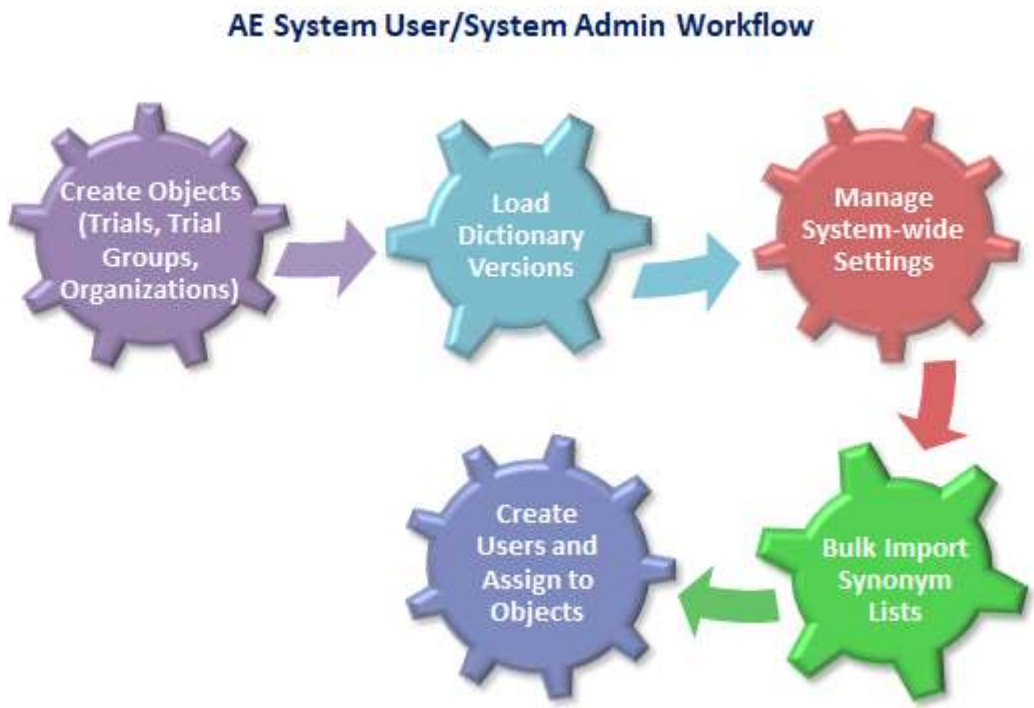
AutoEncoder workflow steps:

1. The System Administrator does the following:
    a. Creates needed objects such as organizations, trial groups, and trials (see Manage Organizations, Manage Trial Groups, or Manage Trials)
    b. Loads all needed Dictionary Versions (see Add New Dictionary Version)
    c. Manages System-Wide Settings (see View/Edit System Settings)
    d. Bulk imports any required Synonym Lists (see Import/Export Synonym List)
    e. Creates any needed users (see Edit/Add a User)
    f. Assigns user(s) to appropriate objects with a corresponding role (see Assign a User to an Object)
2. The System Administrator may assign a user the role "Super User" on an organization (see Assign User to an Object). The Super User, when assigned to an organization, does the following in the context of their parent organization:
    a. Creates new users (see Edit/Add a User)
    b. Assigns user(s) to any object belonging to the Super User's organization (see Assign User to an Object)
    c. Edits users (see Edit/Add a User)
    d. Assign user(s) to any object owned by the organization as any applicable role (see Assign a User to an Object)
    e. Associates dictionary versions with modules (see Manage Mapping)
    f. Matches/maps TrialMaster module and AutoEncoder dictionary terms (see Manage Mapping)
    g. Manages Synonym Lists (see Manage Synonym Lists)
    h. Manages settings on individual objects (see Manage Organizations, Manage Trial Groups, or Manage Trials)
3. Once a module and its associated mapping have been established, the process of autocoding and manual validation begins. Regular users with appropriate permissions can:
    - View, confirm, review and/or approve terms after they load into AutoEncoder (see Confirm/Review/Approve Terms)
    - Manually code and uncode existing terms (see Code/Uncode Matched Terms)
    - Manually uncode pre-filled terms already passed back to the associated application (see Code/Uncode Matched Terms).

4. At any point, Regular Users with the appropriate permission can view reports and view the audit history for individual terms (or various management/objects). (See View Module Reports, View System Reports, and View a Term's Audit History.)

   The System User/System Admin, Super User and Regular User workflow diagrams illustrate the typical workflow process for each user type.





7.0 AutoEncoder Interface

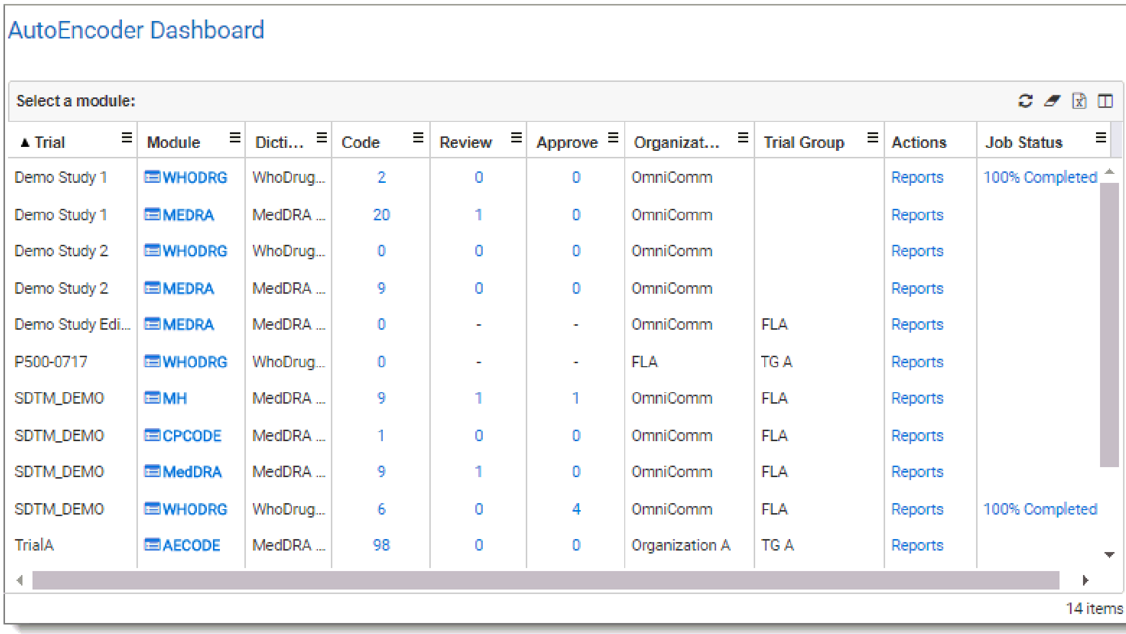
The AutoEncoder window consists of the following:

- Dashboard (Home Page)
- Menus
- Status Bar

Main AutoEncoder Window

7.1 Home Page (Dashboard)

Once you log in the Dashboard displays. See Using the Dashboard for Coding for instructions.



7.2 Status Bar

The Status Bar displays the following information (from left to right):

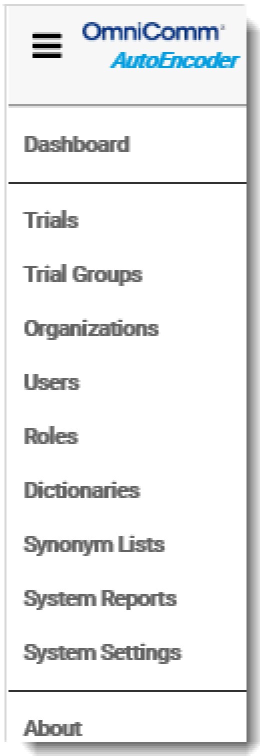
- Main Menu icon – provides access to the main sub menus
- AutoEncoder logo – allows you to return to the home page (Dashboard)
- Active/Timeout – Either displays the time remaining in the session (if the session is inactive) or an "Active" icon when the session is in use
- User – identifies the user name currently logged in
- Role – identifies the role of the user
- User Account icon – allows you to edit your account information, change your password, or log off

7.3 Menus

Note: The menus displayed vary depending upon permissions assigned to the active user and role.

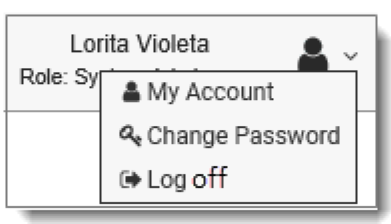
The following menus display in Autoencoder:

- Main Menu – provides access to the main sub menus



Click the **Main Menu** icon (top left) to access specific pages such as Dashboard, Trial Groups, Organizations, and Users.

- User Account

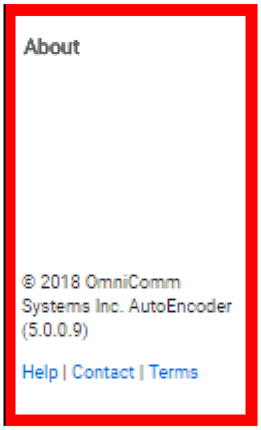


Click the **User Account** icon to do the following:

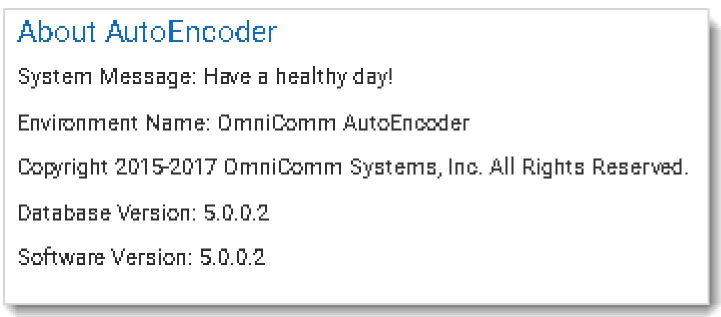
  - Edit your account information
  - Change your password
  - Log off

Note: See Update Your User Account Information for more information about your user account.

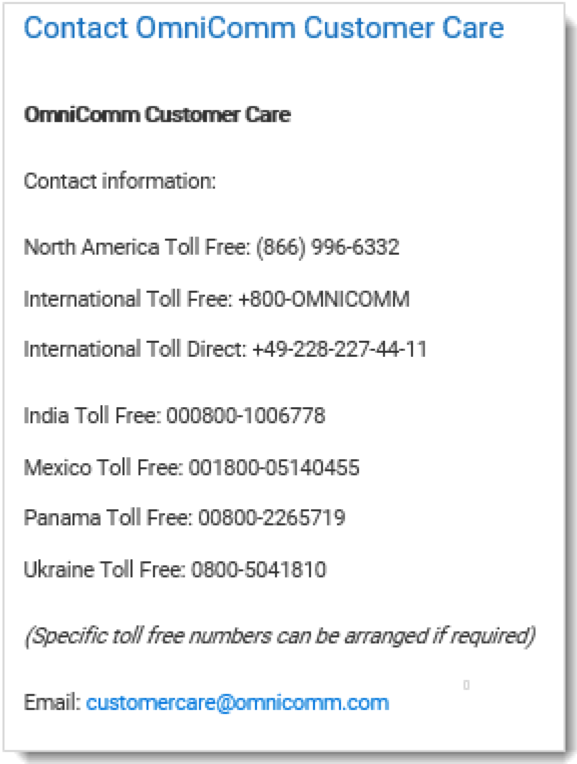
- Information Menu (bottom of main menu) – provides copyright notice and build number and the following links:



  - **Help** – displays the AutoEncoder Help window
  - **About –** displays the **About AutoEncoder page,** which provides the system message, environment, copyright, and database and software versions



  - **Contact** – displays the OmniComm Customer Care page, which provides contact information for different customer regions. It also includes the customer care email



- **Terms** – displays the standard user agreement

Dashboard

7.4 Use the Dashboard for Coding

The Dashboard page displays the dictionary, number of terms that need to be coded/reviewed/approved, organization, trial group, and job status for each module.

The following links are provided to view more detailed information:

- Module/Code/Review/Approve – links to the Coding page of the applicable module where you can confirm/review/approve terms
- Actions – links to reports of the applicable module
- Job Status – links to the Autoencoding Jobs page where you can view more details about each autoencoding job

Note: If a "-" appears in the Review or Approve column rather than a numerical value, this means that AutoReviewApprove (Automatically Review and Approve Terms once Confirmed) setting is on (set to True), and therefore, all items are accessible from the coding stage (Code column). The only exception is when AutoReviewApprove setting is turned on mid-stream. In this case, there could be remnant terms in the Review and/or Approve Stage and once these terms complete the cycle the "-" appears. (See View/Edit System Settings for more information.)

The Dashboard allows you to do the following, depending on your role permissions:

- View coding stages
- View a term's audit history
- Confirm/review/approve terms
- Re-autoencode terms
- Code/uncode matched terms
- View AutoEncoding job details
- View/uncode terms in the Transmission Queue
- View Module Reports

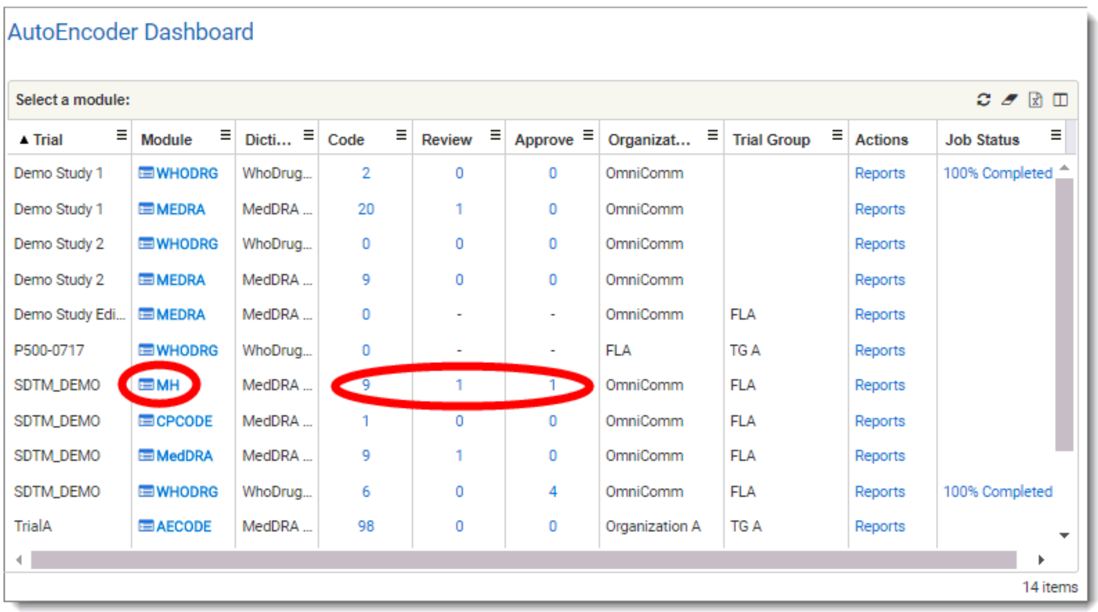
7.4.1 View Coding Stages

You can view coding stages (coding, review, approve) for each group of terms in each module.

To view coding stages:

1. Access the Dashboard after first logging in or by clicking the AutoEncoder logo.

The Dashboard page displays.



AutoEncoder Dashboard

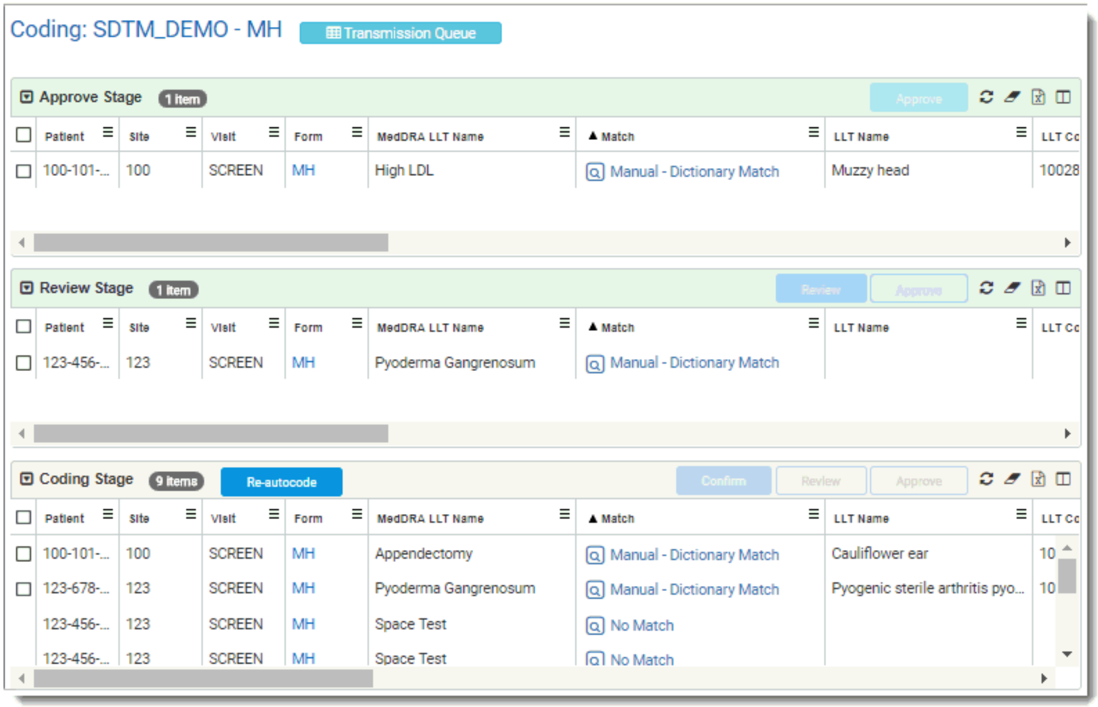
Select a module:

▲ Trial	Module	Dicti...	Code	Review	Approve	Organizat...	Trial Group	Actions	Job Status
Demo Study 1	WHODRG	WhoDrug...	2	0	0	OmniComm		Reports	100% Completed
Demo Study 1	MEDRA	MedDRA ...	20	1	0	OmniComm		Reports	
Demo Study 2	WHODRG	WhoDrug...	0	0	0	OmniComm		Reports	
Demo Study 2	MEDRA	MedDRA ...	9	0	0	OmniComm		Reports	
Demo Study Edi...	MEDRA	MedDRA ...	0	-	-	OmniComm	FLA	Reports	
P500-0717	WHODRG	WhoDrug...	0	-	-	FLA	TG A	Reports	
SDTM_DEMO	MH	MedDRA ...	9	1	1	OmniComm	FLA	Reports	
SDTM_DEMO	CPCODE	MedDRA ...	1	0	0	OmniComm	FLA	Reports	
SDTM_DEMO	MedDRA	MedDRA ...	9	1	0	OmniComm	FLA	Reports	
SDTM_DEMO	WHODRG	WhoDrug...	6	0	4	OmniComm	FLA	Reports	100% Completed
TrialA	AECODE	MedDRA ...	98	0	0	Organization A	TG A	Reports	

14 items

2. Do one of the following:
   - To access all stages, click the applicable link under the **Module** column.
   - To access a specific stage, click the applicable link under the **Code, Approve**, or **Review** column. (The Approve and Review links display a "-" if the AutoReviewApprove setting is set to True.)

The Coding page displays the verbatim term and any corresponding reference items with each patient, site, visit, and form. (These first four columns are specific to TrialMaster.) Links are provided to view the associated TrialMaster form, match (to manual/autocode/history/synonym/ dictionary), and the date the term was last modified (audit history).



Each stage is automatically expanded so all data is viewable. The header of each stage is highlighted with a color and indicates the number of terms included in the stage. You can expand/collapse a stage using the Expand/ Collapse icon.

Note: If a "-" displays in the Review or Approve column rather than a numerical value means that AutoReviewApprove (*Automatically Review and Approve Terms once Confirmed)* setting is On, and therefore, all items are accessible from the Coding Stage (Code column). The only exception is when AutoReviewApprove setting is turned on mid-stream. In this case, there could be remnant terms in the Review and/or Approve Stage and once these terms complete the cycle the "-" displays. (See View/Edit System Settings for more information.)

Note: You can sort and filter the table or export it to Excel. Various table options are also available. (See Use Table Functions.)

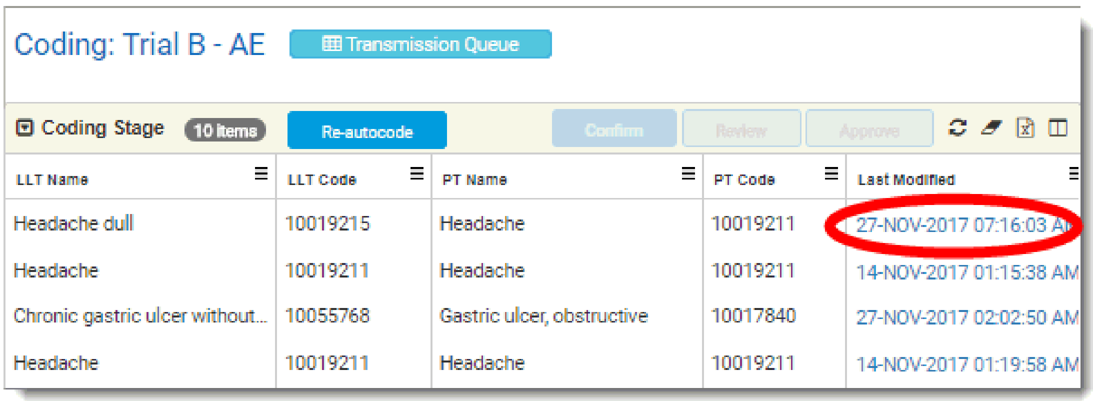
7.4.2 View a Term's Audit History

You can view a term's audit history from the following locations:

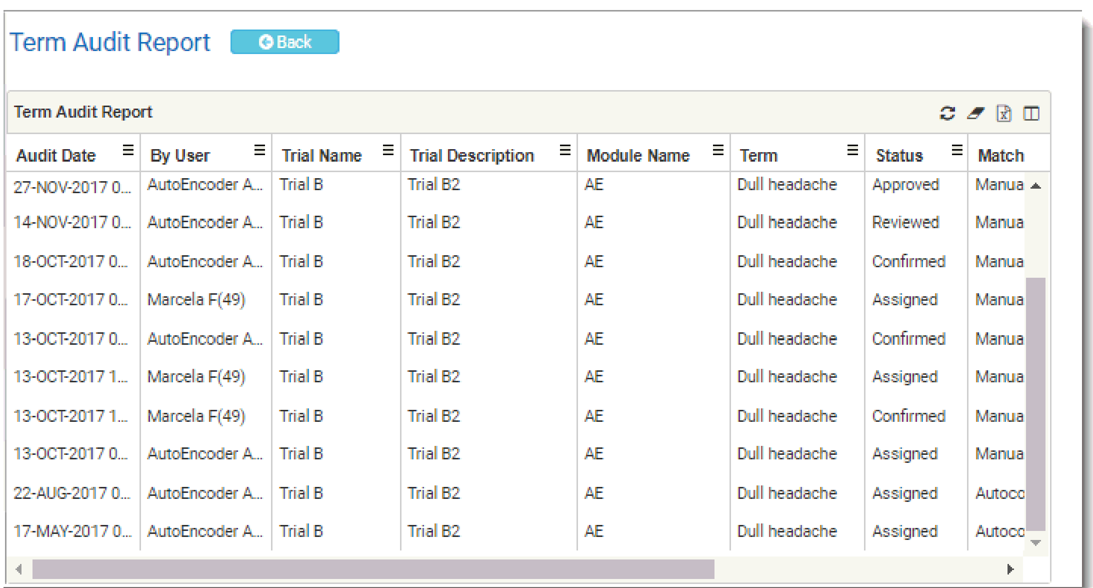
- Coding, Review, or Approve stage
- Transmission Queue

To view a term's audit history:

1. Access the Dashboard and click a code, module, review, or approve link. (See View Coding Stages for guidance.)
2. Do one of the following:
   - Locate the applicable term in the Coding, Review, or Approve stage.
   - Click the **Transmission Queue** button and locate the term.
3. Click the link of the term under the **Last Modified** column (far right).



The Term Audit Report displays the audit history of the term, including the user who performed the action, the trial, module name, status, match, and dictionary term. (If the System Setting, "IncludeTimeZoneInfo" is set to True, the timezone information is appended to all of the timestamps. (See View/Edit System Settings for more information.)



Note: You can sort and filter the report or export it to Excel. Various table options are also available. (See Use Table Functions.)

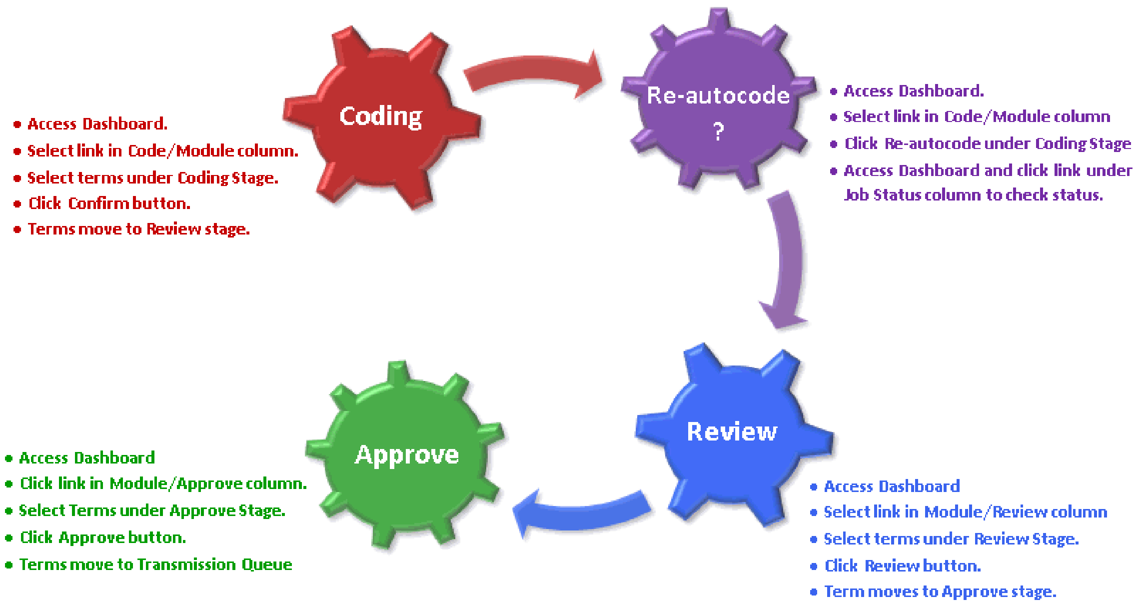
7.4.3 Confirm/Review/Approve Terms

The following actions allow you to move a term to the next Coding Stage:

- Confirm – moves term to Review Stage
- Review – moves item to Approve Stage
- Approve – moves item to Transmit Stage

The Coding Stages diagram illustrates how to move to each stage. As shown in this diagram, you can also re-autocode terms from the Coding Stage before moving them to the Review stage.

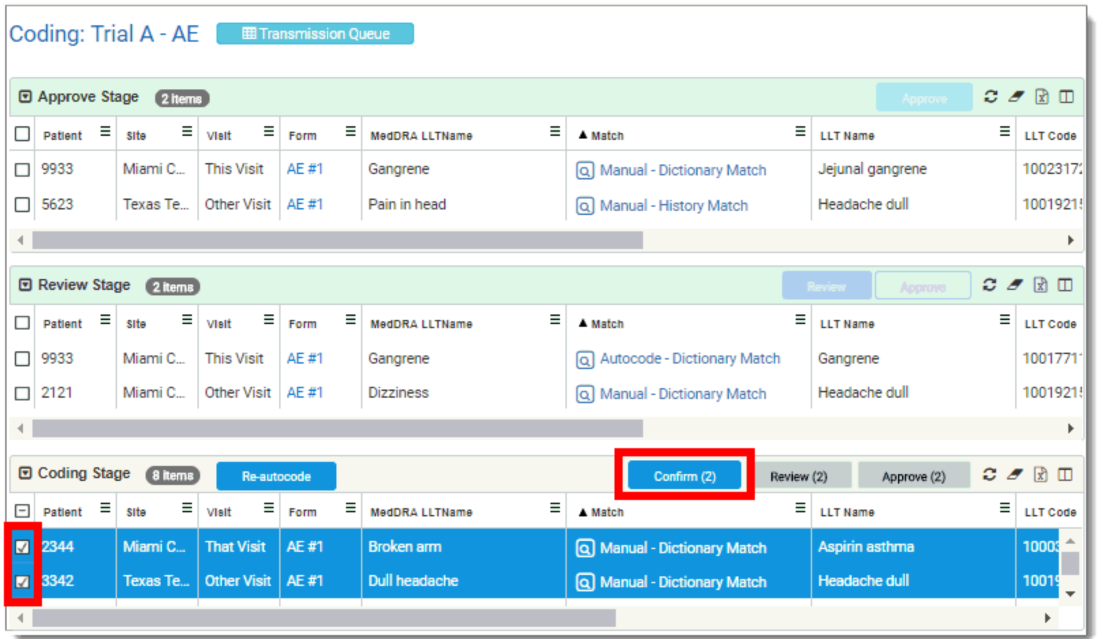
Coding Stages



AutoEncoder is configured so you can skip the Review or Approve Stage via the AutoReviewApprove setting. However, you can change this setting to go through each stage (see Edit Object Settings and View/Edit System Settings).

To confirm/review/approve terms:

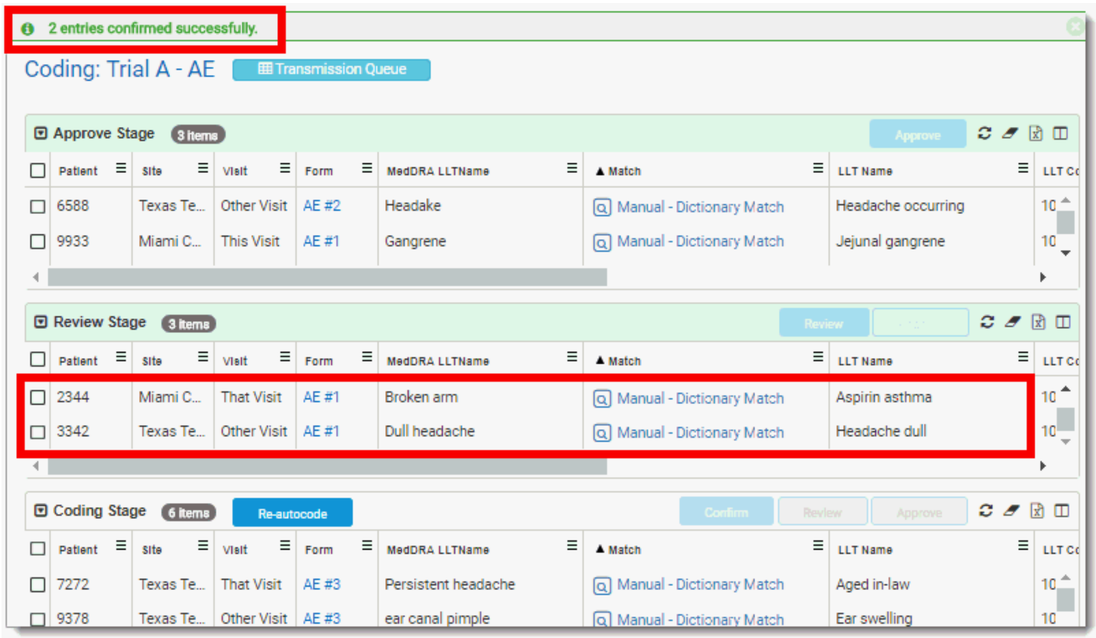
1. Access the Dashboard and click a code, module, review, or approve link. (See View Coding Stages for guidance.)
2. Click the check boxes of the applicable terms under the stage header. (To select all of the items, click the **Select All** check box just below the table header.)



The terms and the applicable button in the header (Confirm/Review/Approve) become highlighted. The header indicates the number of terms you selected. For example, the Confirm button displays when selecting items under the Coding Stage header, as shown in the figure above.

3. Select the **Confirm/Review/Approve** button. (From the Coding Stage, you can click the **Approve** button to skip the Review Stage.)

A confirmation message displays at the top of the page and the term is moved to the next stage. For example, if you confirmed the terms, the terms move to the Review Stage. However, if you selected to approve the terms, they are moved to the Transmission Queue.



4. If you need manually uncode/code a term, see Code/Uncode Matched Terms.

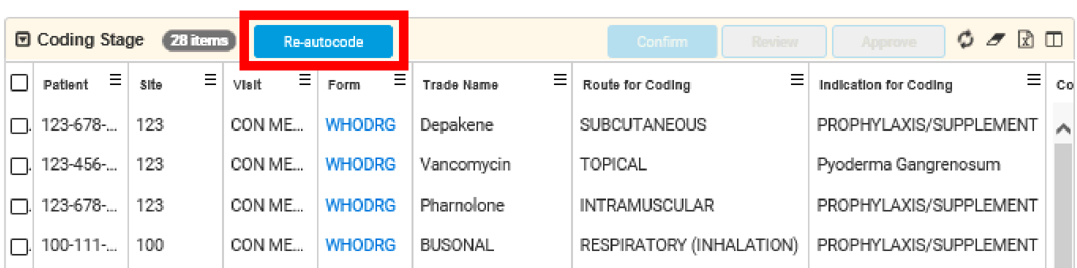
7.4.4 Re-autocode Terms

Re-autocoding is only necessary if you added new synonyms or history terms and then you want to re-code no-match items against them. Normally, autocoding occurs automatically against a term when it is pulled from another application such as TrialMaster.

Note: The re-autocode feature matches the entire module.

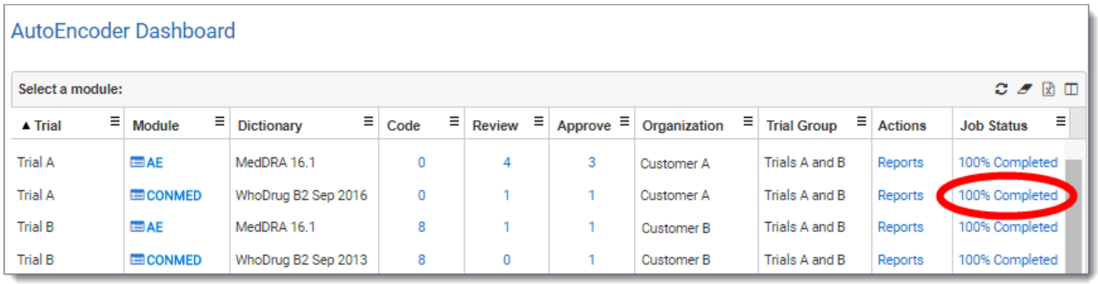
To re-autocode terms:

1. Access the Dashboard and click a code, module, review, or approve link. (See View Coding Stages for guidance.)
2. Click the **Re-autocode** button under the Coding stage.



A green success message displays at the top of the page, indicating the job number and that the autocoding job was started. A red failure message displays at the top of the page if there is a job already in the queue.

3. To check the progress of the job, return to the Dashboard and locate the applicable link under the Job Status column on the left-hand side of the table. The link displays the progress percentage between 0 and 100. (Click the link to view more details.)



▲ Trial	Module	Dictionary	Code	Review	Approve	Organization	Trial Group	Actions	Job Status
Trial A	AE	MedDRA 16.1	0	4	3	Customer A	Trials A and B	Reports	100% Completed
Trial A	CONMED	WhoDrug B2 Sep 2016	0	1	1	Customer A	Trials A and B	Reports	100% Completed
Trial B	AE	MedDRA 16.1	8	1	1	Customer B	Trials A and B	Reports	100% Completed
Trial B	CONMED	WhoDrug B2 Sep 2013	8	0	1	Customer B	Trials A and B	Reports	100% Completed

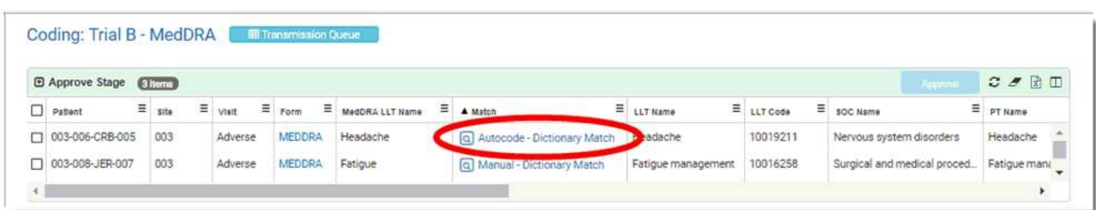
7.4.5 Code/Uncode Matched Terms

You can code/uncode the following types of matched terms:

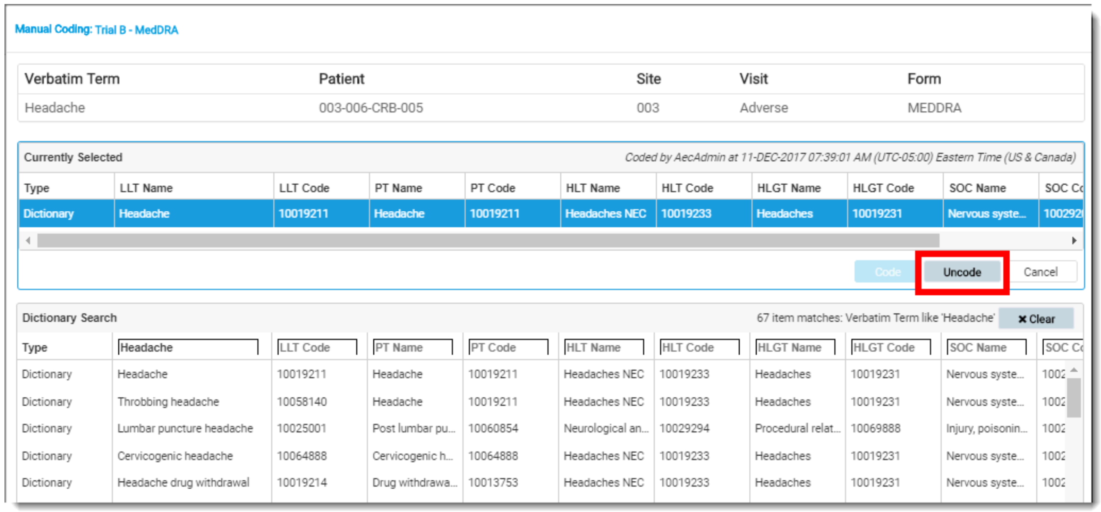
- No Match
- Autocode – History Match
- Autocode – Synonym Match
- Autocode – Dictionary Match
- Manual – History Match
- Manual – Synonym Match
- Manual – Dictionary Match

To code/uncode matched terms:

1. Access the Dashboard and click a code, module, review, or approve link. (See View Coding Stages for guidance.)
2. Click the applicable link under the **Match** column.

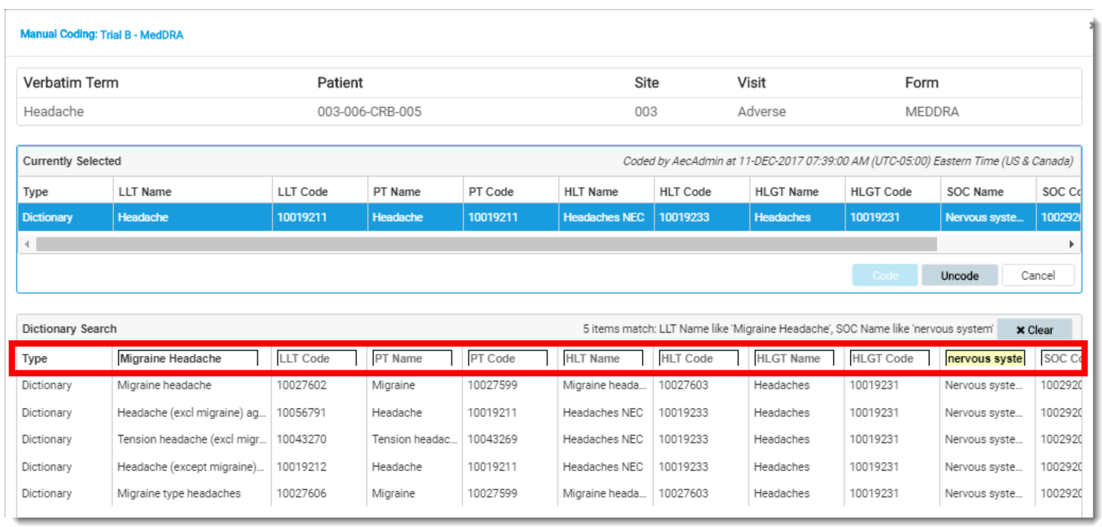


The header of the Manual Coding page displays the verbatim term plus any reference values and application column values. The middle section displays the term that is currently selected and being coded, if there was a dictionary match, or it was autocoded. The bottom section displays the Dictionary Search table where you can search for another verbatim term you want to code/uncode.



Note: If you clicked a **No Match** link, the middle section is empty and you can search for a term in the bottom section.

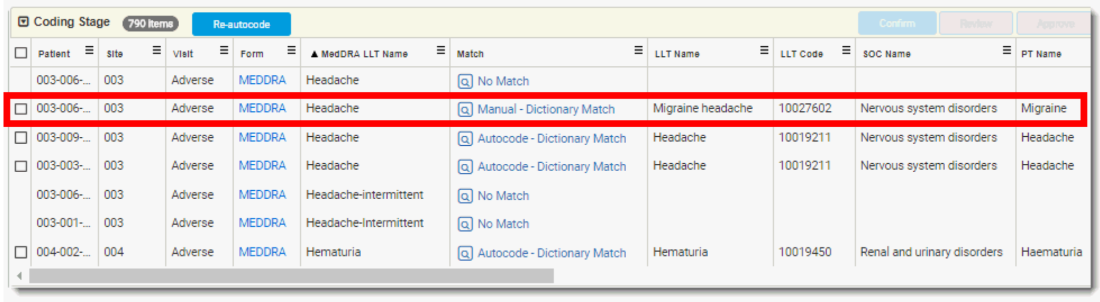
3. If you want to search for another verbatim term, type the applicable search parameters in the corresponding fields and tab out or press the ENTER key. For example, to search for a migraine headache that is a nervous system disorder, type "Migraine Headache" in the first field (LLT Name) and "nervous system disorders" in the SOC Name field.



Note: By default, the dictionary search does an auto search using a like function as indicated in the header of the bottom section. You can clear the search by clicking on the **Clear** button or revert back to the original selection by clicking the **Revert** button (top right of page). Mapped reference columns are pre-filled in the search area.

4. With the term selected (highlighted), click the **Uncode/Code** button. If you want to uncode a searched term in the Dictionary Search table, select (highlight) the term and then click the **Uncode** button.

   The Coding page re-displays and the term you uncoded/coded displays under the Coding Stage. In the example below, the LLT Name was sorted in ascending order by clicking the column header, and the SOC Name was dragged to the left so it is viewable without scrolling. (See Sort and Filter Tables for more information on sorting/filtering tables.)



Coding Stage 790 Items Re-autocode Confirm Review Approve

Patient	Site	Visit	Form	▲ MedDRA LLT Name	Match	LLT Name	LLT Code	SOC Name	PT Name
003-006-...	003	Adverse	MEDDRA	Headache	No Match				
003-006-...	003	Adverse	MEDDRA	Headache	Manual - Dictionary Match	Migraine headache	10027602	Nervous system disorders	Migraine
003-009-...	003	Adverse	MEDDRA	Headache	Autocode - Dictionary Match	Headache	10019211	Nervous system disorders	Headache
003-003-...	003	Adverse	MEDDRA	Headache	Autocode - Dictionary Match	Headache	10019211	Nervous system disorders	Headache
003-006-...	003	Adverse	MEDDRA	Headache-intermittent	No Match				
003-001-...	003	Adverse	MEDDRA	Headache-Intermittent	No Match				
004-002-...	004	Adverse	MEDDRA	Hematuria	Autocode - Dictionary Match	Hematuria	10019450	Renal and urinary disorders	Haematuria

Note: If the term is coded using a history match, an expander shows/hides the history origin. When the history origin is expanded/shown, a message displays, showing where the history match originated. The history term originates from <object1> History, inherited from <object2>. For example, the history term originates from TrialA History, inherited from trial.

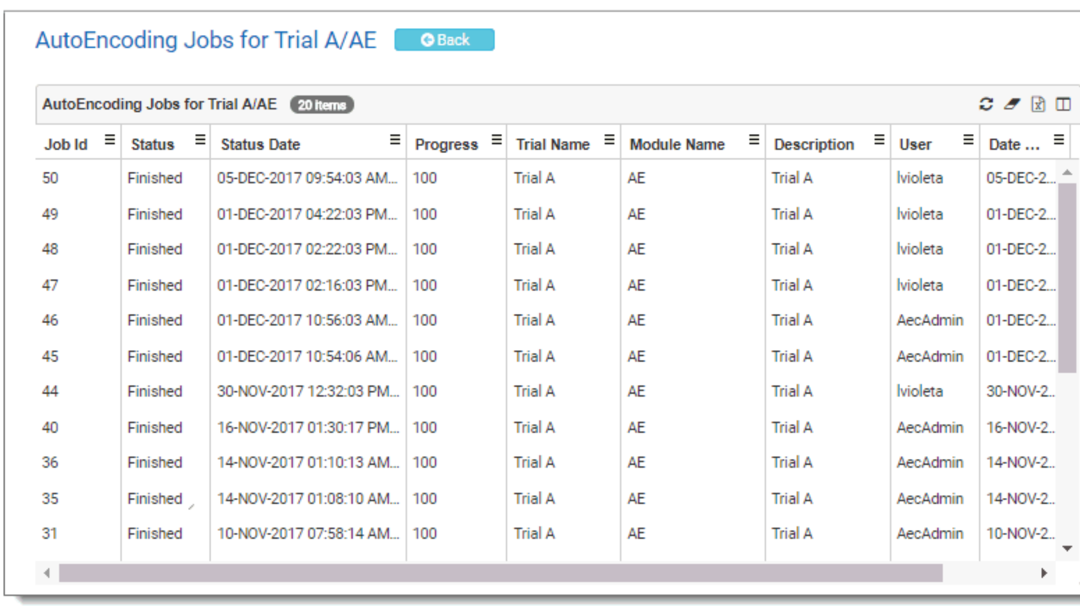
7.4.6 View Autoencoding Job Details

You can view the details of autoencoding jobs. The status of each job may include:

- Submitted
- Processing
- Failed
- Finished

To view job status details:

1. Access the Dashboard and click a code, module, review, or approve link. (See View Coding Stages for guidance.)
2. Click the applicable link under the Job Status column. The AutoEncoding Jobs page displays the number jobs and details about each job, including progress (between 0 and 100%), status, trial and module name, and date submitted.



AutoEncoding Jobs for Trial A/AE Back

AutoEncoding Jobs for Trial A/AE 20 Items

Job Id	Status	Status Date	Progress	Trial Name	Module Name	Description	User	Date ...
50	Finished	05-DEC-2017 09:54:03 AM...	100	Trial A	AE	Trial A	lvioleta	05-DEC-2...
49	Finished	01-DEC-2017 04:22:03 PM...	100	Trial A	AE	Trial A	lvioleta	01-DEC-2...
48	Finished	01-DEC-2017 02:22:03 PM...	100	Trial A	AE	Trial A	lvioleta	01-DEC-2...
47	Finished	01-DEC-2017 02:16:03 PM...	100	Trial A	AE	Trial A	lvioleta	01-DEC-2...
46	Finished	01-DEC-2017 10:56:03 AM...	100	Trial A	AE	Trial A	AecAdmin	01-DEC-2...
45	Finished	01-DEC-2017 10:54:06 AM...	100	Trial A	AE	Trial A	AecAdmin	01-DEC-2...
44	Finished	30-NOV-2017 12:32:03 PM...	100	Trial A	AE	Trial A	lvioleta	30-NOV-2...
40	Finished	16-NOV-2017 01:30:17 PM...	100	Trial A	AE	Trial A	AecAdmin	16-NOV-2...
36	Finished	14-NOV-2017 01:10:13 AM...	100	Trial A	AE	Trial A	AecAdmin	14-NOV-2...
35	Finished	14-NOV-2017 01:08:10 AM...	100	Trial A	AE	Trial A	AecAdmin	14-NOV-2...
31	Finished	10-NOV-2017 07:58:14 AM...	100	Trial A	AE	Trial A	AecAdmin	10-NOV-2...

Note: You can sort and filter the table or export it to Excel. Various table options are also available.

(See Use Table Functions.)

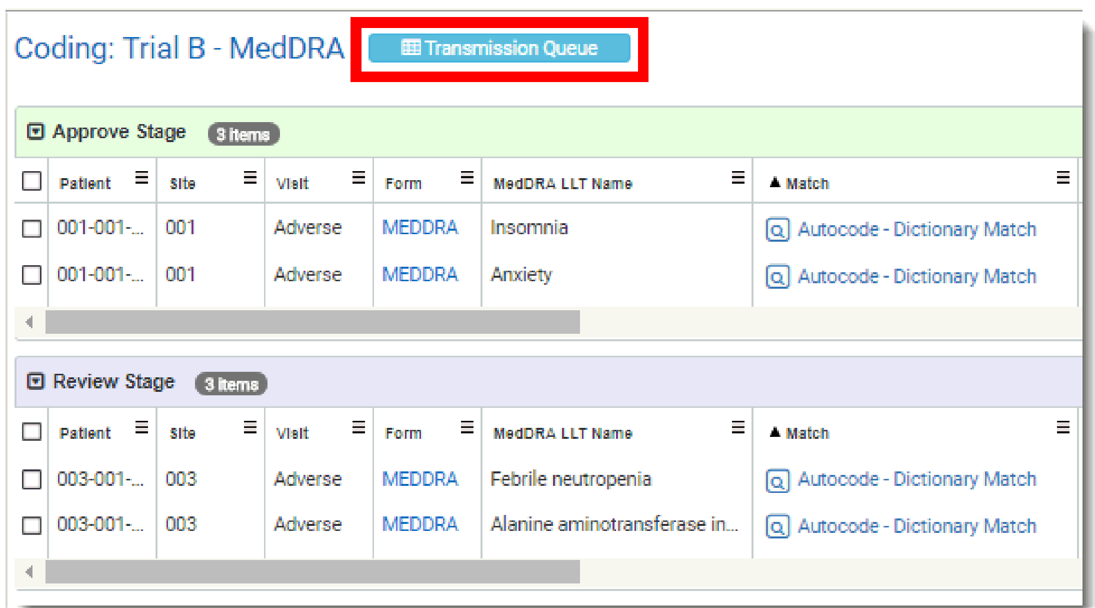
7.4.7 View/Uncode Terms in Transmission Queue

The transmissions queue shows the transmit status, which can be one of the following

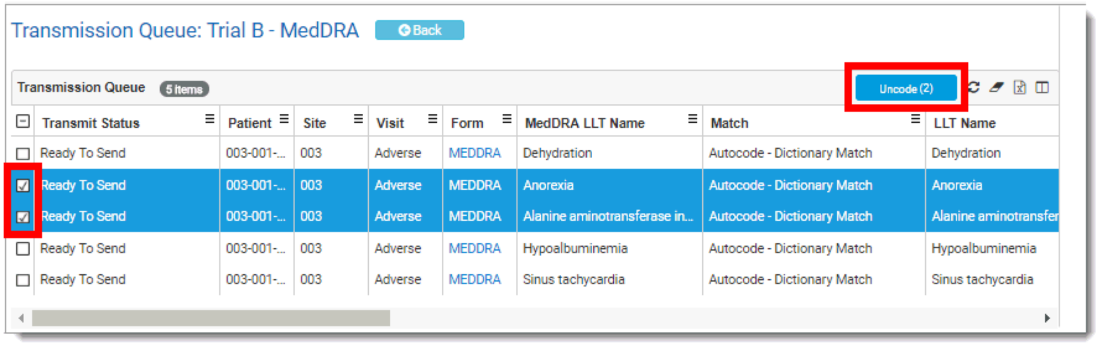
- Ready To Send – The term has reached Approved Status and is ready to be sent to the calling application (TrialMaster). This occurs automatically by the service.
- Sent – AutoEncoder service has sent it to the calling application and is awaiting a response.
    - If the transmission fails, it automatically retries for approximately 1 week: 1 time per hour for 150 times.
    - If there are no issues with the connection, the status changes from Ready to Send directly to Completed.
- Send Failed – AutoEncoder tried to send, but had an error and will retry
- Completed – AutoEncoder got confirmation that the calling application (TrialMaster) has been updated. At this point it is available for uncoding if desired.

To view the transmission queue:

1. Access the Dashboard and click a code, module, review, or approve link. (See View Coding Stages for guidance.)
2. Click the **Transmission Queue** button in the Coding page.



The Transmission Queue page displays the transmit status, patient name, site, visit, form, and dictionary match for each term. (The Form column contains links to the associated forms.)



3. If you need to uncode terms, select the check box of the applicable terms and click the **Uncode** button (top right). (When you select the terms, the Uncode button becomes highlighted and displays the number of terms you selected.)

   The number of terms selected for uncoding display at the top of the page.
4. Click the **Back** button at the top of the page to return to the Coding page.

7.4.8 View Module Reports

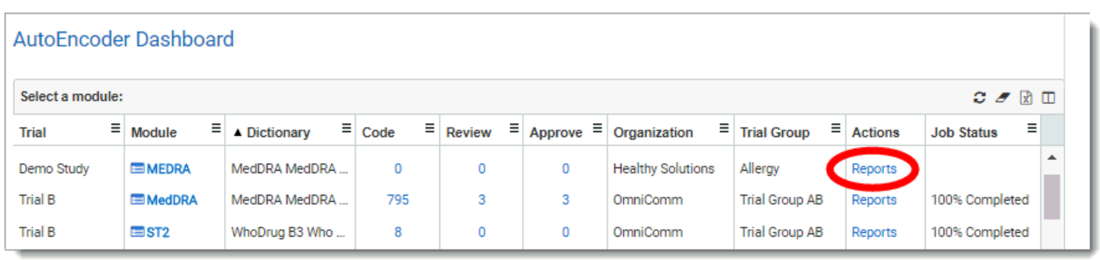
You view the following module reports from the Dashboard:

- Coding
- Coding Transmission History
- Dictionary Mapping History
- Dictionary Version History
- Mapping

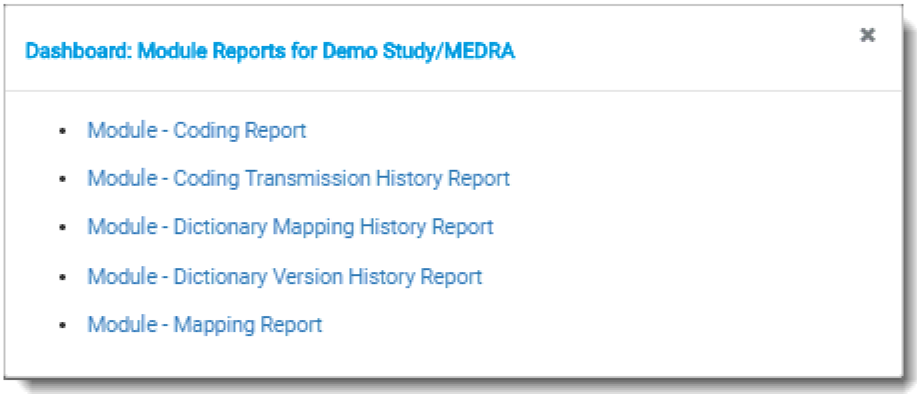
To view module reports:

1. Access the AutoEncoder Dashboard after first logging in or by clicking the AutoEncoder logo.

2. Click the **Reports** link of the applicable module under the Actions column (far right).



The Module Reports page lists module report links.



3. Click a link to review a report.

Note: You can sort and filter the report or export it to Excel. Various table options are also available. (See Use Table Functions.)

Basic AutoEncoder Functions

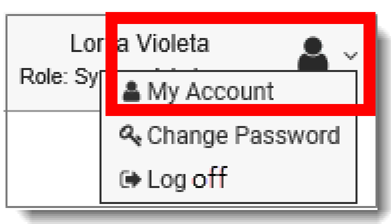
7.5 Update Your Account Information

You can manage user account settings in the following ways:

- Change your account information (name, title, phone, and timezone)
- Change your login password (see Change Password)

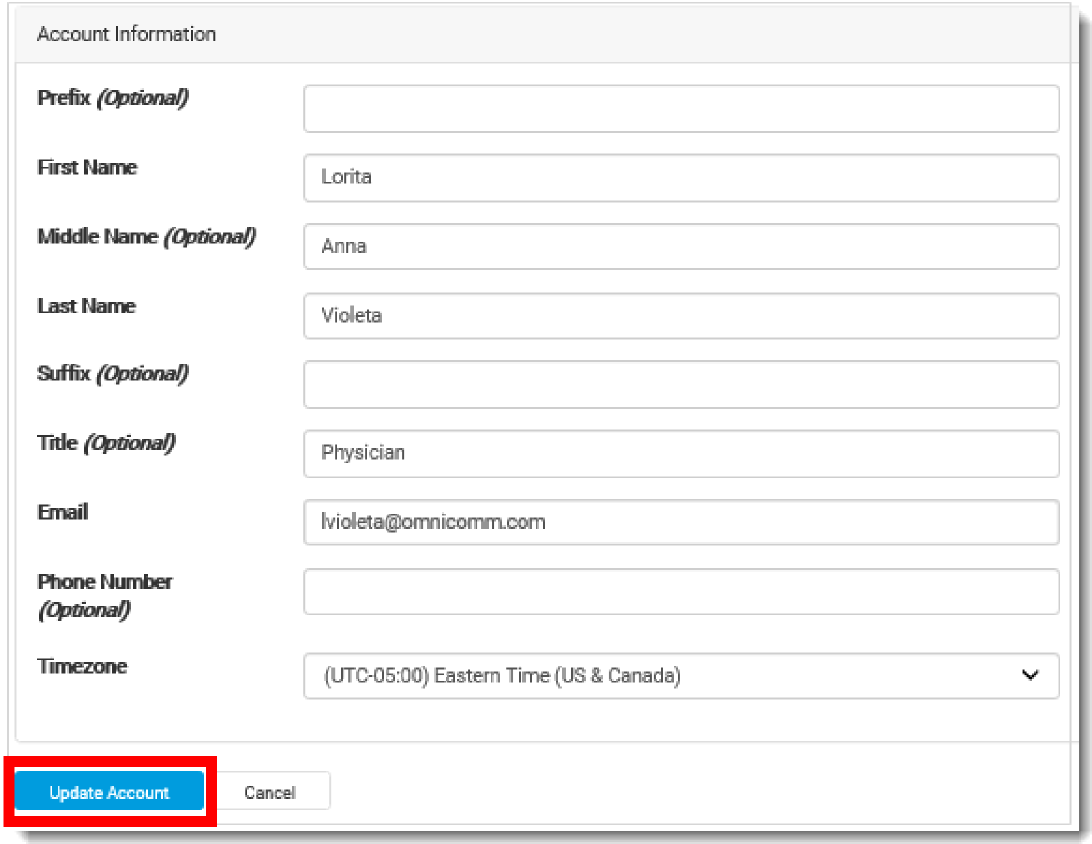
To update your account information:

1. Click the **User Account** icon on the top right of the AutoEncoder status bar.



2. Select **My Account** from the drop-down menu.

   The Account Information page displays.



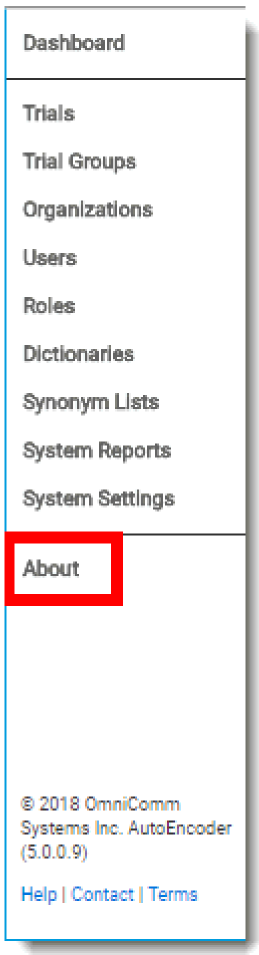
3. Enter/select the applicable information.
4. Click **Update Account** button.

7.6 View System Versions

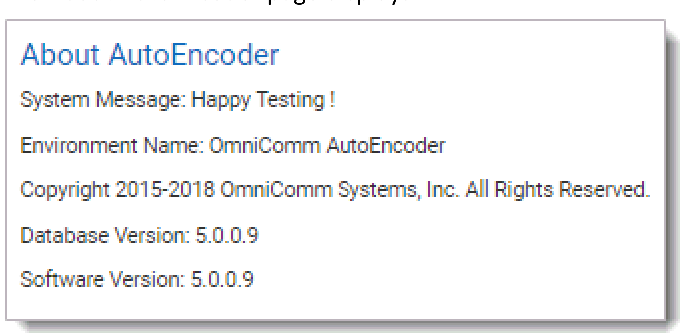
You can view the database and software versions of AutoEncoder in the **About** menu.

To view system version:

1. Click the **Main Menu** icon (top left).
2. Select **About** from the main menu.



The About AutoEncoder page displays.



7.7 Return to Home Page

You can return to the home page (Dashboard) from any AutoEncoder page.

To return to the home page:

1. Locate the AutoEncoder logo on the Status Bar.

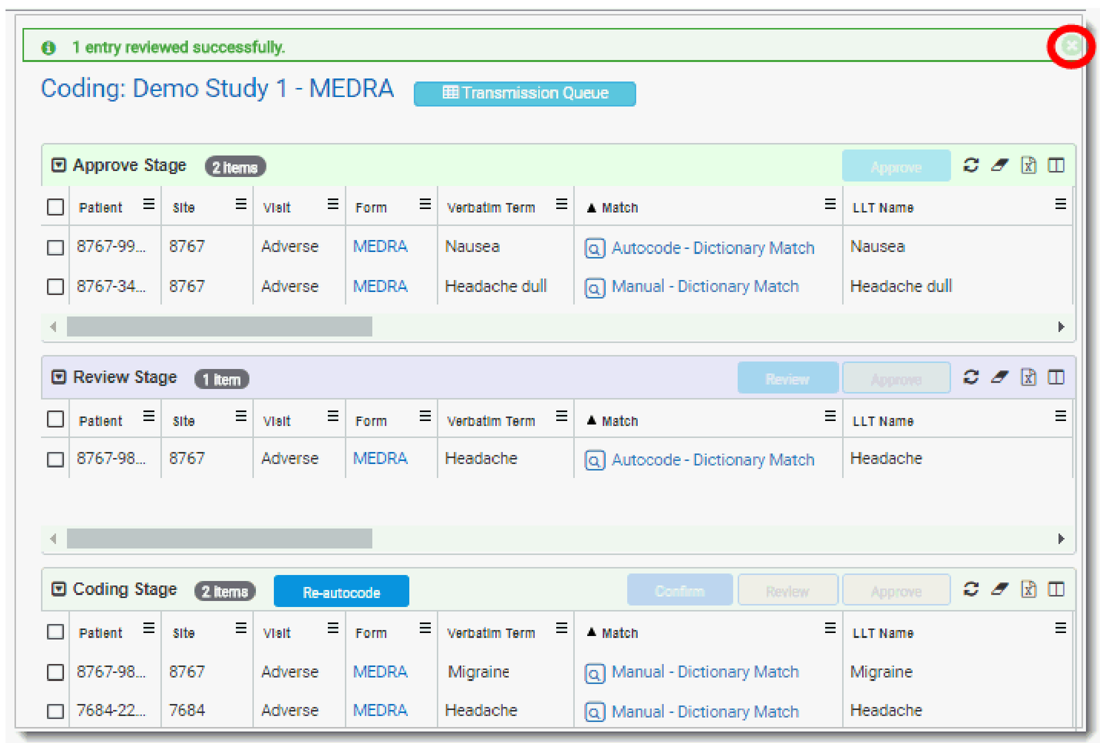
2. Click the **AutoEncoder** logo.

7.8 Remove Message

When you perform an action in AutoEncoder, a message displays until you remove it. Messages may include a confirmation (displays as green text) or warning/error (displays as red text).

To remove a message:

1. Locate the message at the top of the page.



2. Click the **X Close** icon on the right-hand side of the message.

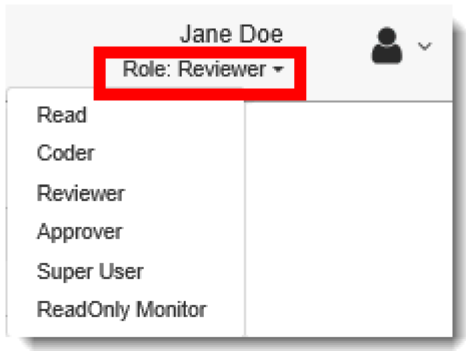
7.9 Change Role

If assigned multiple roles, you can change roles without logging out.

Note: The System Admin user has no other roles than System Admin.

To change a role:

1. Click the role link on the top right of the AutoEncoder status bar.



2. Select the role from the drop-down menu. The new role displays in the status bar and the current page displays the associated data. (Clicking away from the drop-down retains the current role.)

Note: If your new role does not have access to the data on the page, no rows/data are displayed. The only exception is for the Coding page, the user will be returned to the Dashboard.

Table Functions

7.10 Use Table Functions

This section refers to any tabular display of data (tables/grids), such as when running a report.

On the top right-hand side of tables in AutoEncoder, you can click the following icons to perform specific actions:

Refresh icon – updates the data in the table

Reset Grid to Default Layout icon – resets the table to its default (original) layout

CSV Export icon – exports the data in the table to an Excel file

Show/Hide Column**s** icon – displays check boxes where to select (show) or de-select (hide) table columns

The Information icon is located on the top left-hand side of tables in AutoEncoder. This icon provides a brief description of the table.

You can also sort and filter tables, such sorting a column in ascending/descending order, moving a column, or filtering a column on criteria. (Use the **Reset Grid to Default Layout** icon if you want to reset the table.)

Refer to the following sections for instructions:

- Refresh Data
- Reset Table to Default Layout

- Export Data to an Excel file
- Show Hide a Column
- Use information Icon
- Sort and Filter Tables

7.11 Sort and Filter Tables

This section refers to any tabular display of data (tables), such as when running a report.

Important: After sorting or filtering a table, the modification persists until you refresh the current page, navigate to another page, or log off.

You can sort and filter tables in the following ways:

- Sort a column
- Move a column
- Show/hide a column
- Resize a column
- Filter a column on criteria

Note: You can reset the table to default layout if you want to restore the table to its original settings.

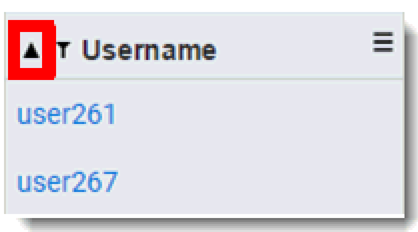
7.11.1 Sort a Column

You can sort columns in ascending or descending order, (except for the Actions column). The default order is ascending.

To sort a column:

1. Click a column header of a table.

   The column menu displays the ▲ icon to signify it is in ascending order.



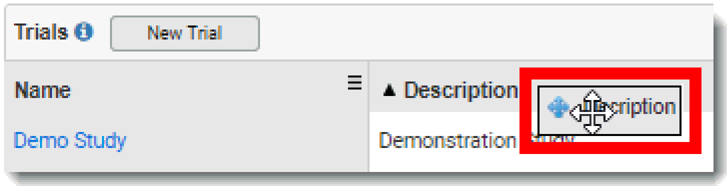
2. To reverse the sort order, click the column again. The ▼ Descending Order icon displays in the column header.
3. To revert back to the default sort order, click the column again and it displays the ▲ Ascending Order icon.

7.11.2 Move a Column

You can move a column to the desired location.

To move a column:

Drag the column header to the desired location.



The Move icon displays when dragging the column. (A icon displays in the background.)

Note: If you accidently move the column outside of the table, click the **Display/Hide** icon and select the check box of the column you moved. (See Display Hide a Column for details.)

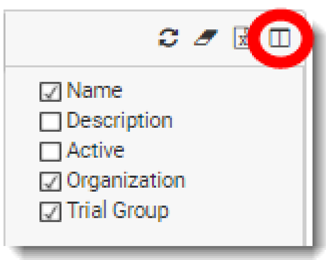
7.11.3 Show/Hide a Column

Certain pages in AutoEncoder allow you to show/hide table columns.

To display/hide table columns:

1. From a table, such as a report, click the **Show/Hide Columns** icon on the top right-hand side of the page.

   A drop-down list displays check boxes that correspond to each table column.



2. Select/de-select the check boxes of the columns you want to display/not display. In the example above, the Description and Active columns will not display in the page and the remaining, checked columns will display in the table.

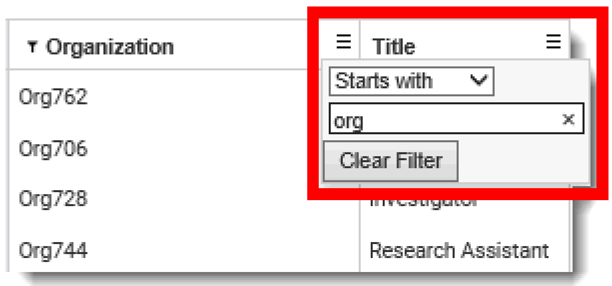
7.11.4 Filter a Column on Criteria

Certain columns contain the ☰ **Filter** icon. When entering the text criteria, you to filter on the following:

- Equals/Not Equals
- Starts/Ends With
- Contains/Not Contains

To filter on criteria:

1. From a table, click the ☰ **Filter** icon of the corresponding column.



2. Select the criteria from the drop-down list.
3. Enter the criteria text. In the example above, the criteria is to filter on organizations that start with "org".

Note: Click the **Clear Filter** button to reset the page with no filters.

7.11.5 Resize a Column

You can resize a column to modify the space between cells.

To resize a column:

1. Using your mouse, place the cursor on right side a column boundary until the ←||→ **Resize** icon displays.

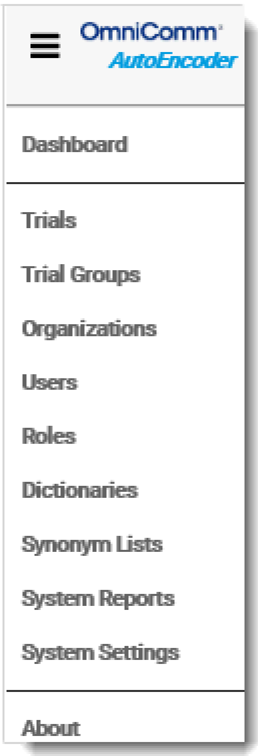
2. Drag the column boundary to the left or right until the desired width displays.

7.12 Export to Excel

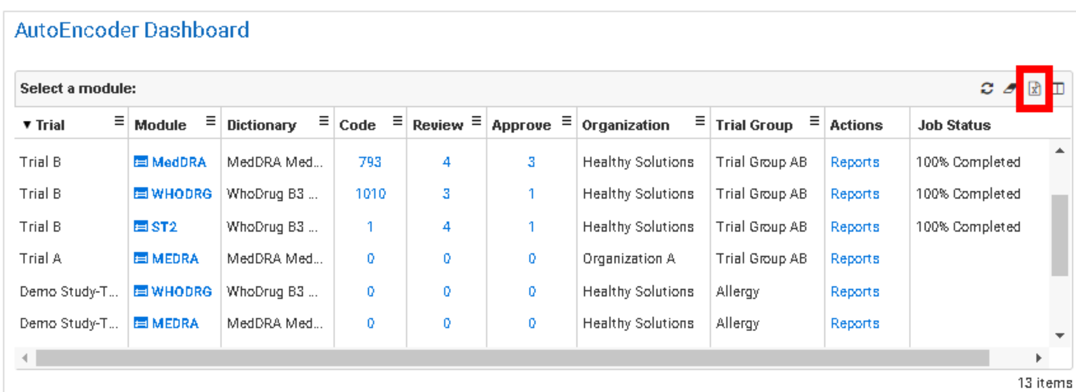
You can view and/or save a report as an Excel file.

To export a report Excel:

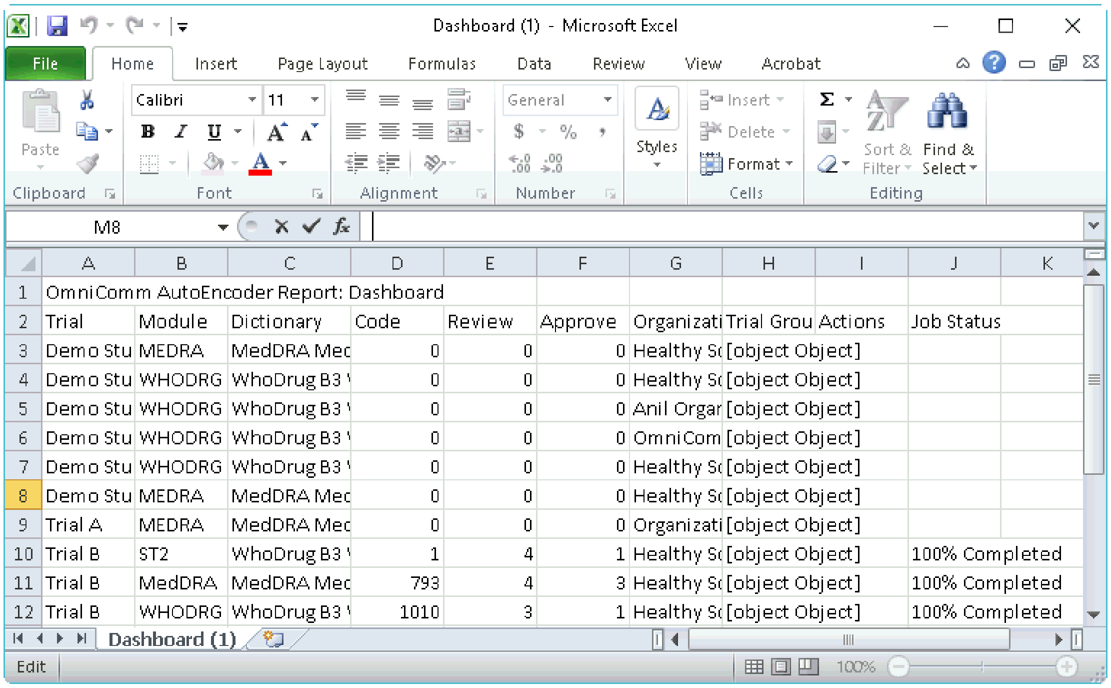
1. Click the ☰ **Main Menu** icon (top left).
2. Access the applicable option from the drop-down list. (After accessing System Reports, click the applicable report link.)



3. Click the **CSV Export** icon on the right-hand side of the table.



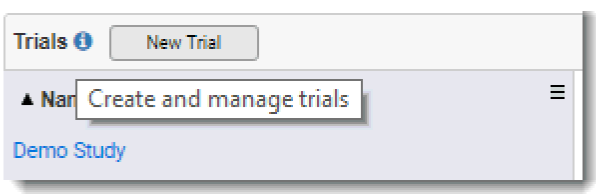
4. Click the applicable button (Open or Save) to open or save the Excel file.



	A	B	C	D	E	F	G	H	I	J	K
1	OmniComm AutoEncoder Report: Dashboard										
2	Trial	Module	Dictionary	Code	Review	Approve	Organizati	Trial Grou	Actions	Job Status	
3	Demo Stu	MEDRA	MedDRA Mec	0	0	0	Healthy Sc	[object Object]			
4	Demo Stu	WHODRG	WhoDrug B3 \	0	0	0	Healthy Sc	[object Object]			
5	Demo Stu	WHODRG	WhoDrug B3 \	0	0	0	Anil Orgar	[object Object]			
6	Demo Stu	WHODRG	WhoDrug B3 \	0	0	0	OmniCom	[object Object]			
7	Demo Stu	WHODRG	WhoDrug B3 \	0	0	0	Healthy Sc	[object Object]			
8	Demo Stu	MEDRA	MedDRA Mec	0	0	0	Healthy Sc	[object Object]			
9	Trial A	MEDRA	MedDRA Mec	0	0	0	Organizati	[object Object]			
10	Trial B	ST2	WhoDrug B3 \	1	4	1	Healthy Sc	[object Object]		100% Completed	
11	Trial B	MedDRA	MedDRA Mec	793	4	3	Healthy Sc	[object Object]		100% Completed	
12	Trial B	WHODRG	WhoDrug B3 \	1010	3	1	Healthy Sc	[object Object]		100% Completed	

7.13 Use Information Icon

Table headers contain the Information icon that provides a brief description of the feature. Hover over this icon to view the description.

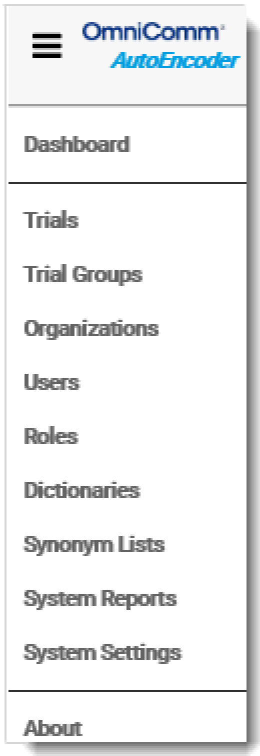


7.14 Refresh Data

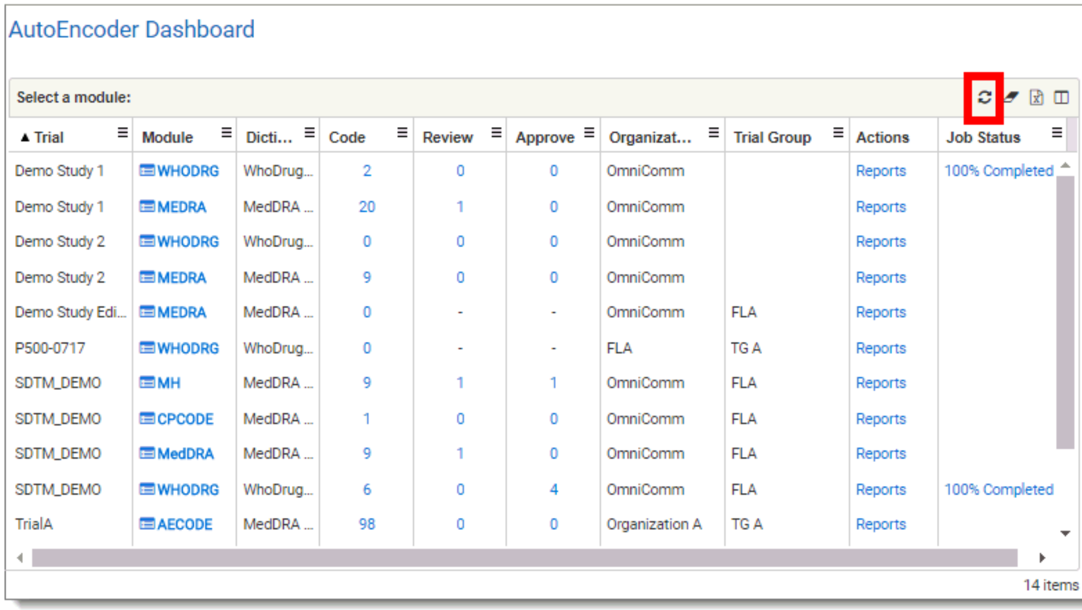
You can refresh a table so it displays the most up-to-date data.

To refresh data:

1. Click the **Main Menu** icon (top left).
2. Access the applicable option from the drop-down list. (After accessing System Reports, click the applicable report link.)



3. Click the **Refresh Data** icon on the right-hand side of the table. A data reload for the current grid occurs. The Refresh Data icon shows the progress of the refresh by turning blue and spinning in place.



7.15 Reset Table to Default Layout

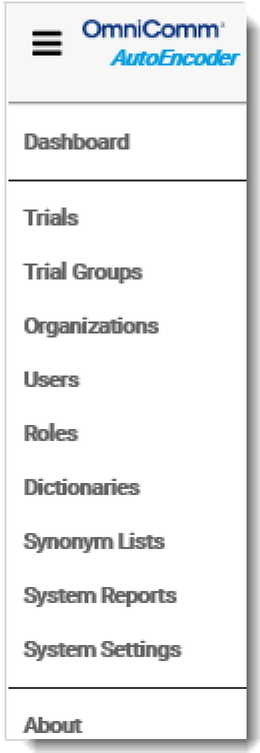
You can reset a table to its default (original) layout. The layout is saved automatically upon any change to the column display, such as resizing, moving, or showing/hiding a column. The current table displays these changes (adjusted for screen resolution) for the current user on reload, navigation, role change, or restart.

The Coding, Transmission Queue, Manage Synonym Terms, Reports, and Jobs pages are specific to their objects (trials, trial groups, and organizations), so changing the columns of Trial 42123_ZKS/Module AE for example, only applies to that specific page and is not reflected in other Trial/Module coding pages.

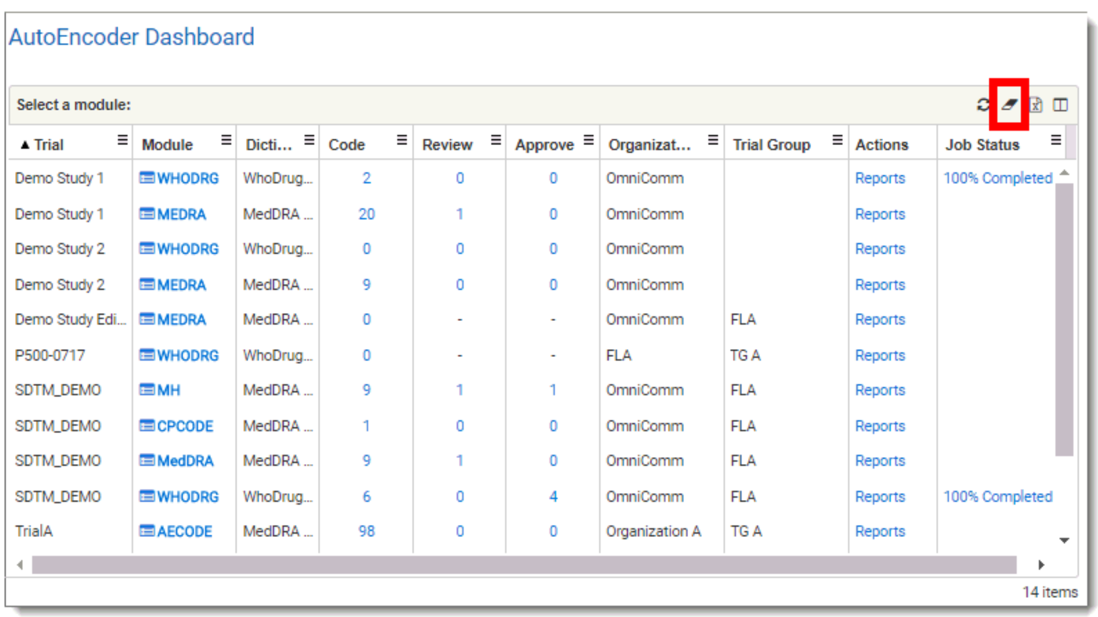
Tables settings are stored per user for the Management type pages, and also per user per module for the Coding, Transmission, reports type pages. For example, one module's Coding page can have certain settings while another module can have totally different settings.

To reset a table to the default layout:

1. Click the **Main Menu** icon (top left).
2. Access the applicable option from the drop-down list. (After accessing System Reports, click the applicable report link.)



3. Click the **Reset Grid to Default Layout** icon on the right-hand side of the table. The current grid is reset to display the defaults, overwriting any previous changes. The new column layout, including column visibility settings are also applied to the CSV Export.



Note: Filters and sorting are not reset because they are not saved as part of layout.

OBJECTS

8.0 Manage Objects

You can manage objects (trials, trial groups, organizations) in the following ways:

- View an object (see View Trials, View Trials within a Trial Group, View Trial Groups, or View Organizations)
- Add an object (see Add a New Trial, Add Trial Group, or Add a New Organization)
- Edit an object
- Delete an object
- Edit object synonym lists
- View object reports
- Edit object settings
- Manage Mapping

Note: The options are available based on user/role privileges.

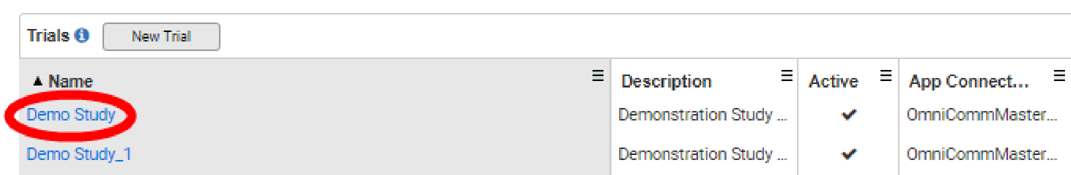
8.1 Edit an Object

You can edit information of the following objects:

- Trial – name, description, associated organization/trial group, and active status
- Trial Group/Organization – name, description, and active status

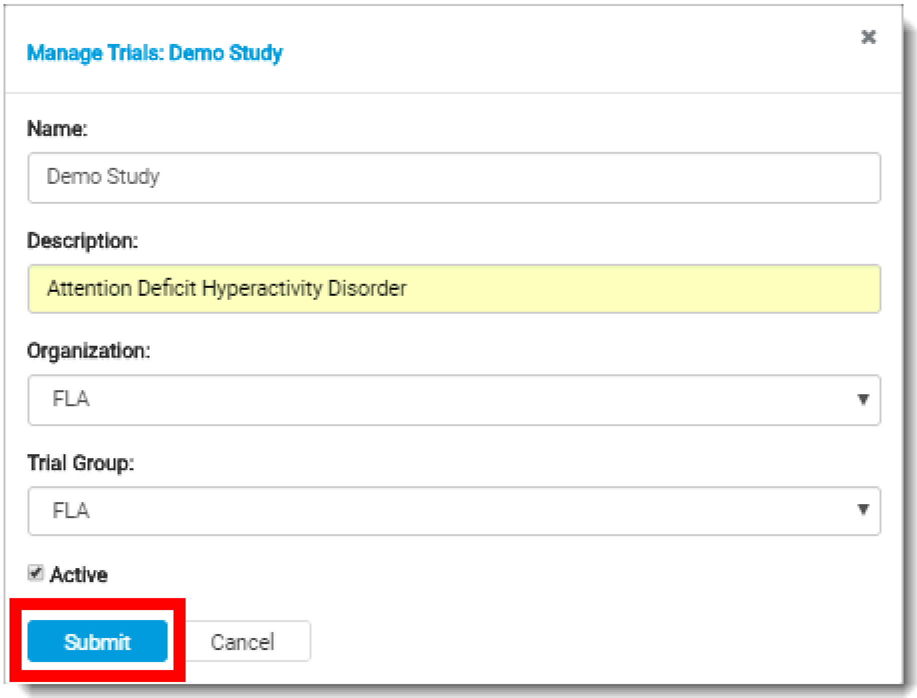
To edit an object:

1. Access the applicable page. (See View Trials, View Trial Groups, or View Organizations for guidance.)
2. Click the object's name (in blue text) under the Name column.



Note: You can also click the **Edit** link under the Actions column to edit an object.

3. Enter/select the applicable information in the trial/trial group/organization Manage Trials dialog.



4. If you want to de-activate the object, de-select the **Active** check box. If deactivated, all objects (trials, trial groups, and organizations) owned by the trial do not automatically display on the Dashboard or Coding pages.
5. Click the **Submit** button.

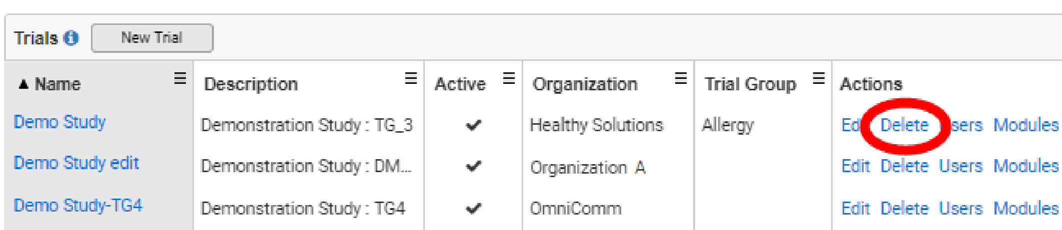
8.2 Delete an Object

You can delete an object (trial, trial group, organization) if you have permission.

Important: Only System Users/System Admins can add or remove a trial from a trial group.

To delete an object:

1. Access the applicable page. (See View Trials, View Trial Groups, or View Organizations for guidance.)
2. Click the **Delete** link under the Action column.



▲ Name	Description	Active	Organization	Trial Group	Actions
Demo Study	Demonstration Study : TG_3	✔	Healthy Solutions	Allergy	Edit Delete Users Modules
Demo Study edit	Demonstration Study : DM...	✔	Organization A		Edit Delete Users Modules
Demo Study-TG4	Demonstration Study : TG4	✔	OmniComm		Edit Delete Users Modules

3. Click the **Yes** button in the message. A confirmation message displays at the top of the page and the object no longer displays.

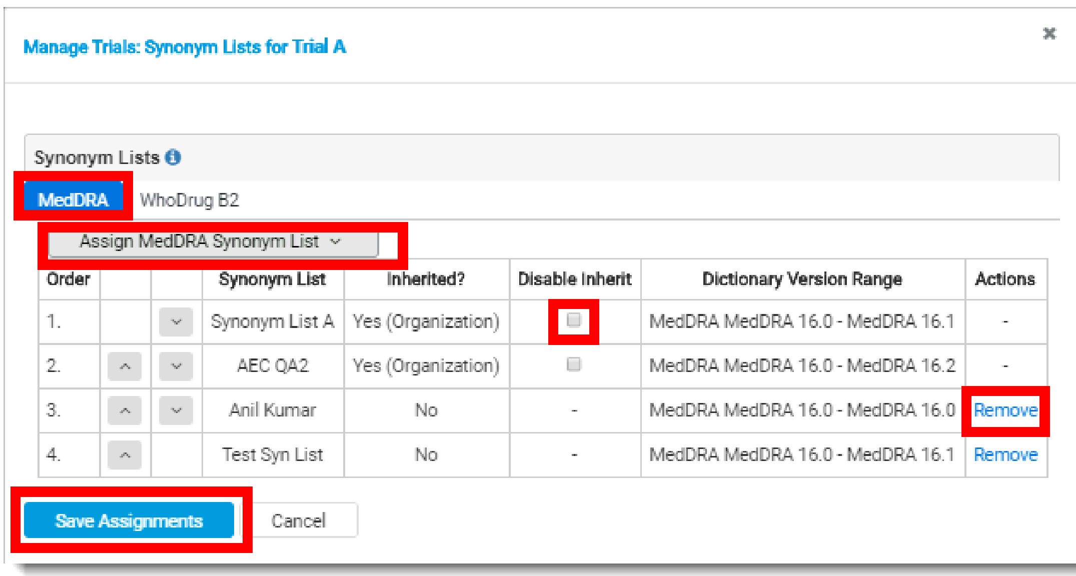
8.3 Edit Object Synonym Lists

You can edit (change inherit settings, assign, or remove) a synonym list of an object (trial, trial group, organization).

To edit object synonym lists:

1. Access the applicable page. (See View Trials, View Trial Groups, or View Organizations for guidance.)
2. Click the **Synonym Lists** link under the Action column.

The Synonym Lists dialog displays the dictionary (tabs), inheritance (System, Trial Group, or Organization), dictionary range of each synonym list. If the synonym list is inherited from a different object, it is indicated in the Inherited column.



Note: See Edit Object Settings for more information about the inheritance hierarchy.

3. Click the tab of the applicable dictionary.
4. If you want to disable the inheritance, click the **Disinherit** check box of the applicable synonym list. This turns off the cascade effect of inheriting a synonym list.
5. Do one of the following:
   - To assign a synonym list, select the synonym list from the **Assign WhoDrug/MedDRA Synonym List** drop-down. The list you selected is added to the bottom row of the table. To move the list to the desired row use the **Move Up** and **Move Down** buttons, then click the **Save Assignments** button.
   - To remove a synonym list, click the **Remove** link of the applicable list under the Actions column. The list is automatically removed.

8.4 View Object Reports

You can view the following reports according to each object type:

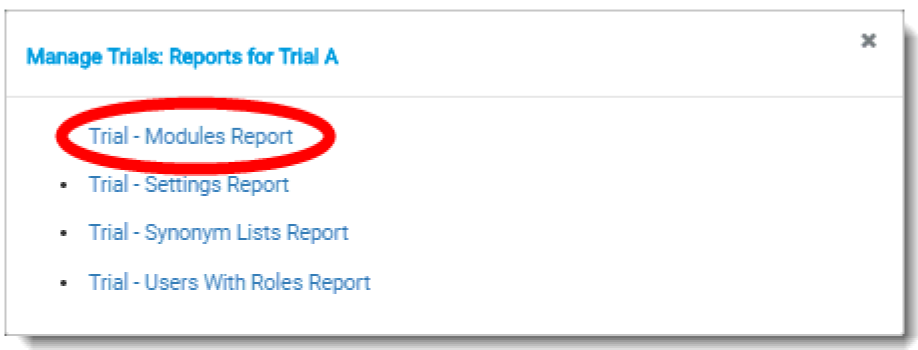
Note: You can only view reports for objects you have access to.

- Trial – Modules, Settings, Synonym Lists, Users With Roles
- Trial Group – Trials, Users With Roles
- Organization – Trials, Users, Users With Roles

To view an object report:

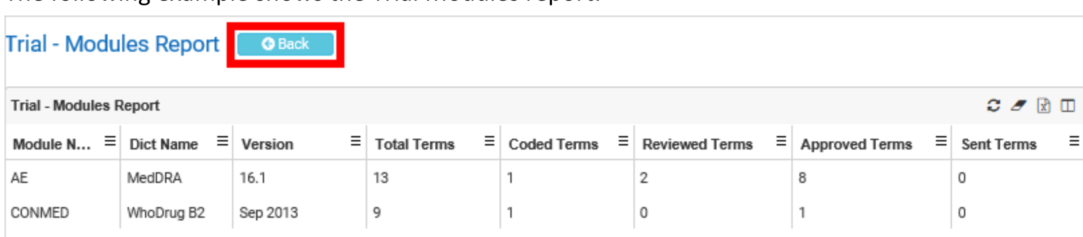
1. Access the applicable page. (See View Trials, View Trial Groups, or View Organizations for guidance.)
2. Click the **Reports** link of the applicable object under the Action column (far right).

The Reports page provides a link and brief description of each report.



3. Click the applicable report link.

The following example shows the Trial Modules report.



4. Click the **Back** button to return to the previous page.

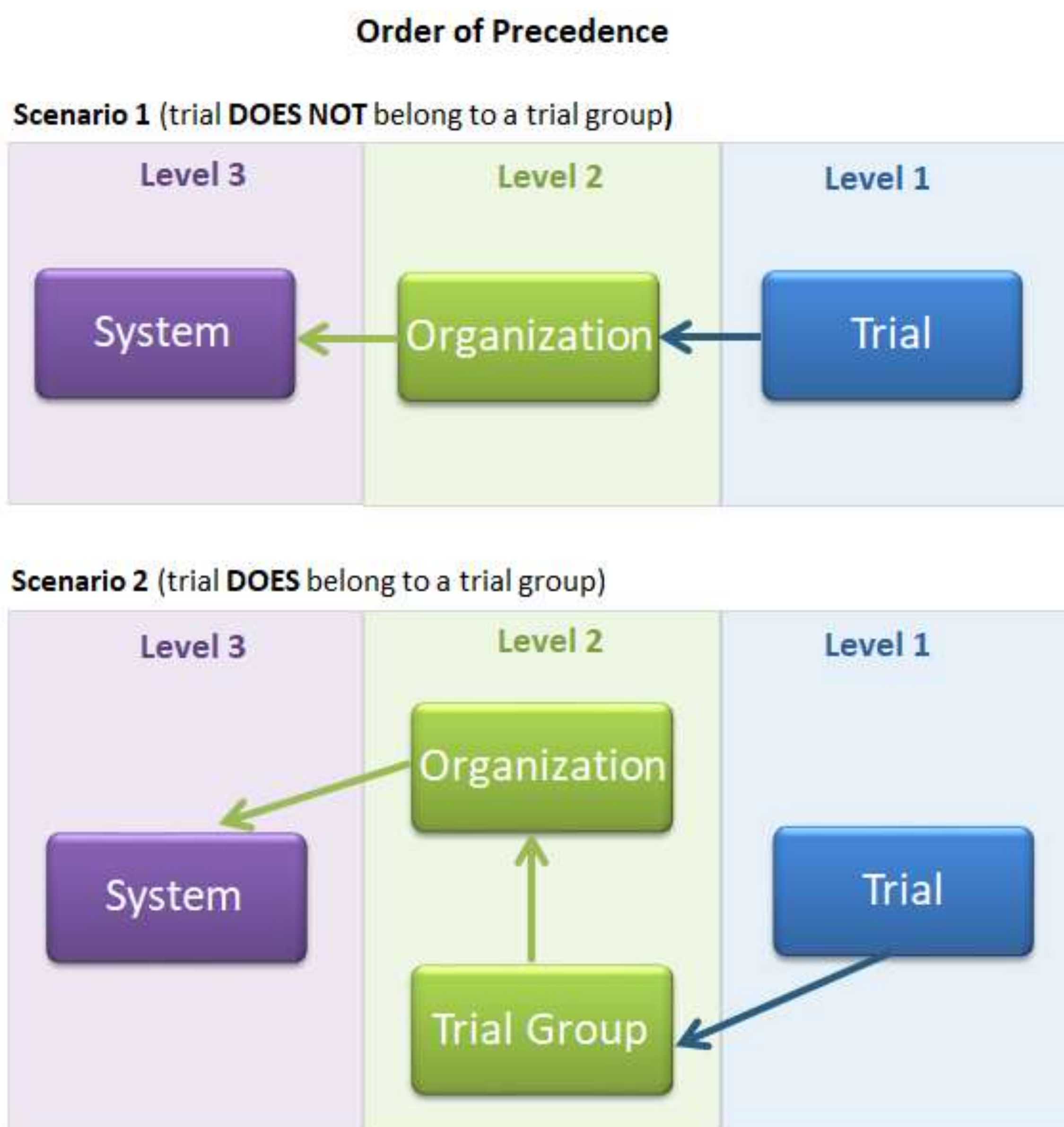
Note: You can sort and filter the report or export it to Excel. Various table options are also available. (See Use Table Functions.)

8.5 Edit Object Settings

You can change the following settings of an object (trial, trial group, organization):

- MedDRA Primary Path – use primary the path only when coding against MedDRA (Yes or No)
- System Synonym Search Rules – search for synonyms by history/synonyms only or in sequence
- HistoryScope – search for the history scope stored at the trial, group, or organization level
- AutoReviewApprove – automatically review and approve terms once confirmed (True of False)

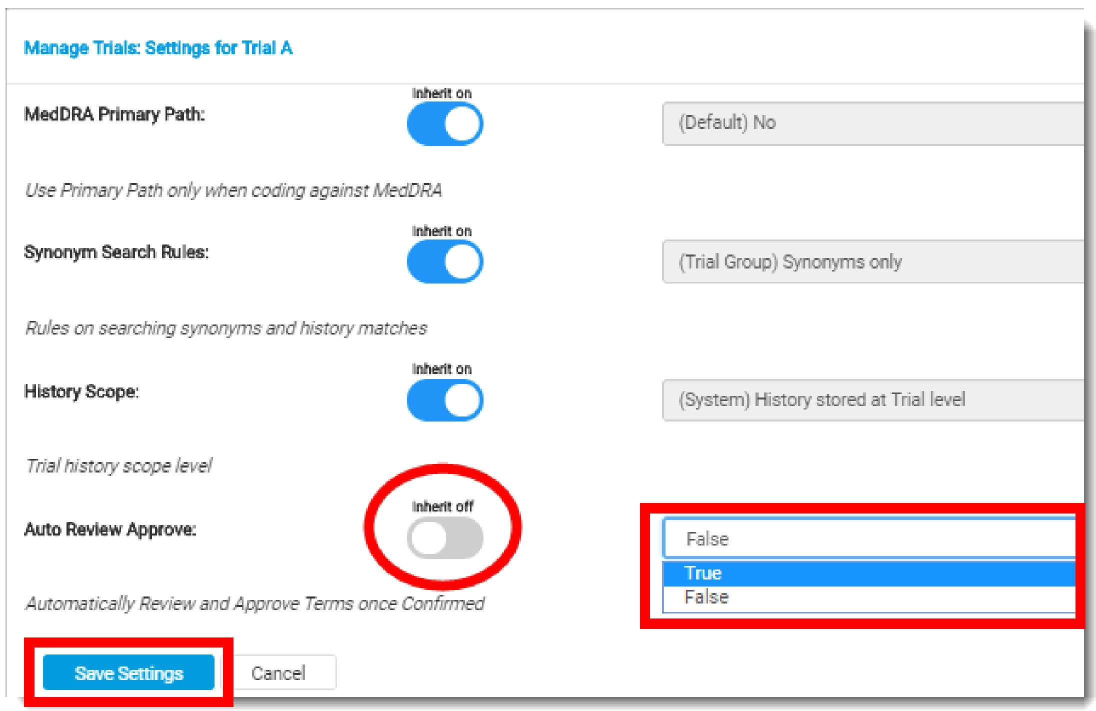
The default settings may be changed at any level (Trial, Trial Group, Organization, and System). Settings are inherited from a higher level or may be explicitly changed at a lower level. The lowest level settings take precedence. The order of precedence is shown below.



To edit object settings:

1. Access the applicable page. (See View Trials, View Trial Groups, or View Organizations for guidance.)
2. Click the **Settings** link under the Action column.

The settings pop-up for the object displays. Each field is defaulted to the inherited system setting.



3. Click to the left of the **Inherit on** toggle to override the inherited value of the applicable setting(s).
   The toggle changes to Inherit off and the drop-down list for the setting becomes enabled.
4. Select the applicable new value(s) from the drop-down list(s).
5. Click the **Save Settings** button. A confirmation message displays, indicating that the settings were updated.

Note: If you turn **Inherit** back on, the text area shows the cascaded inherited value and its origin in the format “(Origin) Value”.

8.6 Manage Trials

You can manage trials in the following ways:

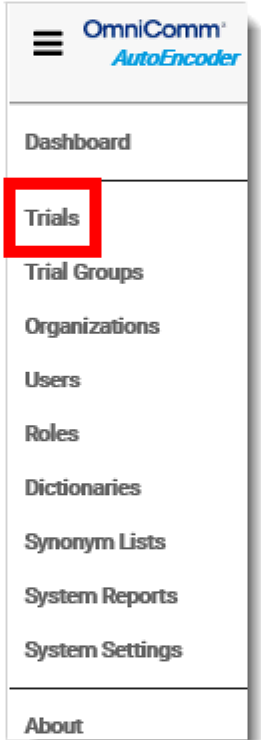
- View trials
- Add a new trial
- Edit a trial
- Delete a trial
- Assign user to a trial
- Manage mapping
- Edit trial synonym lists
- View trial reports
- Edit trial settings

8.6.1 View Trials

You can view details about each trial, including the description, status (active/inactive), organization, and trial group.

To view trials:

1. Click the ☰ **Main Menu** icon (top left).
2. Select **Trials** from the drop-down list.



The Trials page displays the name, description, active status (check marked if active), organization, and trial group, and allowed user/role actions for each trial. (The tasks displayed in the Trials page vary depending upon permissions assigned to the active user and role).

Trials New Trial

▲ Name	Description	Active	Organization	Trial Group	Actions
Demo Study	Demonstration Study : TG_3	✔	Healthy Solutions	Allergy	Edit Delete Users Modules
Demo Study edit	Demonstration Study : DM...	✔	Organization A		Edit Delete Users Modules
Demo Study-TG4	Demonstration Study : TG4	✔	OmniComm		Edit Delete Users Modules

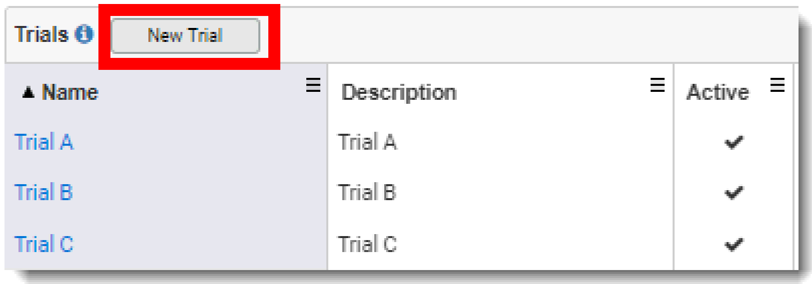
Note: You can sort and filter the table or export it to Excel. Various table options are also available. (See Use Table Functions.)

8.6.2 Add a New Trial

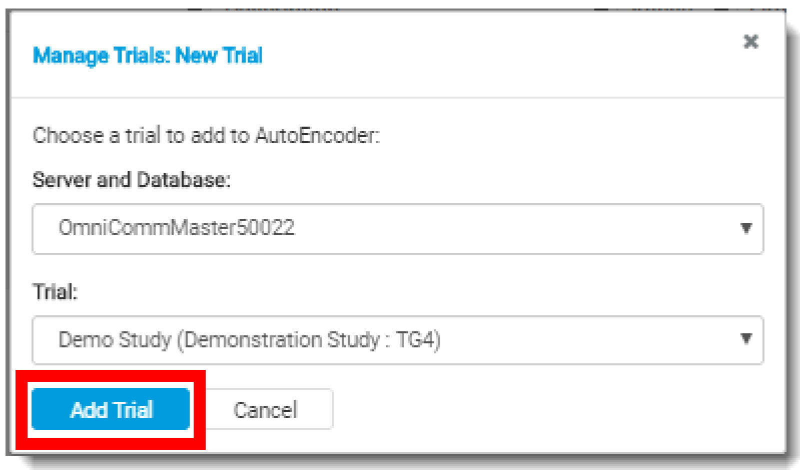
When adding a new trial, you must specify the organization. However, the trial group is not required.

To add a new trial:

1. Access the Trials page. (See View Trials for guidance.)
2. Click the **New Trial** button.

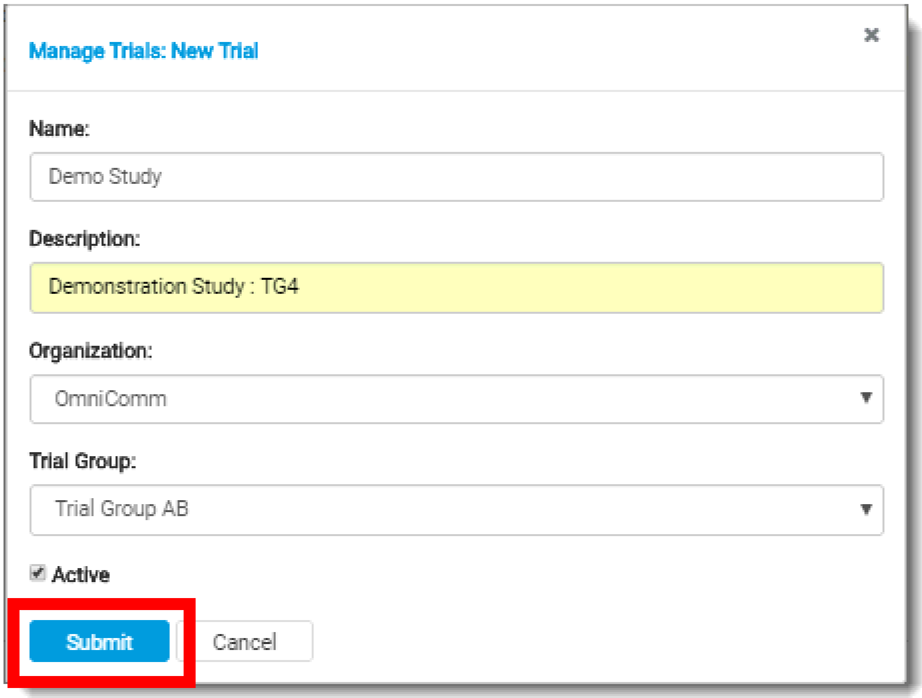


The New Trial dialog displays.



3. Select the **Server and Database** and **Trial** from the drop-down lists.
4. Click the **Add Trial** button.

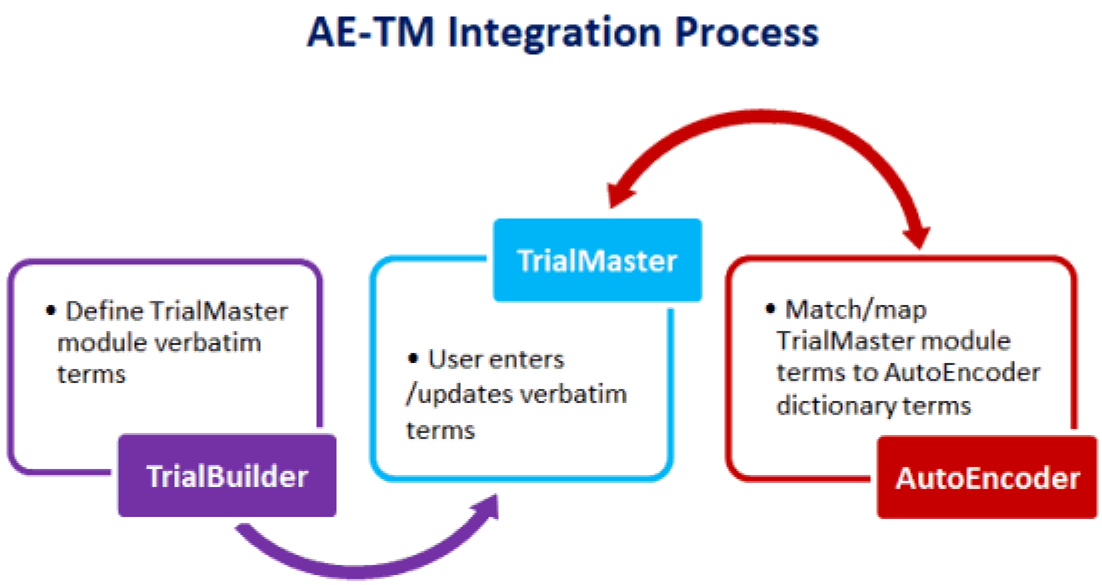
   New fields display in the New Trial dialog.



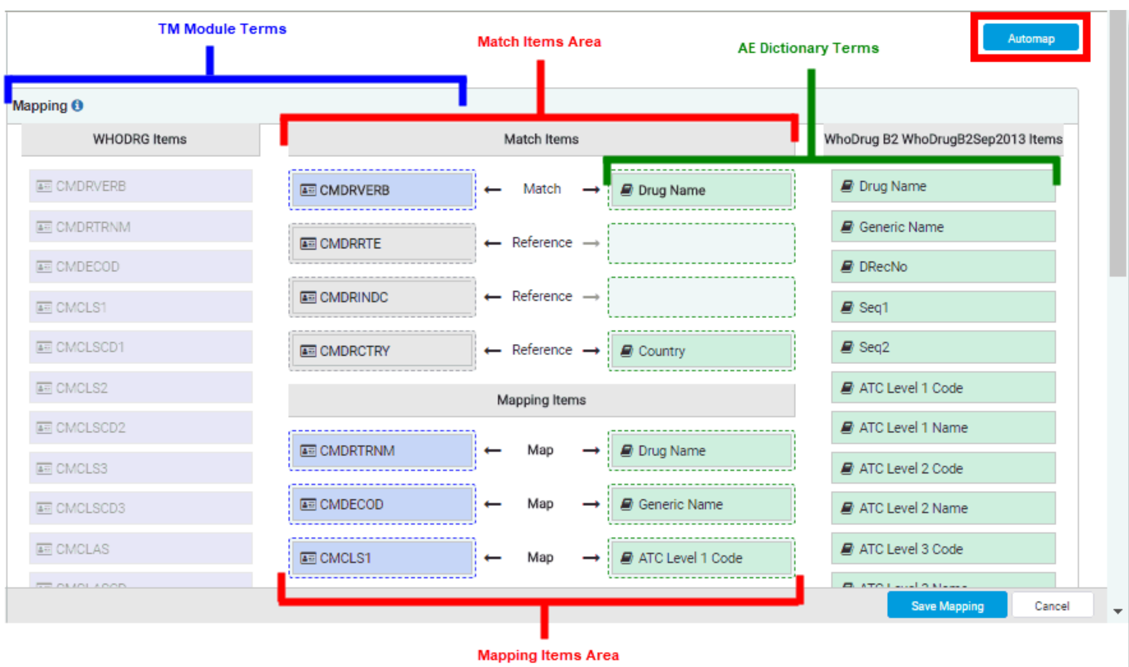
5. Optionally, change the **Name** and **Description**. (The Trial Name length must be at least 3 characters and no longer than 50.)
6. Select the **Organization** and **Trial Group** (not required) form the drop-down lists. (The Organization field is Read-Only unless you are a System User/System Admin.)
7. Click the **Submit** button. A confirmation message displays at the top of the page and the new organization displays in the table.

8.7 Mapping Overview

As shown in AE-TM integration process diagram, the first step to mapping is to define the TrialMaster (TM) module verbatim terms in TrialBuilder. As the user enters/updates the verbatim terms in TM, AutoEncoder (AE) matches/maps the TM module terms to AE dictionary terms.



The Mapping page allows you to create mapping between TM modules and AE dictionary versions.



- You can automatically match/map TM/AE terms via the Automap button (upper right).
- You can manually match/map TM/AE terms by dragging the terms to the corresponding column in the Match/Mapping Items area.

Match Items Area

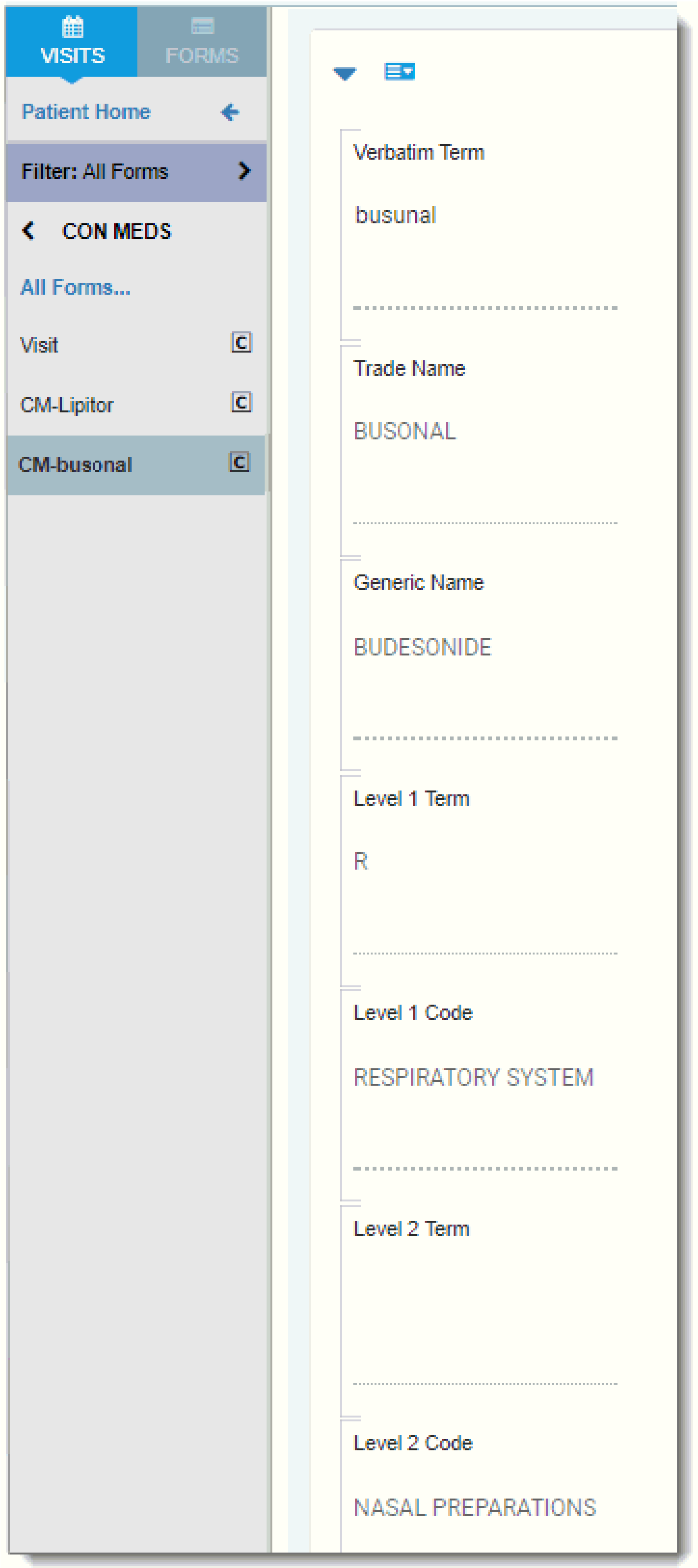
- Reference terms from the module are pre-defined and locked, but the verbatim term is editable. The module's verbatim term **must** have a dictionary match to be a usable module map.
- Reference terms can be either mapped/not mapped against the dictionary: Any module reference terms **not** mapped to dictionary terms display for reference purposes only. Any verbatim and module reference terms mapped to dictionary terms are usable in searches or autocoding.
- Reference fields only display in the Mapping dialog if they exist in the calling application's module definition. (If there are only 3 references then references for 4 and 5 do not display.)

Mapping Items Area

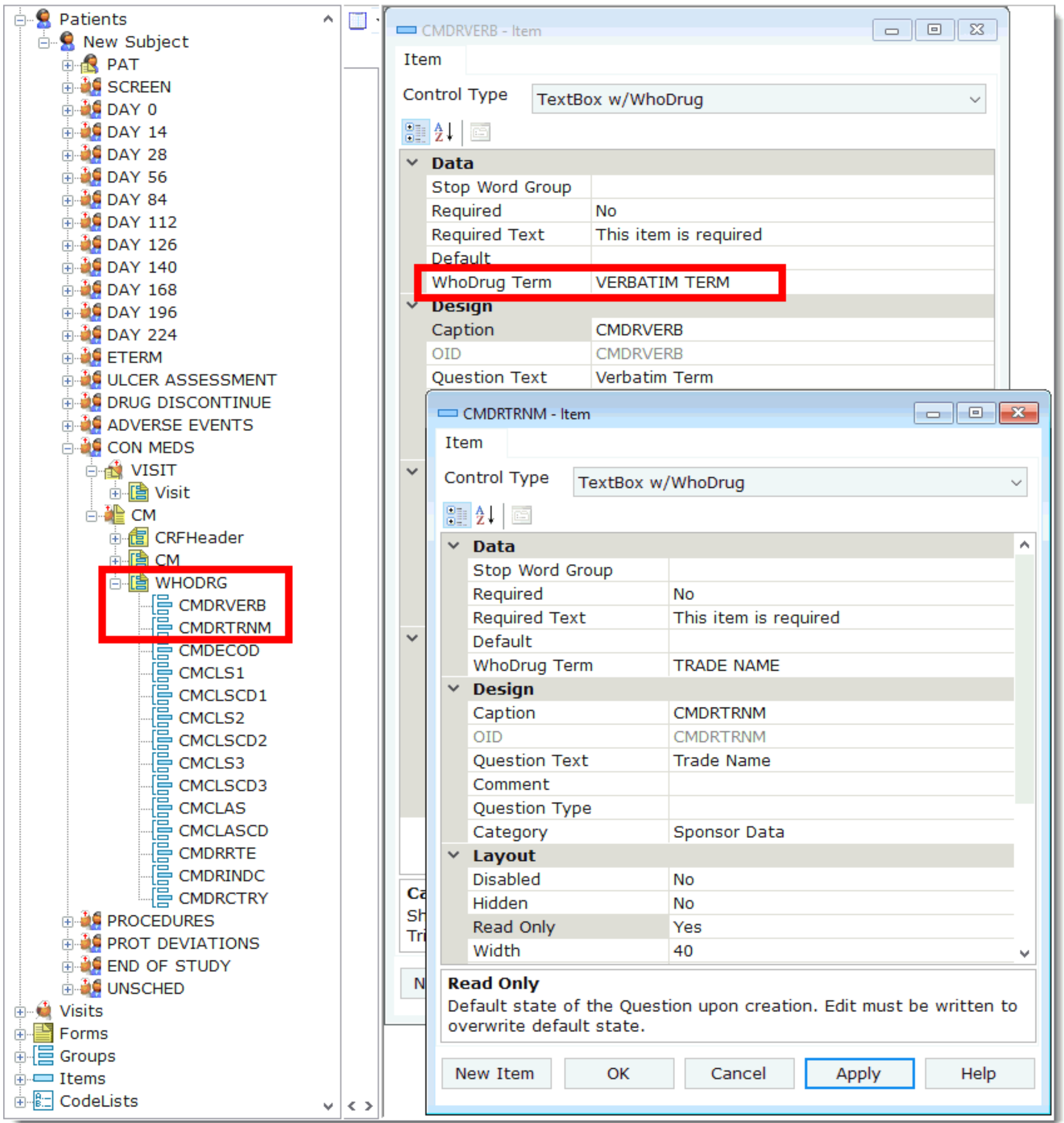
- You can map module terms only once.
- You can use dictionary terms for any number of matches.

After matching/mapping terms, AE defines what terms are written into TM and what fields are automatically populated when users enter certain terms in iCRFs listed under adverse events, concomitant medications, and medical history.

In the following example, when the TM user enters the Verbatim Term "busonal" in the CM-busonal iCRF, the Trade Name, Generic Name, Level 1 Term/Code, and Level 2 Term/Code are automatically populated with the AE dictionary terms in the Verbatim Term section of the iCRF. The matching/mapping of these fields are shown in the Mapping page example above.


VISITS
FORMS
Patient Home
Filter: All Forms
CON MEDS
All Forms...
Visit
CM-Lipitor
CM-busonal
Verbatim Term
busunal
Trade Name
BUSONAL
Generic Name
BUDESONIDE
Level 1 Term
R
Level 1 Code
RESPIRATORY SYSTEM
Level 2 Term
Level 2 Code
NASAL PREPARATIONS

Note: TM module terms are defined in TrialBuilder in the applicable dictionary. The following figure shows how the Verbatim Term and Trade Name can be defined based on the example above. All the terms contained in the CM-busonal iCRF are listed in the Navigation Tree in the left pane. The WhoDrug Term field sets the dictionary term type for AutoEncoder's AutoMapping feature.



Note: See Manage Mapping to get started with the mapping process.

8.7.1 Manage Mapping

You can manage mapping in the following ways:

- View/edit a mapping between modules and a dictionary terms
- Create a mapping between modules and dictionary terms
- Upgrade dictionary version for a module's mapping
- Delete a module mapping between modules and dictionary terms

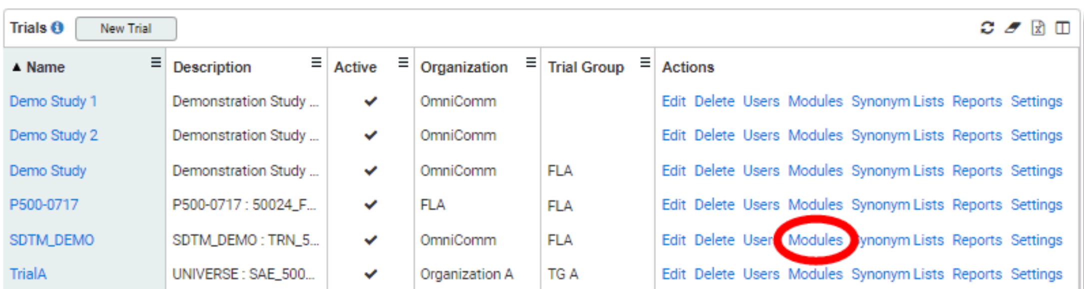
8.7.2 View/Edit a Mapping Between Modules and Dictionary Terms

You can view/edit a mapping between TrialMaster (TM) modules and AutoEncoder (AE) dictionary terms.

Important: Editing a module mapping uncodes all terms and overwrites the previous mapping.

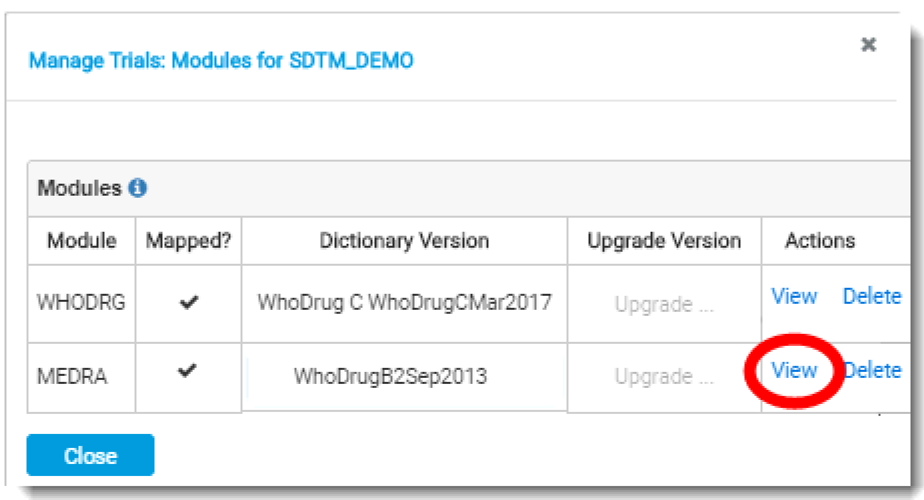
To view/edit a mapping between modules and dictionary terms:

1. Access the Trials page. (See View Trials for guidance.)
2. Click the **Modules** link of the applicable trial under the Actions column.

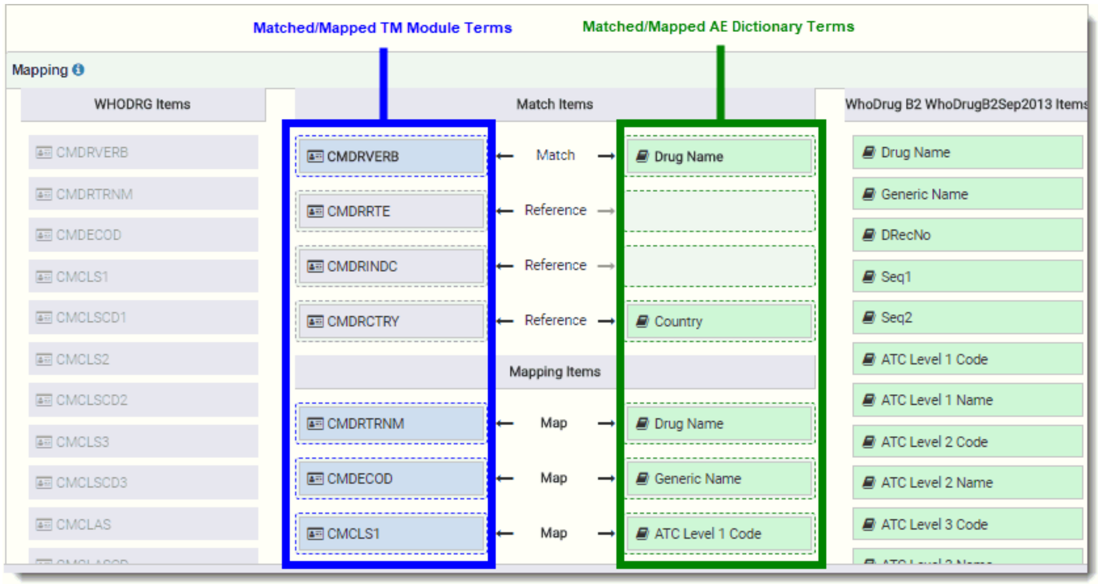


   The Modules page displays each module, the dictionary/upgrade version, and mapping status (A module that was already mapped is indicated by a check mark in the Mapped column and a View link in the Mapping column).

3. Click the **View** link under the Actions column.



   The Mapping page displays the matched/mapped TM Module terms in blue in the left column of the Match/Mapping Items area. The matched/mapped AE dictionary terms display in green in the right column of the Match/Mapping Items area.

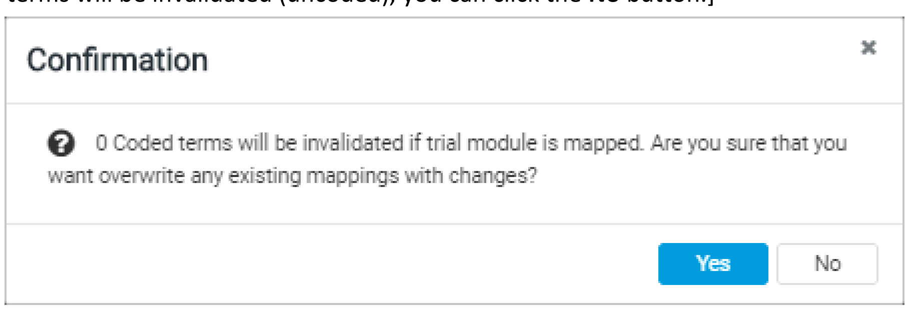


Note: If you do not have edit permissions, the Mapping page is Read-Only for viewing.

4. To edit the mapping, do the following:
   a. To match/map TM module terms to AE dictionary terms, drag the applicable item from the far left column to an empty field in the first column of Match/Mapping Items area. Continue dragging items as needed. (Clicking on the **x** in the upper left corner of the item unmaps/unmatches the item.)
   b. To match/map AE dictionary terms to TM module terms, drag the dictionary item from the far right column to an empty field in the second column of the Match/Mapping items area. Continue dragging items as needed.

   Note: For more information about mapping, refer to Mapping Overview.

   c. Click the **Save Mapping** button. Click the **Yes** button in the Confirmation message displays, indicating that any existing mappings will be overwritten. [If the message indicates that coded terms will be invalidated (uncoded), you can click the **No** button.]



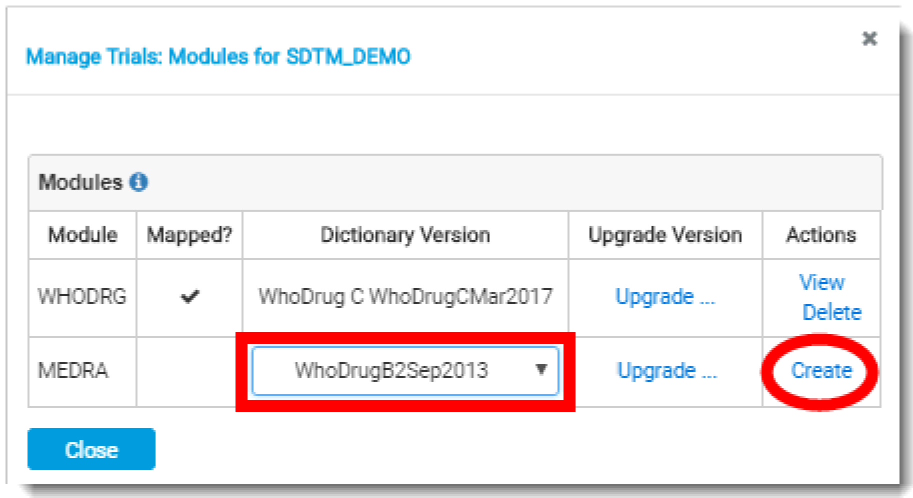
Note: Once a module map is saved the trial, it becomes available in the user's Dashboard if that user has access.

8.7.3 Create a Mapping Between Modules and Dictionary Terms

You can create a mapping between TrialMaster (TM) modules and AutoEncoder (AE) dictionary terms.

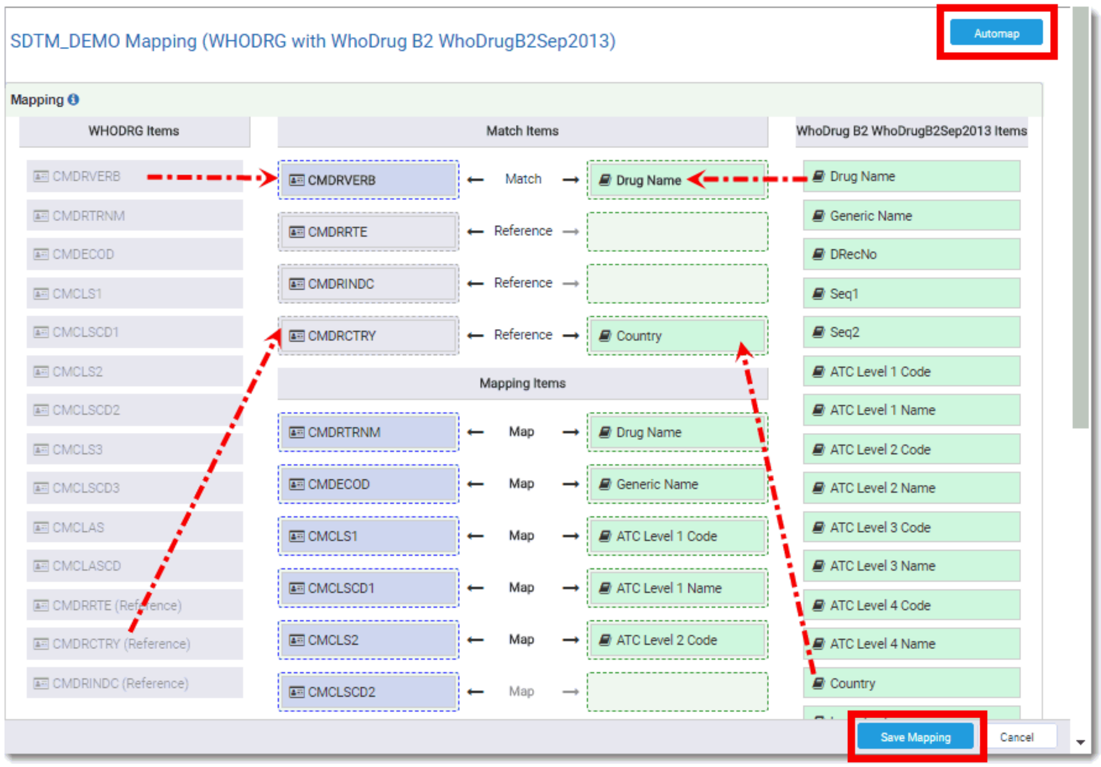
To create a mapping between modules and dictionary terms:

1. Access the Modules page. (See View/Edit a Mapping Between Modules and Dictionary Terms for guidance.)
2. Select the **Dictionary Version.**



3. Click the **Create** link under the Actions column.

   The Mapping page displays. Terms to be coded from the calling application consist of one verbatim term to match against and up to 5 reference fields. The module's verbatim term plus 1-5 reference fields are pre-defined by TrialBuilder.



4. Click the **Automap** button to automatically match/map the TM module to AE dictionary terms.
5. Click the **Yes** button in the confirmation message to overwrite any existing matches/mappings with your new changes.

   The TM module and AE dictionary terms are automatically mapped in the Mapping Items area.

Note: Automapping fields is not possible if the requested dictionary level being defined for the module's fields do not exist.

6. To match/map TM module terms to AE dictionary terms, drag the applicable item from the far left column to an empty field in the first column of Match/Mapping Items area. Continue dragging items as needed. (Clicking on the **x** in the upper left corner of the item unmaps/unmatches the item.)
7. To match/map AE dictionary terms to TM module terms, drag the dictionary item from the far right column to an empty field in the second column of the Match/Mapping items area. Continue dragging items as needed.

   In the figure above, the TM module verbatim term (CMDRVERB) is matched to the AE dictionary Drug Name, the TM module country reference term (CMDRCTRY) term is matched to the AE dictionary Country term. The remaining terms in the Mapping Items area are mapped except for the TM module Leve1 2 term (CMCLSCD2) because there is no corresponding term in the right column of the Mapping Items area.

Note: For more information about mapping, refer to Mapping Overview.

8. Click the **Save Mapping** button. Click the **Yes** button in the warning message displays, indicating that any existing mappings will be overwritten.

   Once a module map is saved the trial, it becomes available in the user's Dashboard if that user has access.

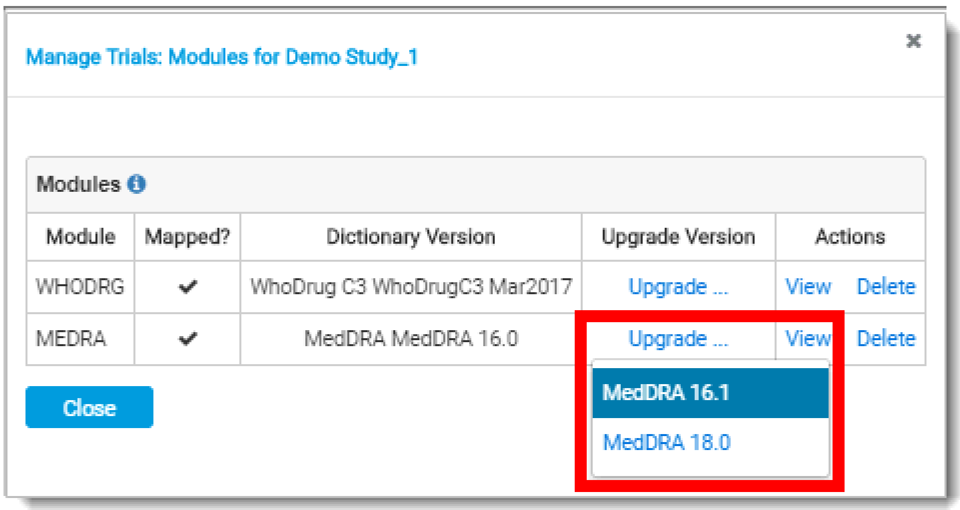
Note: Unmapped modules do not display in the Dashboard as they can't be coded against. If saving an existing module map, all terms are uncoded that were coded using the previous mapping.

8.7.4 Upgrade Dictionary Version for a Module's Mapping

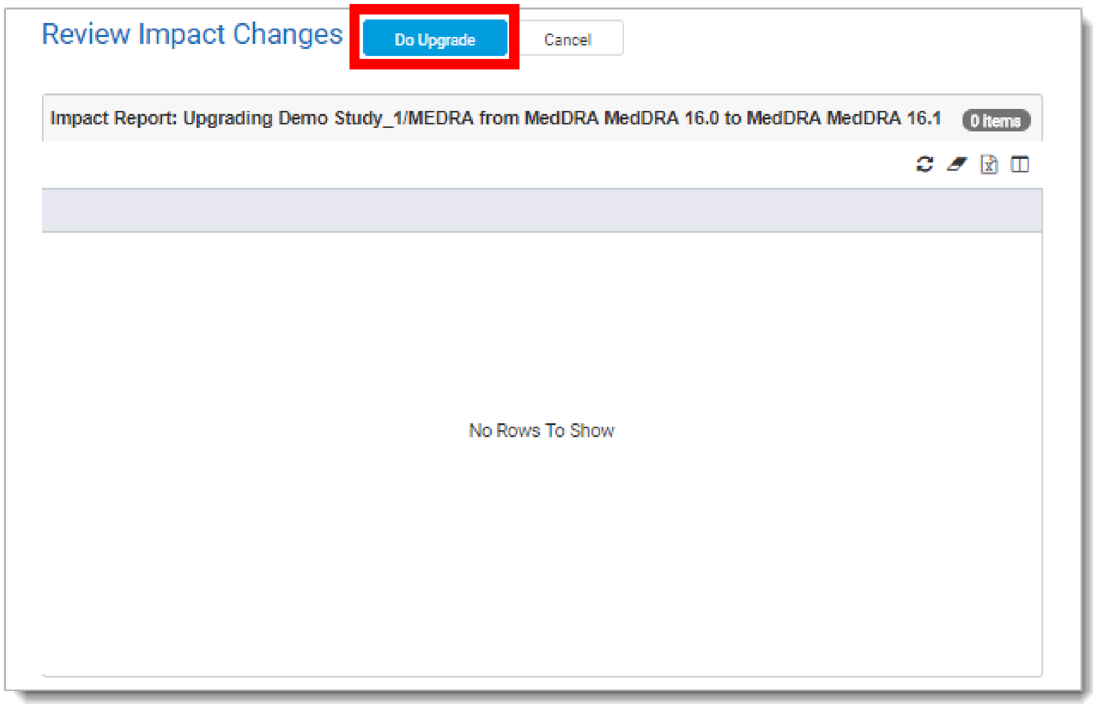
When upgrading a dictionary version, an Impact Report indicates if any conflicts exist between the new and current dictionaries.

To upgrade the dictionary version for a module's mapping:

1. Access the Modules page. (See View/Edit a Mapping Between Modules and Dictionary Terms for guidance.)
2. Select the **Upgrade** link and select the new dictionary version.



The system navigates to the Impact Report, which displays any conflicts between the current and new dictionaries. (No information displays in the report page if there are no conflicts, as shown in the figure above.) These conflicts may consist of one of the two following values:



- Term obsolete – the term against which the user coded (directly or via synonym/history match) does not exist in the new dictionary version
- Hierarchy changed – one or more terms above the preferred term are different in the new dictionary version (e.g., new HLT for MedDRA).

3. After reviewing the impacted terms, click the **Do Upgrade** button to continue with the Dictionary Upgrade, or **Cancel** to exit without making any changes. If you clicked **Do Upgrade**, the Modules dialog re-displays with the new dictionary version.

Note: The Upgrade Version link only displays if one or more later dictionary versions are available. Continuing with the upgrade uncodes all terms in the impact table and the dictionary version is upgraded.

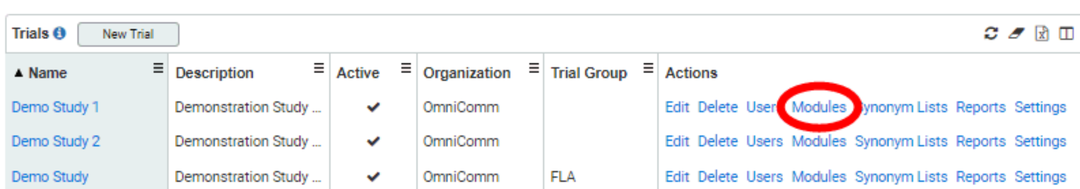
8.7.5 Delete a Mapping Between Modules and Dictionary Terms

You can delete (unmap) a module entirely from its dictionary if your current user role has permissions.

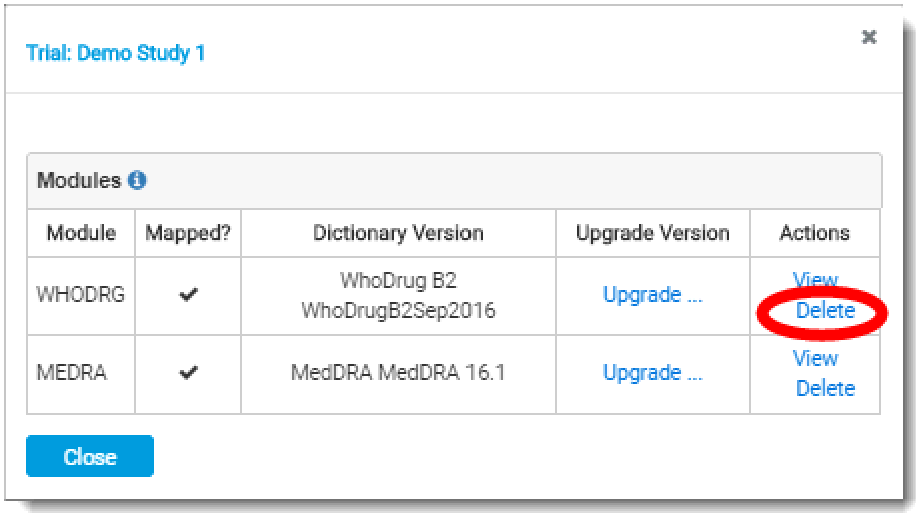
Important: Deleting a module mapping uncodes all terms and deletes the previous mapping.

To delete a module mapping between modules and dictionary terms:

1. Access the Modules page. (See View/Edit a Mapping Between Modules and Dictionary Terms for guidance.)
2. Click the **Modules** link of the applicable trial under the Actions column.

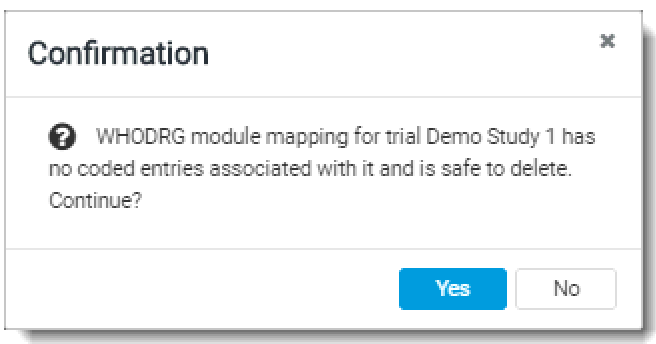


The Modules page displays the module, the dictionary/upgrade version, and mapping status (A module that was already mapped is indicated by a check mark in the Mapped column).

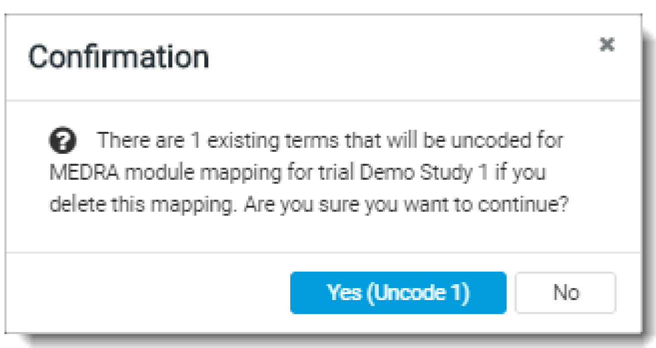


3. Click the **Delete** link of the applicable module under the Actions column.

   If it is safe to delete the module mapping, the Confirmation message indicates that the study has no coded entries associated with the module mapping.



   If existing items must be uncoded to delete the mapping, the Confirmation message indicates the number of uncoded terms within the message and on the **Yes** button. (At this point you may want to click **No** to cancel the deletion.)



4. Click the **Yes** button to confirm the deletion. Depending on how the module mapping, a success or error message displays at the top of the Trials page.

Trial Groups

8.8 Manage Trial Groups

You can manage trial groups in the following ways:

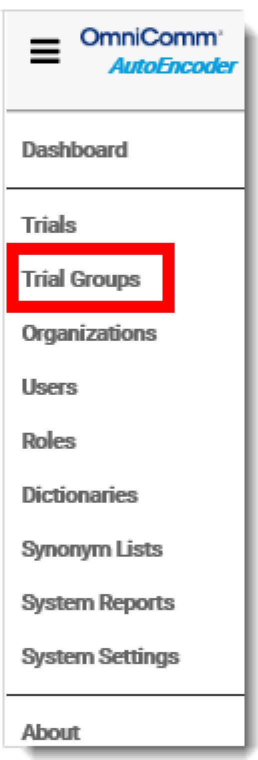
- View trial groups
- View trials within a trial group
- Add a new trial group
- Edit a trial group
- Delete a trial group
- Assign user to a trial group
- Edit trial group synonym lists
- View trial group reports
- Edit trial group settings

8.8.1 View Trial Groups

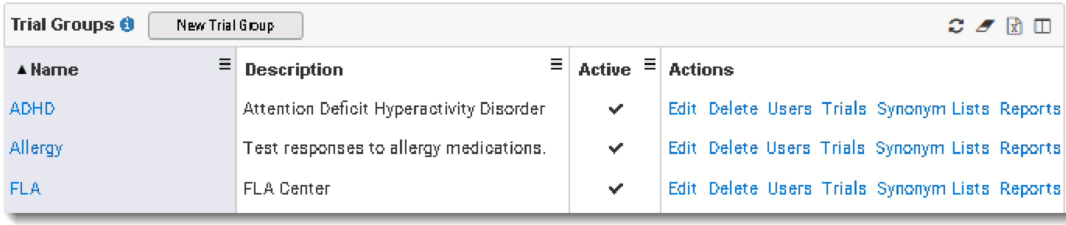
You can view details about each trial group, including the description and status (active/inactive).

To view trial groups:

1. Click the  **Main Menu** icon (top left).
2. Select **Trial Groups** from the drop-down list.



The Trial Groups page displays the name, description, active status (check marked if active), and allowed user/role actions for each trial group



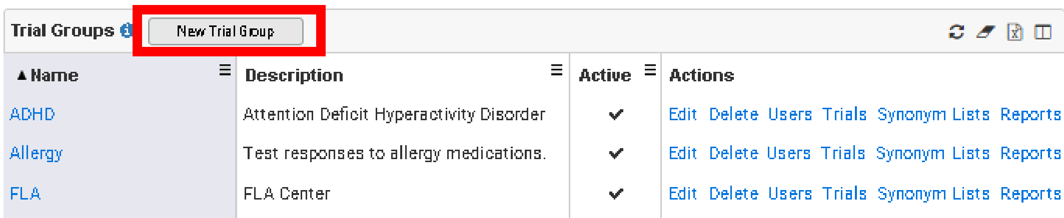
Note: You can sort and filter the table or export it to Excel. Various table options are also available. (See Use Table Functions.)

8.8.2 Add a New Trial Group

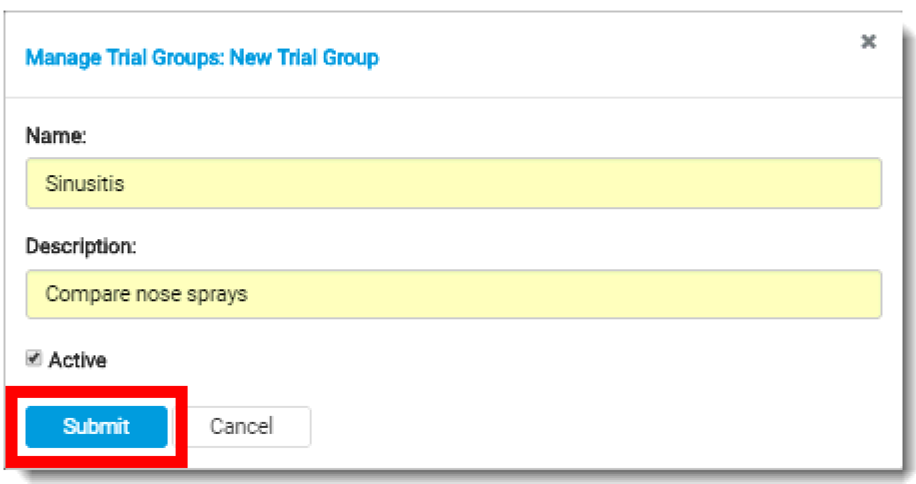
You can add a new trial group to a trial.

To add a new trial group:

1. Access the Trials Groups page. (See View Trial Groups for guidance.)
2. Click the **New Trial Group** button.



The New Trial Group dialog displays.



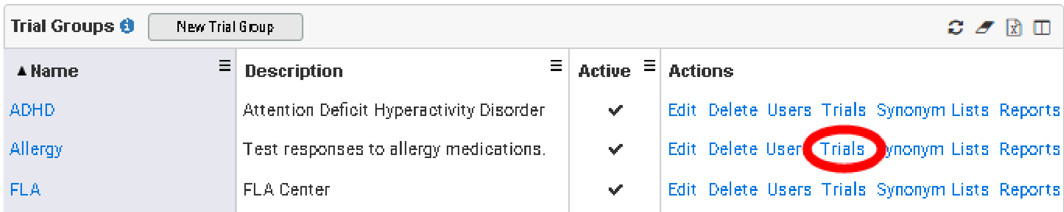
3. Enter the **Name** and **Description** of the trial group.
4. Click the **Submit** button. A confirmation message displays at the top of the page that a new trial group was successfully created and the new organization displays in the table.

8.8.3 View Trials within a Trial Group

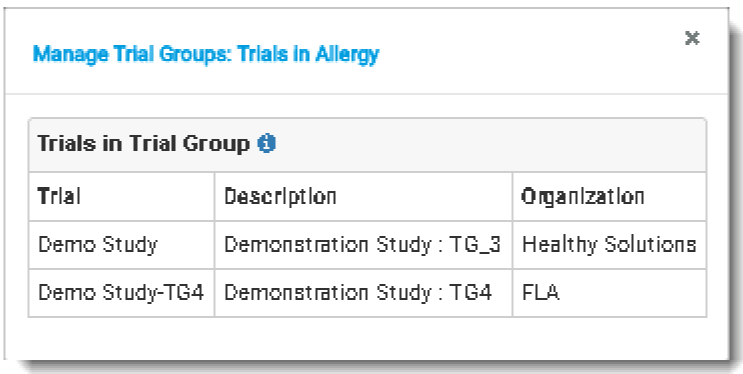
You can view trials that belong to trial groups.

To view trials within a trial group:

1. Access the Trials Groups page. (See View Trial Groups for guidance.)
2. Click the **Trials** link under the Action column.



The Trials in Trial Group table list each trial and organization that belongs to the trial group.


Manage Trial Groups: Trials in Allergy

Trials in Trial Group

Trial	Description	Organization
Demo Study	Demonstration Study : TG_3	Healthy Solutions
Demo Study-TG4	Demonstration Study : TG4	FLA

Note: A trial may appear in only one trial group. (To add a trial to a trial group, see Add a New Trial.)

Organizations

8.9 Manage Organizations

- You can manage organizations in the following ways:
- View organizations
- View Trials within an Organization
- Add a new organization
- Edit an organization
- Delete an organization
- Assign user to an organization
- Edit organization synonym lists
- View organization reports
- Edit organization settings

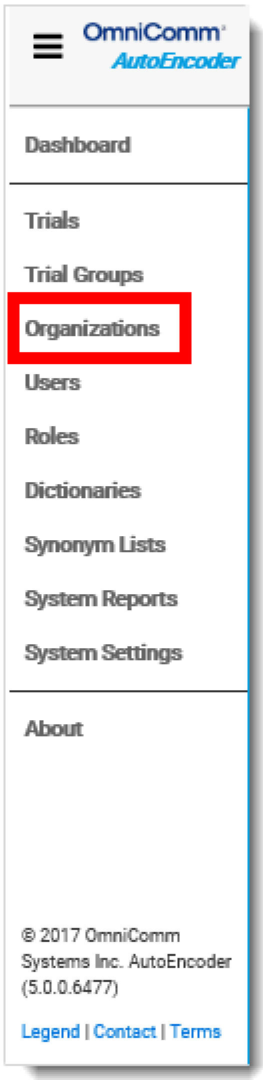
8.9.1 View Organizations

You can view details about each organization, including the description and status (active/inactive).

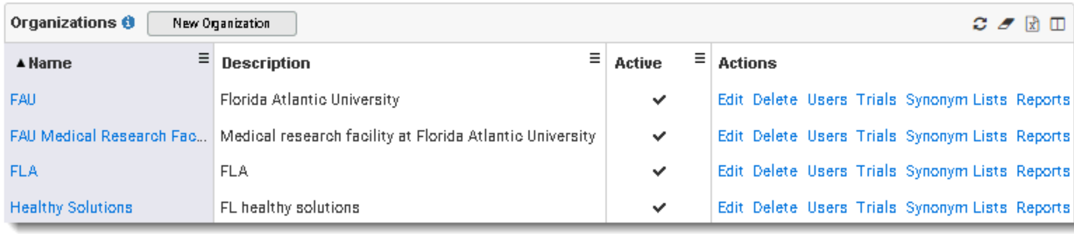
Note: If you are not a System User/System Admin, the page only displays organizations for which your current role has at least Read permissions.

To view organizations:

1. Click the **Main Menu** icon (top left).
2. Select **Organizations** from the drop-down list.



The Organizations page displays the name, description, active status (check marked if active), and allowed user/role actions for each organization.



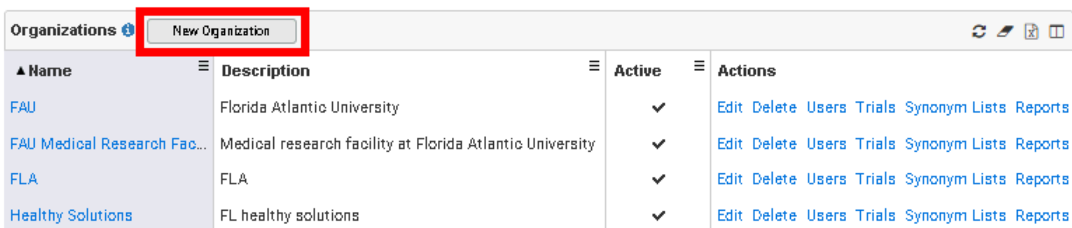
Note: You can sort and filter the table or export it to Excel. Various table options are also available. (See Use Table Functions.)

8.9.2 Add a New Organization

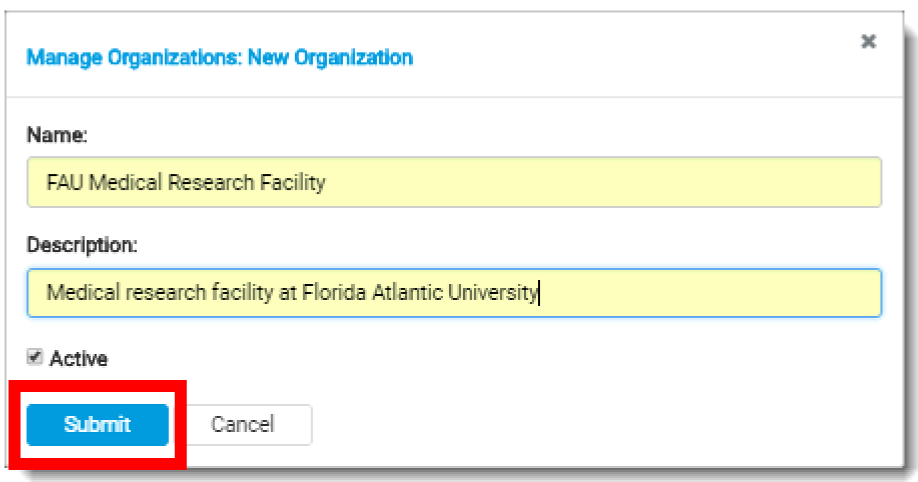
You can add a new organization to a trial.

To add a new organization:

1. Access the Organizations page. (See View Organizations for guidance.)
2. Click the **New Organization** button.



The New Organization dialog displays.



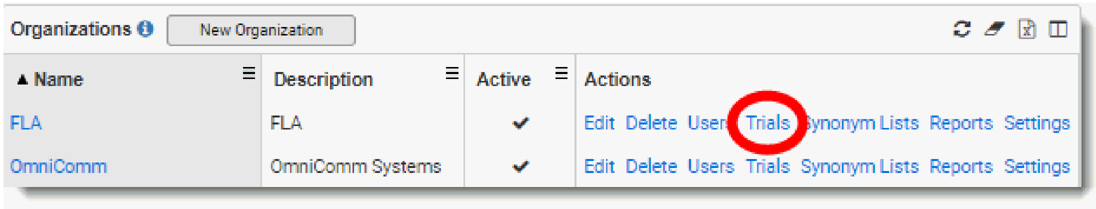
3. Enter the **Name** and **Description** of the trial group.
4. Click the **Submit** button. A confirmation message displays at the top of the page that a new organization was successfully created and the organization displays in the table.

8.9.3 View Trials within an Organization

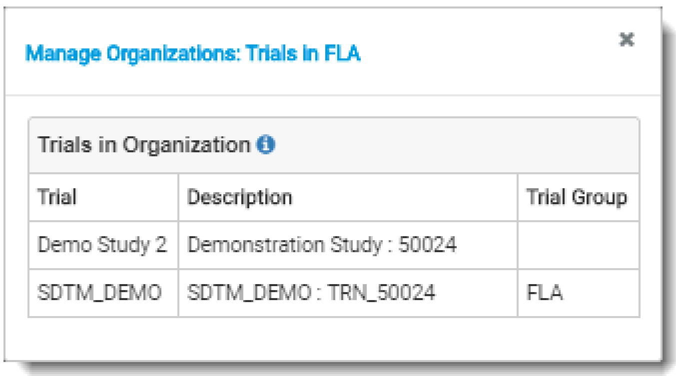
You can view trials that belong to organizations.

To view trials within an organization:

1. Access the Organizations page. (See View Organizations for guidance.)
2. Click the **Trials** link under the Action column.



The Trials in Organization table list each trial and organization that belongs to the trial group.


Manage Organizations: Trials in FLA

Trials in Organization

Trial	Description	Trial Group
Demo Study 2	Demonstration Study : 50024	
SDTM_DEMO	SDTM_DEMO : TRN_50024	FLA

USERS

9.0 Manage Users

There are two types of user in Autoencoder:

- Regular Users – can maintain objects owned by their organization. This user has no access to objects owned by other organizations. Regular users can only edit and grant roles in objects, manage synonym lists, and add new users that belong to his/her organization.
- System Users/System Admins – can perform operations on all objects across all organizations. Only these users can create trials, trial groups, and organizations. A trial group spans organizations, so only a System User/System Admin can create trial groups and grant permissions on trial groups.

Note: Regular users can only become System Users/System Admins if they check the **System User** check box when editing the Regular User. If this user reverts back to a regular user, they have the roles that they had prior to becoming a System user. (See Edit/Add a User for more information.)

You can manage users in the following ways:

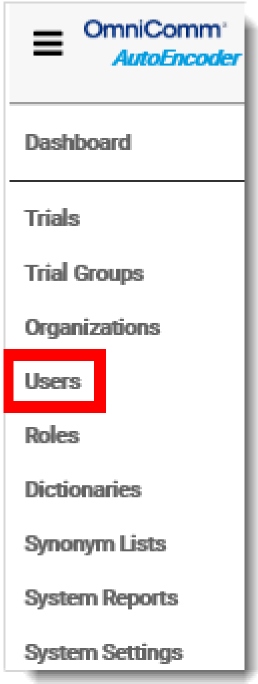
- View users
- Edit/add a user
- Assign user role to an object
- Reset a user password
- View user reports

9.1 View Users

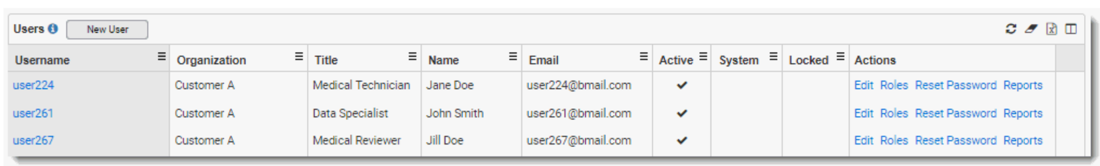
You can view details about Regular User and System Users/System Admins.

To view users:

1. Click the **Main Menu** icon (top left).
2. Select **Users** from the drop-down list.



The Users page displays the username, organization, title, name, email, and status. Under the System column, System Users /System Admins are indicated by a check mark. Regular users have no check mark. Check marks also indicate the user status (active/inactive, locked/unlocked).



Users New User

Username	Organization	Title	Name	Email	Active	System	Locked	Actions
user224	Customer A	Medical Technician	Jane Doe	user224@bmail.com	✔			Edit Roles Reset Password Reports
user261	Customer A	Data Specialist	John Smith	user261@bmail.com	✔			Edit Roles Reset Password Reports
user267	Customer A	Medical Reviewer	Jill Doe	user267@bmail.com	✔			Edit Roles Reset Password Reports

Note: By default, users have read access to everything owned by their organization. (See User Permissions for more information.)

Note: You can sort and filter the table or export it to Excel. Various table options are also available. (See Use Table Functions.)

9.2 Edit/Add a User

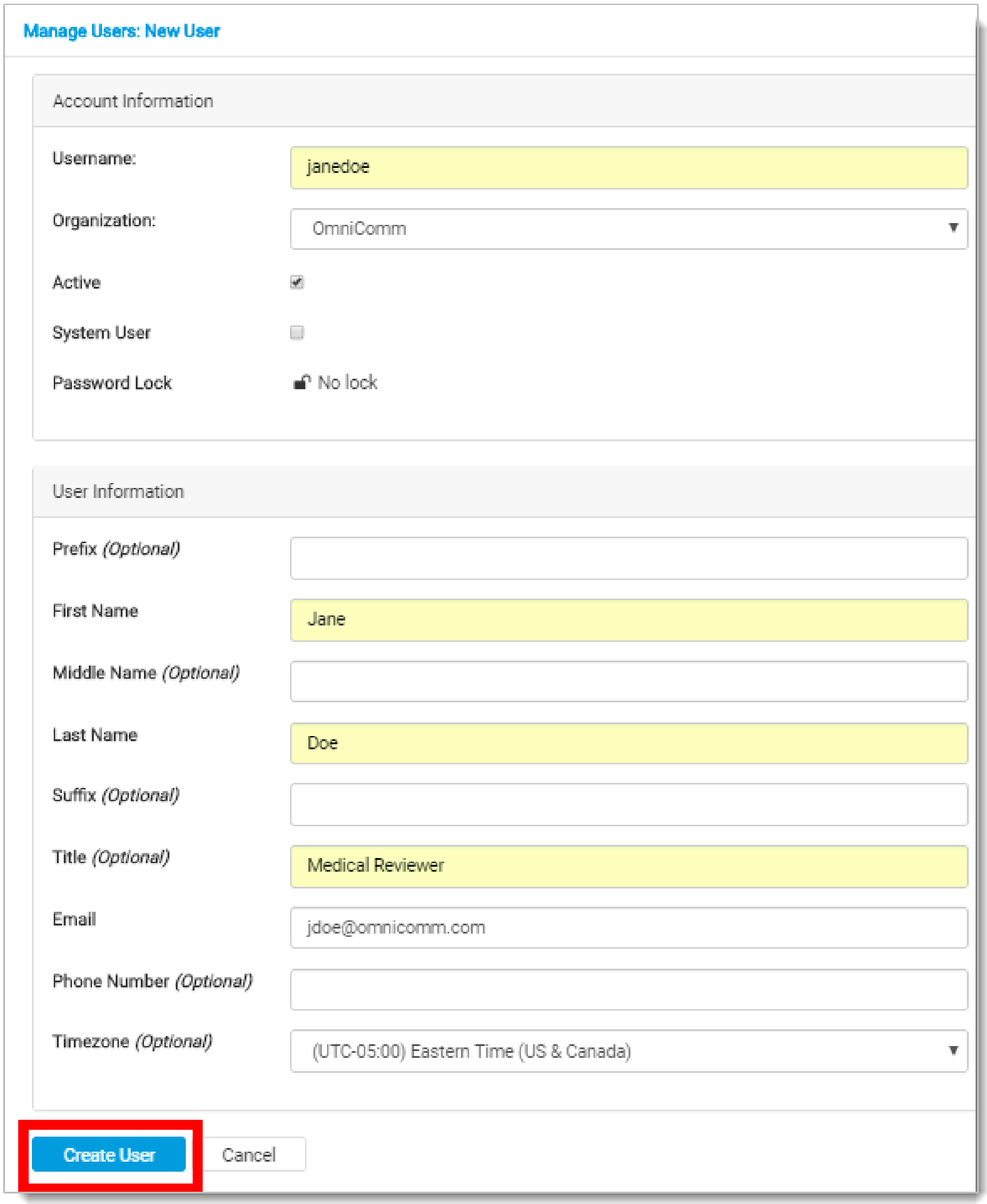
You can edit an existing user's information except for the user name.

If you have permissions, you can add a new user.

To edit/add a user:

1. Access the Users page. (See View Users for guidance.)
2. Click one of the following:
   - A user name (in blue text in the Users column) – to edit a user (You can also click **Edit** under the Actions column to edit a user.)
   - **New User** button – to add a new user

   The Edit/New User page displays.



3. Enter/select the applicable information:
    - **Organization:** Select an organization from the drop-down menu. (This field is Read-Only for regular users; only the System User /System Admin can edit this field.)
    - **Active** (default): Uncheck the Active check box to de-activate a user.
    - **System User:** The System User is unchecked by default and can only be checked by the System User/System Admin.

- **Password Lock: "**No Lock" with an icon displays for users that are not currently locked out. "Locked" with a link displays if the user has been locked out. To unlock the user, click the link. Only a System User /System Admin or a Super User for people in his/her organization can unlock users. Locks eventually time out and unlock automatically according to the "MinutesTillLockoutEnds" system setting. (See View/Edit System Settings for more information.)

  If a user is de-activated and attempts to log in, an error message displays an error: <User ID> has been deactivated in the system, contact your system admin.

  Password Lock settings:

  - The number of invalid password attempts is controlled by the "LockoutOnFailedLogins" setting; the default is 5
  - The length of lockout period is controlled by the "MinutesTillLockoutEnds" setting; the default is 60 minutes. If this setting is zero then the user is locked out forever until a System User/System Admin or a Super User for people in his/her organization unlocks by unchecking the Locked Out check box.

  Once the lockout period expires, the user can attempt logging in again. Prior to the lockout period ending, a System User /System Admin or a Super User for people in his/her organization must click the **Locked** link to allow the user to login again.

- **User Information**: The First and Last Name, and email are required; the remaining fields are optional.

4. Click one of the following buttons:

- **Update User** – to save your edits
- **Create User** – to save the new user. The user receives three notification emails: A notification that a new account has been created, a notification with a temporary password, and a notification that the password has been changed.

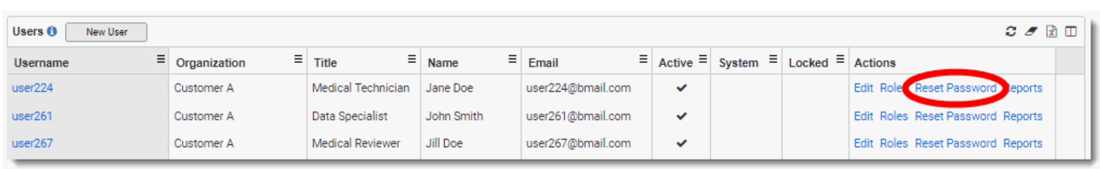
A confirmation message displays at the top of the Users page, indicating that the user was successfully edited/created.

9.3 Reset a User's Password

If you are a System User/System Admin, you can reset a user's password (if the user gets locked out, etc.).

To reset a user's password:

1. Access the Users page. (See View Users for guidance.)
2. Click the **Reset Password** link under the Actions column of the applicable user.


Users New User

Username	Organization	Title	Name	Email	Active	System	Locked	Actions
user224	Customer A	Medical Technician	Jane Doe	user224@bmail.com	✔			Edit Roles Reset Password Reports
user261	Customer A	Data Specialist	John Smith	user261@bmail.com	✔			Edit Roles Reset Password Reports
user267	Customer A	Medical Reviewer	Jill Doe	user267@bmail.com	✔			Edit Roles Reset Password Reports

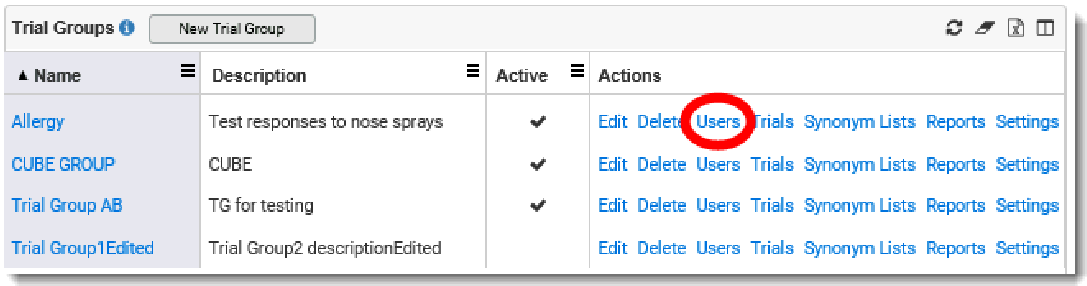
3. Click the **Yes** button in the Confirmation message. A confirmation message displays at the top of the Users page and password notification and temporary password is sent to the user's email address.

9.4 Assign User to an Object

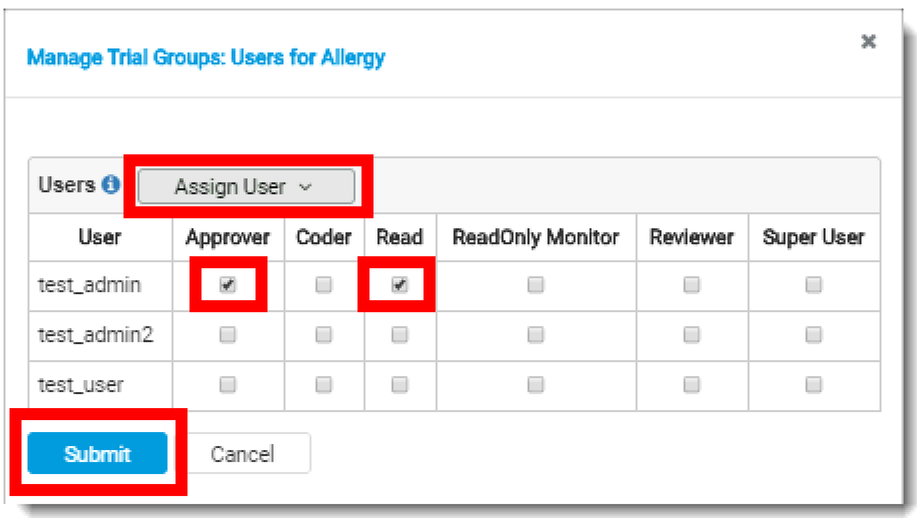
You can assign a user to an object (organization, trial group, trial) if you are a System Administrator. Super Users may assign users within organizations and trials they are assigned to. However, Super Users cannot edit users within a trial group.

To assign a user to an object:

1. Access the Organization, Trial Groups, or Trials page. (See View Organizations, View Trial Groups, or View Trials for guidance.)
2. Click the **Users** link under the Actions column of the applicable organization, trial group, or trial.



3. Select the user from the Assign User drop-down list.



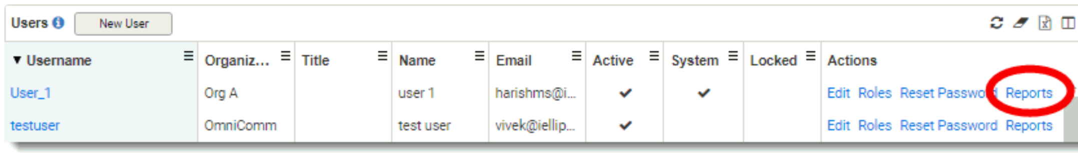
4. To assign roles, click the applicable check box(es) of the new user. In the example above, the test_admin user is assigned the Approver and Read-Only roles.
5. Click the **Submit** button. The user displays the table.

9.5 View User Reports

You can view user reports, such as User Role History or Coding Action reports.

To view a user report:

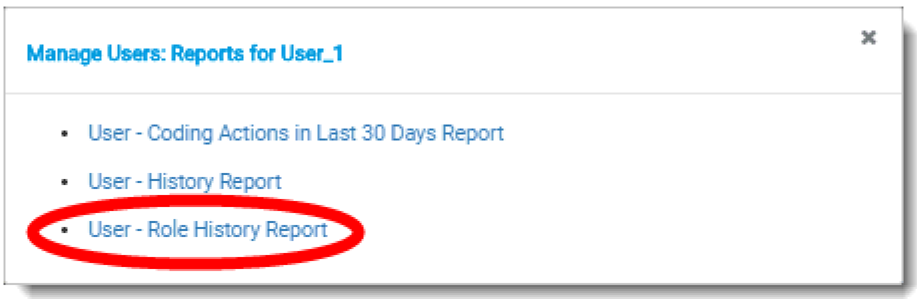
1. Access the Users page. (See View Users for guidance.)
2. Click the **Reports** link under the Actions column of the applicable user.



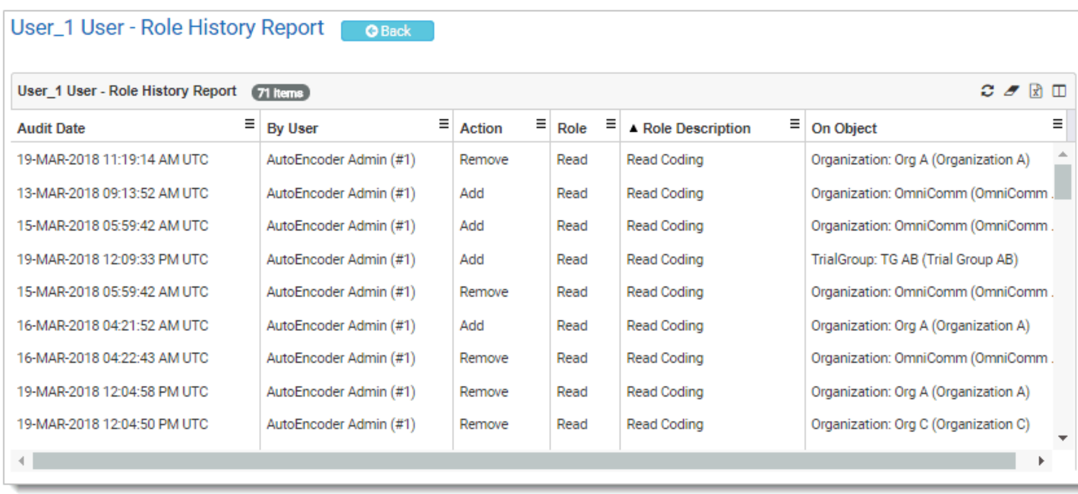
Users | New User

Username	Organiz...	Title	Name	Email	Active	System	Locked	Actions
User_1	Org A		user 1	harishms@i...	✔	✔		Edit Roles Reset Passwo Reports
testuser	OmniComm		test user	vivek@iellip...	✔			Edit Roles Reset Password Reports

The Manage User Reports page displays.



3. Click on a link to view a report. The report displays details about the user. For example, the User Role History Report shows a history of user actions on each object.



User_1 User - Role History Report | Back

User_1 User - Role History Report | 71 Items

Audit Date	By User	Action	Role	Role Description	On Object
19-MAR-2018 11:19:14 AM UTC	AutoEncoder Admin (#1)	Remove	Read	Read Coding	Organization: Org A (Organization A)
13-MAR-2018 09:13:52 AM UTC	AutoEncoder Admin (#1)	Add	Read	Read Coding	Organization: OmniComm (OmniComm...
15-MAR-2018 05:59:42 AM UTC	AutoEncoder Admin (#1)	Add	Read	Read Coding	Organization: OmniComm (OmniComm...
19-MAR-2018 12:09:33 PM UTC	AutoEncoder Admin (#1)	Add	Read	Read Coding	TrialGroup: TG AB (Trial Group AB)
15-MAR-2018 05:59:42 AM UTC	AutoEncoder Admin (#1)	Remove	Read	Read Coding	Organization: OmniComm (OmniComm...
16-MAR-2018 04:21:52 AM UTC	AutoEncoder Admin (#1)	Add	Read	Read Coding	Organization: Org A (Organization A)
16-MAR-2018 04:22:43 AM UTC	AutoEncoder Admin (#1)	Remove	Read	Read Coding	Organization: OmniComm (OmniComm...
19-MAR-2018 12:04:58 PM UTC	AutoEncoder Admin (#1)	Remove	Read	Read Coding	Organization: Org A (Organization A)
19-MAR-2018 12:04:50 PM UTC	AutoEncoder Admin (#1)	Remove	Read	Read Coding	Organization: Org C (Organization C)

Note: You can sort and filter the table or export it to Excel. Various table options are also available. (See Use Table Functions.)

9.6 User Permissions

The following user permissions are available.

Permission	Description
Read Coding	View the coding for a module in a trial
Edit Coding	Perform coding for a module in a trial
Review Coding	Perform the Review for coding decisions
Approve Coding	Approve coding after review
Read Synonyms	View synonym lists and history matches
Edit Synonyms	Load and edit synonym lists and edit history matches
Read Mapping	Read the column mappings for a module
Edit Mapping	Set up and edit column mappings
Read Users Roles	View information about other users within their defined scope (global or organization)
Edit Users Roles	Can set up and edit users within their defined scope
Read Settings	View configuration settings for an assigned object trial, trial group, organization)
Edit Settings	Create and modify settings for an assigned object
Read Object	Read access to assigned objects (trial, trial group, organization)
Edit Object	Create and update access to assigned objects

ROLES

10.0 Manage Roles

The following fixed set of roles and their permissions are pre-defined in the AutoEncoder.

Note: You cannot add a new role, nor to change the permissions for an existing role. However, you can assign roles to objects.

Role	Permissions
Read	Views but not update assigned objects (e.g., coding for a module within a trial)
Coder	Performs coding and view objects that support coding, such as synonym lists
Reviewer	Performs a review of coding decisions
Approver	Approves reviewed coding decisions
Super User	Performs all activities except the creation of objects (trials, trial groups, organizations). The Super User can edit any object owned by the user's organization. General security rules for non System Admin/System Users are: • They must have a role with permissions for the object. • They must belong to that organization. Note: Users should NEVER be able to manage objects outside of their organization.
Read Only Monitor	Read only permissions, to include users
System Admin (System User)	Automatically assigned when the user is a System Admin/System User. Provides all permissions on all objects across all organizations. This user cannot be granted to a Regular User. This user has no other roles other than System Admin/System User. Can perform operations on all objects across all organizations. Only these users can create trials, trial groups, and organizations. A trial group spans organizations, so only a System Admin/System User can create trial groups and grant permissions on trial groups.

You can manage roles in the following ways:

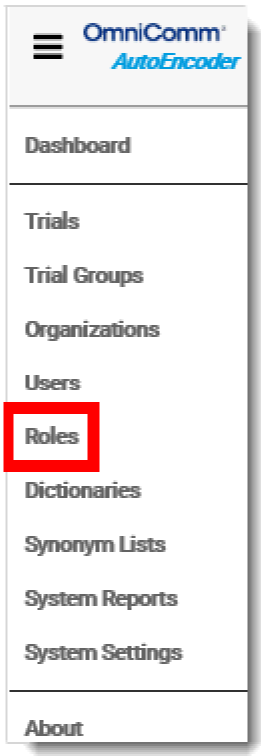
- View roles
- Assign a role to an object

10.1 View Roles

You can view the roles that have been pre-defined by AutoEncoder.

To view roles:

1. Click the ☰ **Main Menu** icon (top left).
2. Select **Roles** from the drop-down list.



The Roles page displays the permissions for each role.

View Roles

Roles

Role	Read Coding	Edit Coding	Review Coding	Approve Coding	Read Synonyms	Edit Synonyms	Read Mappings	Edit Mappings	Read Users Roles	Edit Users Roles
Approver	✔	✔		✔	✔		✔			
Coder	✔	✔			✔		✔			
Read	✔				✔		✔			
ReadOnly Monitor	✔				✔		✔		✔	
Reviewer	✔	✔	✔		✔		✔			
Super User	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
System Admin	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔

Note: You can show/hide table columns or export the table data to Excel. (See Show/Hide a Column or Export to Excel.)

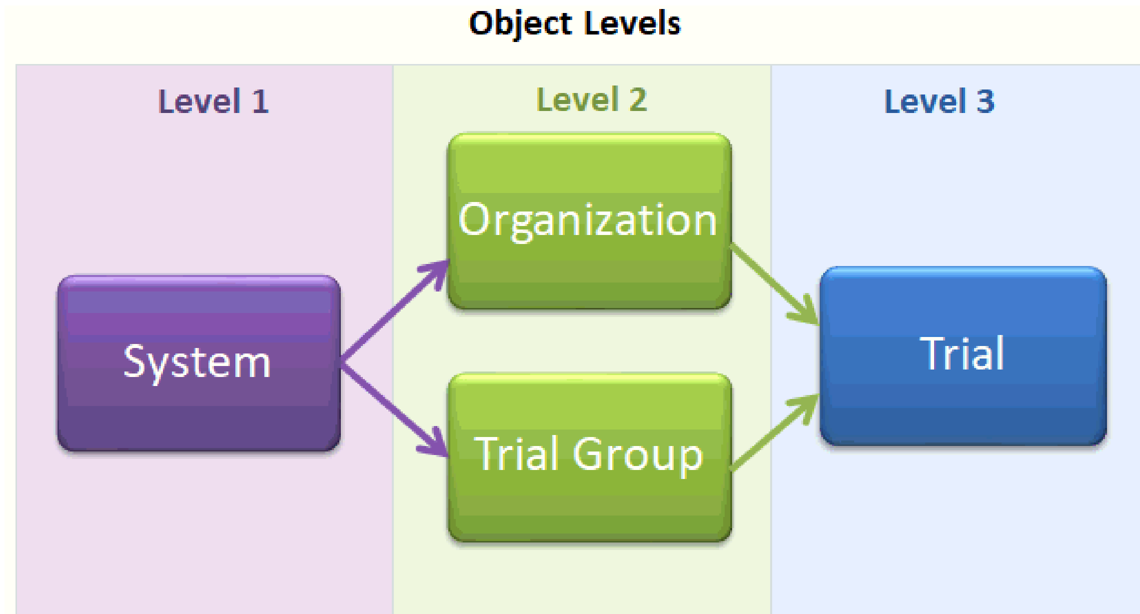
10.2 Assign Role to an Object

Note: A user is created within an organization and is automatically assigned a Read role at the organization level or System Admin if System User was selected. If granted, the user acquires the corresponding permissions on all objects owned by that organization (trials, modules within trials).

You can assign a role to a user within an object (organization, trial group, trial) if your role has the correct permissions and is a member of the object's parent organization.

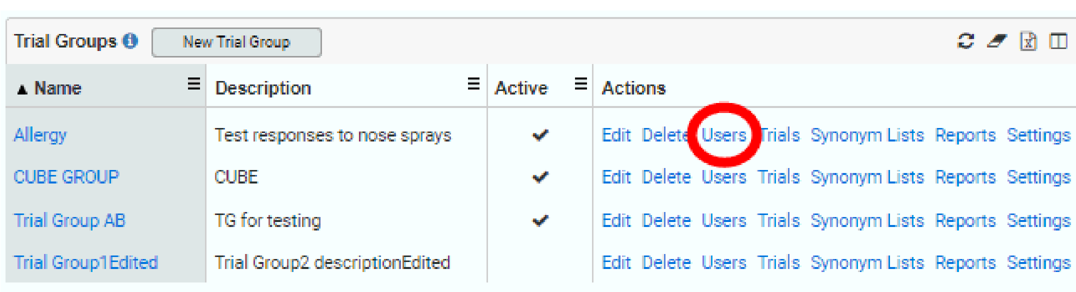
Object Levels

The role that is assigned to an object cascades according to the object level. For example, if a role is assigned to an organization or trial group, the role's permissions cascade down to the trial assigned to that organization or trial group. However, if a role is only assigned to a trial, the role has no permissions to the organization or trial group. (Note that a trial group is independent from the organization. An organization cannot have trial groups assigned; only trials can be assigned to trial groups.)

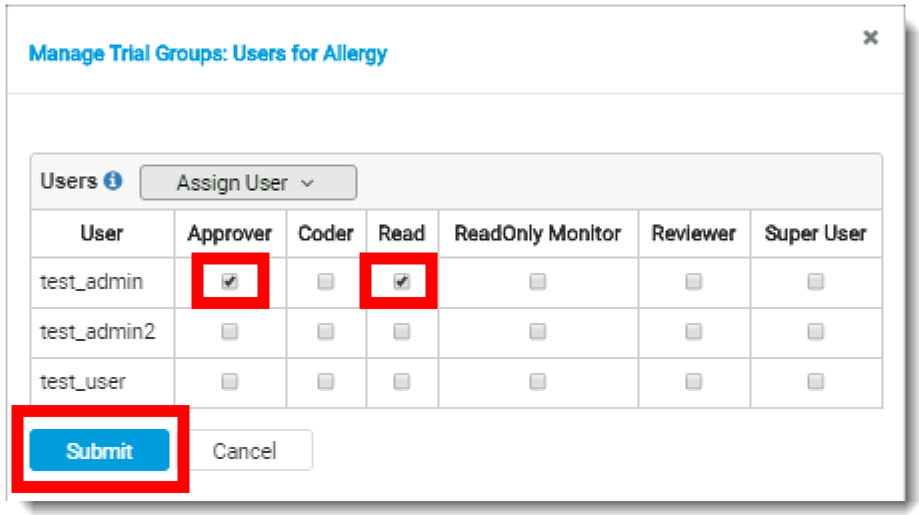


To assign a role to an object:

1. Access the Organization, Trial Groups, or Trials page. (See View Organizations, View Trial Groups, or View Trials for guidance.)
2. Click the **Users** link under the Actions column of the applicable organization, trial group, or trial.



3. Select the role check box(es) of the applicable user(s).



4. Click the **Submit** button. A confirmation message displays at the top of the page, indicating the assigned role was successful.

DICTIONARIES

11.0 Manage Dictionaries

You can manage dictionaries in the following ways:

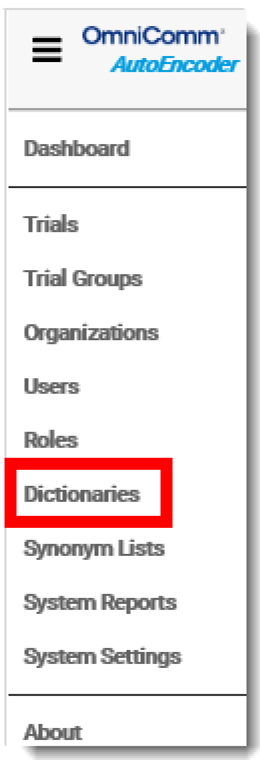
- View dictionaries
- Add a new dictionary version
- Delete a dictionary version

11.1 View Dictionaries

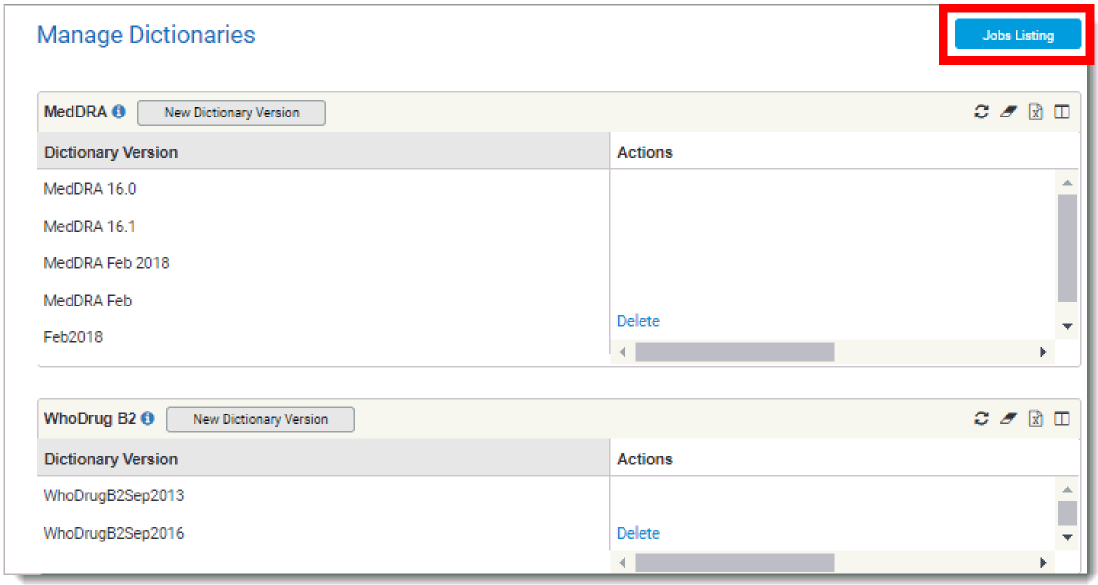
You can view details about the current WHODrug and MedDRA dictionary versions.

To view dictionaries:

1. Click the ☰ **Main Menu** icon (top left).
2. Select **Dictionaries** from the drop-down list.



The Manage Dictionaries page displays the current WHODrug and MedDRA dictionary versions and the allowed user actions.



3. To view the dictionary load job status, click the **Jobs Listing** button.

   The Dictionary Jobs page displays the details of each dictionary load, including the job id and status, dictionary and version, user, date submitted/scheduled, and load/format path. You can export this information to an Excel file by clicking the **Export to Excel** icon.

Dictionary Jobs 20 items

Job Id	Status	Status D...	Dictionary	Version	User	Date Submitt...	Message	Scheduled S...
20	Finished	28-MAR-2018...	MedDRA	MedDRA 18.1	qa_admin	28-MAR-2018 02:46...	Completed	28-MAR-2018 02:4...
19	Failed	28-MAR-2018...	MedDRA	MedDRA 18.1	qa_admin	28-MAR-2018 02:34...	Error: Msg 486...	28-MAR-2018 02:3...
18	Finished	28-MAR-2018...	MedDRA	MedDRA 18.1	qa_admin	28-MAR-2018 02:22...	Completed	28-MAR-2018 02:2...
17	Finished	26-MAR-2018...	MedDRA	MedDRA 18.1	AecAdmin	26-MAR-2018 07:03...	Completed	26-MAR-2018 07:0...
16	Finished	16-MAR-2018...	MedDRA	MedDRA 18.0 2	qa_admin	16-MAR-2018 07:31...	Completed	16-MAR-2018 07:3...
15	Failed	16-MAR-2018...	MedDRA	MedDRA 18.0 2	qa_admin	16-MAR-2018 07:22...	Error: Msg 486...	16-MAR-2018 07:2...
14	Failed	16-MAR-2018...	MedDRA	MedDRA 18.0 2	qa_admin	16-MAR-2018 07:15...	Error: Msg 486...	16-MAR-2018 07:1...
13	Finished	16-MAR-2018...	MedDRA	MedDRA 18.0	qa_admin	16-MAR-2018 07:00...	Completed	16-MAR-2018 07:0...
12	Failed	13-MAR-2018...	WhoDrug C	WHODrugC A...	AecAdmin	13-MAR-2018 01:44...	Error: Msg 867...	13-MAR-2018 01:4...
11	Finished	13-MAR-2018...	MedDRA	MedDRA 16.1	qa_admin	13-MAR-2018 01:14...	Completed	13-MAR-2018 01:1...
10	Finished	13-MAR-2018...	WhoDrug B3	WhoDrugB3 M...	qa_admin	13-MAR-2018 12:22...	Completed	13-MAR-2018 12:2...
9	Finished	12-MAR-2018...	WhoDrug B2	WhoDrugB2 J...	qa_admin	12-MAR-2018 06:23...	Completed	12-MAR-2018 06:2...
8	Finished	12-MAR-2018...	WhoDrug B2	WhoDrugB2 S...	qa_admin	12-MAR-2018 06:22...	Completed	12-MAR-2018 06:2...
7	Finished	12-MAR-2018...	WhoDrug B2	WhoDrug Sep...	qa_admin	12-MAR-2018 05:09...	Completed	12-MAR-2018 05:0...
6	Finished	12-MAR-2018...	WhoDrug C3	WhoDrugC3 M...	AecAdmin	12-MAR-2018 02:29...	Completed	12-MAR-2018 02:2...
5	Finished	12-MAR-2018...	WhoDrug C	WhoDrugC Ma...	AecAdmin	12-MAR-2018 02:29...	Completed	12-MAR-2018 02:2...
4	Finished	12-MAR-2018	WhoDrug B3	WhoDrugB3 M	AecAdmin	12-MAR-2018 02:28	Completed	12-MAR-2018 02:2

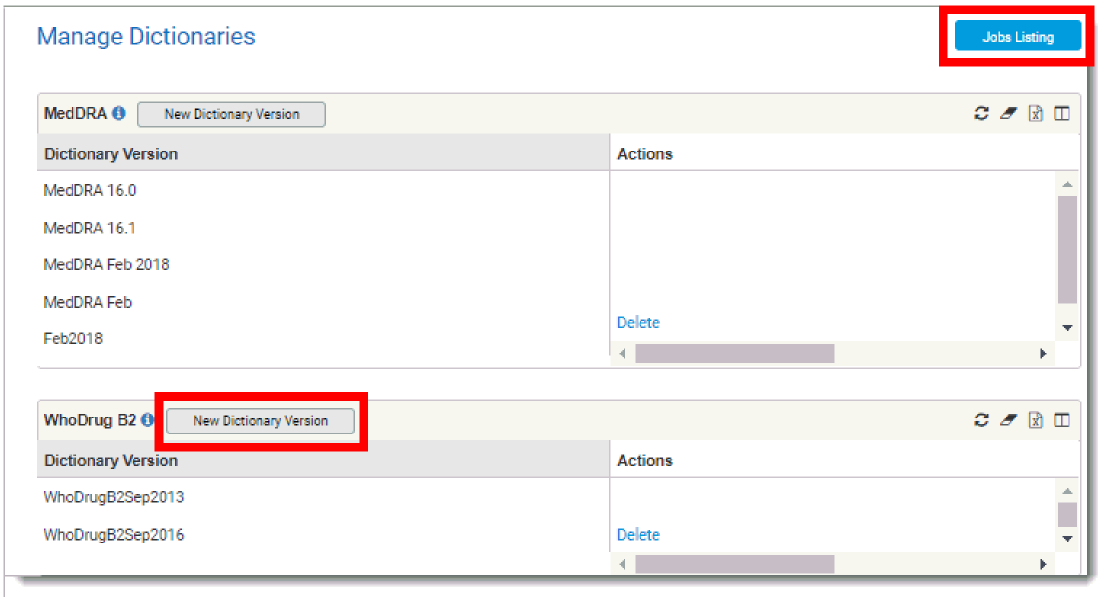
Note: You can sort and filter a table or export it to Excel. Various table options are also available. (See Use Table Functions.)

11.2 Add New Dictionary Version

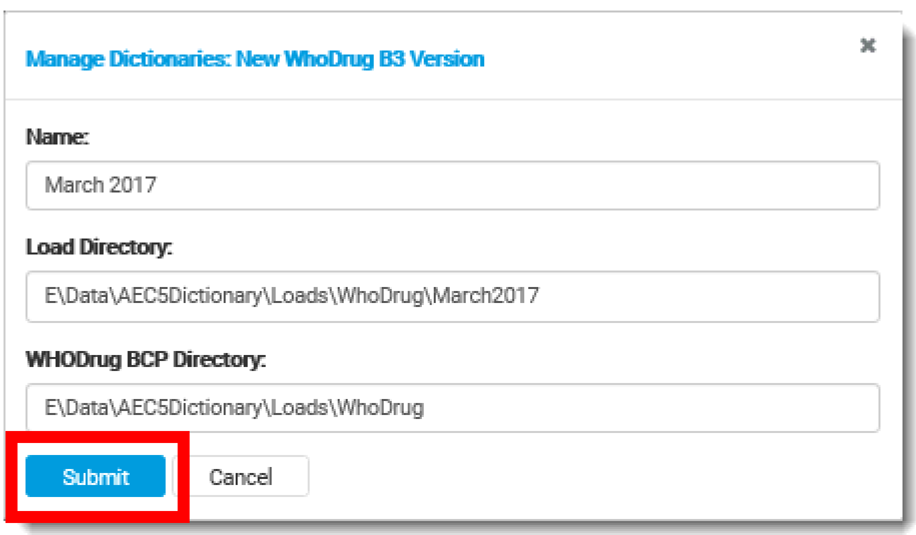
You can add a dictionary version if you have permission.

To add a dictionary version:

1. Access the Manage Dictionaries page. (See View Dictionaries for guidance.)
2. Click the **New Dictionary Version** button.



The New Dictionary Version dialog displays.



3. Enter the dictionary name and load directories. The load names must be unique and the directory must exist on the SQL Server.
4. Click the **Submit** button to submit a job to load the dictionary from the source files in the load directory.

   The new dictionary version displays in the Manage Dictionaries page.

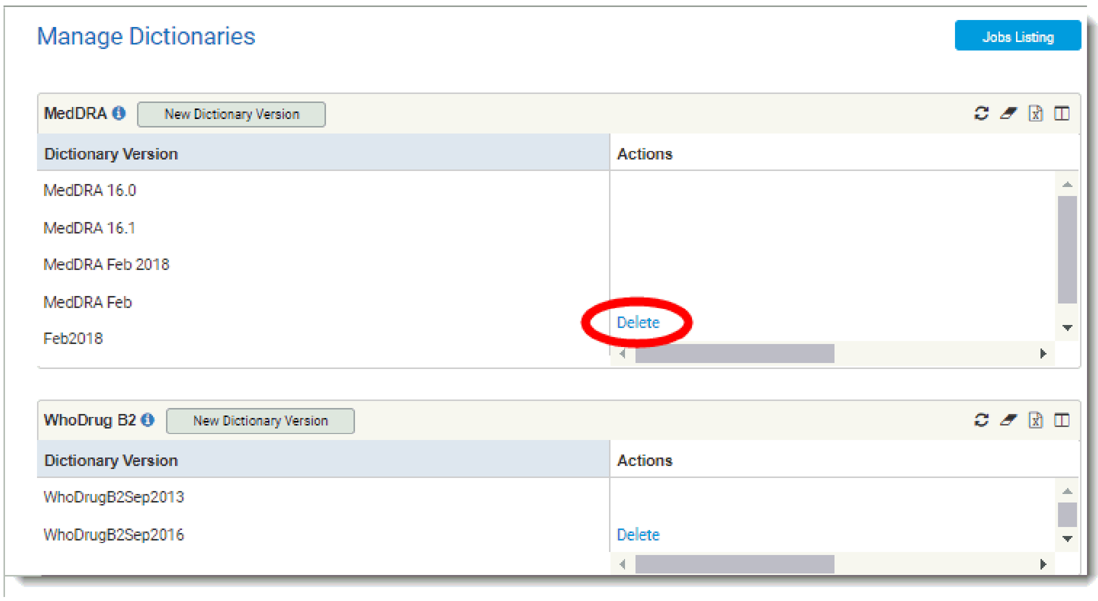
5. To view the load status of the dictionary version, click the **Jobs Listing** button in the top left corner of the Manage Dictionaries page.

11.3 Delete Dictionary Version

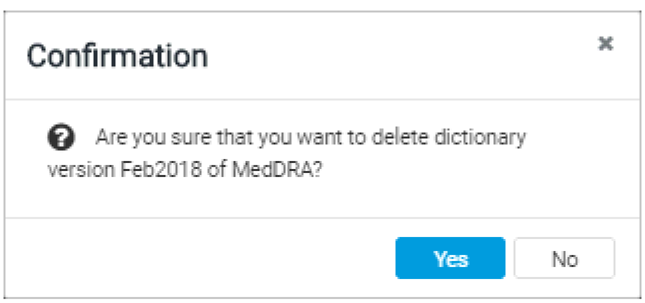
The System User/System Admin can delete the last dictionary version, as long as it is not mapped to anything.

To delete a dictionary version:

1. Access the Manage Dictionaries page. (See View Dictionaries for guidance.)
2. Click the **Delete** link under the Actions column.



3. Click the **Yes** button when the Confirmation message displays.



A confirmation message displays at the top of the page and the dictionary version no longer displays.

SYNONYM LISTS

12.0 Manage Synonym Lists

You can manage synonym lists in the following ways:

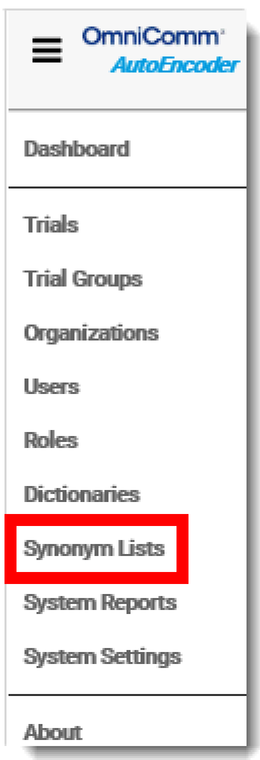
- View synonym lists
- Edit/add synonym lists
- Delete synonym lists
- Import/export synonym list
- Manage synonym terms

12.1 View Synonym Lists

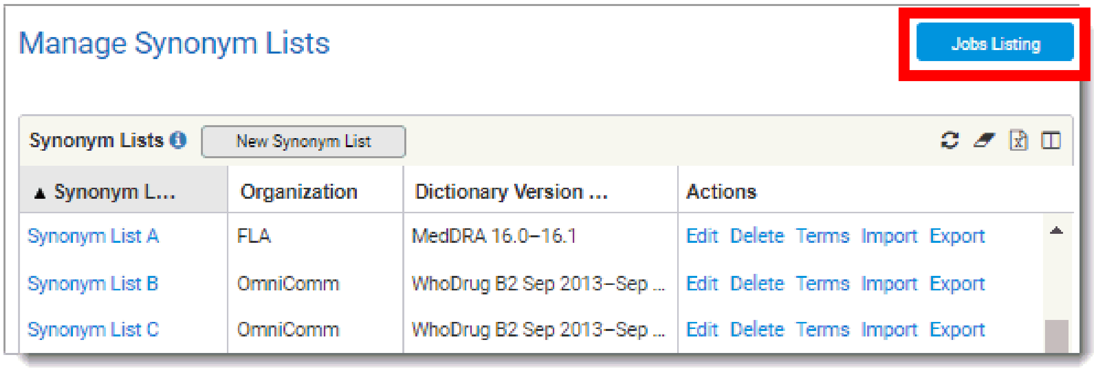
You can view details about each synonym list, including the job status, progress, type, and user.

To view synonym lists:

1. Click the  **Main Menu** icon (top left).
2. Select **Synonym Lists** from the drop-down list.

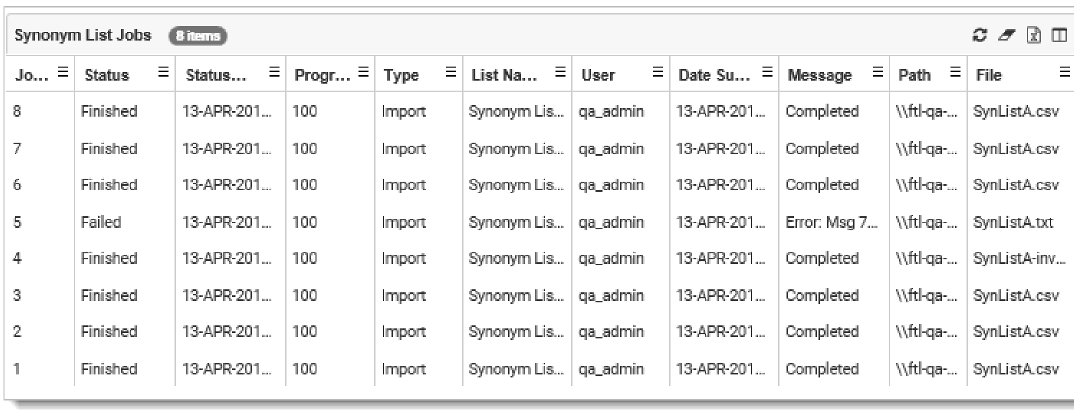


The Manage Synonym Lists page displays each synonym list name, its organization and dictionary version, and the allowed user actions.



3. To view the synonym list jobs, click the **Jobs Listing** button.

   The Synonym List Jobs page displays the job id, status (Submitted, Processing, Failed, or Finished), progress (0 to 100%), type (import or export), list name (synonym list name), user, date submitted, message (Completed or error), and file path/name. You can export this information to an Excel file by clicking the **Export to Excel** icon.


Synonym List Jobs 8 items

Jo...	Status	Status...	Progr...	Type	List Na...	User	Date Su...	Message	Path	File
8	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA.csv
7	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA.csv
6	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA.csv
5	Failed	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Error: Msg 7...	\\ftl-qa-...	SynListA.txt
4	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA-inv...
3	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA.csv
2	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA.csv
1	Finished	13-APR-201...	100	Import	Synonym Lis...	qa_admin	13-APR-201...	Completed	\\ftl-qa-...	SynListA.csv

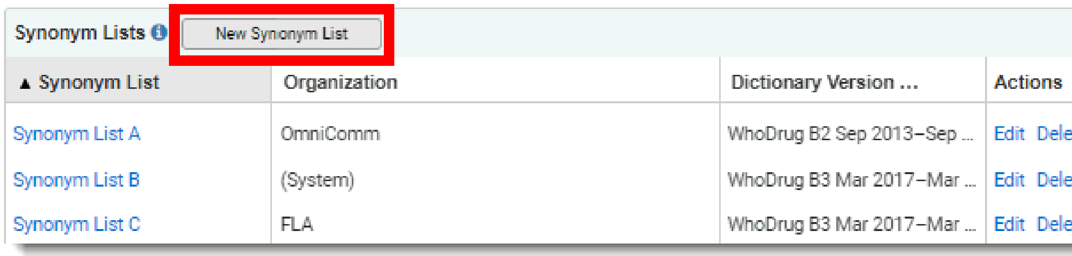
Note: You can sort and filter the table. Various table options are also available. (See Use Table Functions.)

12.2 Edit/Add Synonym Lists

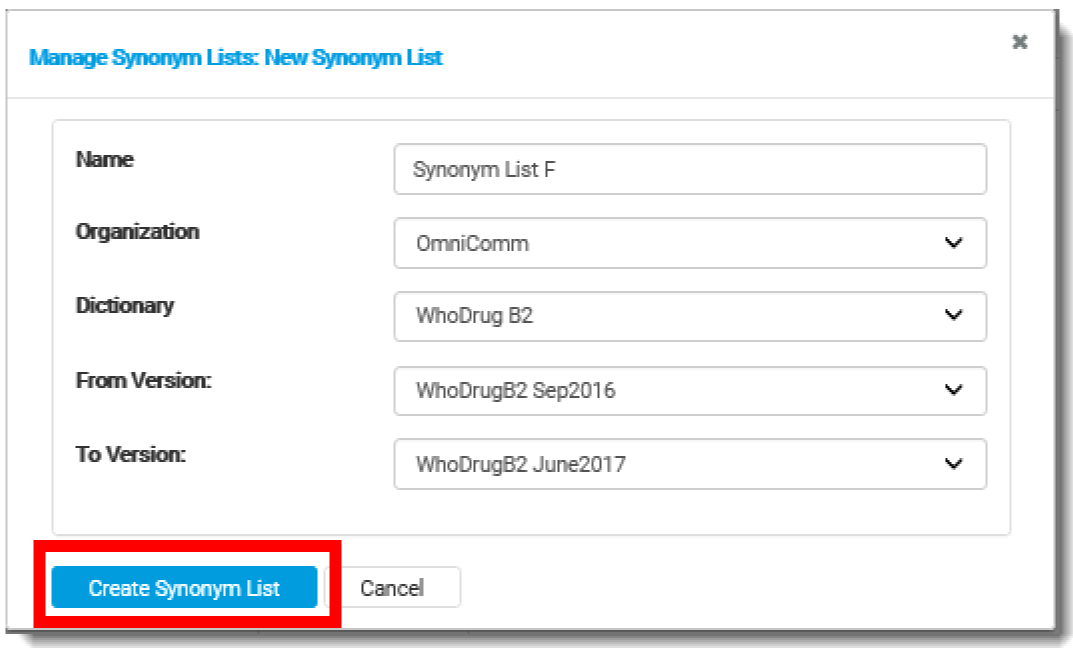
You can edit/add a synonym list if you have permission.

To edit/add a synonym list:

1. Access the Manage Synonym Lists page. (See View Synonym Lists for guidance.)
2. Click one of the following:
   - A name under the Synonym List column – to edit a synonym list
   - **New Synonym List** button – to add a new synonym list



The Edit/New Synonym List dialog displays.



3. Enter/enter the synonym list name and select the organization, dictionary, and from and to versions from the drop-down lists.
4. Click one of the following buttons:
   - **Update Synonym List** – to save your edits
   - **Create Synonym List** – to save the new synonym list

   The edited/new synonym list displays in the Manage Synonym Lists page.

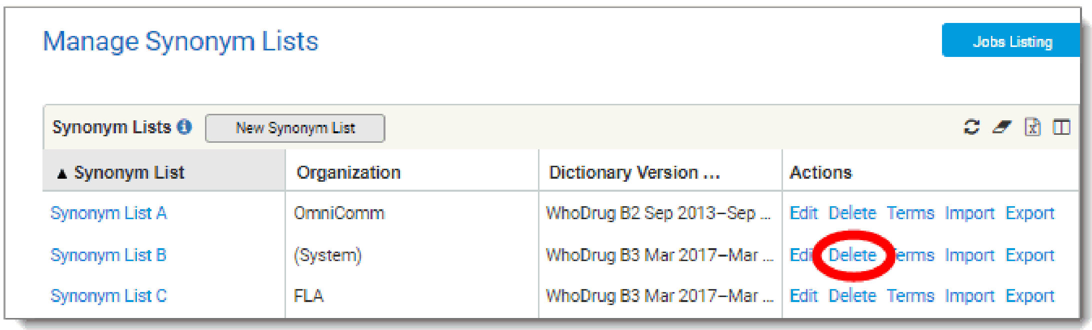
12.3 Delete a Synonym List

You can delete a synonym list if you have permissions to edit synonyms.

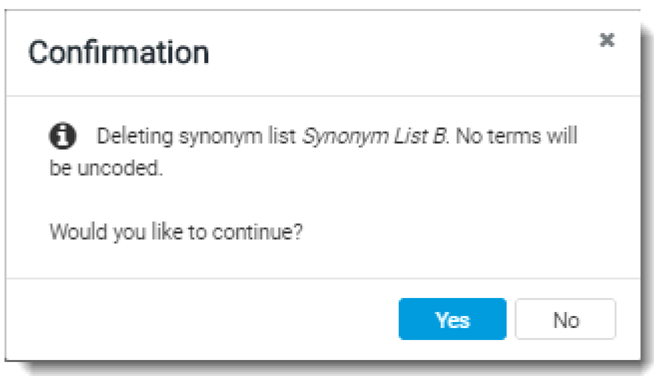
Note: If the synonyms are being used by a coded term, they are automatically uncoded.

To delete a synonym list:

1. Access the Manage Synonym Lists page. (See View Synonym Lists for guidance.)
2. Click the **Delete** link of the applicable synonym list under the Actions column.



The Confirmation message displays, indicating no terms will be uncoded.



3. Click the **Yes** button to confirm the deletion.
   The synonym list no longer displays in the Manage Synonym Lists page.

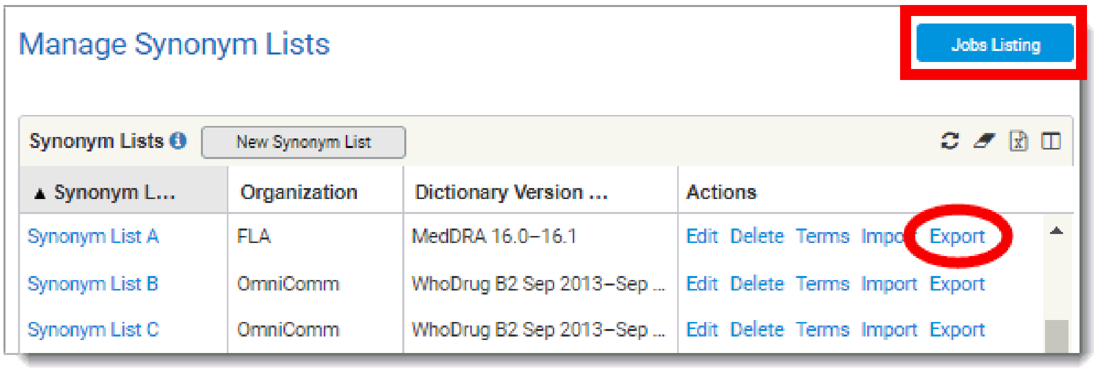
12.4 Import/Export Synonym List Information

You can import/export synonym list information to a specific file location on the SQL Server.

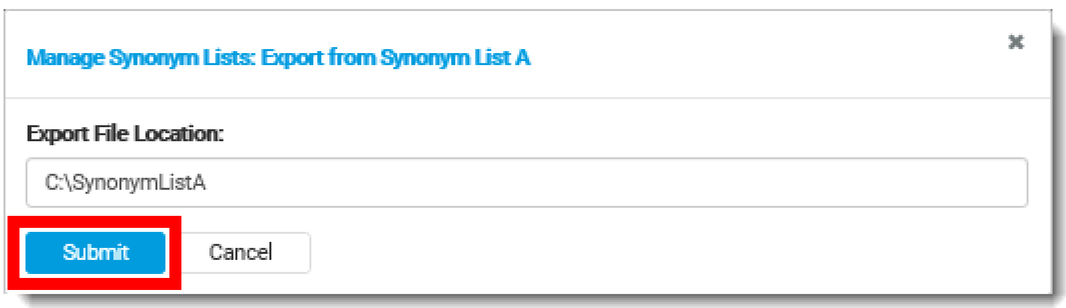
Note: Only a System User/System Admin can export synonyms.

To import/export synonym list information:

1. Access the Manage Synonym Lists page. (See View Synonym Lists for guidance.)
2. Click the **Import/Export** link under the Actions column.



The Import/Export Synonym List dialog displays.



3. Enter the import/export file location.
4. Click the **Submit** button.

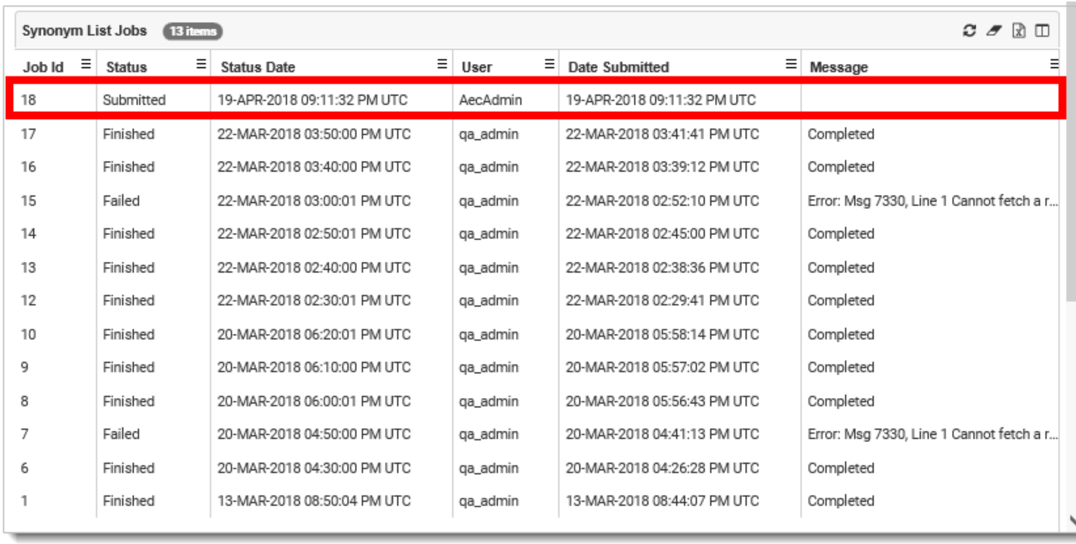
   A confirmation message displays at the top of the page, indicating the export job has started.

   The exported file contains the synonym term and up to 5 Ref fields mapped to the Primary Keys for the following:

   - MedDRA LLT Code, PT Code, HLT Code, HLGT Code, SSOC Code
   - WhoDrug B is the Drug Record Number, SEQ No1, SEQ No2, Country, plus all ATC Codes
   - WhoDrug C is the Medicinal Product ID plus all ATC Codes

5. To view the status of the import/export job, click the **Jobs Listing** button.

   The Synonym List Jobs page displays the new the import/export job, including the status (Submitted, Processing, Failed, or Finished) and progress (0 to 100%) of the import/export.



Synonym List Jobs 13 items

Job Id	Status	Status Date	User	Date Submitted	Message
18	Submitted	19-APR-2018 09:11:32 PM UTC	AecAdmin	19-APR-2018 09:11:32 PM UTC	
17	Finished	22-MAR-2018 03:50:00 PM UTC	qa_admin	22-MAR-2018 03:41:41 PM UTC	Completed
16	Finished	22-MAR-2018 03:40:00 PM UTC	qa_admin	22-MAR-2018 03:39:12 PM UTC	Completed
15	Failed	22-MAR-2018 03:00:01 PM UTC	qa_admin	22-MAR-2018 02:52:10 PM UTC	Error: Msg 7330, Line 1 Cannot fetch a r...
14	Finished	22-MAR-2018 02:50:01 PM UTC	qa_admin	22-MAR-2018 02:45:00 PM UTC	Completed
13	Finished	22-MAR-2018 02:40:00 PM UTC	qa_admin	22-MAR-2018 02:38:36 PM UTC	Completed
12	Finished	22-MAR-2018 02:30:01 PM UTC	qa_admin	22-MAR-2018 02:29:41 PM UTC	Completed
10	Finished	20-MAR-2018 06:20:01 PM UTC	qa_admin	20-MAR-2018 05:58:14 PM UTC	Completed
9	Finished	20-MAR-2018 06:10:00 PM UTC	qa_admin	20-MAR-2018 05:57:02 PM UTC	Completed
8	Finished	20-MAR-2018 06:00:01 PM UTC	qa_admin	20-MAR-2018 05:56:43 PM UTC	Completed
7	Failed	20-MAR-2018 04:50:00 PM UTC	qa_admin	20-MAR-2018 04:41:13 PM UTC	Error: Msg 7330, Line 1 Cannot fetch a r...
6	Finished	20-MAR-2018 04:30:00 PM UTC	qa_admin	20-MAR-2018 04:26:28 PM UTC	Completed
1	Finished	13-MAR-2018 08:50:04 PM UTC	qa_admin	13-MAR-2018 08:44:07 PM UTC	Completed

Note: You can sort and filter the table. Various table options are also available. (See Use Table Functions.)

12.5 Manage Synonym Terms

You can manage synonym terms in the following ways:

- Add (assign) synonym terms to synonym lists
- Delete synonym terms

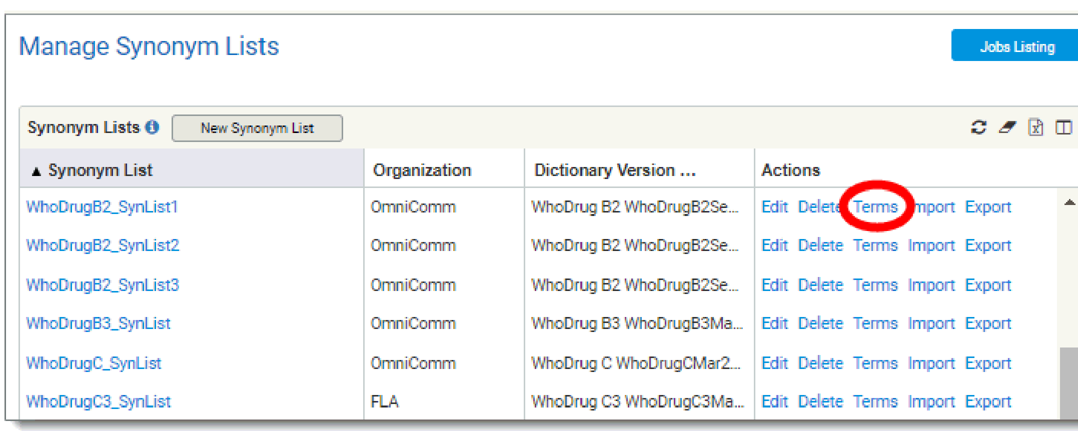
12.5.1 Add Synonym Terms

You can add synonym terms and assign them to a synonym list.

Note: Only one synonym is allowed per verbatim term.

To add a synonym term:

1. Access the Manage Synonym Lists page. (See View Synonym Lists for guidance.)
2. Click the **Terms** link of the applicable synonym list under the Actions column.

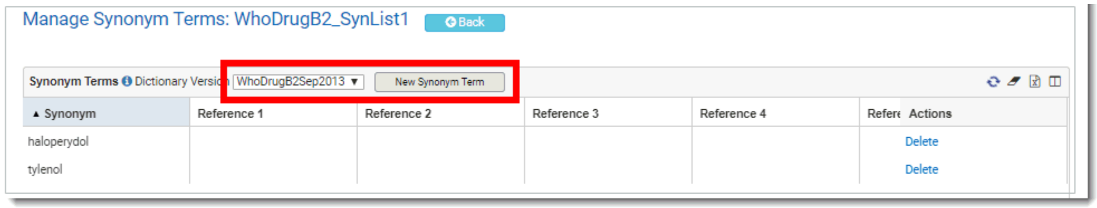


Manage Synonym Lists
Jobs Listing
Synonym Lists New Synonym List

▲ Synonym List	Organization	Dictionary Version ...	Actions
WhoDrugB2_SynList1	OmniComm	WhoDrug B2 WhoDrugB2Se...	Edit Delete Terms Import Export
WhoDrugB2_SynList2	OmniComm	WhoDrug B2 WhoDrugB2Se...	Edit Delete Terms Import Export
WhoDrugB2_SynList3	OmniComm	WhoDrug B2 WhoDrugB2Se...	Edit Delete Terms Import Export
WhoDrugB3_SynList	OmniComm	WhoDrug B3 WhoDrugB3Ma...	Edit Delete Terms Import Export
WhoDrugC_SynList	OmniComm	WhoDrug C WhoDrugCMar2...	Edit Delete Terms Import Export
WhoDrugC3_SynList	FLA	WhoDrug C3 WhoDrugC3Ma...	Edit Delete Terms Import Export

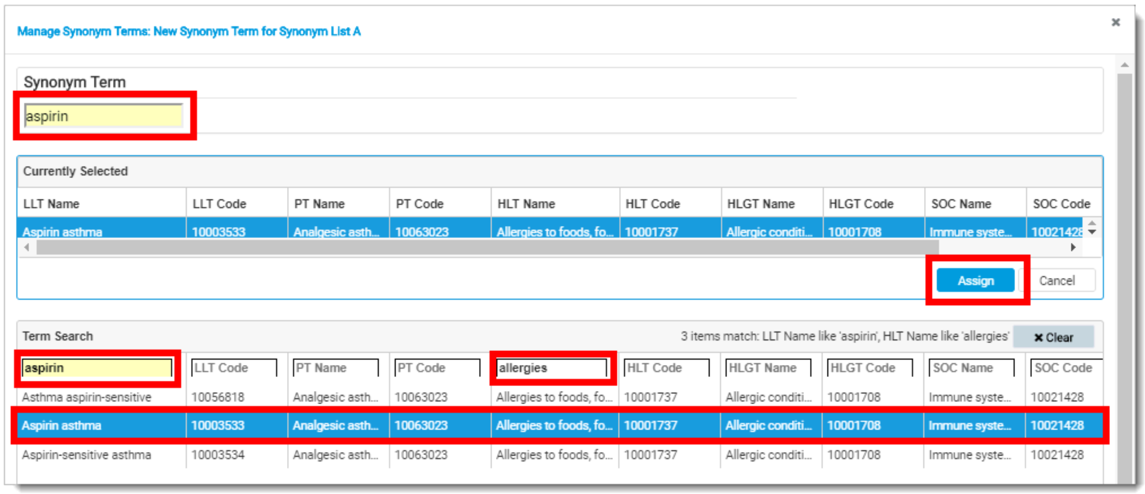
3. Select the **Dictionary Version** from the drop-down list.

The Manage Synonym Terms page displays a list of synonym terms if any exist.



4. Click the **New Synonym Term** button.

   The New Synonym Terms page displays.



5. Enter the **Synonym Term** and **Reference Terms** (if applicable) in the top portion of the page. (You may enter up to 5 reference terms.)

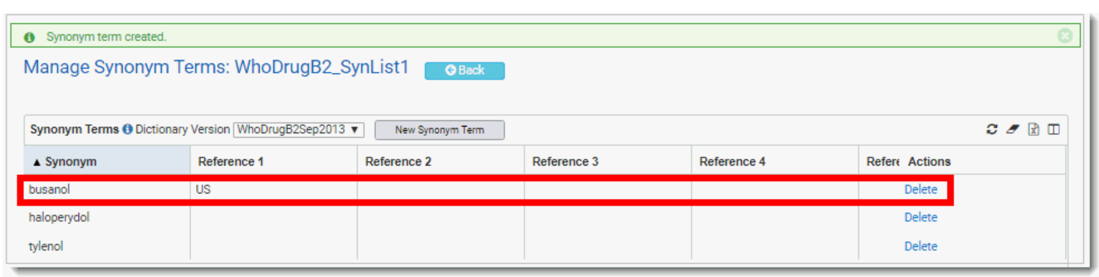
6. Type the applicable search parameters in the corresponding fields and tab out or press the ENTER key on your keyboard. For example, to search for busonal terms relating to respiratory, type "busonal" in the Drug Name field and "respiratory" in the ATC Level 1 Name field (as shown in the example above).

Note: You can clear the search by clicking on the **Clear** button.

7. Choose one of the search results by clicking on the item so that it becomes highlighted.

8. Click the **Assign** button in the right middle portion of the page.

   The Manage Synonym Terms page displays a confirmation message and the new synonym term.



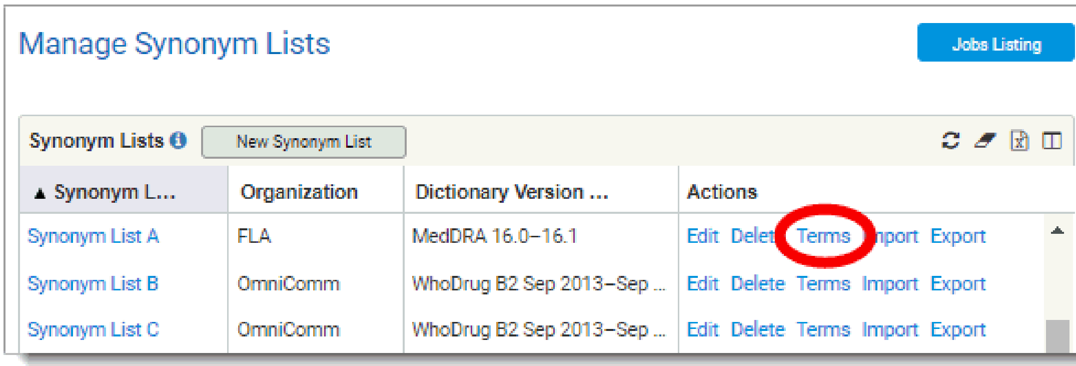
Note: You can sort and filter the table. Various table options are also available. (See Use Table Functions.)

12.5.2 Delete Synonym Terms

You can delete synonym terms that have been assign them to a synonym list.

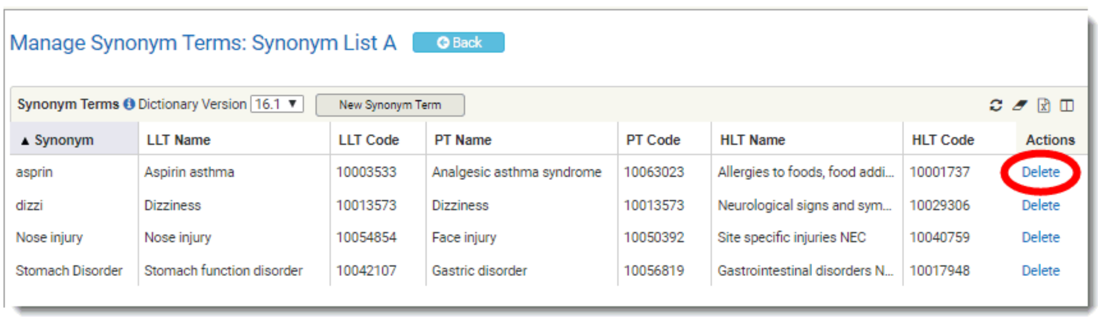
To delete a synonym term:

1. Access the Manage Synonym Lists page. (See View Synonym Lists for guidance.)
2. Click the **Terms** link of the applicable synonym list under the Actions column.

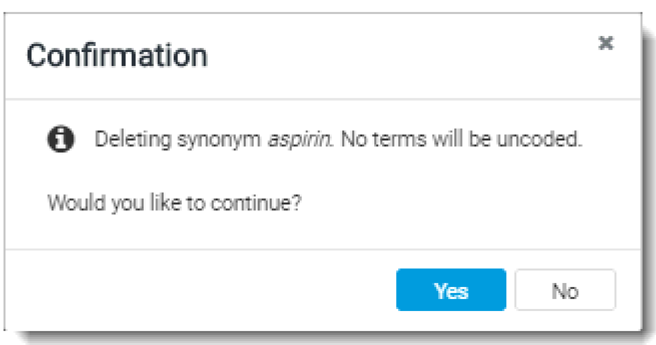


The Manage Synonym Terms page displays.

3. Click the **Delete** link of the applicable synonym term under the Actions column.



The Confirmation message displays, indicating no terms will be uncoded.



4. Click the **Yes** button to confirm the deletion.

   The synonym list no longer displays in the Manage Synonym Terms page.

SYSTEM REPORTS

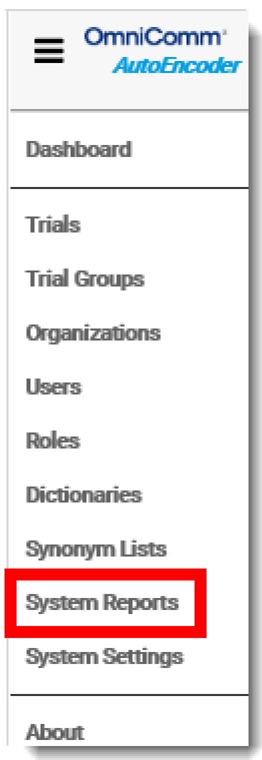
13.0 View System Reports

You can view the following system reports if you are a System Use/System Admin:

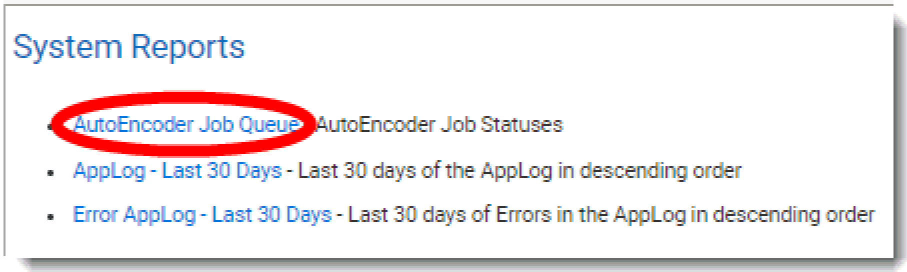
- Autoencoder Job Queue – AutoEncoder Job Statuses
- AppLog – Last 30 Days – last 30 days of the AppLog in descending order
- Error AppLog Last 30 Days – last 30 days of Errors in the AppLog in descending order
- Trials Currently Processed by AutoEncoder Service – current trials being processed by AECWSRV connected to that Autoencoder

To view a system report:

1. Click the **Main Menu** icon (top left).
2. Select **System Reports** from the drop-down list.

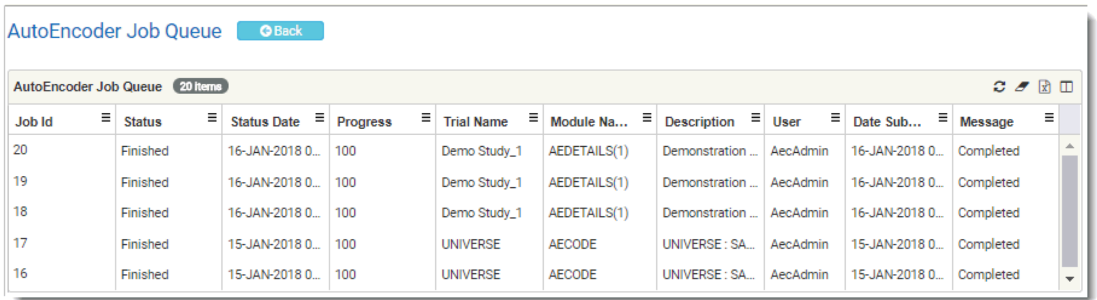


The System Reports page displays report links.



3. Click on the applicable report link.

   The report displays. For example, the AutoEncoder Job Queue report (below).



AutoEncoder Job Queue Back

AutoEncoder Job Queue 20 Items

Job Id	Status	Status Date	Progress	Trial Name	Module Na...	Description	User	Date Sub...	Message
20	Finished	16-JAN-2018 0...	100	Demo Study_1	AEDETAILS(1)	Demonstration ...	AecAdmin	16-JAN-2018 0...	Completed
19	Finished	16-JAN-2018 0...	100	Demo Study_1	AEDETAILS(1)	Demonstration ...	AecAdmin	16-JAN-2018 0...	Completed
18	Finished	16-JAN-2018 0...	100	Demo Study_1	AEDETAILS(1)	Demonstration ...	AecAdmin	16-JAN-2018 0...	Completed
17	Finished	15-JAN-2018 0...	100	UNIVERSE	AECODE	UNIVERSE : SA...	AecAdmin	15-JAN-2018 0...	Completed
16	Finished	15-JAN-2018 0...	100	UNIVERSE	AECODE	UNIVERSE : SA...	AecAdmin	15-JAN-2018 0...	Completed

Note: You can sort and filter the report or export it to Excel. Various table options are also available. (See Use Table Functions.)

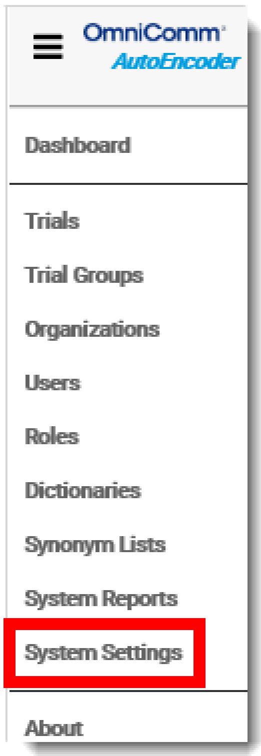
SYSTEM SETTINGS

14.0 View/Edit System Settings

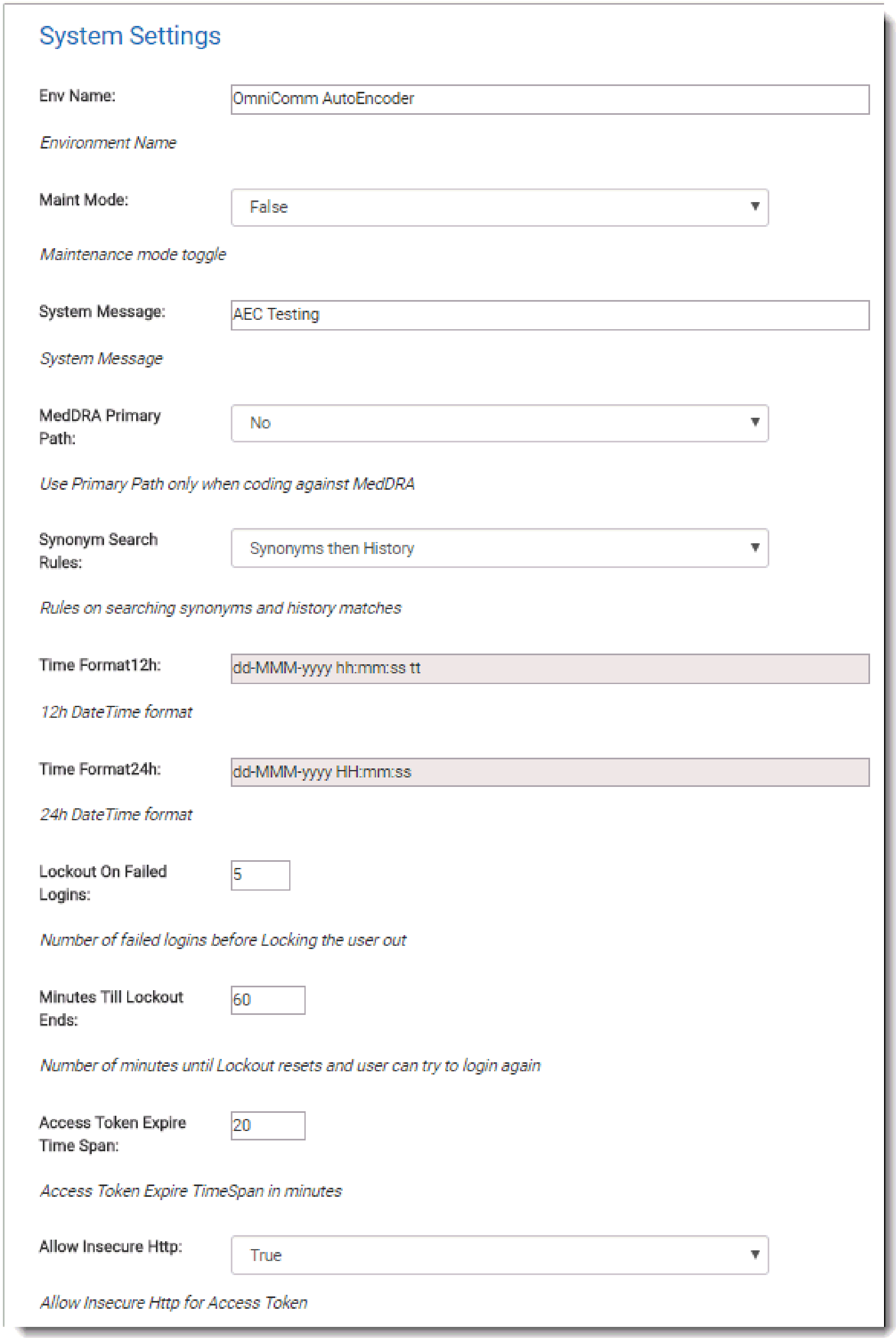
You can view/edit system-wide settings. You can only edit these settings if you are a System User/System Admin.

To view/edit system-wide settings:

1. Click the **Main Menu** icon (top left).
2. Select **System Settings** from the drop-down list.



The System Settings page displays the default value for each setting. These settings cascade to objects (trials, trial groups, organizations). Settings that are set at the object level override any system settings. (See Edit Object Settings for more information.)


System Settings
Env Name:
OmniComm AutoEncoder
Environment Name
Maint Mode:
False
Maintenance mode toggle
System Message:
AEC Testing
System Message
MedDRA Primary Path:
No
Use Primary Path only when coding against MedDRA
Synonym Search Rules:
Synonyms then History
Rules on searching synonyms and history matches
Time Format12h:
dd-MMM-yyyy hh:mm:ss tt
12h DateTime format
Time Format24h:
dd-MMM-yyyy HH:mm:ss
24h DateTime format
Lockout On Failed Logins:
5
Number of failed logins before Locking the user out
Minutes Till Lockout Ends:
60
Number of minutes until Lockout resets and user can try to login again
Access Token Expire Time Span:
20
Access Token Expire TimeSpan in minutes
Allow Insecure Http:
True
Allow Insecure Http for Access Token

3. To edit a setting, enter the information or select it from the drop-down lists. (Read-only fields are disabled and greyed out.)

   The description is provided below each field in the System Settings page. The following provides more detail about these settings:

   - Env (Environment) Name – the name you choose for this installation of AutoEncoder. This is used as an identifying label in places like the About page (click ☰ > **About**)
   - Maint (Maintenance) mode – used for maintenance issues. If set to True, regular users are blocked from logging in. System Users (System Admins) can still login.
   - System Message – text that displays in the About AutoEncoder page. This also shows on the About page, and is used in addition to the default Maintenance Mode message shown to users on the Login page.
   - MedDRA Primary Path – if this is set to 'Yes', then for all MedDRA dictionaries, only entries marked as Primary Path are used for coding across the entire application.
   - System Search Rules – allows the administrator to set the priority of synonyms and histories when making autocoding decisions. You can select to use History only, Synonyms only, or use both with differing priorities (History then Synonyms, Synonyms then History). The settings are as follows:
     - None – only display results from dictionary
     - History only – only display History first and then dictionary results
     - Synonyms only – only display synonyms first and then dictionary results
     - Synonyms then History – display synonyms first, then history and lastly dictionary results
     - History then Synonyms – display history first, then synonyms and lastly dictionary results
   - Time Format12h/24h – date format used across the application for users who have selected to display twelve-hour/twenty-four-hour format for dates and/or times. *For example, "User A" could have the 12-hour format and "User B" could have the 24-hour format.*
   - Lockout on Failed Logins – an integer ranging from 1 to 15 that indicates how many unsuccessful login attempts a user can make before the system automatically locks that user out.
   - Minutes Till Lockout Ends – an integer ranging from 0 to 1440 that indicates that a user who has been locked out due to too many unsuccessful login attempts must wait this amount of time before the system unlocks their account. If set to 0, only a System User/System Admin or a Super User for people in his/her organization can unlock.
   - Access Token Expire Time Span – indicates the time-to-live for the AutoEncoder API access token, and may range from 10 to 1440 minutes.
   - Allow Insecure HTTP – allows insecure HTTP for access token. If set to False, then HTTPS must be used. Therefore on a production system it would be false to enforce HTTPS links to the API.
   - Username Reg Ex – validation pattern used for allowable user names in the application. It is not alterable in the current version of AutoEncoder.
   - Username Warning – message shown when a proposed user name does not match the Username Reg Ex pattern.
   - Password Reg Ex – validation pattern used for allowable user passwords in the application. It is not alterable in the current version of AutoEncoder.
   - Password Warning – message shown when a proposed user password does not match the Password Reg Ex pattern.

- History Scope – application-wide setting that determines on what level trials keep their coding history: unshared (kept at their own trial level), Organization (all trials store their history in their organization, which is then available to all trials under that organization), or Group (all trials store their history in their trial group, if they have one, which is then available to all trials under that trial group). This "global" application scope can be overridden at the Organization, Trial Group or individual Trial levels.
- Auto Review Approve – If set to TRUE, then all trials in the application (unless overridden) only present one grid on their Coding Page, the 'Coding Grid'. Any entries in the coding grid are sent immediately to the Transmission Queue on confirmation, rather than having to pass through the Review and Approval stages.
- Days Till Password Expires – User passwords last this many days before expiring. This is an integer ranging from 0 to 365. Setting the password expiry to 0 disables all expiration.
- Password Days Warning: This is the number of days prior to password expiration that the user will start being warned of the approaching expiration and is encouraged to change their password. It is an integer ranging from 1 to 10.
- Pass (Password) Gen (Generation) Length: The system generates random passwords for new users and users who have forgotten their passwords. This setting is used to determine how many characters the random password should use. It is not alterable in this version of AutoEncoder.
- Password Generation Use Upper Alpha: This Boolean value determines whether or not the random password generator uses uppercase characters. It is not alterable in this version of AutoEncoder.
- Password Generation Use Lower Alpha: This Boolean value determines whether or not the random password generator uses lowercase characters. It is not alterable in this version of AutoEncoder.
- Password Generation Use Numbers: This Boolean value determines whether or not the random password generator uses numeric characters. It is not alterable in this version of AutoEncoder.
- Password Generation Use Punctuation: This Boolean value determines whether or not the random password generator uses any available non-alphanumeric characters. It is not alterable in this version of AutoEncoder.
- Include Time Zone Information: This Boolean setting determines whether or not specific time zone settings are included in timestamps used and displayed by the application.

4. Click the **Save Settings** button on the bottom of the System Settings page.