Working with administration settings

Contents

Configuration changes through the Administration page

The table below describes some of the configuration changes you can make through the Administration page as well as the impact of those changes on the study. Details of some of these settings appear in other chapters.

Note: Any changes made on the study or site level take effect the next time you sign in.

Configuration change	Page Performed On	Description	Notes
Auto unlock interval	Configure Study Settings page	Changes the number of minutes that must pass before the OutcomeLogix application automatically unlocks a locked user or patient.	
Enable Repeat Visit Name	Configure Study Settings page	Indicates whether users can change the name that the application calculates for a repeating visit instance.	
Initial password assigned to users	Configure Study Settings page	Changes the password that the application sends to users and patients to enable them to sign in for the first time.	If study designers specify a default initial password, all new users and patients automatically receive that password on creation. For security reasons, it is recommended that study designers leave the Initial password assigned to users field blank. That way, upon user creation, the new user receives a unique temporary password by email.
Password string	Configure Study Settings page	Changes the masking characters displayed in the Password fields.	Used for user and patient passwords. Length of the masking string does not match password length defined on the Password Rules page.

Configuration change	Page Performed On	Description	Notes
URL for accessing the study	Configure Study Settings page	Changes the internet address of the study.	You can specify only one URL.
Study-specific message on the Sign In page	Configure Study Settings page	Displays study-specific information, notes, or reminders on the Sign In page.	Not translated; appears in the language in which it was entered.
ePRO due counts	Configure Study Settings page	Changes the number of days that must pass before an ePRO form is considered due and appears in the ePRO Status section of the Dashboard.	The ePRO forms included in the Dashboard count have reached or exceeded the number of days specified.
Session timeout	Configure Study Settings page	Changes the number of idle-time minutes before a user session times out.	
Force session timeout	Configure Study Settings page	Changes whether a session can be forced to time out even if the user is active.	
Second password reset question	Configure Study Settings page	Changes the number of reset questions on the Reset Password page so that users need to answer two questions before the password is reset.	
Link expiration day	Configure Study Settings page	Changes the length of time a new user has to sign into the OutcomeLogix application for the first time after receiving a user name and password.	
Whether to support sending emails	Configure Study Settings page	Changes whether the User Profile page includes the option of the user receiving email notifications.	Without this function, users do not receive notifications of password changes, site reassignments, and so on.

Configuration change	Page Performed On	Description	Notes
Help contact support email	Configure Study Settings page	Changes the email address of the Help Desk.	
Showing patient profile core data	Configure Study Settings page	Indicates whether to show the core fields from the patient profile, such as email address, memorable date, reset password, and user name.	The study design determines the fields included on the Patient Profile page.
Study Name	Manage Study Description page	Changes the study name at the top of the navigation bar on every page.	Might cause confusion if changed during an active study.
Sponsor Name	Manage Study Description page	Replaces every occurrence of the sponsor name.	Might cause confusion if changed during an active study.
Therapeutic area	Manage Study Description page	Provides additional information about the study protocol, such as Oncology, if set up for the study.	
Expected number of sites	Manage Study Description page	Number of sites that are expected to be part of the study.	
Hide, mask, or make a form, or items within a form, read-only for selected roles	Edit Display Overrides page	Hidden items do not appear on the Audit Trail page and are not included in reports. Masked items make Protected Health Information unreadable. Read-only items may not be edited.	
Assign access to standard reports to roles	Assign Reports to Roles page	Allows users to access specific standard reports.	

Configuration change	Page Performed On	Description	Notes
Password rules	Manage Password Rules page and Assign Password Rules to Roles page	Sets password parameters for selected roles, including time before expiration and the password default rule.	Might end up with many variations that are difficult to support.
Rights groups	Manage Roles and Rights page and Rights Group page	Creates a role and an associated rights group consisting of selected management and user functions.	Might end up with many variations that are difficult to support.
Localization settings	Manage Localization Settings page	Changes the date formats, name sort options, number formats, and currency formats offered on the User Profile and Site Management pages.	
Upload Informed Consent documents in multiple languages and of different types	Manage ICDs page	Changes the list of available ICDs on the Site Management page. Determines which ICDs are active.	When a new version or different ICD is made active, all patients related to that ICD must re-sign it.
Destination sites associated with the study site	Manage Sites page	Associates destination sites with an originating site as required for patient transfers.	
Site enrollment target numbers and limitations	Manage Sites page	Determines the maximum number of patients that can be enrolled, as well as target enrollment and limits.	The enrollment limit can exceed the target enrollment.
Activate or deactivate a site	Manage Sites page	Changes the status of the site.	

Configuration change	Page Performed On	Description	Notes
Report server information	Edit Report Server Configuration page	Specifies the location of the report server and allows the developer and viewer users to enter or change their passwords.	

Roadmap: Managing sites

Step	Action	Procedure
1	Add a site.	1 Select **Administration** (). 2 The Administration page appears. 3 Click **Manage Sites**. The Manage Sites page appears. Click **Add Site**. 4 Fill in the fields as necessary. 5 Click **Submit**.
2	Display the site list.	1 On the Manage Sites page, do one or more of the following: ▪ **View the site list page by page:** Use the **next page** (**>**), **previous page** (**<**), **last page** (**>|**), and **first page** (**|<**) buttons. ▪ **View a specific page:** From the **Page** drop-down list, select a page number. ▪ **Change the number of displayed records:** From the **Records per Page** drop-down list, select the number of records (rows) to include.
3	Search for a site.	1 Display the site list. 2 Enter search criteria: ▪ **To search by site name:** In the **Search** field, type a full or partial site name, and select **By Name** from the drop-down list. ▪ **To search by number of patients:** In the **Search** field, type the number of patients at the site and select **Number of Patients** from the drop-down list. 3 To the right of the search drop-down lists, click **Submit**.

Step	Action	Procedure
4	Assign a user to a site.	1 On the Administration page, click **Manage Users.** 2 Click the **Profile** link for the user. 3 Scroll down to the Available Sites list. 4 Do one of the following: ▪ From the **Available Sites** list, select one or multiple sites and click the **add** (**>**) button to move the sites to the **Selected Sites** list. ▪ To assign a user to all sites, click the **add all** (**>>**) button. ▪ To assign a user to all sites created in the future, in the **All Sites** field, select **Yes**. 5 Click **Submit**.
5	View the users assigned to a site.	1 Display the site list. 2 Click the **Change** link for the site.
6	Edit a site.	1 Display the site list. 2 Click the **Edit** link for the site. 3 Edit the fields as necessary. 4 Click **Submit**. **Note:** Any changes made on the study or site level take effect the next time you sign in.
7	Change the user assignments for a site.	1 Display the site list. 2 Click the **Change** link for the site. 3 Do one of the following: ▪ To add users to the site, in the **Available users** list, select one or multiple users and click the **add** (**>**) button to move the users to the **Users at site** list. ▪ To remove users from the site, in the **Users at site** list, select one or multiple users and click the **remove** (**<**) button to move the users back to the **Available users** list. ▪ To assign all users to or remove all users from the site, click the **add all** (**>>**) or the **remove all** (**<<**) button. 4 Click **Submit**.

Roadmap: Managing a user

Step	Action	Description
1	Create a user.	1 Select **Administration** (). 2 Click **Manage Users**. 3 Click **Create User**. 4 On the Create User page, complete the user profile, which includes specifying the user name and email address, assigning the user to a role and to a single site, multiple sites, or all sites. 5 Click **Submit**.
2	Activate the user.	• On the Manage Users page, select the user and click **Activate**.
3	Manage the user.	Perform the following procedures as needed.
	Search for a user.	1 On the Manage Users page, enter search criteria: ▪ **To search by user name:** In the **Search** field, type a full or partial user name, and select **By Name** from the drop-down list. ▪ **To search by role:** In the **Search** field, type a full or partial role, and select **By Role** from the drop-down list. 2 To the right of the drop-down list, click **Submit**.
	View and edit a user profile.	1 On the Manage Users page, click the **Profile** link for the user. 2 Edit the fields as necessary. 3 Click **Submit**.
	Deactivate a user.	• On the Manage Users page, select the user and click **Deactivate**.
	Assign a user to a role.	1 On the User Profile page, from the **Role** drop-down list, select the role. 2 Click **Submit**.
	Assign a user or remove a user from a site.	1 On the User Profile page, do one of the following: ▪ From the **Available Sites** list, select one or multiple sites and click the **add** (**>**) button to move the sites to the **Selected Sites** list. ▪ To assign a user to all sites, click the **add all** (**>>**) button. 2 Click **Submit**.
	Lock or unlock a user.	• On the User Profile page, click **Lock User** or **Unlock User**.
	Reset a user password.	• On the User Profile page, click **Reset Password**.

Step	Action	Description
	Set a temporary password for a user.	• On the User Profile page, click **Set Temporary Password**.
	View the audit trail for a user.	• On the User Profile page, click the **Audit Trail** button (**A**).

Roadmap: Managing roles and rights

Step	Action	Description
1	Review the available rights and the default roles included in the application.	The application comes with a predefined set of roles, which are configurable, and rights, which are not configurable. • Determine whether the default roles meet the needs of your study.
2	Modify the rights assigned to the predefined roles as necessary.	1 Select **Administration** (). 2 Click **Manage Roles and Rights**. 3 Click the **Edit** link for the role. 4 Edit the fields as necessary. 5 Click **Submit**.
3	Assign reports to the necessary roles.	1 On the Administration page, click **Assign Reports to Roles**. 2 Click the **Assign Reports to Roles** link for the role. 3 Do one of the following: ▪ From the **Available Reports** list, select the reports to assign to the role, and click **Add**. ▪ To assign all available reports to the role, click **Add All**. 4 Click **Submit**.
4	Assign each user to a role.	1 On the Manage Roles and Rights page, click the **Change Assigned Users** link for the role. 2 Do one of the following: ▪ From the **Available users** list, select the users to assign to the role, and click **Add**. ▪ To assign all available users to the role, click **Add All**. 3 Click **Submit**.

Roadmap: Distributing eCodes

Step	Action	Description
1	The sponsor establishes a policy for distributing eCodes.	This task takes place outside of the OutcomeLogix application.
2	The sponsor loads the supply of eCodes into the OutcomeLogix application.	This task takes place outside of the OutcomeLogix application.
3	The OutcomeLogix application distributes eCodes to patients and other people who have earned them.	This step occurs automatically, triggered by the criteria set up in Step 1. For example, a patient might earn an eCode by completing an ePRO visit. The OutcomeLogix application stores information about eCodes, including the code, the person to whom it was assigned, and the email address. Call Center users can read the eCode to the patient when conducting the interview by phone if no email address is defined for the patient.
4	When all the eCodes are distributed, or a limited supply remains, the OutcomeLogix application notifies the sponsor to load more eCodes.	Notification is by email and occurs automatically. Loading the eCodes takes place outside of the OutcomeLogix application.
5	A sponsor user selects the people who did not receive their earned eCodes or clicks the checkbox next to the column headers on the Send eCodes page to send missed eCodes to everyone listed.	Depending on how your study has been set up, the OutcomeLogix application might automatically send eCodes to the list of people who missed eCodes.
6	If necessary, or if a patient loses an eCode and calls the Help Desk, the Help Desk can resend eCodes that have already been assigned.	Resending eCodes is done by email.

Roadmap: Configuring the Call Center

Step	Action	Description
1	Create the Call Center profile.	The Call Center profile is enabled during study design and can be updated, if allowed in the study, in the Administration user interface. 1 Select **Administration** ( ). 2 Click **Call Center Profile Setting**. 3 Enter details about the Call Center and the web completion windows for each visit. 4 Click **Submit**.
2	Customize the call scripts.	The call scripts are configured during study design and can be updated, if allowed in the study, in the Administration user interface. 1 Select **Administration** ( ). 2 Click **Call Center Script Setting**. 3 Customize each Call Center script. 4 Click **Update**.
3	Add the Call Center staff.	You assign staff to a Call Center by assigning users to the Call Center Manager or Call Center Staff role. Use the Manage Users option on the Administrative menu.
4	Assign patients to Call Center staff.	For each patient on the Call Center List page, select a Call Center staff member from the Assign Staff drop-down list. 1 Select **Call Center List** ( ). 2 From the **Assign Staff** drop-down list, select the Call Center staff member to assign to the patient. 3 Click **Assign Staff**.