

8 Administration

The Administration module is available only to <u>users with appropriate permission</u>. You can perform the following tasks only from the Administration module:

- Create and remove Studies
- Create, remove, and monitor the activity of users
- Configure lockout parameters
- Perform certain actions for users, Subjects, and CRFs across Studies
- Schedule jobs

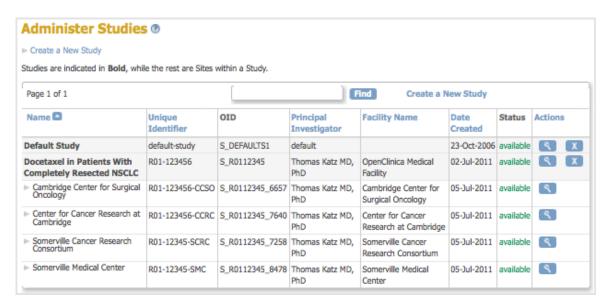
Approved for publication by Ben Baumann. Signed on 2014-03-24 8:46AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

8.1 Administer Studies

In the Administration module, use the Studies features to view all Studies and Sites, create new Studies, remove existing Studies, and restore Studies that were previously removed.

Perform these tasks from the Administer Studies page. To access the page, select Tasks > Administer Studies. The Administer Studies page opens, listing all existing Studies and Sites.



If you want more information about any of the terms in this table, see the <u>Study Setup module</u>. The Study Setup module is also where you make changes to Studies, using its Build Study features.

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:46AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

8.1.1 Create a Study

To create a new Study:

- Select Tasks > Studies.
 The Administer Studies page opens.
- 2. Click Create a New Study (located near the top of the page).

 The Create a New Study page opens, showing the fields in Section A: Study Description.



- 3. Complete at least the required fields. Click any field name that is a link if you want to view its definition at the <u>clinicaltrials.gov</u> website, or you can view descriptions in <u>Create Study Edit Details</u>. Information you enter now can be modified later. While only users with certain permissions can create a Study, additional user Roles and Types typically have permission to complete the fields or modify the information once the Study exists. As part of this step, you can provide access to an existing user who has a Data Manager or Study Director Role in OpenClinica; later you can change that user's access to the Study.
- Click the Save button.

The Administer Studies page opens, and the table now includes the Study you added. The Study Status reported in the table is "pending" because the Study is in the Design state; the Status will be changed to Available as part of the <u>Study Setup process</u>.

8.1.1.1 Re-Using Elements from One Study in Another Study

You cannot replicate an existing Study and just customize the items for the new Study. However, there are some ways to leverage what you've already done for other Studies when you create a new Study.

- You can use CRFs in multiple Studies. You can utilize CRFs for an existing Study as is, or make new versions with customizations for the new Study.
- You can assign existing users to multiple Studies. The user's Role in the new Study can be different than in existing Studies.
- You can use Rules in multiple Studies.
- You can refer to the Study Metadata from a Study to help ensure you are creating all the elements you want from it in the new Study.

8.1.2 Remove or Restore a Study

If a Study is being stopped, for example, to change protocols or to end it, you can remove the Study by clicking the Remove icon in the Actions column of the <u>Administer Studies table</u>. The Study Status changes to "removed," and all the Sites, Users and Roles, Study Event Definitions, and Study Subjects change to a Status of "removed" in the OpenClinica system. The Study information is still available, but nothing can be edited or added for the Study. A Study that has been removed is listed in the Administer Studies table, where you can view Study details or restore the Study, but you cannot access it using features in any of the other modules.

You can restore a Study that has been removed by clicking the Restore icon in the Actions column of the Administer Studies table. When the study is restored, the status of the Sites, Study Event Definitions, Users and Roles, and Study Subjects are also restored.

8.2 Administer Users

In the Administration module, the Administer Users page is where you add new users to the system, view information about users across Studies, remove and restore user accounts from the system, monitor user access, and configure lockout parameters. You can also assign users to Studies and Sites, as well as remove or restore them. Configure Password Requirements feature that allows user to define a password strength policy have been added in OpenClinica 3.1.3. To access the Administer Users page, from the Tasks menu, in the Administration module, select Users.

For important background information, see <u>About User Roles and Types</u>, and <u>Permissions for User Roles and Types</u>.

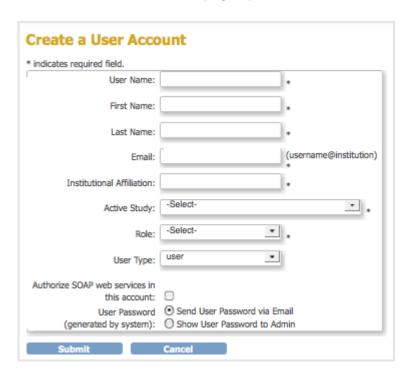
Approved for publication by Ben Baumann. Signed on 2014-03-24 8:46AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

8.2.1 Create a New User

Create a new user when someone needs to work with your OpenClinica system and they have not worked with it before. To create a new user:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. Click the Create New User link (near the top of the page). The Create a User Account page opens.



- 3. Complete the fields. For information about the fields, see <u>About User Information in the Administration Module</u>.
- 4. Click Submit.

The View User Account page opens, presenting the information for the user you just created. The Alerts and Messages sidebar panel reports that you successfully added the user, and if you selected the option "Show User Password to Admin", reports the system-generated, temporary password; record the password to provide to the user.

8.2.2 About User Information in the Administration Module

The following information is helpful when working with user accounts in the Administration module:

- **User Name:** At least five alphanumeric characters. Can include underscores (_). Is case-sensitive. Cannot be the same as any other user name in the system.
- Email: Address for the user. Required for messages that the OpenClinica system sends, such

as notification when a job completes, or a temporary password if the user requests a new password.

- **Status:** The status is "available" if the user can be assigned to Studies and Sites, or "removed" if the user has been removed from the OpenClinica system and cannot be assigned to Studies and Sites.
- Active Study: When you create a user, you assign them to a Study or Site, called the Active Study. After that, you can assign the user to more Studies or Sites, or remove the user from any Study or Site.
- User Type or Business Administrator/Technical Administrator: When you create a user, you assign them a User Type of "user," "business administrator," or "technical administrator." After creating the user, you can change the User Type. For more information, see About User Roles and Types.
- Roles: All Roles the user has in all Studies and Sites in the OpenClinica system. When you first create a user, you assign them a role to the Active Study. After that, you can assign the user to different Roles at other Studies and to Sites within the Studies, and you can change or remove the Role for each Study or Site the user is assigned to. For more information, see About User Roles and Types.
- Owner: The OpenClinica user who created the user whose information you are viewing.
- Authorize SOAP web services in this account: Select this option to allow the user to work on SOAP requests.
- **User Password:** The system generates an initial, temporary password for a new user. When you select the Send User Password via Email option, the system sends the password to the user's email address, which you specified as part of creating the user's account. When you select the Show User Password to Admin option, the system displays the password to you after you complete creating the user or resetting the user password.

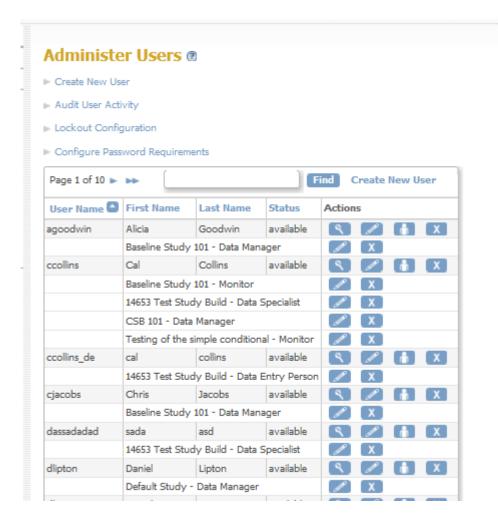
8.2.3 View and Modify User Information

Access the Administer Users page to view information about all users in your OpenClinica system. To access the page, from the Tasks menu, in the Administration module, select Users.

The Administer Users page includes a table that reports the Studies each user is assigned to and their Role in each Study. the table shows users for all Studies in your OpenClinica system, regardless of the current Study or Site. For more about the terms and values, see About User Information in the Administration Module.

For each user, there are at least two rows:

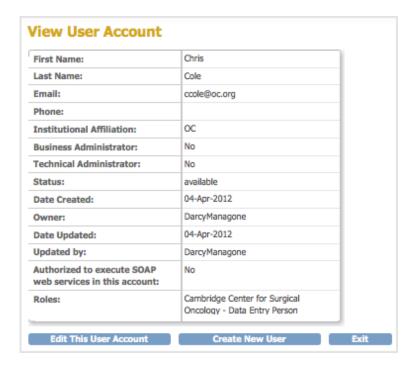
- The first row is for the user in the OpenClinica system.
- There are one or more rows for the user and their role at each Study or Site they are assigned to.



8.2.3.1 View User Information

If you want to view complete information about a user in your OpenClinica system:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. For the user whose information you want to view, click the View icon in the Actions column. The View User Account page opens; for more about the terms and values, see About User Information in the Administration Module.



8.2.3.2 Edit User Information

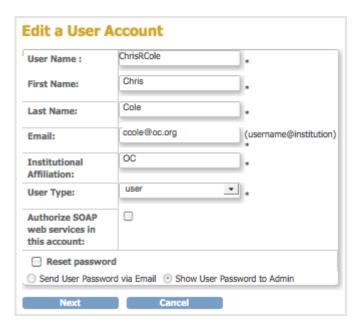
You can edit the following information about a user from the Administration module:

- First and Last Name
- Email address
- Institutional Affiliation
- User Type
- SOAP web services authorization
- User password (reset it to a new, temporary password)

For more about the terms and values, see About User Information in the Administration Module.

To edit the information:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. For the user whose information you want to edit, click the Edit icon in the main (first) row of the Actions column (not the Edit icon in any of the following rows for that user). The Edit a User Account page opens.



- 3. Change the available values and options (User Name cannot be edited). For details, see <u>About User Information</u>.
- 4. Click Next.
 - The Edit a User Account Confirmation Screen opens.
- 5. Verify that the information is correct, then click Confirm.

 The Administer Users page opens, and the Alerts and Messages sidebar panel reports the status of the user information update as successful or not.

8.2.3.3 Change User Role

To change the user Role for a Study or Site that the user is already assigned to, follow these steps.

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- For the user whose Role you want to change, click the Edit icon in the Actions column of the row for that Study or Site (not the first row in the table for that user).The Modify Role page for the user and Study or Site opens.



- 3. From the Role drop-down list, select the Role you want to assign to the user. If the user is currently assigned at the Site level, only Roles appropriate to the Site level display. Similarly, if the user is currently assigned to the Study level, only Roles appropriate to the Study level display.
- 4. Click Submit.

The Administer Users page opens, and the Alerts and Messages sidebar panel reports the status of the user role change as successful or not.

Note: You cannot use the above steps to change the user Role from a Site-level Role to a Study-level Role, or from a Study-level Role to a Site-level Role. Instead, add the new Role by following the steps in <u>Assign User to Study or Site and to Role</u>. The user can then have a Role at both the Study and Site levels, or you can remove the original Role by following the steps in <u>Remove or Restore User</u>.

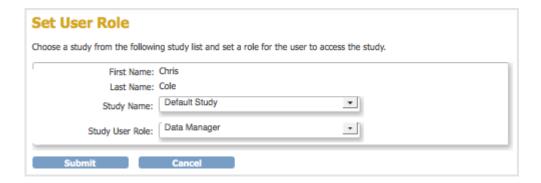
8.2.3.4 Assign User to Study or Site and to Role

From the Administration module, you can assign a user to a Role at any Study or Site that they are not already assigned to. This includes:

- Assigning a user to a Study where they are not currently assigned to the Study or any Sites within it.
- Assigning a user to a Site when they are not currently assigned to the parent Study and are not assigned to any other Sites within the Study.
- Assigning a user to a Site within a Study if they are already assigned at the Study level or to another Site in the Study.
- Assigning a user to the Study level if they are already assigned to one or more Sites within the Study.

To assign a user to a Study or Site:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. For the user you want to assign, click the Set Role icon in the Actions column. The Set User Role page opens for that user.



- 3. From the Study Name drop-down list, select the Study or Site to which you want to assign the user. The list does not include entries for Studies and Sites where the user is already assigned.
- 4. From the Study User Role drop-down list, select the user Role at the selected Study or Site. The list only includes Roles appropriate for the level (Study or Site) that you selected.
- Click Submit.
 The Administer User page opens. The table includes an entry for the assignment you just completed.

8.2.3.5 Remove or Restore User

Remove User from Study or Site

You can remove a user from a Study or Site so they can no longer access it:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. For the user you want to remove, click the Remove icon in the Actions column in that row for the user (not in the main row for the user).
- 3. Click OK in the confirmation window.

 The user is removed, but is still listed in the Administer Users table for that Study or Site with only a Restore icon in the Actions column.

You can also remove a user from the current Study or Site using the Study Setup module.

Remove User from System

Using the Administration module, you can remove a user from your OpenClinica system so that they cannot log in and cannot be assigned to any Studies or Sites.

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. For the user you want to remove, click the Remove icon in the main (first) row of the Actions column (not in any of the following rows) for that user.
- 3. Click OK in the confirmation window.

 The user is removed, but is still listed in the Administer Users table with only a Restore icon in the Actions column.

Restore User

After removing a user, you can restore the account so the user can regain access to the Site, Study, or the OpenClinica system. To restore a user:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. If the user you want to restore had been removed from all Studies and Sites:
 - 1. Click the Restore icon in the main (first) row of the Actions column (not in any of the following rows) for that user.
 - 2. Click OK in the confirmation window.

 The user is restored to the OpenClinica system.
 - 3. If the User Type is Business Administrator or Technical Administrator, reset the user's password or they will not be able to log in: for instructions, see Edit User Information. For User Type of User, the user can log in using the same password they used before being removed and restored.
- 3. Restore the user to the specific Study or Site to which you want them to regain access by clicking the Restore icon in the Actions column in that row for the user.
- 4. Click OK in the confirmation window.

 The user is restored to that Study or Site.

8.2.4 Monitor User Access

You can view all attempts users make to access OpenClinica, and for each attempt, whether they are

successful or not, the user name, and the date and time. To audit user activity:

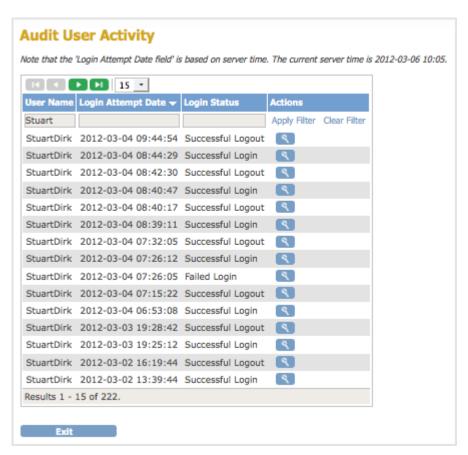
- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. Click the Audit User Activity link.

 The Audit User Activity page opens, presenting a table of all attempts to access OpenClinica.

You can sort the table by any of the columns by clicking the column header; click again to reverse the sort order in that column.

You can filter the list of attempts. Type a string in the filter field for one or more columns (the fields are directly beneath the column headers) and press Enter. The table shows only those attempts whose values match the strings you typed. After filtering, to show all entries again, click Clear Filter.

At the bottom of the page is the total number of pages that match your criteria. To view other pages, use the arrows at the top of the table. To change the number of attempts shown per page, select the value from the drop-down list that is located just above the table.



8.2.5 Configure Access to OpenClinica

To enhance system security, you can configure OpenClinica so that authorized users are only allowed a specified number of failed login attempts, and after that, they are locked out. By default, the feature is disabled. After a user has been locked out, you unlock them so they can successfully log in again.

8.2.5.1 Set Lockout Feature

To set the lockout feature:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. Click the Lockout Configuration link.
 The Lockout Configuration page opens:



- 3. To activate the lockout feature, set the Lockout Enabled value to TRUE.
- 4. For the # of Failed Attempts, enter a value between 1 and 25.
- 5. Click Submit.

 The system displays a confirmation message.

OpenClinica tracks the number of consecutive failed login attempts. After that number equals the value specified for the # of Failed Attempts, the user cannot log in to OpenClinica. For the user to regain access to OpenClinica, an administrator must unlock the user's account in the Administer Users interface.

8.2.5.2 Unlock a Locked-Out User

If a user fails to log in successfully more than the allowed number of times as specified via the lockout feature, you must unlock the user account using the Administration module. To unlock a user account:

- 1. From the Tasks menu, in the Administration module, select Users. The Administer Users page opens.
- 2. Click the Unlock icon in the Actions column for the user whose account you want to unlock.
 - The user account is unlocked. The unlock icon no longer appears in the Administer Users table.
- 3. The user can log in to OpenClinica again using the new, temporary password sent to the user's email account.

8.2.5.3 Additional Password Configuration Options

You can also specify these configuration options for managing user passwords in the datainfo.properties file:

• The default method for how a user receives their password, either via email or from the

business administrator.

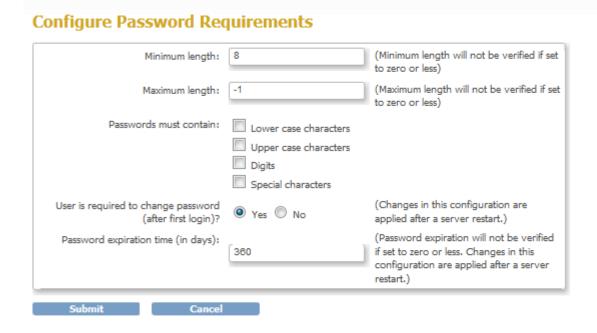
- If a user must change their password on the first log in.
- If a user's password should expire, and if so, the length of time until it expires.

For details, see Configuring the OpenClinica Application.

8.2.5.4 Configure Password Requirements

Starting with OpenClinica 3.1.3, in the Administration module, the Configure Password Requirements page allows an administrator to configure the password policy for your OpenClinica system. A password policy that forces users to use strong passwords makes your system less vulnerable to bruteforce attacks that try to guess a user's password.

To access the Configure Password Requirements page, from the Tasks menu, in the Administration module, select Users, then Configure Password Requirements.



In the Configure Password Requirements, you can define the values for the following options:

- **Minimum length**: minimum number of characters a password may contain. If this value is set to zero or any negative number, OpenClinica will not check the minimum length of the user's password. However, disabling the minimum password length does not allow an user account to have no password in this case valid password consists of at least one character.
- **Maximum length**: maximum number of characters a password may contain. If this value is set to zero or any negative number, OpenClinica will not check the maximum length of the user's password.
- Passwords must contain: Specify types of characters that must be present in a password.
 The character types groups are Lower Case Characters, Upper Case Characters, Digits and Special Characters. The following characters are considered special characters: ! @ # \$ % & * ()
- User is required to change password (after first login): Should the user be forced to change his password upon first login to OpenClinica. When OpenClinica creates a user account, a password is generated and sent via email to the email address configured in the

user's account or shown to the administrative user who created the account. This setting is used to ensure the user won't be able to use the system-generated password after the first login. A change in this configuration will be effective only after restarting the OpenClinica application server.

• Password expiration time (in days): Number of days after a password is set to be considered expired. Once a user authenticates to OpenClinica and their password is expired, the system will prompt the user to change their password. If this value is set to zero or any negative number, OpenClinica never consider a user's password expired. A change in this configuration will be effective only after restarting the OpenClinica application server.

8.3 Administer Subjects

The Administer Subjects features allow you to work with Subjects in all Studies in your OpenClinica system, and to make changes to a Subject record that you cannot make using the <u>Subject Matrix</u>.

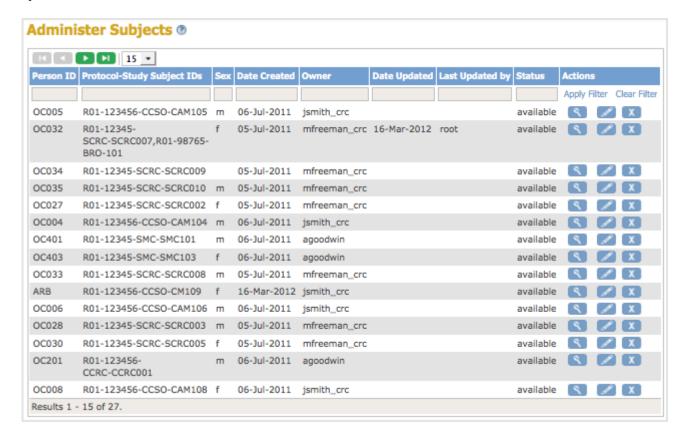
Approved for publication by Ben Baumann. Signed on 2014-03-24 8:47AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

8.3.1 View Subjects in All Studies

To view Subjects in all Studies in the OpenClinica system, select Tasks > Subjects.

The Administer Subjects page opens, listing global information for all Subjects in your OpenClinica system.



The table reports the following information. Some of the information is optional, as specified in the <u>Study Parameters Configuration settings</u>:

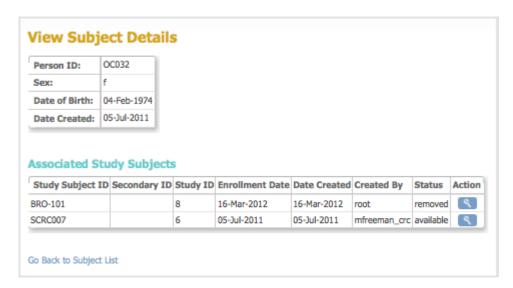
- **Person ID:** Unique identifier for a Subject across all Studies. The value was assigned when you added the Subject. Person ID is an optional value, and can be empty if it is not specified as required in the Study Parameter Configuration settings. If you assigned a Subject to multiple Studies and used the same Person ID, the row shows all information for that Person ID across the Studies.
- **Protocol-Study Subject IDs:** Unique identifier for the Study and the Subject in the Study. When a Subject is assigned to more than one Study, all values are reported here, with each separated by a comma. In the above example screen, Person ID OC032 belongs to two Studies because there are two sets of values in this column: Study Subject SCRC-SCRC007 in Study R01-12345, and Study Subject BRO-101 in Study R01-98765.
- **Sex:** If you do not specify Sex as a required value in the Study Parameter Configuration settings, the value can be blank.
- Date Created: Date when you first added the Subject to your OpenClinica system.
- Owner: User name of the person who first added the Subject to your OpenClinica system.
- Date Updated: The most recent date a user updated global information for the Subject.
- Last Updated By: The user who most recently updated global information for the Subject.
- **Status:** When the Person ID has been removed from the OpenClinica system the Status is "removed," and otherwise the Status is "available."

8.3.2 View Subject Details

In the Administration module, to view additional information about a Subject, follow these steps:

- Select Tasks > Subjects.
 The Administer Subjects page opens.
- 2. For the Subject you want to see more information about, click the View icon in the Actions column.

The View Subject Details page opens for the Subject.



The first table shows information that is common to the Subject across all Studies.

The second table, Associated Study Subjects, shows information about the Subject for each Study the Subject is assigned to. Note you can remove a Subject from each Study they are assigned to, but

keep them <u>available in the OpenClinica system</u>. In that situation, the Status in the Associated Study Subjects table is "removed" for all Studies, while the Status in the Administer Subjects page is "available."

You can view all Subject details for a Study, if that Study is the current Study, by clicking the View icon for the Study. The View Subject page opens, which is the same page you can access for a Subject from the Subject matrix. For more information, see <u>View and Edit Details for a Subject</u>.

8.3.3 Edit Subject Details

You can edit Details for a Subject from the Administration module. Follow these steps to change the Person ID, Sex, or Date of Birth.

- Select Tasks > Subjects.
 The Administer Subjects page opens.
- 2. For the Subject whose information you want to edit, click the Edit icon in the Actions column. The Update Subject Details page opens for the Subject.



- 3. Make changes to the values.
- 4. You can create a Discrepancy Note for an item you change:
 - Click the Discrepancy Note icon.
 The Add Discrepancy Note page opens.
 - 2. Complete the page, then click Submit. For more information, see <u>Notes and Discrepancies</u>.
- 5. On the Update Subject Details page, click Confirm. The Confirm Subject Details page opens.
- 6. Click Submit.

The Subject information is changed.

To make changes to other Subject details:

- Select Tasks > Subjects.
 The Administer Subjects page opens.
- 2. For the Subject whose information you want to change, click the View icon in the Actions column.
 - The View Subject Details page opens for the Subject.
- 3. In the Associated Study Subjects table, click the View icon for the Study in which you want to edit the Subject details.
 - The View Subject page opens, which is the same page you can access for a Subject from the Subject matrix. For more information, see <u>View and Edit Details for a Subject</u>.

8.3.4 Remove and Restore Subject in System

You can remove a Subject from the OpenClinica system. For example, you might want to remove a Subject who has left a Study because the Subject did not meet eligibility requirements or has moved and will not resume participation later. To remove a Subject:

- Select Tasks > Subjects.
 The Administer Subjects page opens.
- 2. In the Actions column, click the Remove icon for the Subject you want to remove.
- 3. Click OK in the confirmation dialog box.

 The Subject is removed from the OpenClinica system. The status of all the Subject's Event CRFs is set to "invalid."

Data for Subjects removed from the system is still maintained in the OpenClinica system and you can view but cannot change data. The data for removed Subjects is not included in datasets you export.

To restore a Subject to the OpenClinica system:

- Select Tasks > Subjects.
 The Administer Subjects page opens.
- 2. In the Actions column, click the Restore icon for the Subject you want to restore.
- 3. Click OK in the confirmation dialog box.
 The Subject is restored to the OpenClinica system.

After a Subject has been restored to the system, you can change data for the Subject and that Subject's data is included in datasets you export.

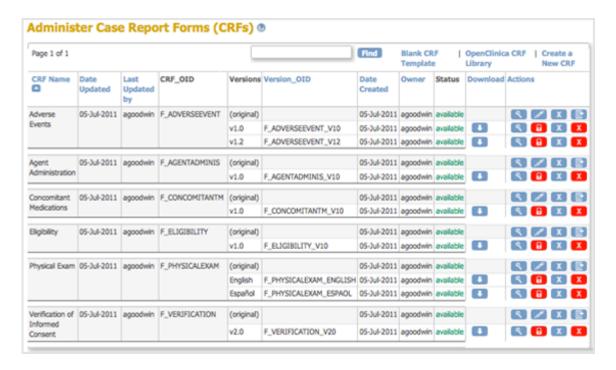
8.4 Administer CRFs

The Administer CRFs features allow you to create and manage defined CRFs used for data entry in OpenClinica. The features are the same as those found in the Study Setup and the Monitor and Manage Data modules (see <u>Create and Modify Case Report Forms</u>), except in the Administration module, you can also archive and unarchive CRFs, which is described here. When you archive a version of a defined CRF:

- That version of the CRF cannot have been used for entering Study Event data for Subjects.
- Any data already captured using that version of the CRF is maintained in the system, although you cannot modify it.
- Data already captured using that version of the CRF is included in data extracts you create.
- The version of the CRF can be unarchived.

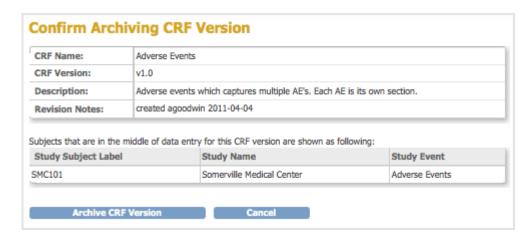
To archive a version of a defined CRF:

1. From the Tasks menu, in the Administration module, select CRFs. The Administer Case Report Forms (CRFs) page opens.



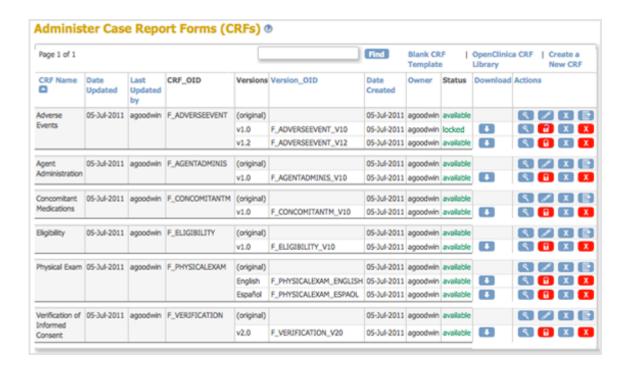
2. For the version of the CRF you want to archive, click the Archive icon in the Actions column.

The Confirm Archiving CRF Version page opens. For the example shown here, the Adverse Events CRF, version v1.0 is being archived.



3. Verify the information, then click Archive CRF Version.

The Administer CRFs page opens. The version you archived now has an Unarchive icon in the Actions column, and its status is "locked."



To unarchive a version of a defined CRF:

- 1. Click the Unarchive icon 1 in the Actions column for the CRF you want to unarchive. The Confirm Unarchiving CRF Version dialog box opens.
- 2. Verify the information, then click Unarchive CRF Version.

 The Administer CRFs page opens. The version of the CRF you unarchived has an Archive icon in the Actions column and a status of "available."

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:47AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

8.5 Jobs

With the Jobs features, you can:

- Create Jobs to automatically import and export data, which you schedule to run on a regular basis
- View all scheduled Jobs
- Modify the Jobs.

To access the Jobs features, select Tasks > Jobs, then use the Administer All Jobs page. You can access Jobs features for all Studies and Sites from this page, no matter what the current Study or Site is:

Administer All Jobs @

- ▶ View All Export Data Jobs
 ▶ View All Import Data Jobs
 ▶ View Currently Executing Data Export Jobs

Note that the job is set to run on the server time. The current server time is 22-Mar-2012 18:25:45.

Approved for publication by Ben Baumann. Signed on 2014-03-24 8:47AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

8.5.1 Scheduled Import Jobs

You can schedule a Job to regularly import data that is in a properly-formatted XML file. For background information about importing data into OpenClinica, see Import Data.

8.5.1.1 Create an Import Job

Before you can create an import Job, the file(s) to be imported must exist at a location specified in your OpenClinica system configuration. For information about creating an import file, see <u>Data File</u> for Import. For more about the location of the import files, see filePath in the datainfo.properties file in Configuring the OpenClinica Application.

To create an import Job:

- 1. Select Tasks > Jobs. The Administer All Jobs page opens.
- 2. Click View All Import Data Jobs. The View Scheduled Import Data Jobs page opens.
- 3. Click Create a New Import Data Job. The Create Scheduled Job: Import Data page opens.

Create Scheduled Job: Import Data								
Note that the job is set to run on the server time. The current server time is 30-Mar-2012 09:46:29.								
* indicates required field.								
Import Job Name:	*							
Import Job Description:		*						
Import Job Study:	-Select- 🗘 *							
The default filepath to import from will be this location:	/usr/local/tomcat/openclinica.data/scheduled_data_import/							
You can create a new directory here, or leave it blank to take files from the root directory:								
Frequency:	Run every 0 \$\display hours and 0 \$\display minutes. *							
The frequency you select it to run the first time will be the time it runs every other time unless you edit this job.								
Contact Email:								
Save	Cancel							

- 4. Complete at least the required fields. Refer to the following information as needed:
 - Import Job Name: The name must be unique among all Job names on your OpenClincia system.
 - **Import Job Study:** The Study or Site where the data will be imported to.
 - The default filepath to import from: The value reported here is the filePath specified
 in the datainfo.properties file; see <u>Configuring the OpenClinica Application</u> for details. If
 your files are being imported from multiple locations, put all of the files into the filePath
 location.
 - You can create a new directory here ...: If you want to put the files to be imported for this Job in a subdirectory of the location specified in filePath, enter the name of the subdirectory here. The subdirectory must exist.
 - **Frequency:** When you complete creating the Job, it runs for the first time. After that, it runs regularly at the interval you specify here. For example, if the current time when you save this page is 08:10, and you specify a frequency of 12 hours, the Job will run at 08:10 today, and again today at 20:10, then again at 08:10 and 20:10 tomorrow and each day after that.
 - Contact Email: Each time the Job completes running, the OpenClinica system sends an email notification to the addresses you specify here, stating that the imported data Job has completed. Separate multiple email addresses with a comma, for example: dmanagone@institution.org, sdirk@institution.org.
- 5. Click Save.

The import Job runs and an email including a link to OpenClinica is sent to all email addresses provided. OpenClinica moves the files from the filePath location to another folder so that the same files are not imported the next time the Job runs. The View Scheduled Import Data Jobs page opens. It now includes the scheduled import Job you just created, showing that the Previous Fire Time is the current time and the Next Fire Time is based on the interval you specified for Frequency.

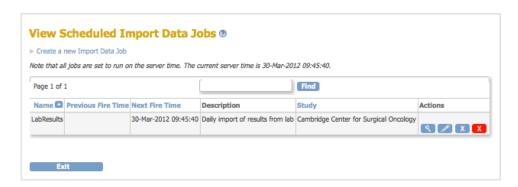
8.5.1.2 View Scheduled Import Jobs

To view all scheduled import data Jobs:

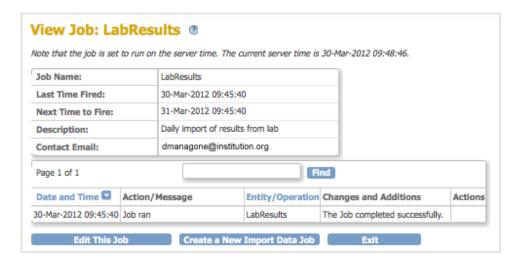
Select Tasks > Jobs.
 The Administer All Jobs page opens.

2. Click View All Import Data Jobs.

The View Scheduled Import Data Jobs page opens, listing all scheduled import Jobs and information about them such as the Previous Fire Time (last date and time the Job executed), and Next Fire Time (the next date and time the Job is scheduled to execute). The time used is server time, which is reported on the page.



- 3. View summary information about the Jobs in the table. You can click any of the column header links to sort the Jobs by that column. Use the Find field to find all Jobs whose Name, Description, Study, or Times includes the text you specify.
- 4. To see details about a Job, click the View icon for it. The View Job page opens for that Job.



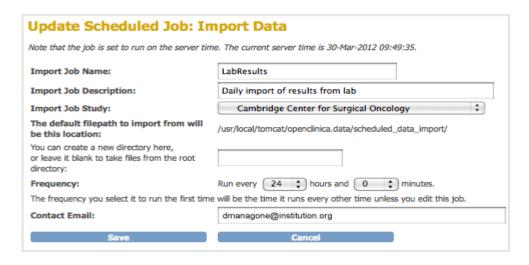
8.5.1.3 Modify Scheduled Import Jobs

You can edit the parameters of an import Job, remove or restore an import Job, or delete an import Job.

Edit an Import Job

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- 2. Click View All Import Data Jobs.

 The View Scheduled Import Data Jobs page opens, listing all scheduled import Jobs.
- 3. For the Job you want to edit, click the Edit icon.
 The Update Scheduled Job: Import Data page opens.



4. Make changes to the values, then click Save.

The Scheduled Import Data Jobs page opens, reflecting the changes you made to the Job.

Remove an Import Job

Remove a scheduled import Job to stop it from running at the specified frequency. You can later restore the Job. To remove an import Job:

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- Click View All Import Data Jobs.
 The View Scheduled Import Data Jobs page opens, listing all scheduled import Jobs.
- 3. For the Job you want to remove, click the Remove icon \square .
- 4. Click OK in the confirmation dialog box.

 The View Scheduled Import Data Jobs page opens. The Job you removed is still listed, but with no value for Next Fire Time.

Restore an Import Job

When you want to resume running a Job according to the specified frequency after it has been removed, restore the Job as follows:

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- 2. Click View All Import Data Jobs.

 The View Scheduled Import Data Jobs page opens, listing all scheduled import Jobs.
- 3. For the Job you want to restore, click the Restore icon .
- 4. Click OK in the confirmation dialog box.

 The View Scheduled Import Data Jobs page opens. The Job you restored is listed, and the Next Fire Time now shows when the Job will next run.

Delete an Import Job

Delete an import Job when you no longer want the Job to run. You cannot restore a deleted Job. To delete a scheduled import Job:

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- 2. Click View All Import Data Jobs.

The View Scheduled Import Data Jobs page opens, listing all scheduled import Jobs.

- 3. For the Job you no longer want, click the Delete icon 🔼.
- 4. Click OK in the confirmation dialog box.

 The View Scheduled Import Data Jobs page opens. The Job you deleted is no longer listed. If you need the Job again, you can re-create it.

8.5.2 Scheduled Export Jobs

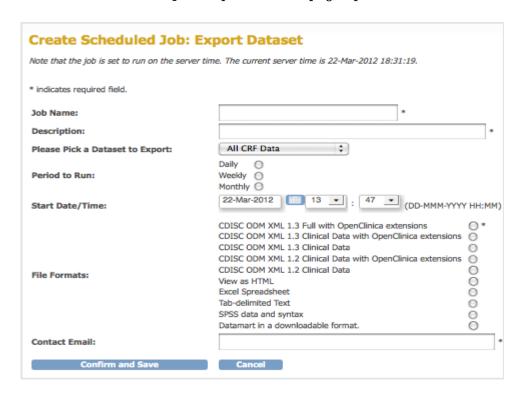
You can schedule a Job to regularly export data for an existing dataset definition. For background information about exporting data from OpenClinica, see Extract Data.

8.5.2.1 Create an Export Job

Before you can create an export Job, the dataset definition must exist. For information, see <u>Define</u> <u>Dataset</u>.

To create an export Job:

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- Click View All Export Data Jobs.The Scheduled Export Data Jobs page opens.
- 3. Click Create a New Export Data Job.
 The Create Scheduled Job: Export Dataset page opens.



- 4. Complete at least the required fields. Refer to the following information as needed:
 - \circ The list of datasets to export includes dataset definitions that already exist for all Studies.
 - \circ Set the time using server time, which is shown just below the title and uses a 24-hour format. The Job will run for the first time on the date and at the time you specify in Start

- Date/Time. The Job will run again at the same time on a date that is based on the interval you specify in the Period to Run.
- Each time the Job completes running, the OpenClinica system sends an email notification to the addresses you specify here that the exported dataset Job has completed. Separate multiple email addresses with a comma, for example: dmanagone@institution.org, sdirk@institution.org.
- For information about file formats, see Formats for Dataset Files.
- 5. Click Confirm and Save.

The Scheduled Export Data Jobs page opens. It now includes the scheduled export Job you just created.

8.5.2.2 View Scheduled Export Jobs

To view all scheduled export Jobs:

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- 2. Click View All Export Data Jobs.

The Scheduled Export Data Jobs page opens, listing all scheduled export Jobs and information about them such as the Previous Fire Time (last date and time the Job executed), and Next Fire Time (the next date and time the Job is scheduled to execute). The time used is server time, which is reported on the page.



- 3. View information about the Jobs. You can click any of the column header links to sort the Jobs by that column. Use the Find field to find all Jobs whose Name, Description, Period, or Dataset includes the text you specify.
- 4. Click the View icon for a Job to see details about it. The View Job page opens for that Job.

View Job: Docetaxel Adverse Events Daily ®									
Note that the job	is set t	to run on the server time. The curren	t server time is 24-M	lar-2012 13:38:14.					
Job Name:	Job Name: Docetaxel Adverse Events Daily								
Last Time Fired: 24-Mar-2012 12:53:00									
Next Time to Fire: 25-Mar-2012 12:53:00									
Description:	Description: Daily run of all Adverse Events for Docetaxel Study								
Dataset:	set: DocetaxelAdverseEvents								
Period to Run: daily									
Contact Email: dmanagone@institution.or		dmanagone@institution.org							
File Formats:	Excel Spreadsheet								
Page 1 of 1 Find									
Date and Time	Action/Message			Entity/Operation	Changes and Additions	Actions			
24-Mar-2012 12:53:00	You may access the Excel Spreadsheet file by changing your study/site to Somerville Medical Center and selecting the Export Data icon for DocetaxelAdverseEvents dataset on the View Datasets page.			Docetaxel Adverse Events Daily	The Job completed successfully.				
Edit 1	This Jo	b Create a New Expo	ort Data Job	Exit					

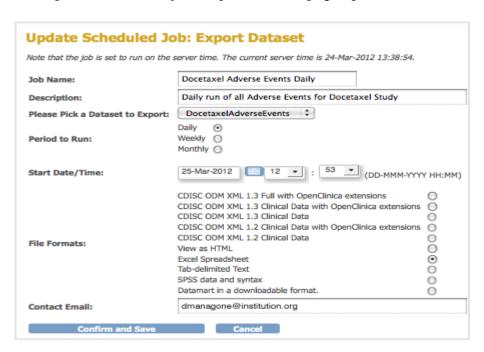
To view the dataset file created by the export Job, see Archive of Exported Dataset Files.

8.5.2.3 Modify Scheduled Export Jobs

You can edit the parameters of an export Job, remove or restore an export Job, or delete an export Job.

Edit an Export Job

- Select Tasks > Jobs.
 The Administer All Jobs page opens.
- Click View All Export Data Jobs.
 The Scheduled Export Data Jobs page opens, listing all scheduled export Jobs.
- 3. For the Job you want to edit, click the Edit icon.
 The Update Scheduled Job: Export Dataset page opens.



4. Make changes to the values, then click Confirm and Save.

The Scheduled Export Data Jobs page opens, reflecting the changes you made to the Job.

Remove an Export Job

If you want to stop a scheduled export Job from running at the specified frequency, remove the Job. You can later restore it. To remove an export Job:

- 1. Select Tasks > Jobs.
 - The Administer All Jobs page opens.
- 2. Click View All Export Data Jobs.
 - The Scheduled Export Data Jobs page opens, listing all scheduled export Jobs.
- 3. For the Job you want to remove, click the Remove icon \square .
- 4. Click OK in the confirmation dialog box.
 - The Scheduled Export Data Jobs page opens. The Job you removed is listed, with no value for Next Fire Time. The datasets created by the Job are not removed.

Restore an Export Job

Restore an export Job that was previously removed when you want to resume running the Job according to the specified frequency. To restore an export Job:

- 1. Select Tasks > Jobs.
 - The Administer All Jobs page opens.
- 2. Click View All Export Data Jobs.
 - The Scheduled Export Data Jobs page opens, listing all scheduled export Jobs.
- 3. For the Job you want to restore, click the Restore icon
- 4. Click OK in the confirmation dialog box.
 - The Scheduled Export Data Jobs page opens. The Job you restored is listed, and the Next Fire Time now shows when the Job will next run.

Delete an Export Job

Delete an export Job when you no longer want the Job run. You cannot restore a deleted Job. The data extract file created the last time the Job ran is not deleted. To delete a scheduled export Job:

- 1. Select Tasks > Jobs.
 - The Administer All Jobs page opens.
- 2. Click View All Export Data Jobs.
 - The Scheduled Export Data Jobs page opens, listing all scheduled export Jobs.
- 3. For the Job you no longer want, click the Delete icon 🔼.
- 4. Click OK in the confirmation dialog box.
 - The Scheduled Export Data Jobs page opens. The Job you deleted is no longer listed. The datasets created by the Job are not deleted.
 - If you need the Job again, you can re-create it.

8.5.3 View or Cancel Data Exports

All exports that are scheduled to run or are currently running are said to be in the queue. You can view the queue and cancel any of the exports in it. The queue includes scheduled export Jobs, as well as exports you manually executed using the Extract Data module: see <u>Generate and Download</u> <u>Dataset</u> for more information.

1. Select Tasks > Jobs.

The Administer All Jobs page opens.

2. Click View Currently Executing Data Export Jobs.

The Currently Executing Data Export Jobs page opens, listing all scheduled export Jobs and any extracts you manually-executed that have not yet completed running.



- 3. To help you find specific exports, or organize the exports shown, you can sort the queue by clicking any of the column headers. For example, click Fire Time to show queue entries in the order they will be executed. You can also filter the entries by entering text in any of the fields beneath the column headers and clicking Apply Filter.
- 4. If you want to stop the entry that is currently running, or remove any entry from the queue, click Cancel Job, then click OK in the confirmation dialog box.
 - If the export you canceled is one that you manually executed, it no longer appears in the queue.
 - If the export you canceled is a scheduled Job, it remains in the queue, but the value for next Fire Time advances: it cancels only the next scheduled export for that Job. If you want to stop a scheduled Job from running more than once, see <u>Modify Scheduled Export</u> <u>Jobs - Remove Job</u>.
 - If the next export in the queue was waiting for the export you just canceled, that next scheduled export will start running.