

Randomize.net Coordinating Centre User Manual

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1. *Coordinating Centre* Account

As the name implies, the ***Coordinating Centre*** coordinates all activities. It creates all other types of user accounts, such as the *Clinical Sites* that recruit and randomize patients. It also creates the Administrator accounts, a particular type of which manages the *Kit Numbers* for blinded trial. The ***Coordinating Centre*** also creates the randomization applications for your clinical trials. Keep in mind that you can create any number of clinical trials and *Clinical Sites*, and any subset of the *Clinical Sites* can be activated to randomize patients on any particular trial.

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2. Administrator Accounts

There are three types of Administrator accounts. Signing into an ***Auditor*** account allows the user to see everything the *Coordinating Centre* can see but does not allow the user to make any changes or deletions. Signing into a ***Full Administrator*** account provides the user with all the functions available to the *Coordinating Centre*. Signing into a ***Kit Administrator*** account allows an unblinded user to import and assign *Kit Numbers* for blinded trials.

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Randomization application for **Clinical Trials** can be created by the *Coordinating Centre* or any *Full Administrator*. Once the trial is created the *Coordinating Centre* can edit trial details and add treatment arms. Optionally, the *Coordinating Centre* can add inclusion/exclusion criteria, stratification information, notification emails and set limits on the number of patients randomized.

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Kit Numbers can be used to blind (mask) *Clinical Site* users to the allocated treatment. When the user logs-in and randomizes a patient, instead of being given the actual allocated treatment, they are given a ***Kit Number***, confirmed by an email message. The ***Kit Number***, either

- i. corresponds to an actual physical kit containing the allocated treatment, located somewhere in the *Clinical Site*, or
- ii. appears on a list, together with the allocated treatment, most likely held by a pharmacist located at the *Clinical Site*.

The ***Kit Numbers*** with corresponding treatment are imported to the *Randomize.net* system by a *Kit Administrator*. See [Section 2.3](#) for creating a *Kit Administrator*.

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1.1 Create and Login to Coordinating Centre Account

Create a *Coordinating Centre* account by clicking on “SIGN UP NOW” from www.randomize.net.

As the name implies, the *Coordinating Centre* coordinates all activities. It creates all other types of user accounts, such as the *Clinical Sites* that recruit and randomize patients. The *Coordinating Centre* also creates the randomization applications for your clinical trials. Keep in mind that you can create any number of clinical trials applications and *Clinical Sites*, and any subset of the *Clinical Sites* can be activated to randomize patients on any particular trial.

Although Randomize.net is designed to be “self-serve”, we are happy to work with you to create the randomization applications for your trials at no extra charge.

Furthermore, there is no charge until the application is activated, at which time an invoice will be sent.

RANDOMIZE.NET

HOME FEATURES TESTIMONIALS PUBLICATIONS PRICING FAQ CONTACT SIGN IN

A COMPREHENSIVE INTERNET-BASED RANDOMIZATION SERVICE FOR CLINICAL TRIALS

CREATE YOUR RANDOMIZATION APPLICATION IN JUST MINUTES

SIGN UP NOW

EASY TO SET UP
Set up a randomization application for your trial in just minutes.
Sign Up Now »

TRULY UNLIMITED IWRS
Unlimited trial duration, number of subjects, clinical sites, treatment arms and stratification variables, all for a one-time fee.
Pricing »

DOUBLE-BLINDED TRIALS
Full support for double-blinded trials, including kit management, kit replacement and emergency unblinding.
Details »

ADVANCED ALGORITHMS
Randomize.net supports permuted blocked stratification, minimization and simple randomization algorithms.
Details »

Providing internet-based randomization for over 15 years
with hundreds of trials completed

User Management
Create multiple Coordinating Center users, each with their own role: Administrator, Auditor or Kit Administrator.

Email Notifications
Fully configurable email notifications.

Free To Sign Up
There is no cost until the trial is

Provide the following information:

Login ID,

Label for *Coordinating Centre*,

Password,

Name and Email Address of Contact Person,

Name, Address and Phone Number of the *Coordinating Centre*.

Keep in mind that the login ID cannot be changed.

Ideally, this should reflect your organization, rather than a specific trial since many trials can be created by the same Coordination Centre.

You can also indicate how you heard of Randomize.net and if you are interested in any of our additional services.

When completed, click on “Create Coordinating Centre”.

The screenshot shows the 'Create Coordinating Center' form on the Randomize.net website. The form is titled 'RANDOMIZE.NET' and has a navigation bar with links: HOME, FEATURES, TESTIMONIALS, PUBLICATIONS, PRICING, FAQ, CONTACT, and SIGN IN. The form fields are as follows:

- Login ID: democc
- Coordinating Centre: Demo Coordinating Centre
- Password: (masked with asterisks)
- Contact Person Name: Andy Willan
- Contact Person Email: andy@randomize.net
- Address: Interrand Inc., 533 Highland Avenue, Ottawa, Ontario, Canada, K2A 2J8
- Phone Number: +1-613-878-8356
- How did you hear about us? (dropdown menu)

Below the form, there is a section titled 'Please indicate if you are interested in additional services:' with four checkboxes:

- ☐ Protocol Review
- ☐ Clinical Trial Methodology
- ☐ Data Analysis Plan
- ☐ Sample Size Determination

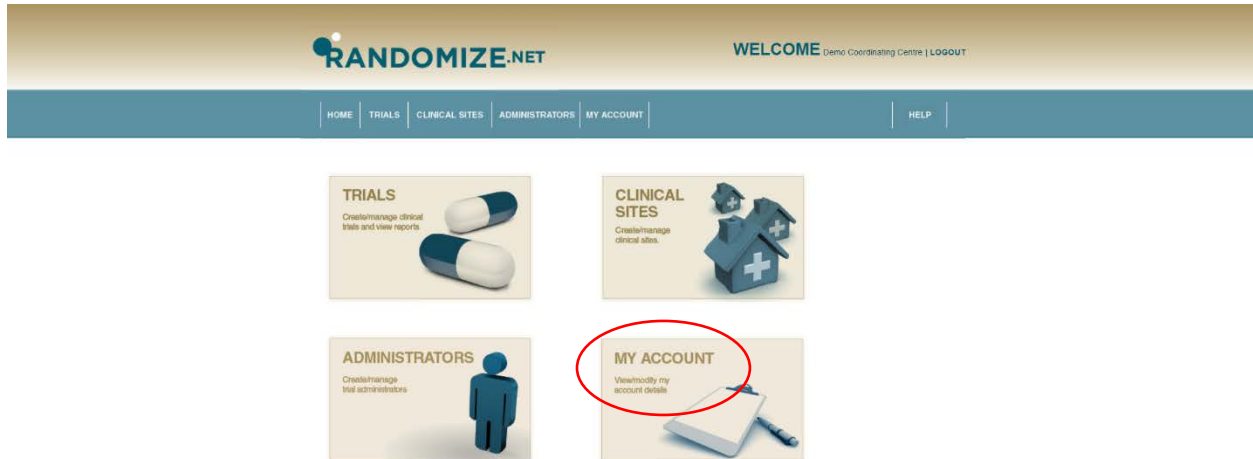
The 'Create Coordinating Center' button is highlighted with a red oval.

To login to the *Coordinating Centre* Account, from www.randomize.net click on “SIGN IN” and provide the login credentials. Then click on “LOGIN”.

The screenshot shows the Randomize.net website. The top navigation bar includes links for HOME, FEATURES, TESTIMONIALS, PUBLICATIONS, PRICING, FAQ, CONTACT, and SIGN IN. The SIGN IN link is circled in red. Below the navigation bar, there is a hero section with the text "A COMPREHENSIVE INTERNET-BASED RANDOMIZATION SERVICE FOR CLINICAL TRIALS" and a "SIGN UP NOW" button. Below the hero section, there is a login form. The login form has a "LOGIN" heading, two input fields (one for email/username and one for password), and a "LOGIN" button. The login form is circled in red. Below the login form, there are links for "Forgot password?", "Don't have an account?", and "Create an account". At the bottom of the page, there is a "Contact Us" link.

1.2 Edit *Coordinating Centre* Account Details

To view/edit the *Coordinating Centre* Account details, from your home page click on “MY ACCOUNT”.



To edit the *Coordinating Centre* details, click on “Edit Details”.

The screenshot shows the RANDOMIZE.NET website. At the top, there is a header with the logo and a welcome message: "WELCOME Demo Coordinating Centre | LOGOUT". Below the header is a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled "COORDINATING CENTER DETAILS". Below this title, there are two links: "Edit Details" (which is circled in red) and "Change Password". Below the links is a table containing the following information:

LOGIN ID	democc
COORDINATING CENTER NAME	Demo Coordinating Centre
CONTACT PERSON	Andy Willan
E-MAIL	andy@randomize.net
ADDRESS 1	Interrand Inc.
ADDRESS 2	633 Highland Avenue
CITY	Ottawa
STATE/PROVINCE	Ontario
COUNTRY	Canada
ZIP/POSTAL CODE	K2A 2J8
PHONE	+1-613-878-8356

When the changes are completed, click on “SAVE CHANGES”.

The Login ID cannot be changed.

Clicking on “CANCEL” takes you back to the *Coordinating Centre* details without making any changes.

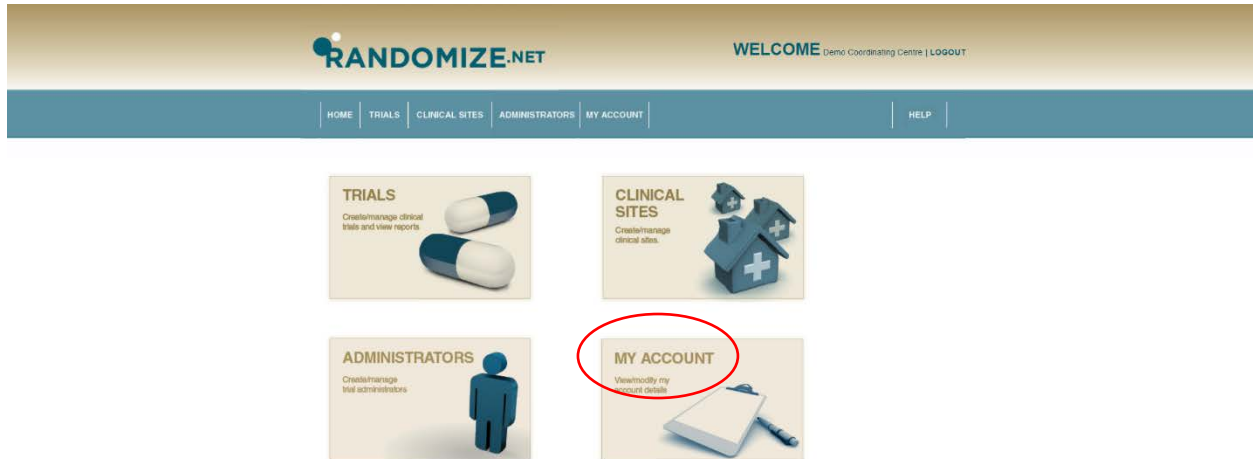
The screenshot displays the 'EDIT COORDINATING CENTER DETAILS' page on the Randomize.NET website. The header includes the Randomize.NET logo and a 'WELCOME' message for the 'Demo Coordinating Centre' with a 'LOGOUT' link. A navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, there are links for 'View Details' and 'Edit Details'. The main heading is 'EDIT COORDINATING CENTER DETAILS'. The form contains the following fields:

- Login ID: democc
- Coordinating Center Name: Demo Coordinating Centre
- Contact Person: Andy Willen
- E-mail: andy@randomize.net
- Address 1: Interrand Inc.
- Address 2: 533 Highland Avenue
- City: Ottawa
- State/Province: Ontario
- Country: Canada
- ZIP/Postal Code: K2A 2J8
- Phone: +1-613-578-8356


At the bottom of the form, there are two buttons: 'SAVE CHANGES' and 'CANCEL'. These buttons are circled in red.

1.3 Reset Coordinating Centre Account Password

To reset the *Coordinating Centre* Account password, click on “MY ACCOUNT” from the *Coordinating Centre* home page.



Click on “Change Password”.



WELCOME Demo Coordinating Centre | LOGOUT

HOME

TRIALS

CLINICAL SITES

ADMINISTRATORS

MY ACCOUNT

HELP

View Details

COORDINATING CENTER DETAILS

Edit Details

Change Password

LOGIN ID	democc
COORDINATING CENTER NAME	Demo Coordinating Centre
CONTACT PERSON	Andy Willan
E-MAIL	andy@randomize.net
ADDRESS 1	Interrand Inc.
ADDRESS 2	633 Highland Avenue
CITY	Ottawa
STATE/PROVINCE	Ontario
COUNTRY	Canada
ZIP/POSTAL CODE	K2A 2J8
PHONE	+1-613-878-8356

Provide the current “Old Password” and confirm the new password by entering it twice.

When completed, click on "CHANGE PASSWORD" and then “OK”.

Clicking on “CANCEL” takes you back to the *Coordinating Centre* details without making any changes.

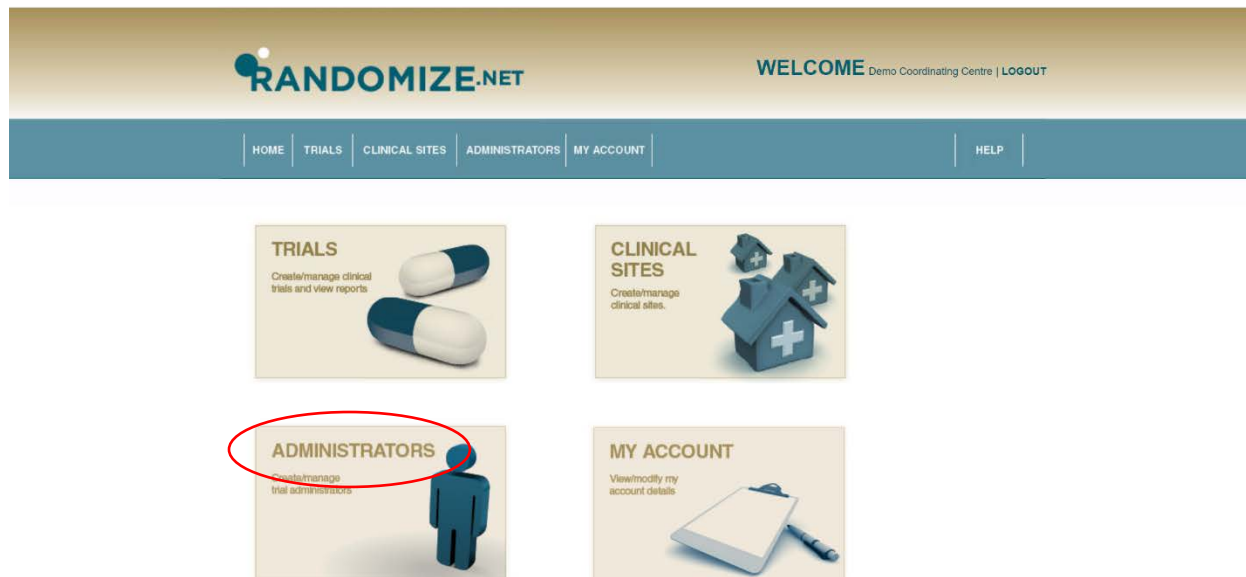
The screenshot shows the 'CHANGE PASSWORD' interface on the RANDOMIZE.NET website. The header includes the site logo and a 'WELCOME' message for the 'Demo Coordinating Centre' with a 'LOGOUT' link. A navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, there are links for 'View Details' and 'Change Password'. The main heading is 'CHANGE PASSWORD'. The form contains the following fields:

- Login ID: democc
- Old Password: [password field]
- New Password: [password field]
- Confirm New Password: [password field]

At the bottom of the form, there are two buttons: 'CHANGE PASSWORD' and 'CANCEL'. These buttons are circled in red in the original image.

2.1 Create an *Auditor* Account

To create an *Auditor* Account, click on “ADMINISTRATORS” from the *Coordinating Centre* home page.




Click on “CREATE ADMINISTRATOR”.

The screenshot shows the Randomize.NET website interface. At the top, there is a header with the Randomize.NET logo and a welcome message: "WELCOME Demo Coordinating Centre | LOGOUT". Below the header is a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled "ADMINISTRATORS" and includes a sub-header "Select Administrator". Below this is a table with the following data:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demofa	Demo Full Admin	demofa@randomize.net	Full Admin	True
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True

Below the table, there is a button labeled "CREATE ADMINISTRATOR" which is circled in red.

Provide “Login ID”, “Name”, “Email” address, and tick “Auditor”, as shown on next page.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

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CREATE ADMINISTRATOR

Login ID:

Name:

Email:

Enrollment Type: ☒ Email ☐ Set Password

☐ Full Admin

Roles: ☐ Auditor

☐ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.

Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.

Kit Administrator - An unblinded administrator that can import/assign/view Kits and can also view all trial and Clinical Site information.

CREATE ADMINISTRATOR

CANCEL

Once completed, click on “CREATE ADMINISTRATOR” and the *Auditor* account will be created, and you will be taken to the screen on the next page.

Clicking on “CANCEL” will take you back and not create the *Auditor* account.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

CREATE ADMINISTRATOR

Login ID: demoauditor

Name: Demo Auditor

Email: demoaud@randomize.net

Enrollment Type: ☒ Email ☐ Set Password

Role: ☒ Auditor ☐ Full Admin ☐ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.
Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.
Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

CREATE ADMINISTRATOR CANCEL

Selecting “Email”, the default, will send an email to the *Auditor* requesting them to set a password for their account. Selecting “Set Password” will require you to set the password and send it to the *Auditor*.

Details of the *Auditor* account are shown.


Clicking on “ADMINISTRATORS” takes you to the screen on the next page.

The screenshot shows the RANDOMIZE.NET interface. The top navigation bar includes links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS (circled in red), MY ACCOUNT, and HELP. Below the navigation bar, a breadcrumb trail reads 'Select Administrator > Administrator Details'. A yellow message box states 'Account successfully created.' The main section is titled 'ADMINISTRATOR DETAILS' with a sub-link 'Edit Administrator Details | Send Password Reset Email'. A table displays the details for the 'demoauditor' account:

LOGIN ID	demoauditor
NAME	Demo Auditor
E-MAIL	demoaud@randomize.net
ENABLED	True
ROLES	Auditor

A red arrow points from the 'ENABLED' field to a text box that reads: 'By default, “ENABLED” is set to “True” . To set it to “False”, click on “Edit Administrator Details”.

The new *Auditor* account is now shown.



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Select Administrator

ADMINISTRATORS

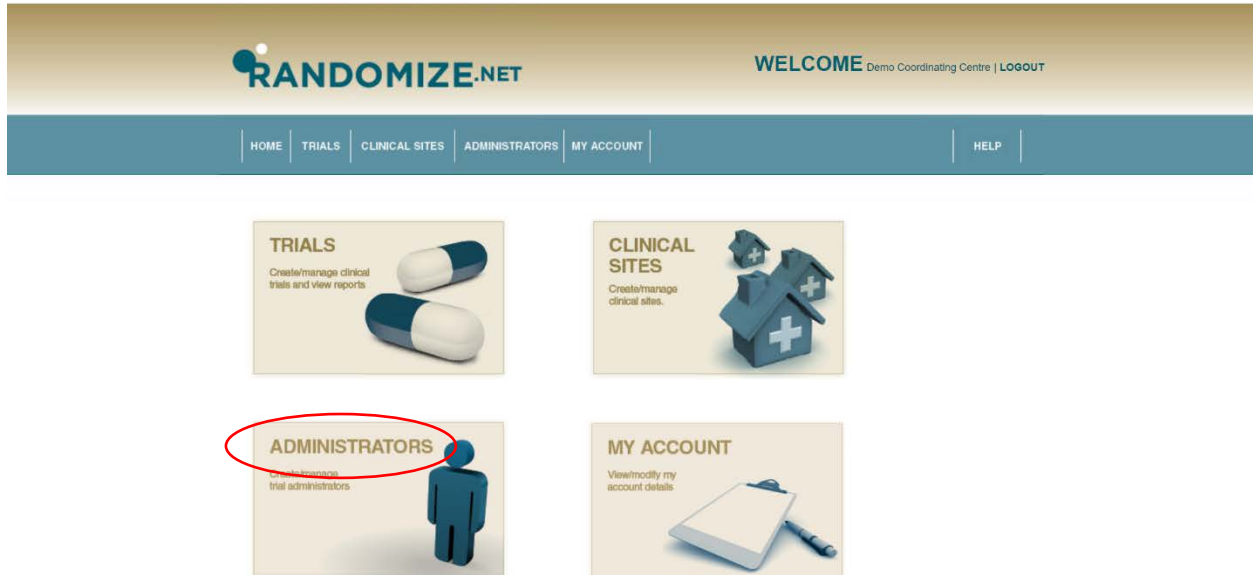
Select an administrator to manage:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demoaud	Demo Auditor	demoaud@randomize.net	Auditor	True
demofa	Demo Full Admin	demofa@randomize.net	Full Admin	True
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True

CREATE ADMINISTRATOR

2.2 Create a *Full Administrator* Account

To create a *Full Administrator* Account, click on “ADMINISTRATORS” from the *Coordinating Centre* home page.




Click on “CREATE ADMINISTRATOR”.

The screenshot shows the Randomize.NET website interface. At the top, there is a header with the Randomize.NET logo and a welcome message: "WELCOME Demo Coordinating Centre | LOGOUT". Below the header is a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled "ADMINISTRATORS" and includes a sub-header "Select Administrator". Below this, there is a table with the following data:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True

Below the table, there is a button labeled "CREATE ADMINISTRATOR" which is circled in red.

Provide “Login ID”, “Name”, “Email” address, and tick “Full Admin”, as shown in the screen on the next page.



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CREATE ADMINISTRATOR

Login ID:

Name:

Email:

Enrollment Type: ☒ Email ☐ Set Password

Roles: ☐ Full Admin
☐ Auditor
☐ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.

Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.

Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

CREATE ADMINISTRATOR

CANCEL

Once completed, click on “CREATE ADMINISTRATOR” and the *Full Administrator* will be created, and you will be taken to the screen on the next page.

Clicking on “CANCEL” will take you back and not create the *Full Administrator*.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

CREATE ADMINISTRATOR

Login ID: demofa

Name: Demo Full Admin

Email: demofa@randomize.net

Enrollment Type: ☒ Email ☐ Set Password

Roles: ☒ Full Admin ☐ Auditor ☐ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.
Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.
Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

CREATE ADMINISTRATOR CANCEL

Selecting “Email”, the default, will send an email to the *Full Administrator* requesting them to set a password for their account. Selecting “Set Password” will require you to set the password and send it to the *Full Administrator*.

Details of the *Full Administrator* account are shown.

Clicking on “ADMINISTRATORS” takes you to the screen on the next page.


The screenshot displays the RANDOMIZE.NET interface. The top navigation bar includes links for HOME, TRIALS, CLINICAL SITE, ADMINISTRATORS (highlighted with a red circle), MY ACCOUNT, and HELP. Below the navigation bar, a message states "Account successfully created." The main section is titled "ADMINISTRATOR DETAILS" and includes a table with the following information:

LOGIN ID	demofa
NAME	Demo Full Admin
E-MAIL	demofa@randomize.net
ENABLED	True
ROLES	Full Admin

A red arrow points from a text box to the "ENABLED" field in the table. The text box contains the following text:

By default, “ENABLED” is set to “True”. To set it to “False”, click on “Edit Administrator Details”.

The new *Full Administrator* account is now shown.

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Select Administrator

ADMINISTRATORS

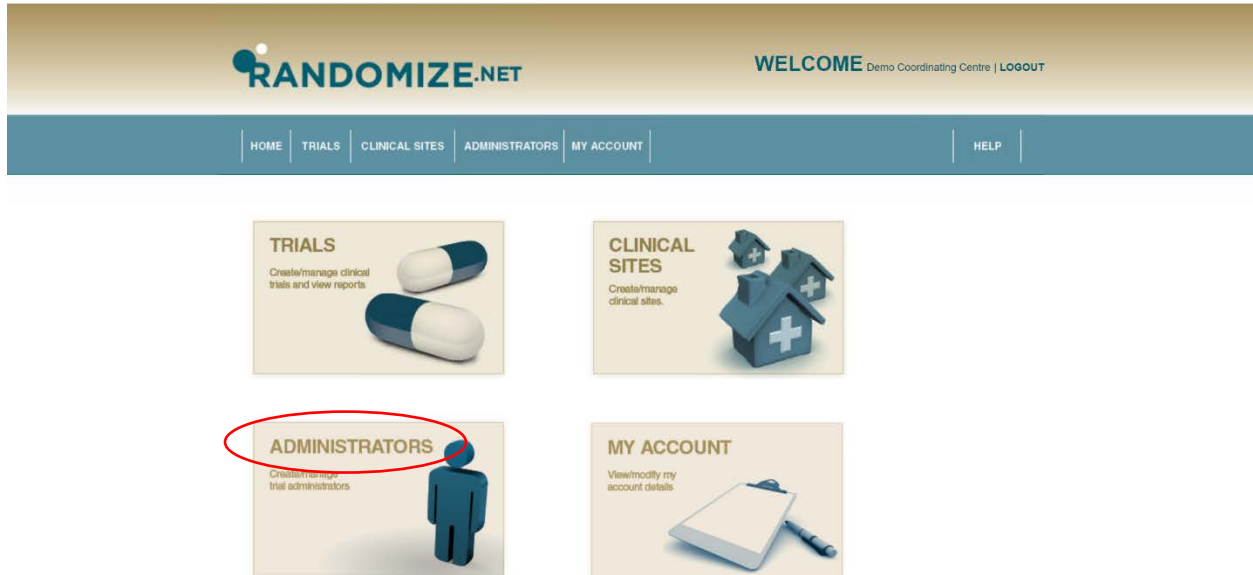
Select an administrator to manage:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demofa	Demo Full Admin	demofa@randomize.net	Full Admin	True
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True

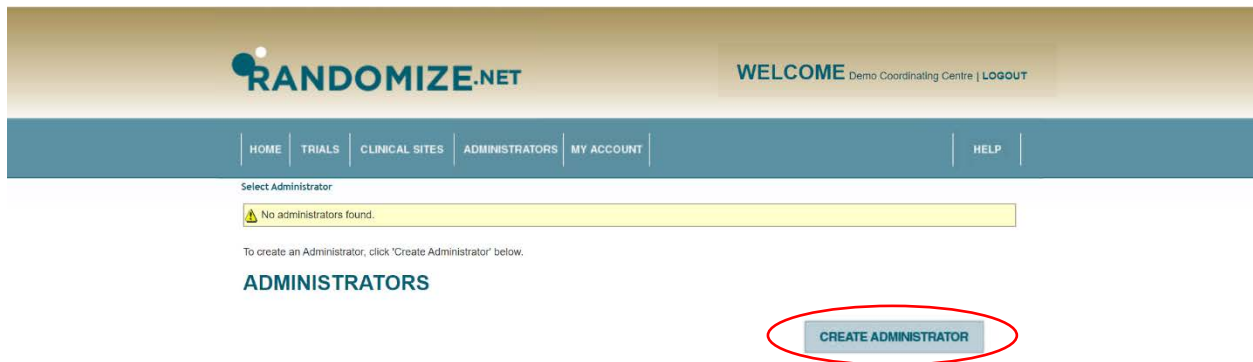
CREATE ADMINISTRATOR

2.3 Create a *Kit Administrator* Account


To create an *Kit Administrator* Account for uploading and assigning kits, click on “ADMINISTRATORS” from the *Coordinating Centre* home page.



Click on “CREATE ADMINISTRATOR”.



Provide “Login ID”, “Name”, “Email” address, and tick “Kit Administrator”, as shown in the screen on the next page.



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CREATE ADMINISTRATOR

Login ID:

Name:

Email:

Enrollment Type: ☒ Email ☐ Set Password

Roles: ☐ Full Admin
☐ Auditor
☐ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.

Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.

Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

CREATE ADMINISTRATOR

CANCEL

Once completed, click on “CREATE ADMINISTRATOR” and the *Kit Administrator* will be created and you will be taken to the screen on the next page.

Clicking on “CANCEL” will take you back to the screen on the previous page and not create the *Kit Administrator*.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

CREATE ADMINISTRATOR

Login ID:

Name:

Email:

Enrollment Type: ☒ Email ☐ Set Password

Roles: ☐ Full Admin ☐ Auditor ☒ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.
Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.
Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

Selecting “Email”, the default, will send an email to the Kit Administrator requesting them to set a password for their account. Selecting “Set Password” will require you to set the password and send it to the Kit Administrator.

The details for the newly created “Demo Kit Administrator” are shown.

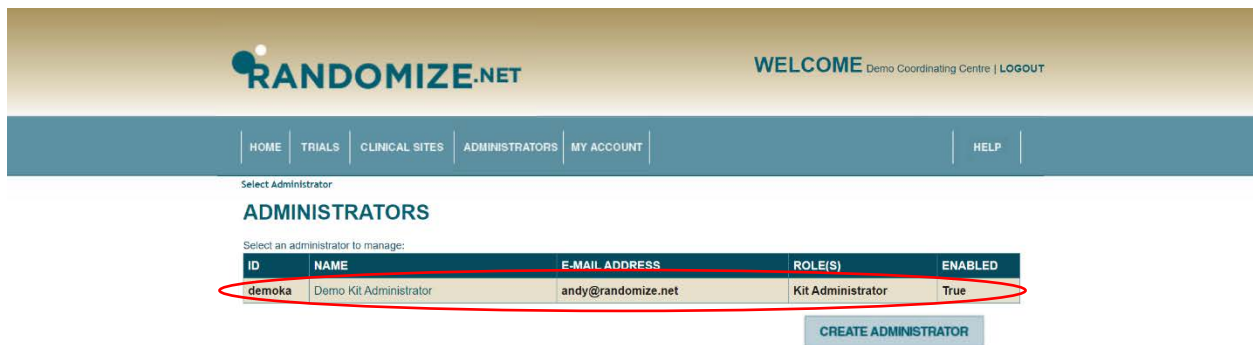
Click on “ADMINISTRATORS” takes you to the screen on the next page.

The screenshot shows the Randomize.NET interface. The top navigation bar includes links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS (highlighted with a red circle), MY ACCOUNT, and HELP. Below the navigation bar, the page title is "ADMINISTRATOR DETAILS" with a breadcrumb "Select Administrator > Administrator Details". A sub-header "Edit Administrator Details | Send Password Reset Email" is present. The main content is a table with the following details:

LOGIN ID	demoka
NAME	Demo Kit Administrator
E-MAIL	andy@randomize.net
ENABLED	True
ROLES	Kit Administrator

A red callout box points to the "ENABLED" field with the text: "By default, “ENABLED” is set to “True”. To set it to “False”, click on “Edit Administrator Details”.

The newly created *Kit Administrator* account is now shown.



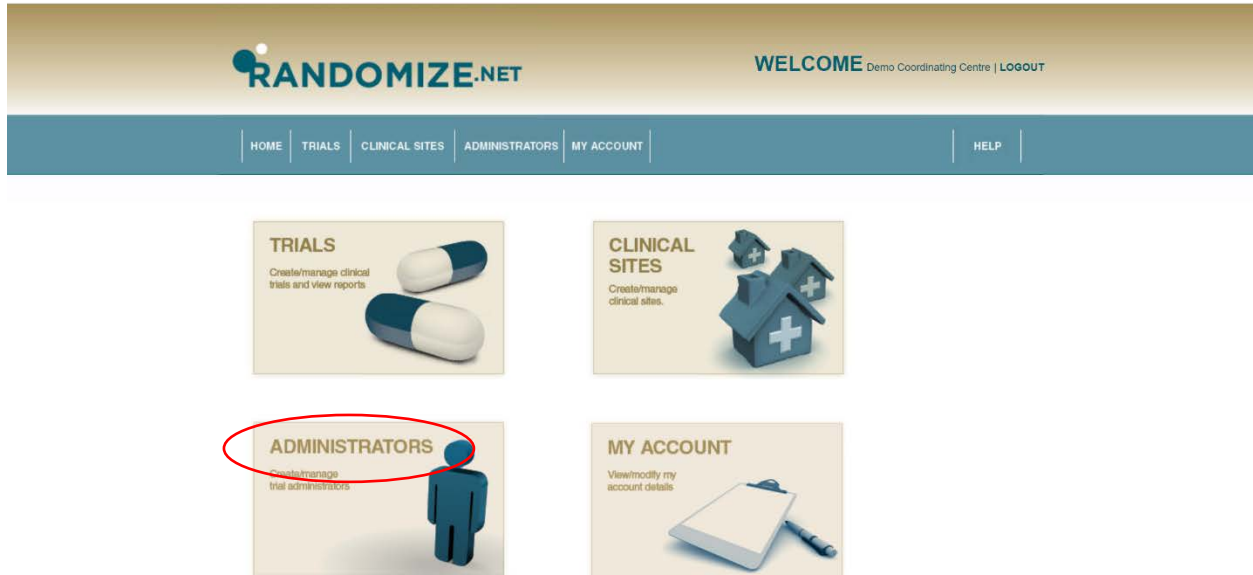
The screenshot shows the RANDOMIZE.NET website interface. The header includes the logo and a welcome message for the Demo Coordinating Centre. A navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, the page title is "ADMINISTRATORS" with a sub-header "Select Administrator". A table lists administrators, with one entry highlighted by a red circle. The table has columns for ID, NAME, E-MAIL ADDRESS, ROLE(S), and ENABLED. Below the table is a "CREATE ADMINISTRATOR" button.

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True


CREATE ADMINISTRATOR

2.4 Edit *Administrator* Account Details

To edit an *Administrator* Account details, click on “ADMINISTRATORS” from the *Coordinating Centre* home page.



Click on the name of the *Administrator* you want to edit.



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Select Administrator


ADMINISTRATORS

Select an administrator to manage:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demoauditor	Demo Auditor	demoaud@randomize.net	Auditor	True
demofa	Demo Full Admin	demofa@randomize.net	Full Admin	True
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True

CREATE ADMINISTRATOR

Administrator details are shown. Click on “Edit Administrator Details”.



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Select Administrator » Administrator Details

ADMINISTRATOR DETAILS

[Edit Administrator Details](#) | [Send Password Reset Email](#)

LOGIN ID	demoauditor
NAME	Demo Auditor
E-MAIL	demoaud@randomize.net
ENABLED	True
ROLES	Auditor

You can then edit the “Name”, “Administrator Email” address, reset the “Enabled” setting and change the “Roles”. See screen on the next page for an example.

You cannot change the “Login ID”.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Administrator » Administrator Details » Edit Administrator Details

EDIT ADMINISTRATOR

Login ID: **demoauditor**

Name:

Administrator Email:

Enabled: ☒ True ☐ False

☐ Full Admin

Roles: ☒ Auditor ☐ Kit Administrator

Administrator Roles Help
Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.
Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.
Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

In this example we have reset “Enabled” to “False” and changed to role to “Full Admin”.

Clicking on “SAVE CHANGES” saves the edits and takes you to the screen on the next page.

Clicking on “CANCEL” returns you to the screen on the previous page without saving the changes.

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Select Administrator » Administrator Details » Edit Administrator Details

EDIT ADMINISTRATOR

Login ID: **demoauditor**

Name: Demo Auditor

Administrator Email: demoaud@randomize.net

Enabled: ☐ True ☒ False

☒ Full Admin


Roles: ☐ Auditor ☐ Kit Administrator

Administrator Roles Help

Full Admin - An full administrator that perform all the same tasks as the Coordinating Center.
Auditor - A read-only administrator that cannot make any changes to the trials or Clinical Sites.
Kit Administrator - An unblinded administrator that can import/assign/view kits and can also view all trial and Clinical Site information.

SAVE CHANGES **CANCEL**

The changes are now shown. Clicking on “ADMINISTRATORS” takes you to the screen on the next page.



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Select Administrator » Administrator Details


Account details successfully updated.

ADMINISTRATOR DETAILS

[Edit Administrator Details](#) | [Send Password Reset Email](#)

LOGIN ID	demoauditor
NAME	Demo Auditor
E-MAIL	demoaud@randomize.net
ENABLED	False
ROLES	Full Admin

The new settings are shown in the list of *Administrators*.



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Select Administrator

ADMINISTRATORS

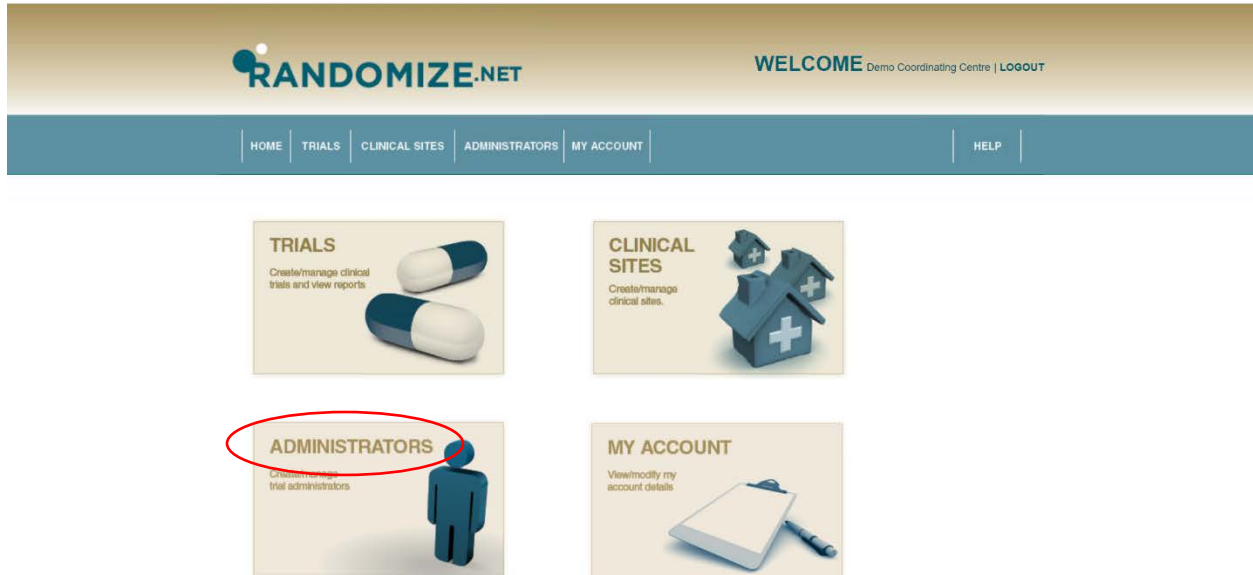
Select an administrator to manage:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demoauditor	Demo Auditor	demoaud@randomize.net	Full Admin	False
demofa	Demo Full Admin	demofa@randomize.net	Full Admin	True
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True


CREATE ADMINISTRATOR

2.5 Reset *Administrator* Account Passwords

To reset *Administrator* Account password, click on “ADMINISTRATORS” from the *Coordinating Centre* home page.



Click on the name of the *Administrator* for whom you want to reset the password.



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Select Administrator


ADMINISTRATORS

Select an administrator to manage:

ID	NAME	E-MAIL ADDRESS	ROLE(S)	ENABLED
demoauditor	Demo Auditor	demoaud@randomize.net	Auditor	True
demofa	Demo Full Admin	demofa@randomize.net	Full Admin	True
demoka	Demo Kit Administrator	andy@randomize.net	Kit Administrator	True

CREATE ADMINISTRATOR

Administrator details are shown. Click on “Send Password Reset Email” and an email message is sent to the *Administrator* to allow them to reset their password.



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Select Administrator » Administrator Details

ADMINISTRATOR DETAILS

Edit Administrator Details | [Send Password Reset Email](#)

LOGIN ID	demoka
NAME	Demo Kit Administrator
E-MAIL	andy@randomize.net
ENABLED	True
ROLES	Kit Administrator

Click on “OK”.

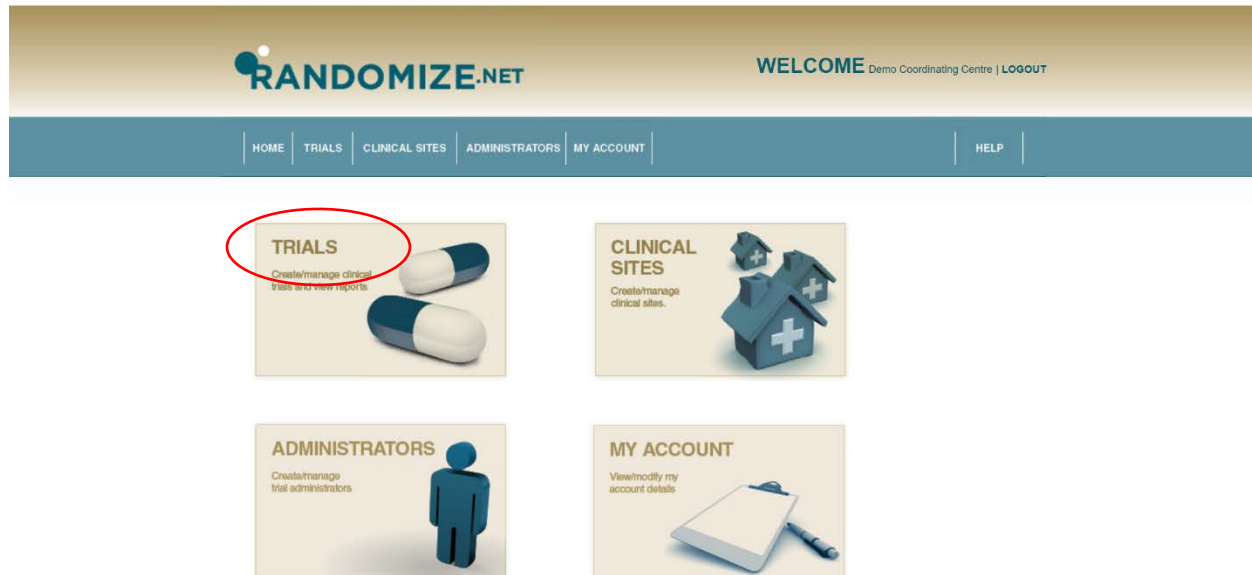
The screenshot shows a web browser window with the URL `randomize.net/Randomize/CoordinatingCenter/Accounts.aspx`. A confirmation dialog box is displayed in the center, asking: "Are you sure you want to send password reset email to this administrator?". The dialog box has two buttons: "OK" (highlighted with a red circle) and "Cancel".

The background page is titled "ADMINISTRATOR DETAILS" and shows the details for an administrator named "demoka". The page includes a navigation menu with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The administrator details are as follows:

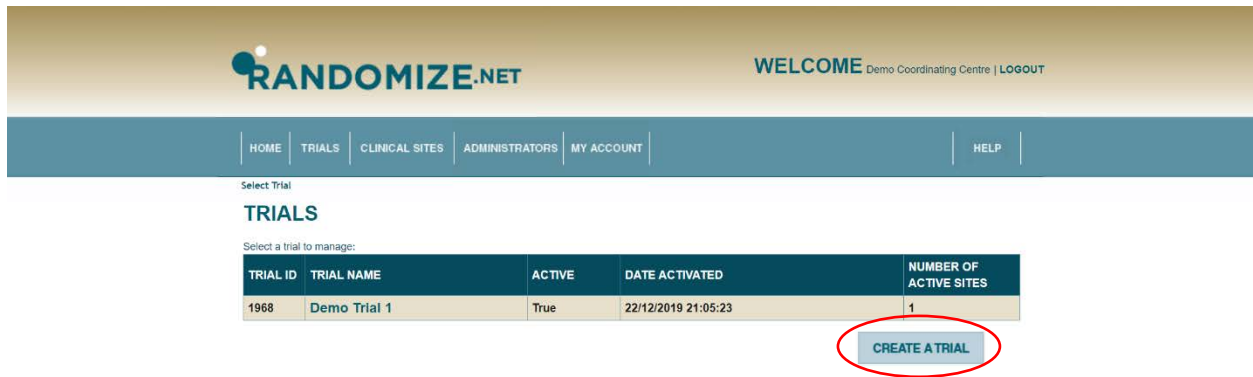
PROPERTY	VALUE
LOGIN ID	demoka
NAME	Demo Kit Administrator
E-MAIL	andy@randomize.net
ENABLED	True
ROLES	Kit Administrator

3.1 Create a New Clinical Trial

To create a randomization application for a new clinical trial, click on “TRIALS” from the *Coordinating Centre* home page.



Then click on “CREATE A NEW TRIAL”.

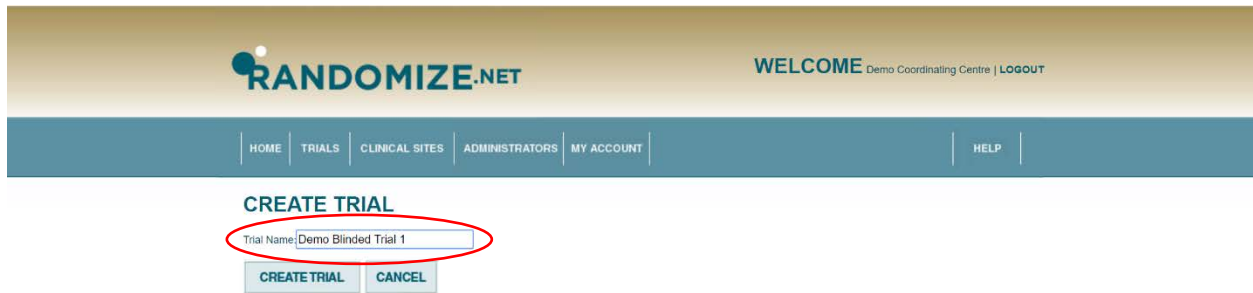


The screenshot shows the Randomize.NET website interface. At the top, there is a header with the logo and a welcome message. Below the header is a navigation bar with links to HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled "TRIALS" and includes a sub-header "Select a trial to manage:". Below this is a table with the following data:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1

Below the table, there is a button labeled "CREATE A TRIAL" which is circled in red.

Type in the name to identify the trial. Clicking on “CREATE TRIAL” will create the randomization application for the new trial and take you to the screen on the next page. Clicking on “CANCEL” will take you back to the screen on the previous page and not create the trial.



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CREATE TRIAL

Trial Name: Demo Blinded Trial 1

CREATE TRIAL CANCEL

The trial details are given on this page. A newly created trial has the defaults as shown below.

Some of the details can be edited by clicking on “Edit Trial Details”.

Other features of the trial can be added/edited by selecting the appropriate task, such as “Notification Emails”, “Edit Inclusion/Exclusion Criteria”, *etc.*

The “TRIAL ID” (in this case “1972”) is automatically assigned as a unique identifier and is used by the software in the background.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

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Select Trial > Trial Details

Trial successfully created.

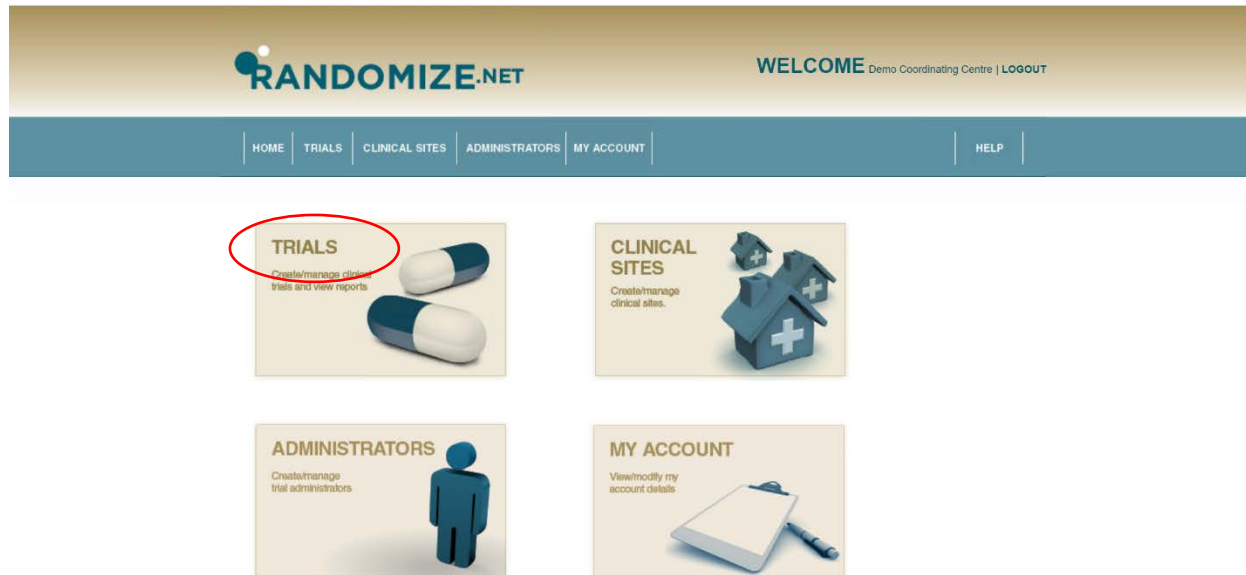
TRIAL DETAILS

Edit Trial Details Notification Emails Edit Inclusion/Exclusion Criteria Edit Stratification Information Edit Treatments Activate Clinical Sites Limits Activate Trial


TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

3.2 Edit Clinical Trial Details

To edit the details for a clinical trial, click on “TRIALS” from the *Coordinating Centre* home page.



Click on the Clinical trial whose details you want to edit.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	22-01-2020 20:06:43	0

CREATE A TRIAL

Click on “Edit Trial Details”.



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Select Trial > Trial Details

Trial successfully created.

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Edit Stratification Information](#) | [Edit Treatments](#) | [Activate Clinical Sites](#) | [Limits](#) | [Activate Trial](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

From this page some of the defaults can be changed. Clicking on “SAVE CHANGES” will save the changes and take you back to the screen on the previous page.

Clicking on “CANCEL” will remove all changes made during the session and take you back to the screen on the previous page.

Details on how to add a variable to be collected at the time of randomization are given on the next page.

RANDOMIZE.NET

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT

Select Trial » Trial Details » Edit Trial Details

EDIT TRIAL DETAILS

Trial Name: Demo Blinded Trial 1

Record Patient Initials: ☐ Yes ☒ No

Record Patient Birthdate: ☐ Yes ☒ No

[+ Add Other Recorded Variable](#)

Allow registration of patients prior to randomization: ☒ Yes ☐ No

Minimum Patient ID Length: 1

Maximum Patient ID Length: 12

Auto-Increment Patient ID: ☒ Yes ☐ No

Timezone Preference: (UTC-05:00) Eastern Time (US & Canada)

Datetime format: dd/MM/yyyy HH:mm:ss (e.g. 09/01/2020 21:25:06)

Trial Patient ID Prefix (Optional):

Double Blind Trial: ☐ Yes ☒ No

Confirmation Screen: ☒ Yes ☐ No

[SAVE CHANGES](#) [CANCEL](#)

Callout Boxes:

- Top Left:** The length of the Patient ID can be restricted. The length does NOT include any pre-set prefixes.
- Top Right:** If "Yes", the Patients Initials and/or Birthdate will be recorded when the patient is randomized by the Clinical Site.
- Middle Right:** Other patient-level variables can be recorded at randomization. Details given on next page. Since the Patient ID is required elsewhere, it should not be included here as "Other Recorded Variable."
- Bottom Left:** If "Yes", Patient IDs will be automatically incremented and pre-filled for the Clinical Site starting at 001. If Clinical Site prefixes are to be used, the numbering will start at 001 at each Clinical Site. Otherwise, Patient IDs will increment across Clinical Sites.
- Bottom Left (continued):** If "Yes", it is important not to change Patient ID Prefix settings after the first patient has been registered or randomized.
- Bottom Left (continued):** If "Yes", leave Minimum and Maximum ID length as the defaults of 1 and 12, respectively.
- Bottom Left (continued):** If "Yes" then "Allow registration of patients prior to randomization" must be "No".
- Bottom Right:** If "Yes", a Clinical Site can register a patient and then randomize them in a later session.
- Bottom Right:** If "Yes" then "Auto-Increment Patient ID" must be "No".
- Bottom Right:** Details of the date stamp recorded when the patient is randomized.
- Bottom Right:** Specifies a pre-filled prefix for the ID of all patients.
- Bottom Right:** If "Yes", the Clinical Site is given a *Kit Number* at the time of randomization rather than the actual treatment assignment.
- Bottom Right:** If "Yes", the Clinical Site will be asked to confirm the Patient ID and stratification information prior to randomization.

After clicking on the “+” sign just to the left of “Add Other Recorded Variable” you will need to provide some information. From this page some of the defaults can be changed.

Note: Patient ID number, Clinical Site and the value of all stratification variables will be recorded, so there is no need to add them as “Add Other Recorded Variable”.

Clicking on “SAVE CHANGES” will add the variable to be collected.

Clicking on “CANCEL” will remove the variable and it will not be collected.

The screenshot shows the 'EDIT TRIAL DETAILS' page on the RANDOMIZE.NET website. The page has a header with the logo and navigation links. The main content area is titled 'EDIT TRIAL DETAILS' and contains various settings for a trial named 'Demo Blinded Trial 1'. Red callout boxes with arrows point to specific options, providing detailed explanations for each.

Callout Boxes:

- Provide the name of the variable as displayed to the Clinical Site.** (Points to the 'Record Other Variable 1' text field)
- If "Yes", the patient cannot be randomized unless a value for the variable is recorded.** (Points to the 'Is value required?' radio buttons)
- If "Text" is selected, the variable is a text field with up to 23 characters.** (Points to the 'Text' radio button)
- If "Month/Year" is selected, month will be entered from a drop-down box and year as a 4-digit number.** (Points to the 'Month/Year' radio button)
- If "Drop Down List" is selected, you will be asked to provide the items for the drop-down list. Only one item can be selected per patient.** (Points to the 'Drop Down List' radio button)
- If "Large Text Area" is selected, the variable is a text field with up to 4000 characters.** (Points to the 'Large Text Area' radio button)
- If "Date" is selected, the variable will be in dd/mm/yyyy format.** (Points to the 'Date' radio button)
- If "Multi-Select list" is selected, you will be asked to provide the items for the list. More than one item can be selected per patient.** (Points to the 'Multi-Select List' radio button)

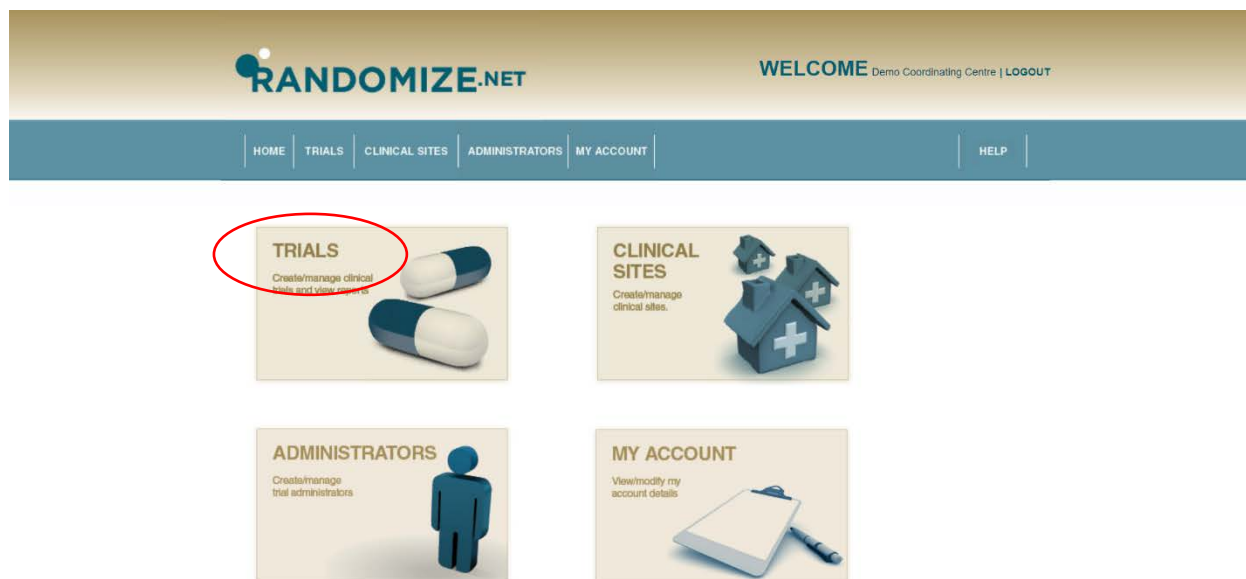
Form Fields and Options:

- Trial Name: Demo Blinded Trial 1
- Record Patient Initials: Yes (selected) / No
- Record Patient Birthdate: Yes (selected) / No
- Record Other Variable 1: [Text Field]
- Is value required? Yes (selected) / No
- Type: Text (selected) / Month/Year / Drop Down List / Multi-Select List / Large Text Area / Date
- Allow registration of patients prior to randomization: Yes (selected) / No
- Minimum Patient ID Length: 1
- Maximum Patient ID Length: 12
- Auto-Increment Patient ID: Yes (selected) / No
- Timezone Preference: (UTC-05:00) Eastern Time (US & Canada)
- Datetime format: MM/dd/yyyy HH:mm:ss (selected) / E.g. 01/19/2020 00:16:49
- Trial Patient ID Prefix (Optional): [Text Field]
- Double Blind Trial: Yes (selected) / No
- Confirmation Screen: Yes (selected) / No
- Buttons: SAVE CHANGES, CANCEL


3.3 Add / Edit / Delete Treatment Arms

To add, edit or delete treatment arms, click on “TRIALS” from the *Coordinating Centre* home page.

By default, patients have an equal probability of being randomized to each treatment arm. However, other ratios can be configured by request to info@randomize.net.



Click on the trial you want to add Treatment arms to.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Edit Treatments”.



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Select Trial » Trial Details

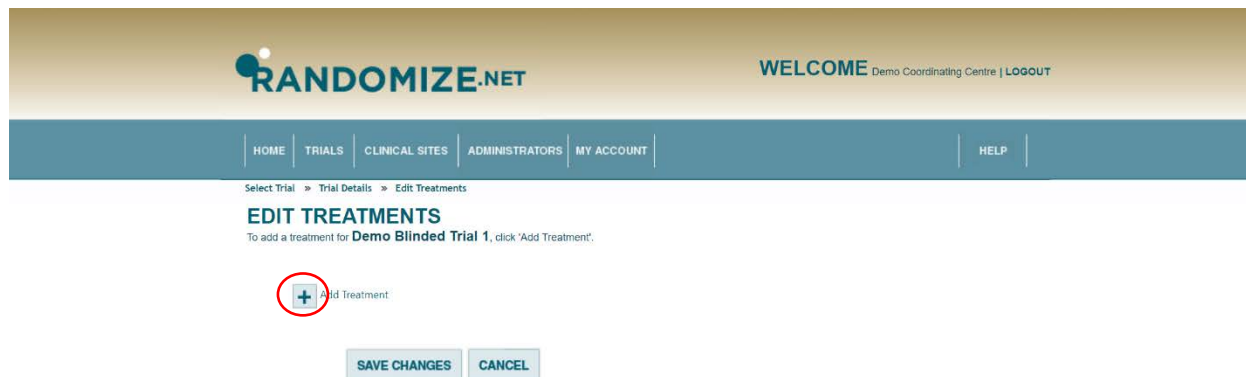
Trial successfully created.

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Edit Stratification Information | [Edit Treatments](#) | [Activate Clinical Sites](#) | Limits | Activate Trial

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

Click on the “+” sign next to “Add Treatment”.



Type in the name of the Treatment Arm and click on the “disk” sign to the right to save. Clicking on the “red cross” will remove the treatment arm.



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Select Trial > Trial Details > Edit Treatments

EDIT TREATMENTS

To add a treatment for **Demo Blinded Trial 1**, click 'Add Treatment'.

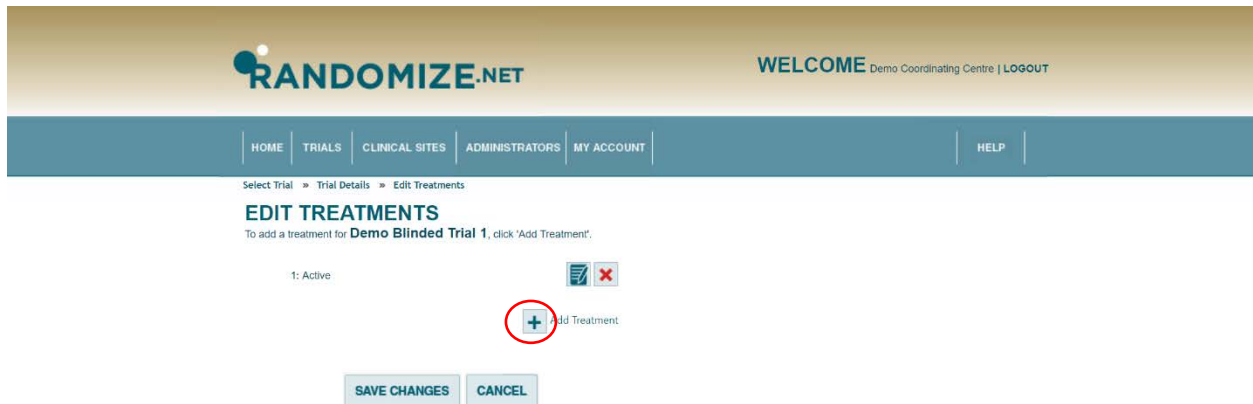
1: Active	 
-----------	---

+ Add Treatment

SAVE CHANGES CANCEL

javascript:_doPostBack('ctl00\$ContentPlaceHolder1\$LinkButtonAddTreatment','')

The process can be repeated to add additional treatment arms.



Adding a Placebo treatment arm.

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Select Trial » Trial Details » Edit Treatments

EDIT TREATMENTS

To add a treatment for **Demo Blinded Trial 1**, click 'Add Treatment'.

1: Active

2: Placebo

+ Add Treatment

SAVE CHANGES CANCEL

javascript:_doPostBack('ctl00\$ContentPlaceHolder1\$LinkButtonAddTreatment','')

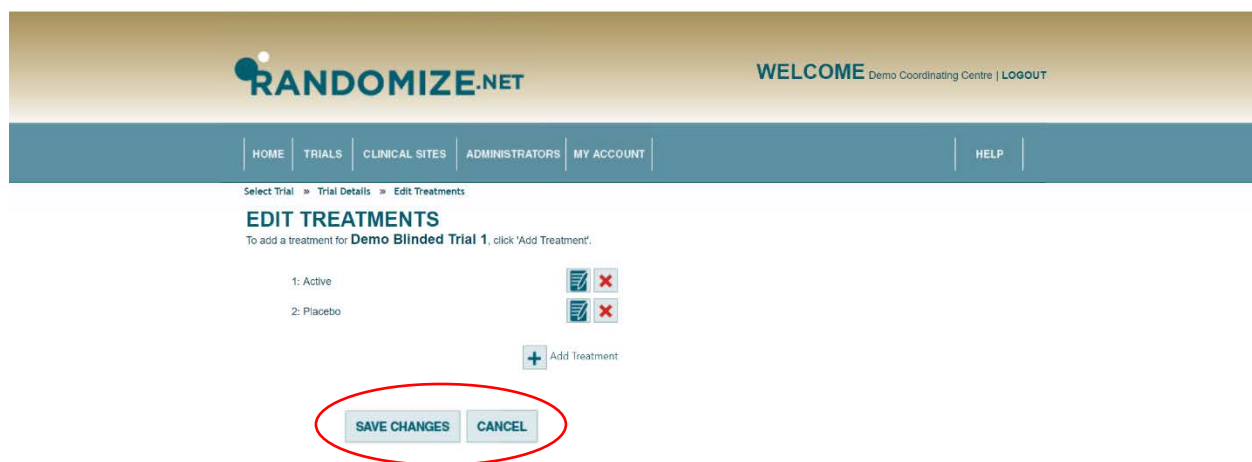
By default, patients have an equal probability of being randomized to each treatment arm. However, other ratios can be configured by request to info@randomize.net.

Clicking on “SAVE CHANGES” will save all actions processed during the session.

Prior to activating the trial, a treatment arm can be deleted by clicking on the “red cross”, or edited by clicking on the “edit” symbol.

Once the trial has be activated, a treatment arm CANNOT be added, deleted, nor edited.

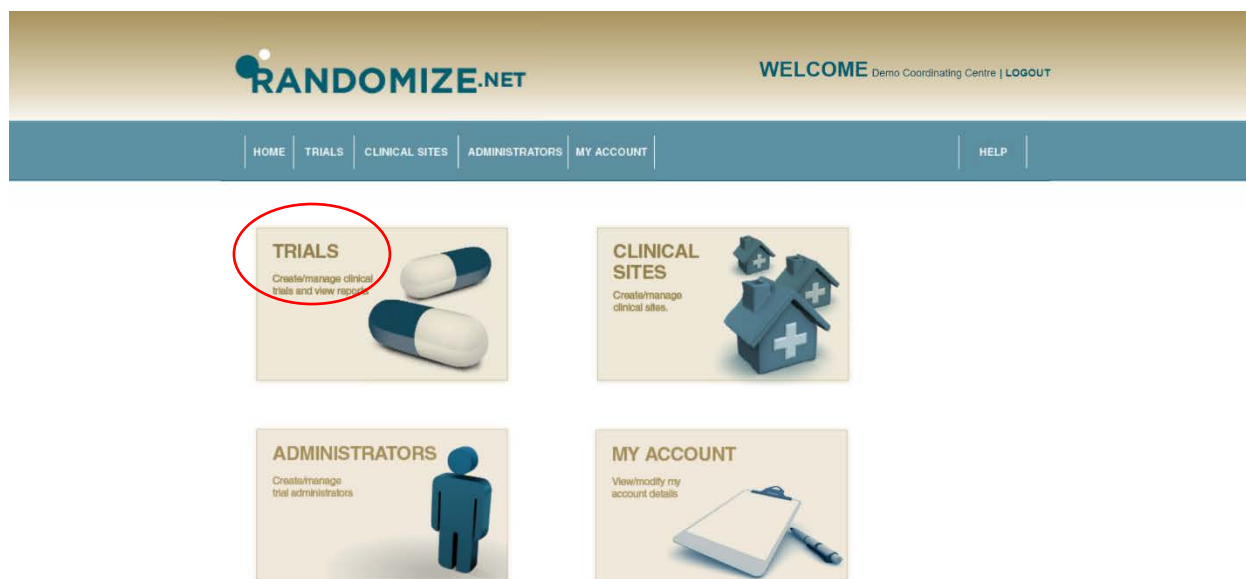
Clicking on “CANCEL” will remove all actions processed during the session.




3.4 Add Inclusion and Exclusion Criteria (optional)

As an optional feature, inclusion and exclusion criteria can be added. The criteria are framed as questions. Each time a *Clinical Site* logs in to randomize a patient, they must answer the questions. For a patient to be eligible the answer to all the inclusion criteria must be ‘yes’ and the answer to all the exclusion criteria must be ‘no’. If the answer to an inclusion criterion is ‘no’ or the answer to an exclusion criterion is ‘yes’, the patient cannot be randomized.

From the *Coordinating Centre* home page, click on “TRIALS”.



Click on trial for which criteria is to be added. In this case “Demo Blinded Trial 1”.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Edit Inclusion/Exclusion Criteria”.



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Select Trial » Trial Details

Trial successfully created.

TRIAL DETAILS

Edit Trial Details | Notification Emails | [Edit Inclusion/Exclusion Criteria](#) | Edit Stratification Information | Edit Treatments | Activate Clinical Sites | Limits | Activate Trial

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

Click on the “+” sign next to “Add Inclusion Criteria”.


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Select Trial > Trial Details > Edit Inclusion/Exclusion Criteria

EDIT INCLUSION/EXCLUSION CRITERIA (Optional)

Inclusion Criteria: Should be framed as a question, so that the answer must be 'yes' if the patient is eligible.

 Add Inclusion Criteria

Exclusion Criteria: Should be framed as a question, so that the answer must be 'no' if the patient is eligible.

 Add Exclusion Criteria

SAVE CHANGES **CANCEL**

Type in the first inclusion criterion and then click on the disk symbol just to the right.

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Select Trial » Trial Details » Edit Inclusion/Exclusion Criteria

EDIT INCLUSION/EXCLUSION CRITERIA (Optional)

Inclusion Criteria: Should be framed as a question, so that the answer must be 'yes' if the patient is eligible.

1: Does the patient have the relevant health condition?

+ Add Inclusion Criteria

Exclusion Criteria: Should be framed as a question, so that the answer must be 'no' if the patient is eligible.

+ Add Exclusion Criteria

SAVE CHANGES CANCEL

The process can be repeated to add additional inclusion criteria.

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Select Trial > Trial Details > Edit Inclusion/Exclusion Criteria

EDIT INCLUSION/EXCLUSION CRITERIA (Optional)


Inclusion Criteria: Should be framed as a question, so that the answer must be 'yes' if the patient is eligible.

1: Does the patient have the relevant health condition?

 Add Inclusion Criteria

Exclusion Criteria: Should be framed as a question, so that the answer must be 'no' if the patient is eligible.

 Add Exclusion Criteria

SAVE CHANGES **CANCEL**

When all the inclusion criteria have been added, click on the “+” sign next to “Add Exclusion Criteria”. Add the relevant text and click on the disk symbol just to the right. The process can be repeated until all the exclusion criteria have been added.

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Select Trial » Trial Details » Edit Inclusion/Exclusion Criteria

EDIT INCLUSION/EXCLUSION CRITERIA (Optional)

Inclusion Criteria: Should be framed as a question, so that the answer must be 'yes' if the patient is eligible.

- 1: Does the patient have the relevant health condition?
- 2: Can the patient communicate in English or Spanish?
- 3: Has the patient signed informed consent?

+ Add Inclusion Criteria

Exclusion Criteria: Should be framed as a question, so that the answer must be 'no' if the patient is eligible.

- 1: Is the patient less than 18 years for age?

+ Add Exclusion Criteria

SAVE CHANGES CANCEL

Additional criteria can be added at any time. To edit a particular criterion, click on the “edit” symbol just to the right.

To finalize click on “SAVE CHANGES”. Clicking on “CANCEL” will delete all criteria added during the session.

The screenshot displays the 'EDIT INCLUSION/EXCLUSION CRITERIA (Optional)' page on the Randomize.NET platform. The header includes the site logo and navigation links. The main content area is divided into two sections: 'Inclusion Criteria' and 'Exclusion Criteria'. Each section contains a list of criteria with associated edit and delete icons. At the bottom of the page, there are two buttons: 'SAVE CHANGES' and 'CANCEL'. The 'SAVE CHANGES' button is circled in red, indicating the final step to save the changes.

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Select Trial » Trial Details » Edit Inclusion/Exclusion Criteria

EDIT INCLUSION/EXCLUSION CRITERIA (Optional)

Inclusion Criteria: Should be framed as a question, so that the answer must be 'yes' if the patient is eligible.

- 1: Does the patient have the relevant health condition? [edit] [delete]
- 2: Can the patient communicate in English or Spanish? [edit] [delete]
- 3: Has the patient signed informed consent? [edit] [delete]

+ Add Inclusion Criteria

Exclusion Criteria: Should be framed as a question, so that the answer must be 'no' if the patient is eligible.

- 1: Is the patient less than 18 years of age? [edit] [delete]
- 2: Is the patient greater than 65 years of age? [edit] [delete]

+ Add Exclusion Criteria

SAVE CHANGES **CANCEL**

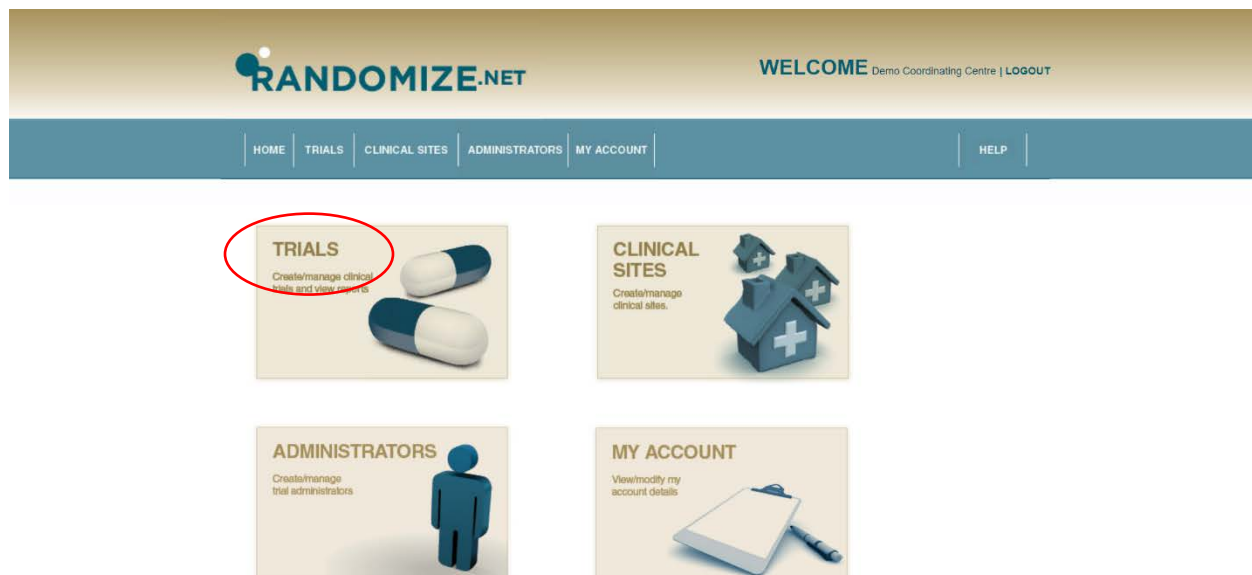
3.5 Add / Edit Stratification Information (optional)

To edit stratification information, click on the “TRIALS” from the *Coordinating Centre* home page.


Note: If you want to use simple randomization, set “Stratify by Clinical Site” to “No”, see [page 71](#). Do NOT add any Blocking Factors or Stratification Variables. Then prior to activating the trial, email info@randomize.net to inform us that you want to use simple randomization. We will configure the simple randomization and inform you when it is done. Be sure to include the *Coordinating Centre* login ID and the trial name and number. Once you have been informed that the simple randomization has been configured, you can activate the trial.

Note: Stratification information CANNOT be changed once the trial is activated.

Note: If you want to use a minimization routine, define the minimization variables and their associated levels using the instructions in this section and, prior to activating the trial, email info@randomize.net to inform us that you want to use a minimization routine. We will configure the minimization routine for you and inform you when it is done. Be sure to include the *Coordinating Centre* login ID and the trial name and number. Once you have been informed that the minimization routine has been configured, you can activate the trial. For a description of the minimization algorithm, please go to [Appendix I](#).



Click on the trial for which you want to edit stratification information.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Edit Stratification Information”.



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Select Trial » Trial Details

Trial successfully created.

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | **Edit Stratification Information** | Edit Treatments | Activate Clinical Sites | Limits | Activate Trial

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

When a trial is created “Stratify by Clinical Site” is set to “yes” by default. This can be changed on this page.

To add a *Blocking Factor*, click on the “+” sign just to the left of “Add Blocking Factor”.

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Select Trial » Trial Details » Edit Stratification Information

EDIT STRATIFICATION INFORMATION

Stratify By Clinical Site: If Yes, system will stratify based on the Clinical Site that is randomizing the patient.

☒ Yes ☐ No

Blocking Factors: The blocking factor is the number of times each treatment appears in a block. Therefore, the block size is the number of treatments multiplied by the blocking factor. For example, a two arm trial with a blocking factor of 3 yields a block size of 6. If more than one blocking factor is configured, the system will randomly choose between the blocking factors when a new block is created.

Add Blocking Factor

Stratification Variables (Optional): For each stratification variable, provide a stratification name and at least two levels.

Add Stratification Variable

To save the *Blocking Factor*, click on the “disk” symbol just to the right. To delete it click on the “red cross”.

A *Blocking Factor* is the number of times a treatment arm appears in a block, so a *Blocking Factor* of two for a two-arm trial results in block sizes of four (*i.e.* 2x2). A *Blocking Factor* of three for a two-arm trial results in block sizes of six (*i.e.* 3x2). When more than one *Blocking Factor* is specified, block sizes are chosen at random from the specified sizes.

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Select Trial > Trial Details > Edit Stratification Information


EDIT STRATIFICATION INFORMATION

Stratify By Clinical Site: If 'Yes', system will stratify based on the Clinical Site that is randomizing the patient.


☒ Yes ☐ No

Blocking Factors: The blocking factor is the number of times each treatment appears in a block. Therefore, the block size is the number of treatments multiplied by the blocking factor. For example, a two arm trial with a blocking factor of 3 yields a block size of 6. If more than one blocking factor is configured, the system will randomly choose between the blocking factors when a new block is created.

2  

 Add Blocking Factor

Stratification Variables (Optional): For each stratification variable, provide a stratification name and at least two levels.

 Add Stratification Variable

SAVE CHANGES CANCEL

To add a stratification variable, click on the “+” sign just to the left of “Add Stratification Variable”.

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Select Trial » Trial Details » Edit Stratification Information


EDIT STRATIFICATION INFORMATION

Stratify By Clinical Site: If 'Yes', system will stratify based on the Clinical Site that is randomizing the patient.


☒ Yes ☐ No

Blocking Factors: The blocking factor is the number of times each treatment appears in a block. Therefore, the block size is the number of treatments multiplied by the blocking factor. For example, a two arm trial with a blocking factor of 3 yields a block size of 6. If more than one blocking factor is configured, the system will randomly choose between the blocking factors when a new block is created.

2  

 Add Blocking Factor

Stratification Variables (Optional): For each stratification variable, provide a stratification name and at least two levels.

 Add Stratification Variable

SAVE CHANGES CANCEL

javascript:__doPostBack('ctl00\$ContentPlaceHolder1\$LinkButtonAddStratificationVariable','')

The name of the stratification variable and two levels of the variable can be added. Additional levels of the variable can be added by clicking on the “+” symbol just to the left of “Add Level”

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Select Trial » Trial Details » Edit Stratification Information

EDIT STRATIFICATION INFORMATION

Stratify By Clinical Site: If 'Yes', system will stratify based on the Clinical Site that is randomizing the patient.
☒ Yes ☐ No

Blocking Factors: The blocking factor is the number of times each treatment appears in a block. Therefore, the block size is the number of treatments multiplied by the blocking factor. For example, a two arm trial with a blocking factor of 3 yields a block size of 6. If more than one blocking factor is configured, the system will randomly choose between the blocking factors when a new block is created.
2

Add Blocking Factor

Stratification Variables (Optional): For each stratification variable, provide a stratification name and at least two levels.

Variable 1:

Level a:

Level b:

Add Level

Add Stratification Variable

SAVE CHANGES CANCEL

Clicking on the “disk” symbols just to the right will save the variable name and its levels.

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Select Trial » Trial Details » Edit Stratification Information


EDIT STRATIFICATION INFORMATION

Stratify By Clinical Site: If 'Yes', system will stratify based on the Clinical Site that is randomizing the patient.



☒ Yes ☐ No



Blocking Factors: The blocking factor is the number of times each treatment appears in a block. Therefore, the block size is the number of treatments multiplied by the blocking factor. For example, a two arm trial with a blocking factor of 3 yields a block size of 6. If more than one blocking factor is configured, the system will randomly choose between the blocking factors when a new block is created.



2  


 Add Blocking Factor


Stratification Variables (Optional): For each stratification variable, provide a stratification name and at least two levels.

Variable 1:  

Level a:  

Level b:  

 Add Level

 Add Stratification Variable

Additional stratification variables can be added by repeating the process.

Clicking on “SAVE CHANGES” will save all additions/changes made during the session.

Clicking on “CANCEL” will remove all additions/changes made during the session.

Prior to the trial being activated, additional stratification information can be added and existing information can be edited or deleted.

Once the trial is activated, changes to the stratification information CANNOT be made.

The screenshot displays the 'RANDOMIZE.NET' interface for editing stratification information. The header includes the logo and a 'WELCOME' message. The navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The breadcrumb trail indicates the current path: Select Trial > Trial Details > Edit Stratification Information.

The main section is titled 'EDIT STRATIFICATION INFORMATION'. It contains three main sections:

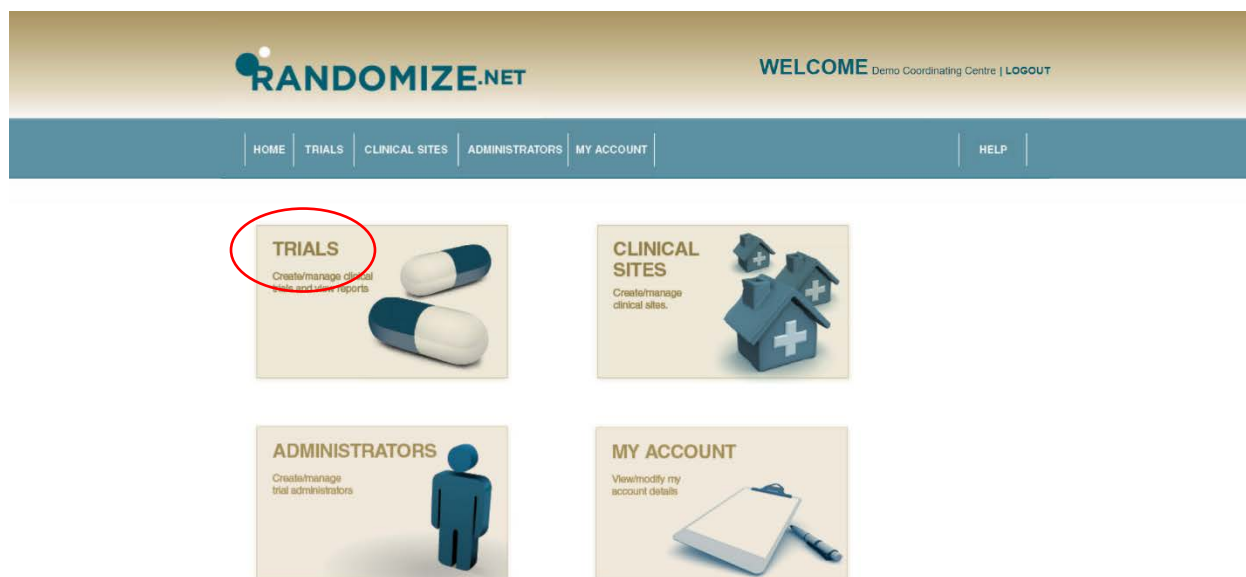
- Stratify By Clinical Site:** A section with a heading 'Stratify By Clinical Site: If "Yes", system will stratify based on the Clinical Site that is randomizing the patient.' and two radio buttons for 'Yes' (selected) and 'No'.
- Blocking Factors:** A section with a heading 'Blocking Factors: The blocking factor is the number of times each treatment appears in a block. Therefore, the block size is the number of treatments multiplied by the blocking factor. For example, a two arm trial with a blocking factor of 3 yields a block size of 6. If more than one blocking factor is configured, the system will randomly choose between the blocking factors when a new block is created.' It shows a value of '2' with edit and delete icons, and an 'Add Blocking Factor' button.
- Stratification Variables (Optional):** A section with a heading 'Stratification Variables (Optional): For each stratification variable, provide a stratification name and at least two levels.' It shows 'Variable 1: Duration since injury' with two levels: 'Level a: Less than 2 years' and 'Level b: 2 years or more'. Each level has edit and delete icons. There is an 'Add Level' button and an 'Add Stratification Variable' button (circled in red).

At the bottom of the form, there are two buttons: 'SAVE CHANGES' and 'CANCEL', both of which are circled in red.


3.6 Add / Edit / Delete Notification Emails (optional)

By default, when a patient is randomized an email notification is sent to the *Coordinating Centre* and to all enabled users at the *Clinical Site* where the patient was randomized. The email notification includes the treatment allocation for an unblinded trial or the *Kit Number* for a blinded trial. To change the default settings, see [page 83](#).

To add people to receive email notifications of randomizations, click on “TRIALS” from the *Coordinating Centre* home page.



Click on the trial for which the additional email notifications are required.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Notification Emails”



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Select Trial » Trial Details

Trial successfully created.

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Edit Stratification Information](#) | [Edit Treatments](#) | [Activate Clinical Sites](#) | [Limits](#) | [Activate Trial](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

Click on the “+” sign next to “Add new email”.

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Select Trial » Trial Details » Notification Emails

NOTIFICATION EMAILS (Optional)

If you want randomization email notifications for **Demo Blinded Trial 1**, add them here.


Send Email to Coordinating center: ☒

Send Email to Clinical Sites: ☒

Exclude Treatment for Clinical Sites: ☐

Include Stratification Details: ☒

Name	Email Address	For Site(s)
1: Andy Willan	andy+100@randomize.net	All Sites
2: Demo Clin Site 1	democlin-site1@randomize.net	Demo Clinical Site 1 <input type="checkbox"/> Exclude treatment

 Add new email

SAVE CHANGES CANCEL

You can then add the name and email address of the new person to receive the notifications, select for which sites they are to receive notifications, and choose to hide the treatment allocation from them by ticking the box to the left of “Exclude treatment”.

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HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Trial » Trial Details » Notification Emails

NOTIFICATION EMAILS (Optional)


If you want randomization email notifications for **Demo Blinded Trial 1**, add them here.

Send Email to Coordinating center: ☒
Send Email to Clinical Sites: ☒
Exclude Treatment for Clinical Sites: ☐
Include Stratification Details: ☒

Name	Email Address	For Site(s)
1: Andy Willan	andy+100@randomize.net	All Sites
2: Demo Clin Site 1	democlinite1@randomize.net	Demo Clinical Site 1 <input type="checkbox"/> Exclude treatment
<input type="text"/>	<input type="text"/>	All Sites <input type="checkbox"/> Exclude treatment

Add new email

As an example Mary Smith with email address mary.smith@whatever.com will receive email notification of patients randomized from All Sites. When completed click on the disk symbol to the right to update. Clicking on the red cross with remove Mary Smith.



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Select Trial » Trial Details » Notification Emails

NOTIFICATION EMAILS (Optional)



If you want randomization email notifications for **Demo Blinded Trial 1**, add them here.


Send Email to Coordinating center: ☒

Send Email to Clinical Sites: ☒

Exclude Treatment for Clinical Sites: ☐

Include Stratification Details: ☒

Name	Email Address	For Site(s)
1: Andy Willan	andy+100@randomize.net	All Sites
2: Demo Clin Site 1	democlin-site1@randomize.net	Demo Clinical Site 1 <input type="checkbox"/> Exclude treatment
3: <input type="text" value="Mary Smith"/>	<input type="text" value="mary.smith@whatever.com"/>	<div>All Sites <input type="checkbox"/> Exclude treatment</div> <div> </div>

 Add new email

SAVE CHANGES

CANCEL

After clicking on the disk symbol Mary Smith has been added. Additional people can also be added by repeating the process. When all the new people have been added click on “SAVE CHANGES”. Clicking on “CANCEL” will remove all the new people that were added during the session.

It is **important to note** that for the emergency unblinding of a patient in a blinded trial, all recipients of the original confirmation email will receive the unblinding email message and therefore will be aware of which treatment the unblinded patients was randomize to.

By unticking the appropriate boxes, you can prevent the *Coordinating Centre* and *Clinical Site* users from receiving the email notifications.

By ticking the appropriate box, you can prevent all *Clinical Sites* users from seeing the allocated treatment for an unblinded trial or the *Kit Number* for a blinded trial.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Trial » Trial Details » Notification Emails

NOTIFICATION EMAILS (Optional)

If you want randomization email notifications for **Demo Blinded Trial 1**, add them here.



Send Email to Coordinating center: ☒


Send Email to Clinical Sites: ☒

Exclude Treatment for Clinical Sites: ☐

Include Stratification Details: ☒

Click this box if you want the stratification information to appear in the notification email.

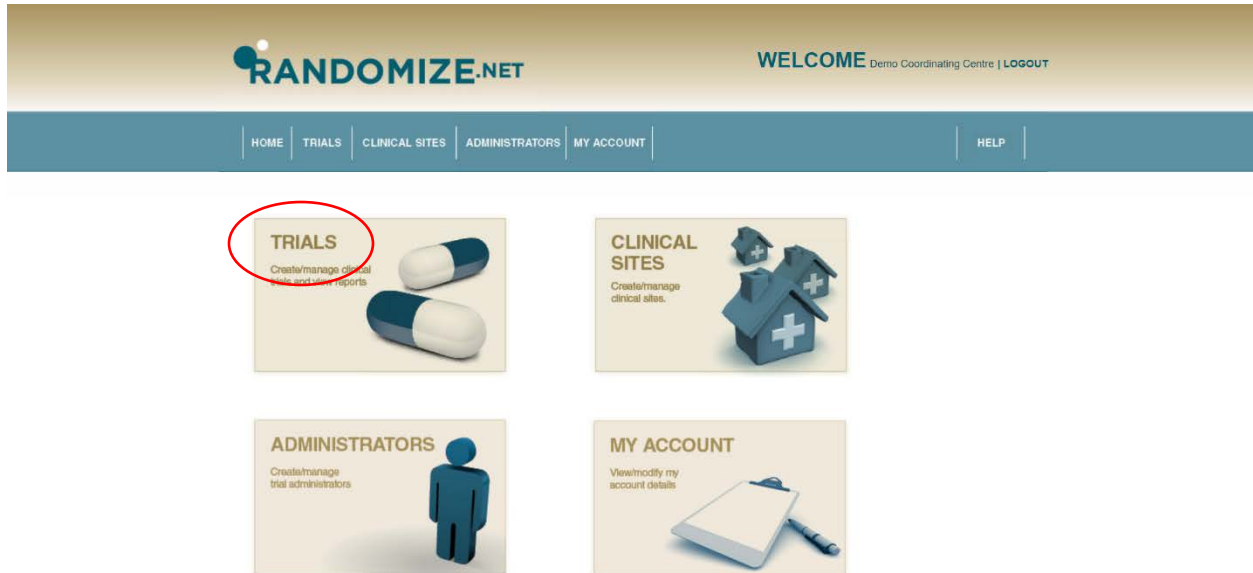
Name	Email Address	For Site(s)
1: Andy Willan	andy+100@randomize.net	All Sites
2: Demo Clin Site 1	democlinite1@randomize.net	Demo Clinical Site 1 <input type="checkbox"/> Exclude treatment
3: Mary Smith	mary.smith@whatever.com	All Sites <input type="checkbox"/> Exclude treatment  

 Add new email


SAVE CHANGES CANCEL

3.7 Add Stratification Information to Notification Emails (optional)

To add the stratification information to the notification emails, click on “TRIALS” from the *Coordinating Centre* home page.



Click on the trial for which the stratification information is to be added to the notification emails.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Notification Emails”



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Select Trial » Trial Details

Trial successfully created.

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Edit Stratification Information](#) | [Edit Treatments](#) | [Activate Clinical Sites](#) | [Limits](#) | [Activate Trial](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

Select Trial » Trial Details » Notification Emails

NOTIFICATION EMAILS (Optional)

If you want randomization email notifications for **Demo Blinded Trial 1**, add them here.

Send Email to Coordinating center: ☒

Send Email to Clinical Sites: ☒

Exclude Treatment for Clinical Sites: ☐

Include Stratification Details: ☒

Tick this box and then click on "SAVE CHANGES"

Name

1: Andy Willan

2: Demo Clin Site 1

Email Address

andy+100@randomize.net

democlin1@randomize.net

For Site(s)

All Sites

Demo Clinical Site ☐ Exclude treatment
1

[+](#) Add new email

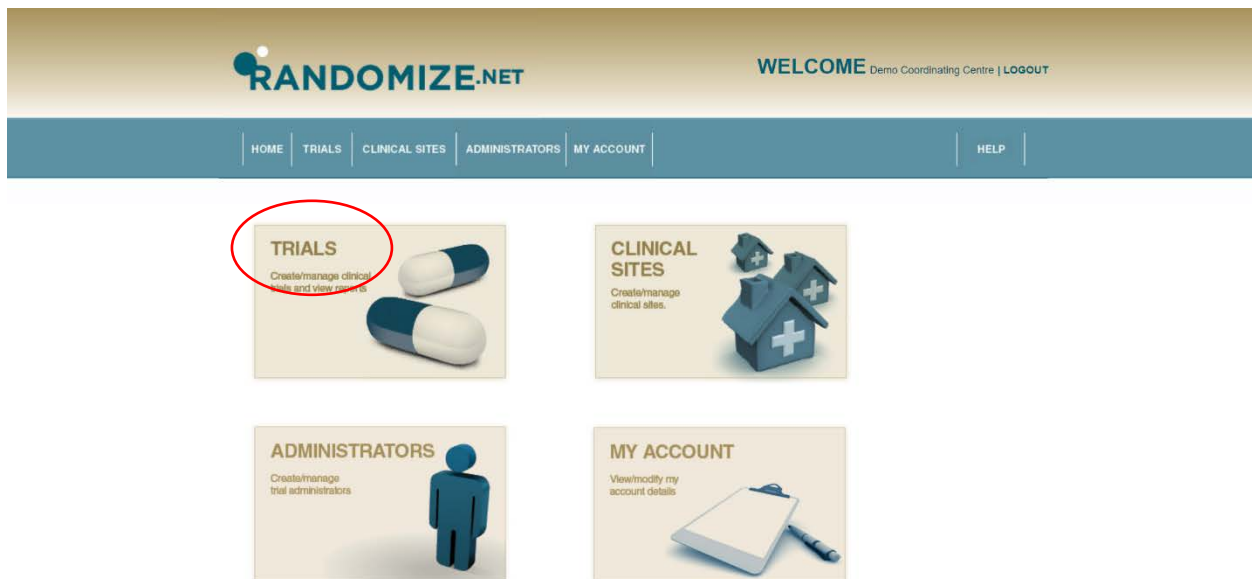
SAVE CHANGES

CANCEL


3.8 Add Limits on the Number of Patients (optional)

To set limits on the number patients, click on “TRIALS” from the *Coordinating Centre* home page.

Limits can be set or re-set even after the trial is activated, but the limits cannot be less than the number of patients already recruited.



Click on the trial you want set limits for.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Limits”.



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Select Trial » Trial Details

Trial successfully created.

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Edit Stratification Information | Edit Treatments | Activate Clinical Site | **Limits** | Activate Trial

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	None
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	None
BLOCK SIZES	N/A
STRATIFICATION VARIABLES	None

By clicking on “Yes” you will be able to:

- set a limit on the total number of patients in the trial,
- set a limit on the number of patients for each activated Clinical Site,
- set a limit on the number of patients for each level on the stratification variables within each Clinical Site.

Clicking on “SAVE CHANGES” will save all actions processed during the session.

Clicking on “CANCEL” will remove all actions processed during the session.

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Select Trial » Trial Details » Set Limits

SET PATIENT LIMITS

Limit patient randomizations: ☒ Yes ☐ No

Overall Trial Limit (0=Unlimited)
Limit number of patients in trial to:

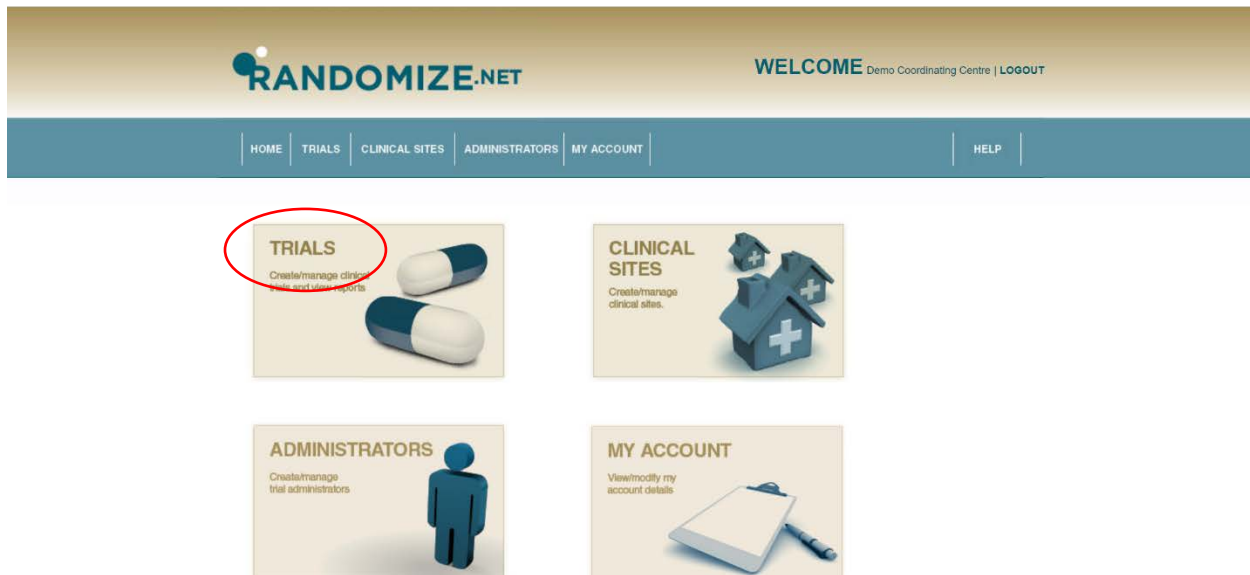
Overall Site Limit (0=Unlimited)
Demo Clinical Site 1

Stratification Level Limit (per site) (0=Unlimited)
Duration since injury
Less than 2 years
2 years or more


3.9 Activate a *Clinical Trial* to Allow Patient Randomization

To activate a trial, click on “TRIALS”.

NOTE: Once a trial has been activated you will not be able to edit the stratification information or add or delete treatment arms.



Click on the trial you want to activate.



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Select Trial

TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

At this point the trial is not activated and there are no active Clinical Sites.

To activate the trial, click on “Activate Trial”.

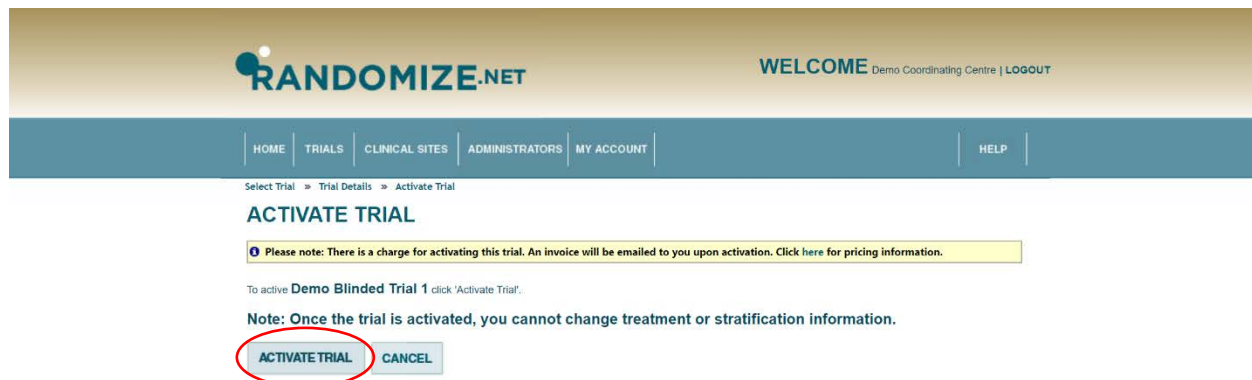
The screenshot shows the Randomize.NET interface. At the top, there is a header with the logo and a welcome message. Below the header is a navigation bar with links to HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area shows the 'TRIAL DETAILS' for 'Demo Blinded Trial 1'. The trial is not activated, and the 'Activate Trial' link is circled in red. The trial details table is as follows:

Field	Value
TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	No
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more


To activate the trial, click on “ACTIVATE TRIAL”. You will be taken to the screen on the next page.

If you click on “CANCEL” the trial will not be activated and you will be taken back to the screen on the previous page.

NOTE: There is a charge for activating a trial. An invoice will be emailed to you.



The trial is now shown as “ACTIVATED” and the time and date of activation is shown.



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Select Trial » Trial Details

Trial successfully activated.

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Activate Clinical Sites | Limits | Reports | Deactivate Trial

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	22/01/2020 19:06:43
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

To deactivate the trial, click on “Deactivate Trial” and then on “Ok”.

The screenshot displays the Randomize.net web application. At the top, a confirmation dialog box asks, "Are you sure you want to deactivate this trial?" with "OK" and "Cancel" buttons. The "OK" button is circled in red. Below the dialog is a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area shows the "TRIAL DETAILS" for trial ID 1972, titled "Demo Blinded Trial 1". The trial is activated, with details including the activation date (22/01/2020 19:06:43), one active clinical site, and various stratification variables. The "Deactivate Trial" link in the top navigation bar is also circled in red.

www.randomize.net says
Are you sure you want to deactivate this trial?

OK Cancel

HOME Demo Coordinating Centre | LOGOUT Deactive clinical trial

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP


Select Trial » Trial Details

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Activate Clinical Sites | Limits | Reports | Deactivate Trial

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	22/01/2020 19:06:43
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

To activate one or more Clinical Sites, allowing them to randomize patients, click on “Activate Clinical Sites”.



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Select Trial > Trial Details

Trial successfully activated.

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Units](#) | [Reports](#) | [Deactivate Trial](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	22/01/2020 19:06:43
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Tick all the *Clinical Sites* you want to activate.

Clicking on “SAVE CHANGES” will activate the ticked *Clinical Sites* allowing them to randomize patients on “Demo Blinded Trial 1”. You will also be taken to the screen shown on the next page.

Clicking on “CANCEL” will take you back to the screen on the previous page and no *Clinical Sites* will be activated.

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Select Trial » Trial Details » Activate Clinical Sites

ACTIVATE CLINICAL SITES

To activate clinical sites for **Demo Blinded Trial 1**, check the 'activate' check box.

ACTIVATE	CLINICAL SITE NAME
<input type="checkbox"/>	Concept Medical, Demo 1
<input checked="" type="checkbox"/>	Demo Clinical Site 1

SAVE CHANGES CANCEL

One *Clinical Site* is now shown as activated.

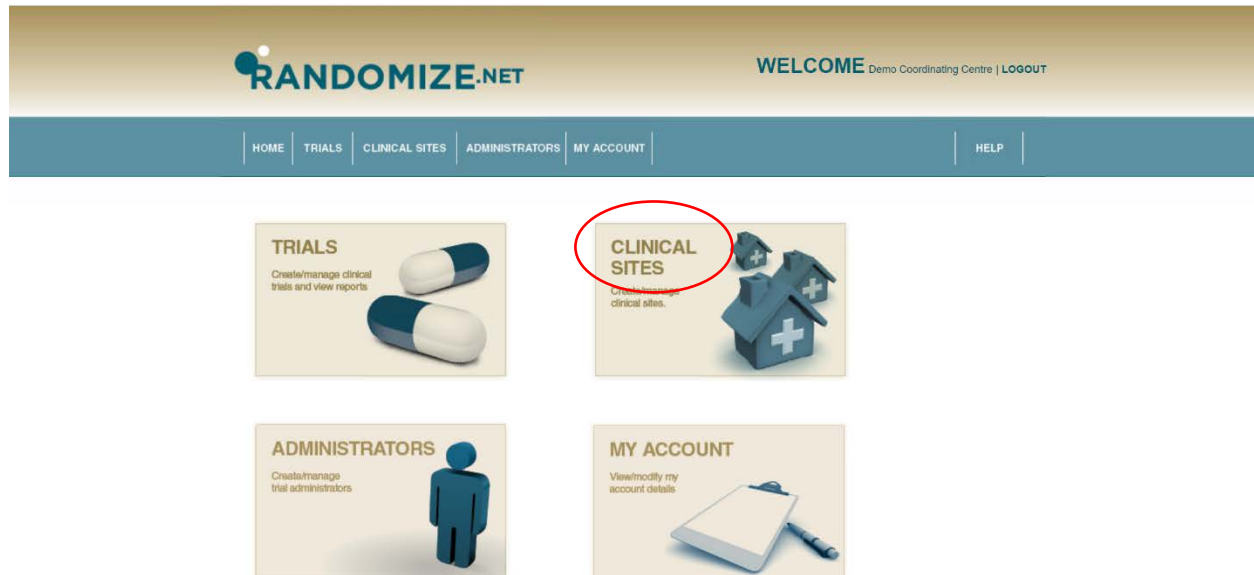
To deactivate a *Clinical Site*, click on “Activate Clinical Sites”, untick the *Clinical Site* and click on “SAVE CHANGES”.

The screenshot displays the Randomize.NET web application. At the top, the logo 'RANDOMIZE.NET' is on the left, and 'WELCOME Demo Coordinating Centre | LOGOUT' is on the right. A navigation bar below contains links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, a breadcrumb trail reads 'Select Trial > Trial Details'. A yellow status bar indicates 'Clinical Sites successfully activated/deactivated.' Below this, the 'TRIAL DETAILS' section is shown with a sub-menu: 'Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Activate Clinical Sites | Limits | Reports | Deactivate Trial'. The main content is a table with trial information:

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	22/01/2020 19:06:43
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

4.1 Create a *Clinical Site*

To create a new *Clinical Site*, click on “CLINICAL SITES” from the *Coordinating Centre* home page.



Click on “CREATE CLINICAL SITE”.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Clinical Site

CLINICAL SITES

Select a clinical site to manage:

CLINICAL SITE NAME	PATIENT ID PREFIX
Concept Medical, Demo 1	

[CREATE CLINICAL SITE](#)

Complete the fields as appropriate.

When completed, click on “CREATE SITE” and the new *Clinical Site* will be created. You will then be sent to the screen on the next page.

Clicking on “CANCEL” will take you the screen on the previous page without creating the *Clinical Site*.

The screenshot shows the 'CREATE CLINICAL SITE' form on the RANDOMIZE.NET website. The form is divided into two main sections: 'Site Details' and 'Primary User'. The 'Site Details' section includes a 'Clinical Site Name' field (containing 'Demo Clinical Site 1') and a 'Patient ID Prefix (Optional)' field. The 'Primary User' section includes fields for 'Login ID' (containing 'democlinsite1'), 'Name' (containing 'Andy Willen'), and 'Email' (containing 'andy@randomize.net'). There are also radio buttons for 'Enrollment Type' with 'Email' selected and 'Set Password' as an option. At the bottom are 'CREATE SITE' and 'CANCEL' buttons. Red boxes with arrows point to specific fields, each with an explanatory text box.

Site Details:

Clinical Site Name:

Patient ID Prefix (Optional):

The prefix will be added to the patient ID entered by the clinical site.

Primary User:

Login ID:

Name:

Email:

Enrollment Type: ☒ Email ☐ Set Password

Annotations:

- Provide a name for the *Clinical Site*.** (Points to Clinical Site Name field)
- You can provide a Patient ID prefix that will be added to the ID for all patients from this *Clinical Site*. This is an optional feature.** (Points to Patient ID Prefix field)
- Provide the Login ID, name, and email address for the Primary User account.** (Points to Login ID, Name, and Email fields)
- Selecting “Email”, the default, will send an email to the Primary User requesting them to set a password for their account. Selecting “Set Password” will require you to set the password and send it to the Primary User.** (Points to Enrollment Type radio buttons)


The new *Clinical Site* “Demo Clinical Site 1” is now listed. Clicking on the new *Clinical Site* name will show the details in the screen on the next page.

The screenshot displays the RANDOMIZE.NET interface. At the top, there is a navigation bar with links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled 'CLINICAL SITES' and includes a sub-header 'Select a clinical site to manage:'. Below this is a table with two columns: 'CLINICAL SITE NAME' and 'PATIENT ID PREFIX'. The table contains two rows: 'Concept Medical, Demo 1' and 'Demo Clinical Site 1'. The 'Demo Clinical Site 1' row is circled in red. A 'CREATE CLINICAL SITE' button is located at the bottom right of the table.

CLINICAL SITE NAME	PATIENT ID PREFIX
Concept Medical, Demo 1	
Demo Clinical Site 1	

CREATE CLINICAL SITE

Clinical Site details are shown.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

[Select Clinical Site](#) > [Clinical Site Details](#)

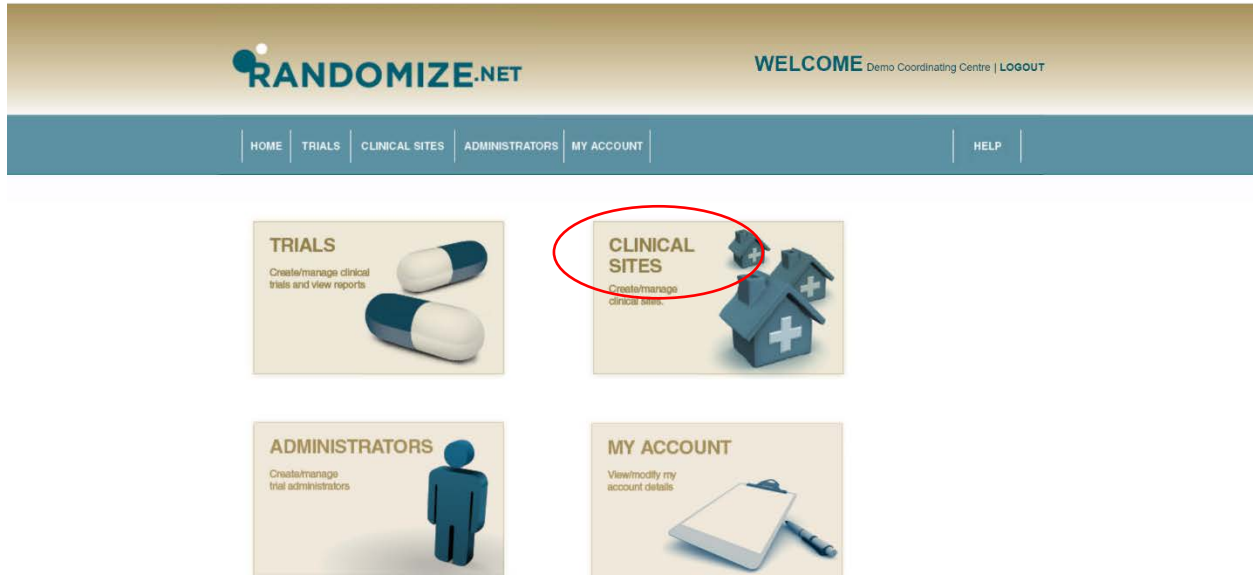
CLINICAL SITE DETAILS

[Edit Clinical Site Details](#) | [Manage Clinical Site Users](#)


NAME	Demo Clinical Site 1
PATIENT ID PREFIX	
NUMBER OF USERS	1
ACTIVE TRIALS	None (You must activate sites from the Trials menu)

4.2 Edit *Clinical Site* Details

To edit *Clinical Site* details, click on “CLINICAL SITES” from the *Coordinating Centre* home page.



Click on the *Clinical Site* whose details you wish to edit.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Clinical Site

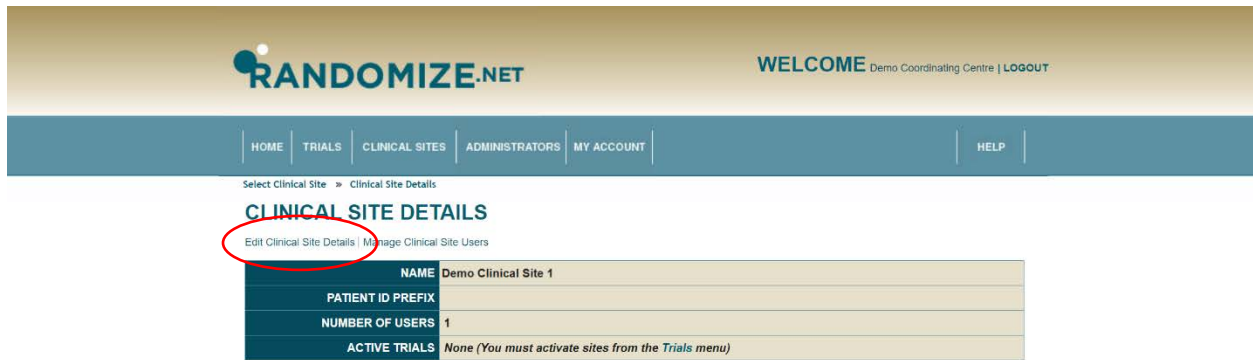
CLINICAL SITES

Select a clinical site to manage:

CLINICAL SITE NAME	PATIENT ID PREFIX
Concept Medical, Demo 1	
Demo Clinical Site 1	

CREATE CLINICAL SITE

Click on “Edit Clinical Site Details”.



RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Clinical Site > Clinical Site Details

CLINICAL SITE DETAILS

[Edit Clinical Site Details](#) / [Manage Clinical Site Users](#)

NAME	Demo Clinical Site 1
PATIENT ID PREFIX	
NUMBER OF USERS	1
ACTIVE TRIALS	None (You must activate sites from the Trials menu)

You can then edit the *Clinical Site* name and/or the optional “Patient ID Prefix”.

Clicking on “SAVE CHANGES” will take you to the screen on the previous page and save all changes made during the session.

Clicking on “CANCEL” will take you to the screen on the previous page without saving any of the changes.



The screenshot shows the 'EDIT CLINICAL SITE' page on the Randomize.NET platform. The header features the Randomize.NET logo and a 'WELCOME' message for the 'Demo Coordinating Centre' with a 'LOGOUT' link. A navigation bar includes links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, a breadcrumb trail reads 'Select Clinical Site > Clinical Site Details > Edit Clinical Site Details'. The main heading is 'EDIT CLINICAL SITE'. The form contains two input fields: 'Clinical Site Name' with the value 'Demo Clinical Site 1' and 'Patient ID Prefix (Optional)' which is currently empty. A note states 'The prefix will be added to the patient ID entered by the clinical site.' At the bottom of the form are two buttons: 'SAVE CHANGES' and 'CANCEL'.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Clinical Site > Clinical Site Details > Edit Clinical Site Details

EDIT CLINICAL SITE

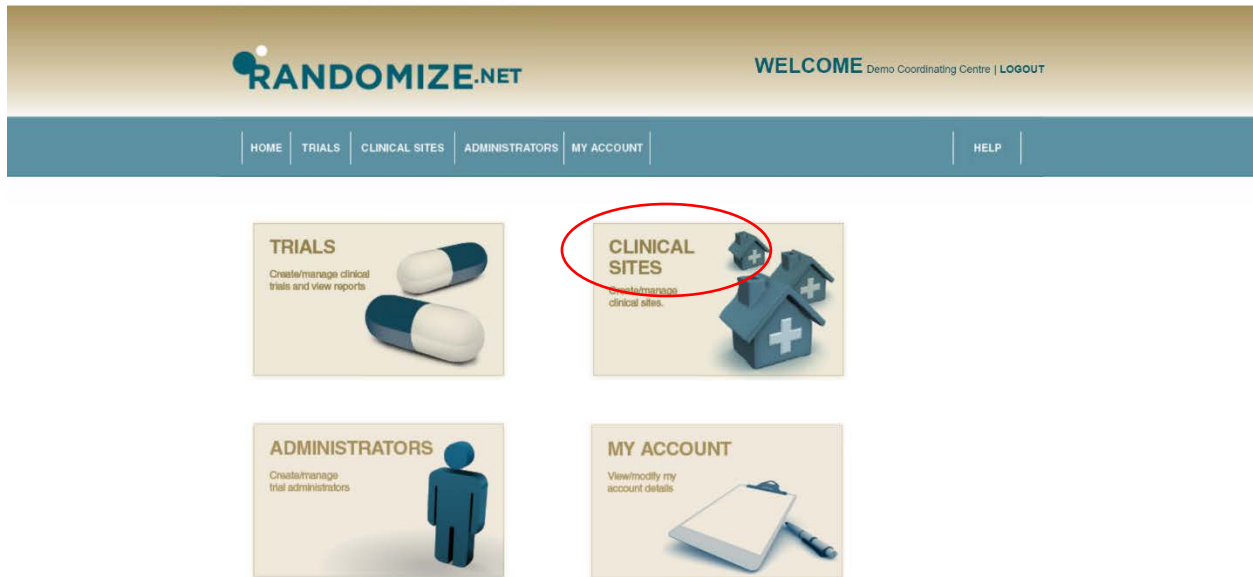
Clinical Site Name: Demo Clinical Site 1

Patient ID Prefix (Optional): The prefix will be added to the patient ID entered by the clinical site.

SAVE CHANGES CANCEL

4.3 Add Clinical Site Users

To add an additional *Clinical Site* user, click on “CLINICAL SITES” from the *Coordinating Centre* home page. The additional Clinical Site user will be able to randomize patients for that *Clinical Site*.



Click on the *Clinical Site* to which you want to add an additional user.

The screenshot shows the RANDOMIZE.NET interface. At the top, there's a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main heading is 'CLINICAL SITES'. Below it, a table lists clinical sites. The second site, 'Demo Clinical Site 1', is highlighted with a red circle. A 'CREATE CLINICAL SITE' button is located at the bottom right of the table area.

CLINICAL SITE NAME	PATIENT ID PREFIX
Concept Medical, Demo 1	
Demo Clinical Site 1	

CREATE CLINICAL SITE

Click on “Manage Clinical Site Users”.

The screenshot shows the Randomize.NET interface. At the top, there's a header with the logo and a welcome message. Below that is a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled 'CLINICAL SITE DETAILS' and shows a table with site information. The 'Manage Clinical Site Users' link is circled in red.

Select Clinical Site » Clinical Site Details

CLINICAL SITE DETAILS

Edit Clinical Site Details Manage Clinical Site Users

NAME	Demo Clinical Site 1
PATIENT ID PREFIX	
NUMBER OF USERS	1
ACTIVE TRIALS	Demo Blinded Trial 1

Click on “CREATE USER”.

The screenshot shows the Randomize.NET web interface. At the top, there is a header with the logo and a welcome message. Below the header is a navigation bar with links to HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled 'CLINICAL SITE USERS' and includes a breadcrumb trail: 'Select Clinical Site > Clinical Site Details > Select User'. Below this, there is a table with the following data:

LOGIN ID	NAME	EMAIL ADDRESS	ENABLED
democlinsite1	Demo Clin Site 1	andy@andywillan.com	True

Below the table, there is a button labeled 'CREATE USER' which is circled in red.

Enter the “Login ID”, “Name” and “Email” address of the additional user. The “Login ID” cannot be changed once the user has been created.

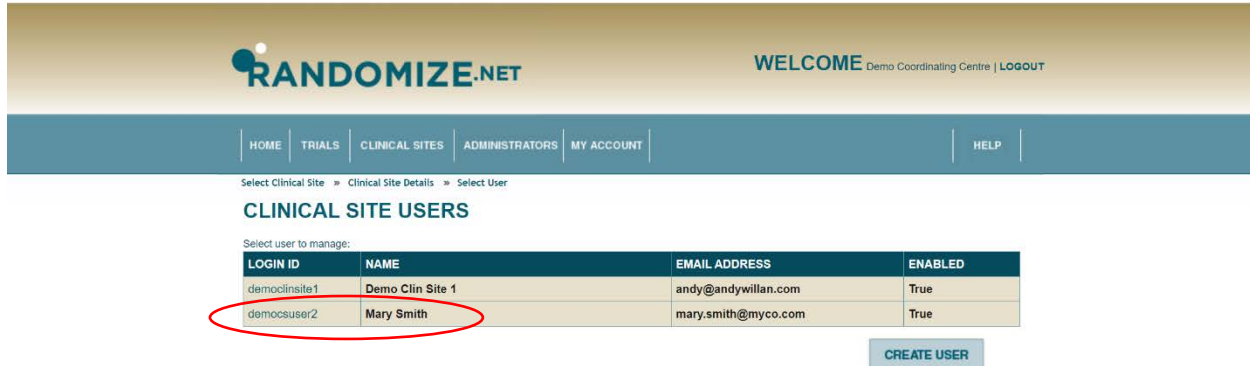
Clicking on “CREATE USER” will create the user and take you to the screen on the next page.

Clicking on “CANCEL” will not create the user and take you to the screen on the previous page.

The screenshot shows the RANDOMIZE.NET 'CREATE USER' interface. At the top, the header includes the RANDOMIZE.NET logo and a 'WELCOME' message for the 'Demo Coordinating Centre' with a 'LOGOUT' link. A navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main section is titled 'CREATE USER' and contains a form with the following fields: 'Login ID' (pre-filled with 'democuser2'), 'Name' (pre-filled with 'Mary Smith'), and 'Email' (pre-filled with 'mary.smith@myco.com'). Below these fields is the 'Enrollment Type' section with two radio buttons: 'Email' (selected) and 'Set Password'. At the bottom of the form are two buttons: 'CREATE USER' and 'CANCEL'. Two red callout boxes provide additional information: one points to the form fields stating 'Provide the Login ID, name, and email address for the new user account.', and the other points to the 'Email' radio button stating 'Selecting “Email”, the default, will send an email to the new user requesting them to set a password for their account. Selecting “Set Password” will require you to set the password and send it to the new user.'

The additional user (democsuser2) is now listed.

The additional user is set to the default "ENABLED" which means they will be able to register/randomize patients on any trial for which this *Clinical Site* is activated.



RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Clinical Site » Clinical Site Details » Select User

CLINICAL SITE USERS

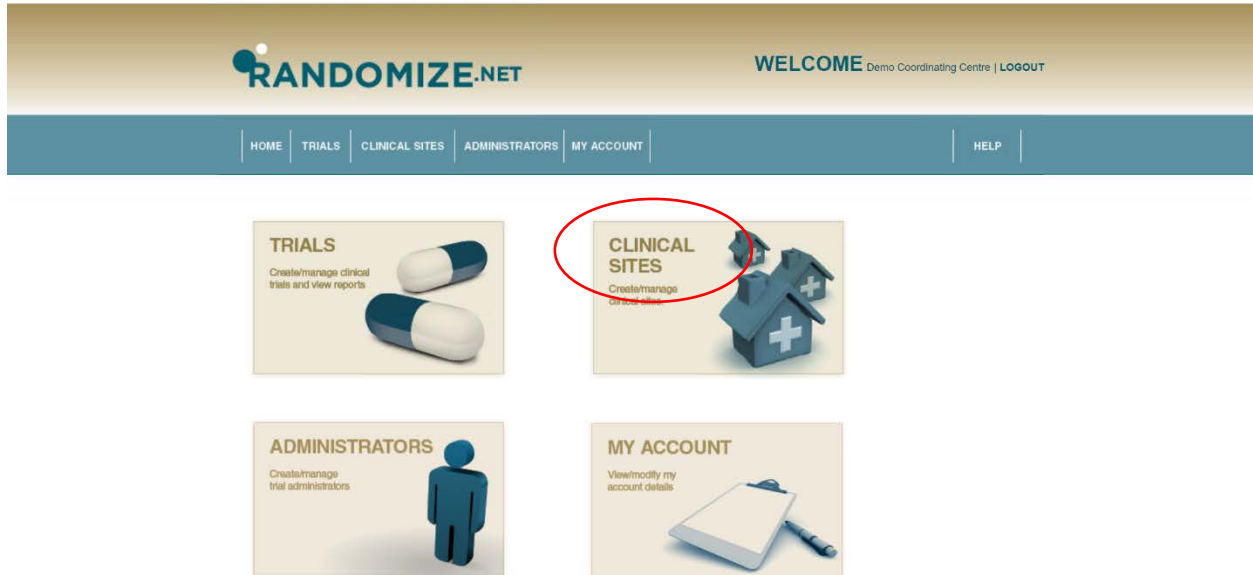
Select user to manage:

LOGIN ID	NAME	EMAIL ADDRESS	ENABLED
democlinite1	Demo Clin Site 1	andy@andywillan.com	True
democsuser2	Mary Smith	mary.smith@myco.com	True

CREATE USER

4.4 Edit *Clinical Site* Users' Details

To edit *Clinical Site* users' details, click on “CLINICAL SITES” from the *Coordinating Centre* home page.



Click on the *Clinical Site* whose users' details you want to edit.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Clinical Site


CLINICAL SITES

Select a clinical site to manage:

CLINICAL SITE NAME	PATIENT ID PREFIX
Concept Medical, Demo 1	
Demo Clinical Site 1	

CREATE CLINICAL SITE

Click on “Manage Clinical Site Users”.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)


Select Clinical Site » Clinical Site Details

CLINICAL SITE DETAILS

Edit Clinical Site Details | [Manage Clinical Site Users](#)

NAME	Demo Clinical Site 1
PATIENT ID PREFIX	
NUMBER OF USERS	2
ACTIVE TRIALS	Demo Blinded Trial 1

Click on the user whose details you want to edit.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

[Select Clinical Site](#) » [Clinical Site Details](#) » [Select User](#)

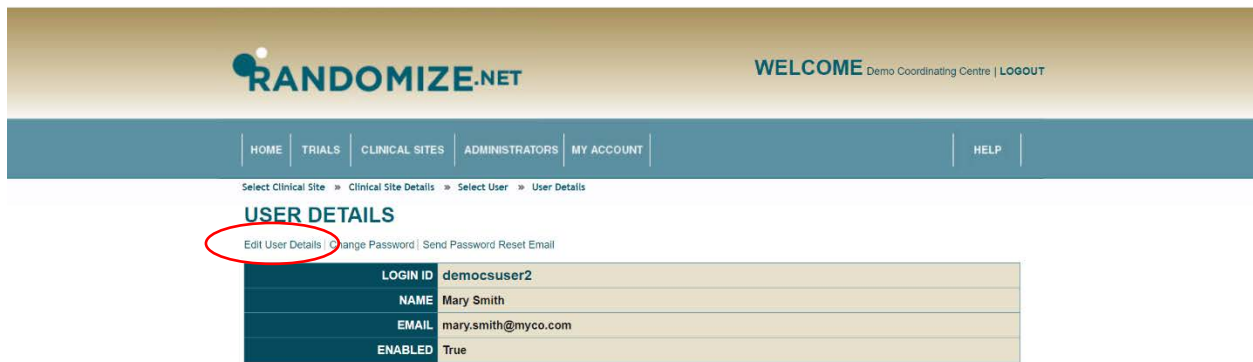
CLINICAL SITE USERS

Select user to manage:

LOGIN ID	NAME	EMAIL ADDRESS	ENABLED
democlinite1	Demo Clin Site 1	andy@andywillan.com	True
democuser2	Mary Smith	mary.smith@myco.com	True

CREATE USER

Click on “Edit User Details”.



The screenshot shows the RANDOMIZE.NET web application interface. At the top, there is a header with the logo and a welcome message: "WELCOME Demo Coordinating Centre | LOGOUT". Below the header is a navigation bar with links: HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. A breadcrumb trail indicates the current location: Select Clinical Site » Clinical Site Details » Select User » User Details. The main section is titled "USER DETAILS". Below this title, there are two links: "Edit User Details" (which is circled in red) and "Change Password | Send Password Reset Email". A table displays the user's details:

LOGIN ID	democuser2
NAME	Mary Smith
EMAIL	mary.smith@myco.com
ENABLED	True

You will be able to change the user's "Name" and "Email" address. You can also set "Enable" to "False" to prevent the user from registering/randomizing patients on all trials.

Clicking on "SAVE CHANGES" will save all the changes.

Clicking on "CANCEL" will not save the changes.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Clinical Site » Clinical Site Details » Select User » User Details » Edit User Details

EDIT USER

Login ID: **democuser2**

Name:

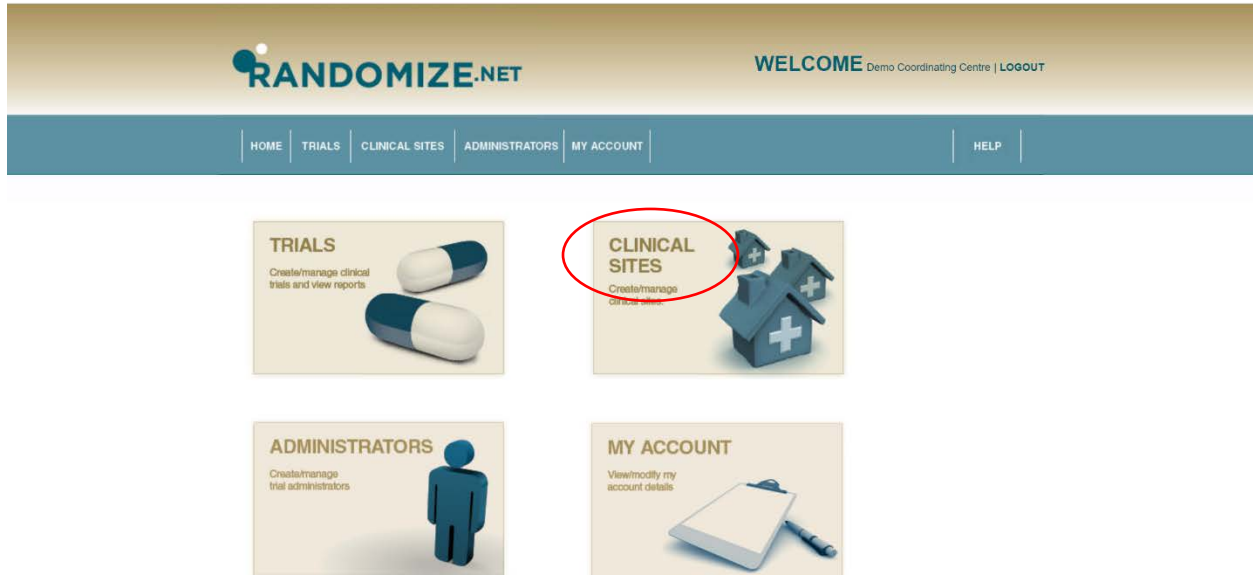
Email:

Enabled: ☒ True ☐ False

By default, "Enabled" is set to "True" allowing the user to register/randomize patients. To prevent the user from registering/randomizing patients, set to "False".

4.5 Reset *Clinical Site* Users' Password

To reset *Clinical Site* users' passwords, click on “CLINICAL SITES” from the *Coordinating Centre* home page.



Click on the *Clinical Site* whose users' password you want to change.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Clinical Site


CLINICAL SITES

Select a clinical site to manage:

CLINICAL SITE NAME	PATIENT ID PREFIX
Concent Medical Demo 1	
Demo Clinical Site 1	

CREATE CLINICAL SITE

Click on “Manage Clinical Site Users”.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)


Select Clinical Site » Clinical Site Details

CLINICAL SITE DETAILS

Edit Clinical Site Details | [Manage Clinical Site Users](#)

NAME	Demo Clinical Site 1
PATIENT ID PREFIX	
NUMBER OF USERS	2
ACTIVE TRIALS	Demo Blinded Trial 1

Click on the user whose password you want to change.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Clinical Site » Clinical Site Details » Select User

CLINICAL SITE USERS

Select user to manage:

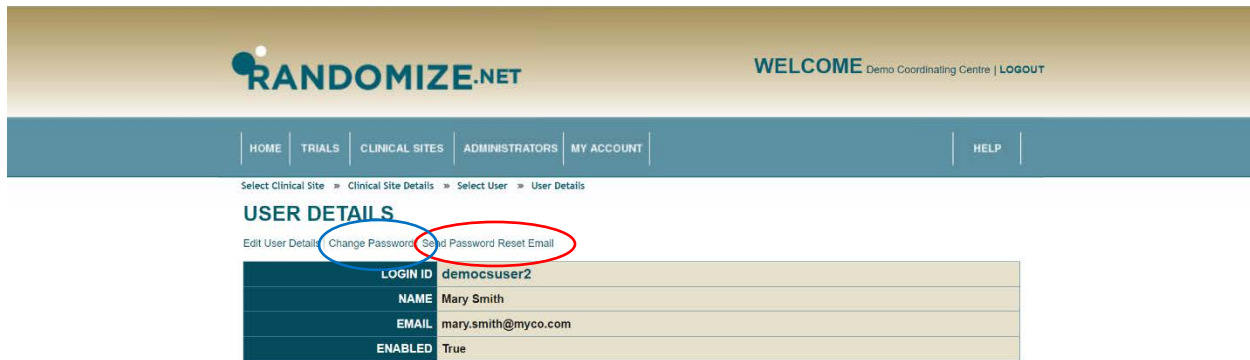
LOGIN ID	NAME	EMAIL ADDRESS	ENABLED
democlinite1	Demo Clin Site 1	andy@andywillan.com	True
democuser2	Mary Smith	mary.smith@myco.com	True

CREATE USER

You can change the user's password in two ways.

The first is to click on **"Send Password Reset Email"** and then "OK". This will send an email message to the user requesting that they reset their password.

The second is to click on **"Change Password"** which will take you to the screen on the next page.



LOGIN ID	democuser2
NAME	Mary Smith
EMAIL	mary.smith@myco.com
ENABLED	True

Enter and confirm the new password. You will need to notify the user about the new password.

Clicking on “SAVE CHANGES” will reset the password and take you back to the screen on the previous page.

Clicking on “CANCEL” will not reset the password and take you back to the screen on the previous page.

RANDOMIZE.NET WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Clinical Site » Clinical Site Details » Select User » User Details » Change Password

CHANGE PASSWORD

Login ID: **democuser2**

Password:

Confirm Password:

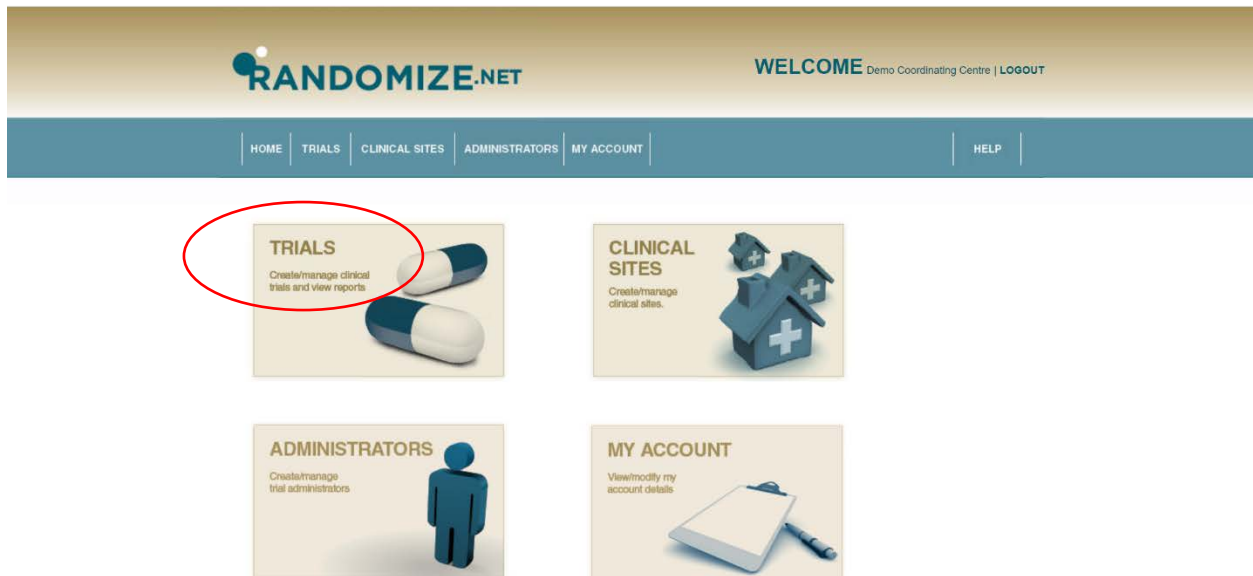
[SAVE CHANGES](#) [CANCEL](#)

4.6 Activate / Deactivate a *Clinical Site* for a Clinical Trial


To activate a *Clinical Site* to allow them to randomize patients on a trial, click on “TRIALS” from the *Coordinating Centre* home page.

Clinical Sites can be activated or deactivated at anytime.

To deactivate a *Clinical Site*, see [page 128](#).



Click on the trial for which you want to activate a *Clinical Site*.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	True		0

CREATE A TRIAL

There currently no active *Clinical Sites*. To activate one or more *Clinical Sites*, allowing them to randomize patients, click on “Activate Clinical Sites”


WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial > Trial Details

Trial successfully activated.

TRIAL DETAILS

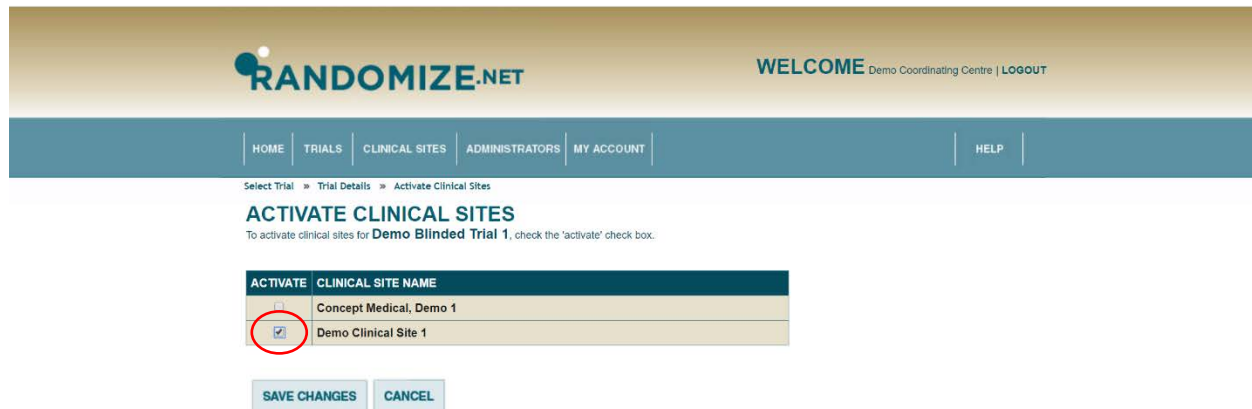
[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Links](#) | [Reports](#) | [Deactivate Trial](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	23/01/2020 19:06:43
NUMBER OF ACTIVE CLINICAL SITES	0
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Tick all the *Clinical Sites* you want to activate.

Clicking on “SAVE CHANGES” will activate the ticked *Clinical Sites* allowing them to randomize patients on “Demo Blinded Trial 1”. You will also be taken to the screen shown on the next page.

Clicking on “CANCEL” will take you back to the screen on the previous page and no *Clinical Sites* will be activated.



RANDOMIZE.NET WELCOME Demo Coordinating Centre | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Trial » Trial Details » Activate Clinical Sites

ACTIVATE CLINICAL SITES

To activate clinical sites for **Demo Blinded Trial 1**, check the 'activate' check box.

ACTIVATE	CLINICAL SITE NAME
<input type="checkbox"/>	Concept Medical, Demo 1
<input checked="" type="checkbox"/>	Demo Clinical Site 1

SAVE CHANGES CANCEL

One *Clinical Site* is now shown as activated.

To deactivate a *Clinical Site*, click on “Activate Clinical Sites”, untick the *Clinical Site* and click on “SAVE CHANGES”.

The screenshot displays the Randomize.NET interface. At the top, the logo and navigation links are visible. A yellow message bar indicates that clinical sites were successfully activated/deactivated. The 'TRIAL DETAILS' section is active, showing various trial parameters. The 'Activate Clinical Sites' link in the sub-navigation is circled in red. The 'NUMBER OF ACTIVE CLINICAL SITES' is also circled in red and shows the value '1'.

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	22/01/2020 19:06:43
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

5.1 Import Assigned *Kit Numbers*

Prior to importing “assigned” *Kit Numbers*, create a comma delimited (*.csv) file as shown below. The term “assigned” in this context means the *Kits Numbers* have been assigned to a specific *Clinical Site*.

The file has four columns.

The first column (A) contains the Login ID of the *Clinical Site* to which the *Kit Number* has been “assigned”. *Kit Numbers* for several *Clinical Sites* can be in the same *.csv file.

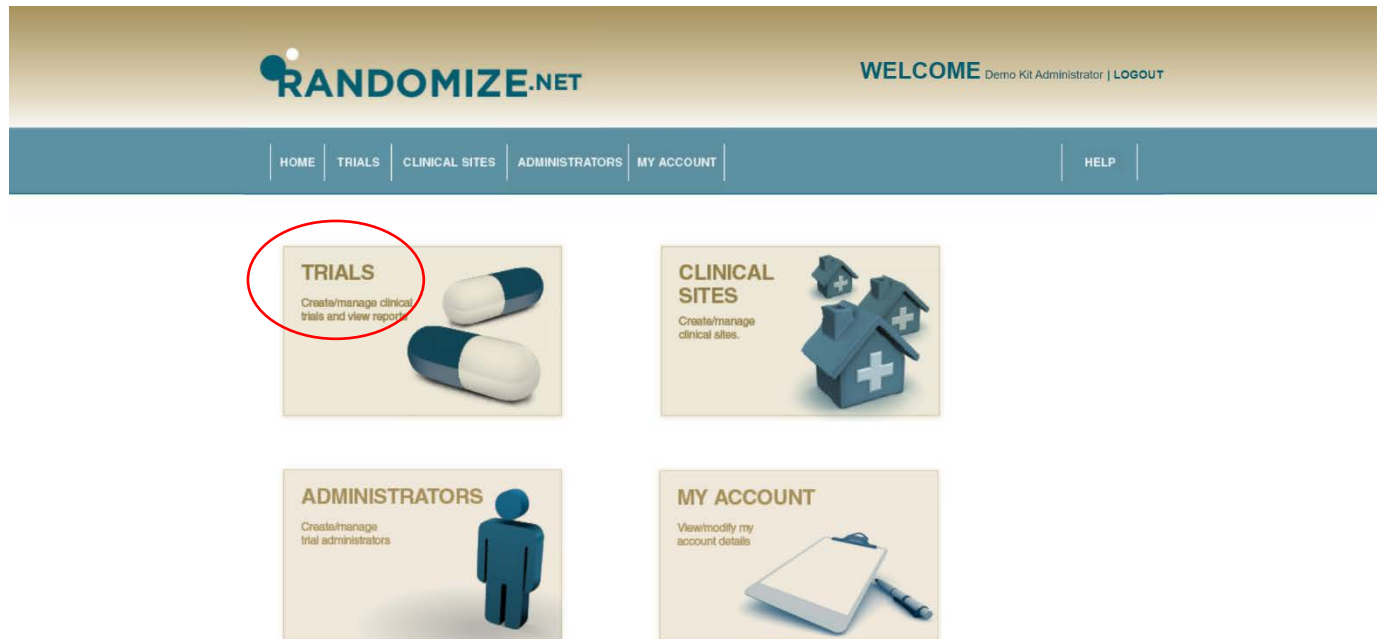
The second column (B) contains the Treatment ID. In this case “1” is Active and “2” is Control. The Treatment IDs are displayed under “TRIAL DETAILS”, see [page 132](#).

The third column (C) is the actual *Kit Number*.


The fourth column (D) is an indicator variable. “1” indicates that the corresponding *Kit* is available in the *Clinical Site* now. “0” indicates that it can be made available at a later date. See [Section 5.2](#) for the procedure to indicate that previously imported *Kit Numbers* are now available.

	A	B	C	D	E	F	G	H	I	J
1	democlinsite1	2 A51		1						
2	democlinsite1	1 A52		1						
3	democlinsite1	1 A53		1						
4	democlinsite1	2 A54		1						
5	democlinsite1	1 A55		1						
6	democlinsite1	1 A56		0						
7	democlinsite1	2 A57		0						
8	democlinsite1	1 A58		0						
9	democlinsite1	2 A59		0						
10	democlinsite1	2 A60		0						
11										
12										
13										
14										
15										
16										

Once the *csv file is ready, click on “TRIALS” from the *Kit Administrator* home page.



Click on the trial to which you want to import *Kit Numbers*.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial

TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1

The “TRIAL DETAILS” are shown.

Note the Treatment IDs are displayed “1” for active and “2” for Placebo.

Click on “Manage Kits”.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial > Trial Details

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Activate Clinical Sites | Limits | Reports | **Manage Kits**

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Fifty *Kit Numbers* have already been imported and assigned to “Demo Clinical Site 1”. Seven have been used (*i.e.* already assigned to patients) and 43 “REMAINING KITS” are available for patients. No *Kit Numbers* are “NOT YET AVAILABLE”.

Clicking on “View/Edit” will display the list of the 50 *Kits*, although this is not necessary for importing new *Kit numbers*. The list of the 50 *Kits* is shown on the next page.

The screenshot shows the RANDOMIZE.NET interface. The header includes the logo and a welcome message for the Demo Kit Administrator. The navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The breadcrumb trail indicates the current location: Select Trial » Trial Details » Manage Kits. The main section is titled 'MANAGE KITS' and includes links for Edit Kit Preferences, Import Kits, and Assign Kits. A table displays the kit status for 'Demo Clinical Site 1'.

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	43	0

Select Trial » Trial Details » Manage Kits » Manage Kits For Site

MANAGE KITS for Demo Clinical Site 1

CLINICAL SITE NAME	SITE ID	TREATMENT ID	TREATMENT	KIT NUMBER	IS USED	AVAILABLE	ASSIGNED
Demo Clinical Site 1	democlinsite1	1	Active	A28	True		
Demo Clinical Site 1	democlinsite1	1	Active	A30	True		
Demo Clinical Site 1	democlinsite1	1	Active	A40	True		
Demo Clinical Site 1	democlinsite1	1	Active	A41	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A50	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A02	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A48	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A42	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A29	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A47	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A49	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A39	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A33	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A03	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A09	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A07	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A37	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A01	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A23	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A45	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A15	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A16	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A34	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A35	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A38	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A43	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A08	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A46	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A44	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A31	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A36	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A05	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A32	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

These 7 Kit Numbers have been used.

A tick in this column means the *Kit* has been assigned to the Clinical Site identified in the first two columns.

A tick in this column indicates that the *Kit* is available in the *Clinical Site* now.

SAVE CHANGES

CANCEL

Click on "CANCEL" to return to the screen on the next page.

To import more *Kit Numbers*, click on “Import Kits”.

The screenshot shows the RANDOMIZE.NET web application. The header includes the logo and a welcome message for the Demo Kit Administrator. A navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, a breadcrumb trail reads: Select Trial » Trial Details » Manage Kits. The main section is titled 'MANAGE KITS' and contains a sub-menu with 'Edit Kit Preferences', 'Import Kits' (circled in red), and 'Assign Kits'. A table displays kit usage data for 'democlinsite1'.

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	43	0

Click on “Choose file”.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Manage Kits » Manage Kits For Site

IMPORT KITS

Choose file

Kit Upload Help

Importing assigned kits:
Please upload a CSV (comma-separated values) file with four columns with the following order:

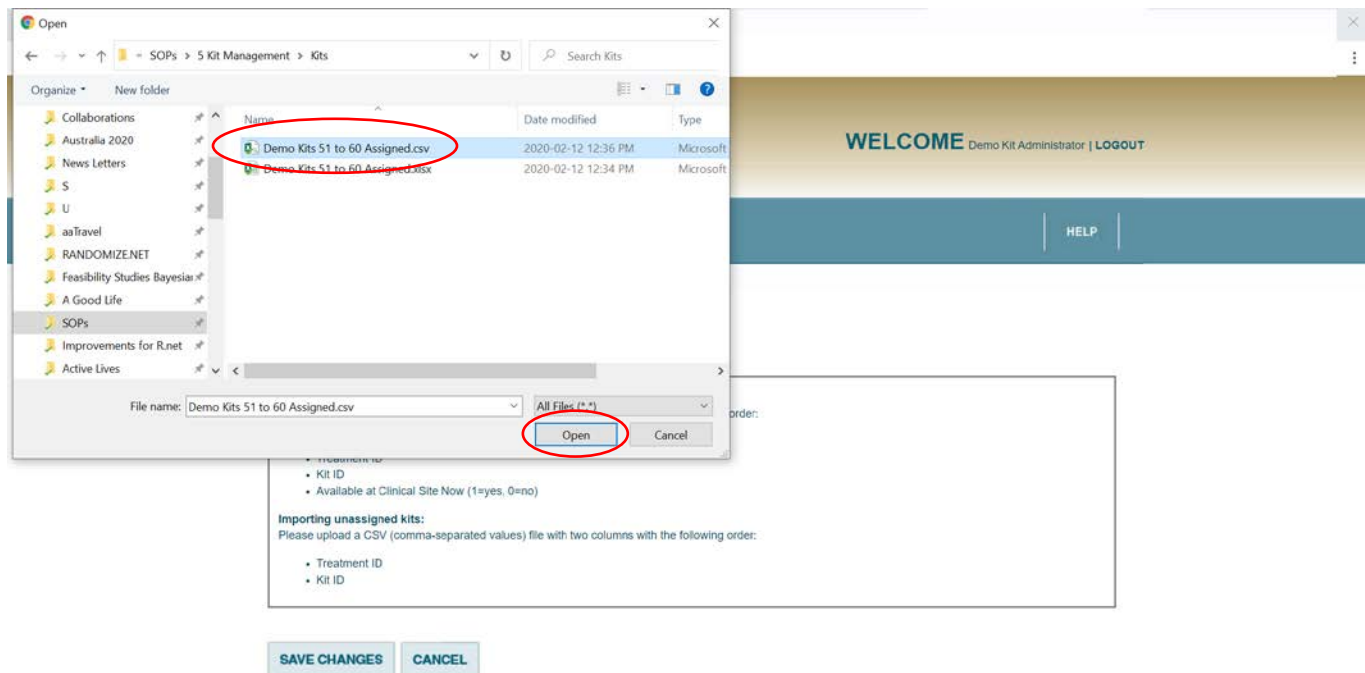
- Clinical Site Primary User Login ID
- Treatment ID
- Kit ID
- Available at Clinical Site Now (1=yes, 0=no)

Importing unassigned kits:
Please upload a CSV (comma-separated values) file with two columns with the following order:

- Treatment ID
- Kit ID

SAVE CHANGES **CANCEL**

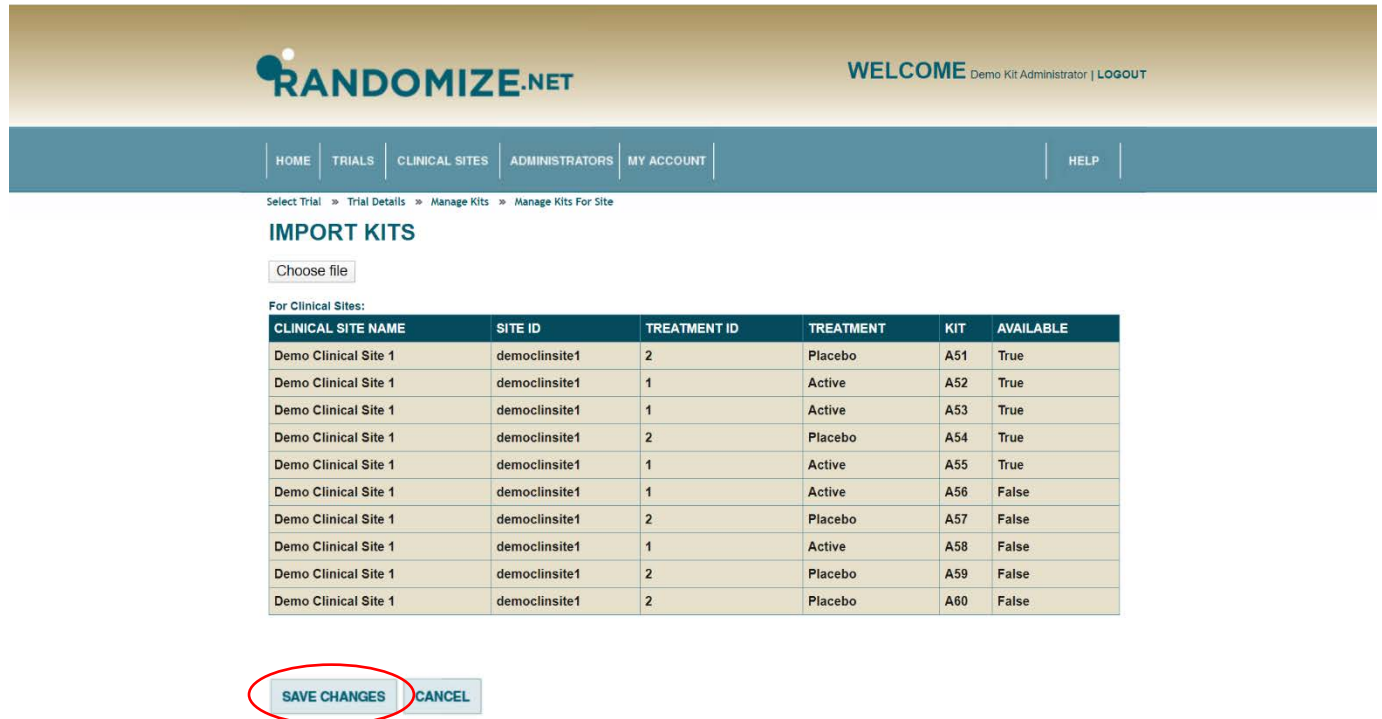
Navigate to the file contain the list of *Kit Numbers*, click on it, and click on “Open”.



The newly important *Kit Numbers* will be displayed.

Clicking on “SAVE CHANGES” will complete the importation and take you to the screen on the next page.

Clicking on “CANCEL” will cancel the importation procedure.



RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Trial » Trial Details » Manage Kits » Manage Kits For Site

IMPORT KITS

Choose file

For Clinical Sites:

CLINICAL SITE NAME	SITE ID	TREATMENT ID	TREATMENT	KIT	AVAILABLE
Demo Clinical Site 1	democlinsite1	2	Placebo	A51	True
Demo Clinical Site 1	democlinsite1	1	Active	A52	True
Demo Clinical Site 1	democlinsite1	1	Active	A53	True
Demo Clinical Site 1	democlinsite1	2	Placebo	A54	True
Demo Clinical Site 1	democlinsite1	1	Active	A55	True
Demo Clinical Site 1	democlinsite1	1	Active	A56	False
Demo Clinical Site 1	democlinsite1	2	Placebo	A57	False
Demo Clinical Site 1	democlinsite1	1	Active	A58	False
Demo Clinical Site 1	democlinsite1	2	Placebo	A59	False
Demo Clinical Site 1	democlinsite1	2	Placebo	A60	False

SAVE CHANGES CANCEL

You can click on “View/Edit” to verify the importation procedure.

The screenshot shows the RANDOMIZE.NET web application. The header includes the logo and a welcome message for the Demo Kit Administrator. The navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The breadcrumb trail indicates the current location: Select Trial » Trial Details » Manage Kits. A yellow notification bar states "Kits imported successfully." Below this, the "MANAGE KITS" section is displayed, with sub-links for Edit Kit Preferences, Import Kits, and Assign Kits. A table lists clinical sites with columns for Site ID, Clinical Site Name, Used Kits, Remaining Kits, and Not Yet Available. The first row shows "democlinsite1" with 7 used kits, 48 remaining, and 5 not yet available. The "View/Edit" link for this site is circled in red.

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	48	5

Demo Clinical Site 1	democlinsite1	1	Active	A42	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A29	9	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A19	10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A47	11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A49	12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A39	13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A22	14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A33	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A18	16	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A03	17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A09	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A14	19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A26	20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A27	21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A07	22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A37	23	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A01	24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A12	25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A52	26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A53	27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A55	28	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A56	29	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A58	30	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A23	1	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A45	2	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A15	3	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A16	4	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Newly imported Kit Numbers

Kits not yet available at the Clinical Site

Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A46	16	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A24	17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A13	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A44	19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A17	20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A31	21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A36	22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A05	23	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A21	24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A32	25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A51	26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A54	27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A57	28	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A59	29	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A60	30	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>

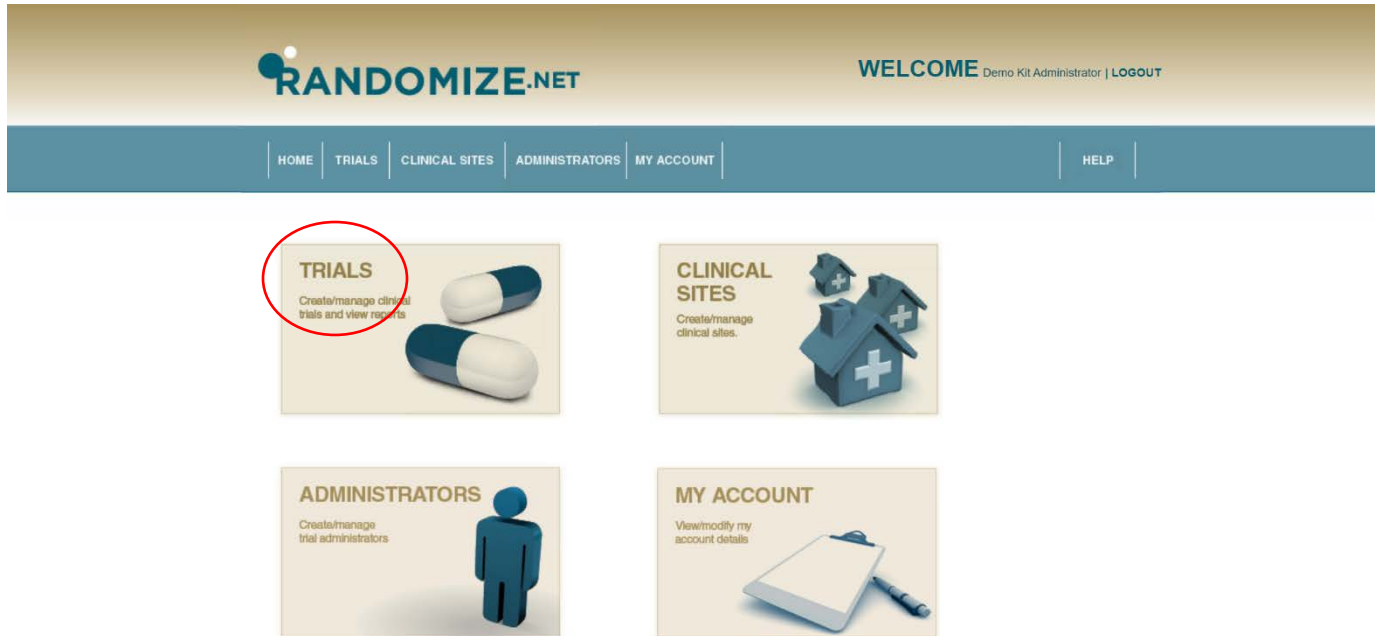
SAVE CHANGES

CANCEL


Click "CANCEL" to return to the screen on the next page.

5.2 Indicate *Kit Numbers* are Available

To indicate that previously imported *Kit Numbers* are now available at the *Clinical Site*, click on “TRIALS” from the *Kit Administrator* home page.



Click on the appropriate trial.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1

The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial » Trial Details

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Limits](#) | [Reports](#) | [Manage Kits](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Sixty *Kit Numbers* have already been imported and assigned to “Demo Clinical Site 1”. Seven have been used (*i.e.* already assigned to patients), 48 “REMAINING KITS” are available for future patients, and 5 are “NOT YET AVAILABLE”.

Clicking on “View/Edit” and the list of the 60 *Kits* is displayed as on the next page.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Manage Kits

MANAGE KITS

Edit Kit Preferences | Import Kits | Assign Kits

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	48	5

Demo Clinical Site 1	democlinsite1	1	Active	A33	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A18	16	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A03	17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A09	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A14	19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A26	20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A27	21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A07	22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A37	23	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A01	24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A12	25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A52	26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A53	27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A55	28	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A56	29	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A58	30	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A23	1	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A45	2	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A15	3	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A16	4	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Ticking the boxes in the "Available" column indicates that the *Kits* are now available at the *Clinical Site* identified in the first two columns. See the screen on the next page.

Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A46	16	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A24	17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A13	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A44	19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A17	20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A31	21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A36	22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A05	23	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A21	24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A32	25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A51	26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A54	27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A57	28	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A59	29	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A60	30	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>

SAVE CHANGES CANCEL

Demo Clinical Site 1	democlinsite1	1	Active	A09	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A14	19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A26	20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A27	21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A07	22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A37	23	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A01	24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A12	25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A52	26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A53	27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A55	28	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A56	29	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	1	Active	A58	30	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A23	1	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A45	2	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A15	3	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A16	4	True		
Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A46	16	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A24	17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A13	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>


Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A46	16	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A24	17	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A13	18	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A44	19	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A17	20	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A31	21	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A36	22	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A05	23	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A21	24	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A32	25	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A51	26	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A54	27	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A57	28	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A59	29	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 1	democlinsite1	2	Placebo	A60	30	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Click "SAVE CHANGES" to indicate that the Kits are now available and return to the screen on the next page.

SAVE CHANGES CANCEL

Click "CANCEL" to return to the screen on the previous page without indicating that the Kits are now available.


With the changes, 60 *Kit Numbers* have been imported and assigned to “Demo Clinical Site 1”. Seven have been used (*i.e.* already assigned to patients), 53 “REMAINING KITS” are available for future patients, and 5 are “NOT YET AVAILABLE”.



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[Select Trial](#) » [Trial Details](#) » [Manage Kits](#)

 Kits saved successfully.

MANAGE KITS

[Edit Kit Preferences](#) | [Import Kits](#) | [Assign Kits](#)

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	0

5.3 Import Unassigned *Kit Numbers*

Prior to importing “Unassigned” *Kit Numbers*, create a comma delimited (*.csv) file as shown below. The term “unassigned” in this context means the Kits Numbers have not yet been assigned to a specific *Clinical Site*.

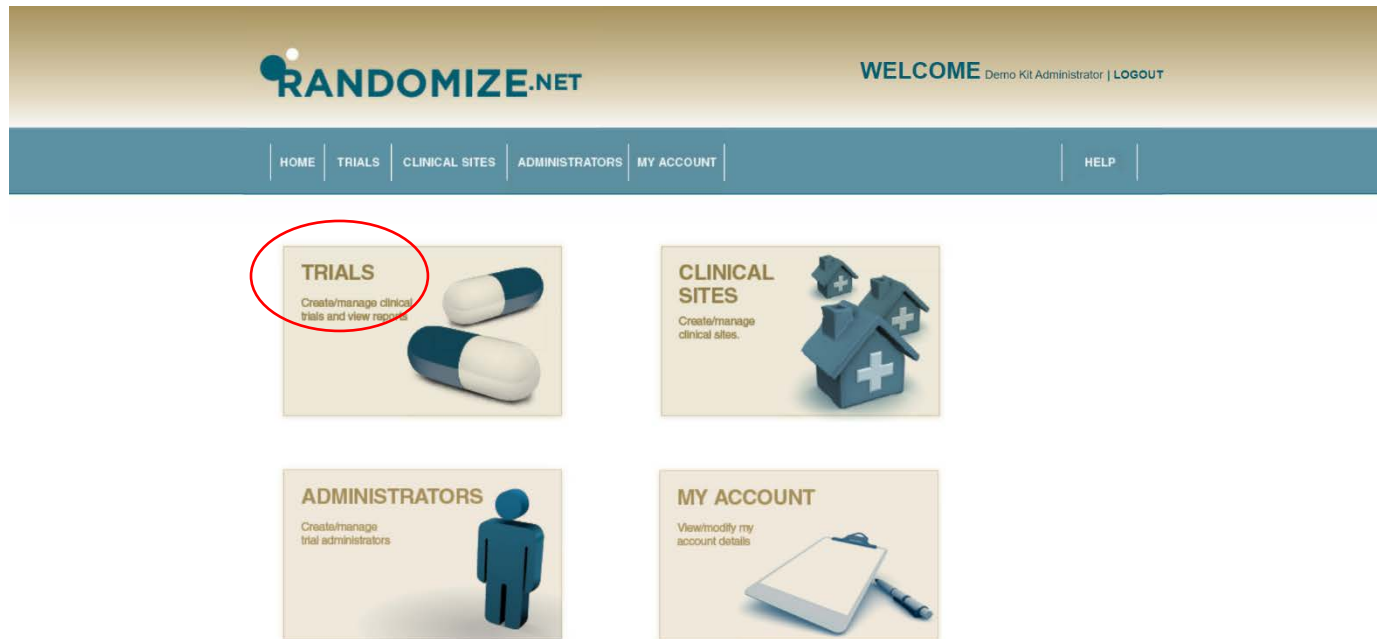
The file has two columns.

The first column (A) contains the Treatment ID. In this case “1” is Active and “2” is Control. The Treatment IDs are displayed under “TRIAL DETAILS”, see [page 151](#).


The second column (B) is the actual *Kit Number*.

	A	B	C	D	E	F	G	H	I	J	K
1	2	A61									
2	1	A62									
3	2	A63									
4	1	A64									
5	1	A65									
6	1	A66									
7	2	A67									
8	2	A68									
9	2	A69									
10	1	A70									
11											
12											
13											
14											
15											
16											

Once the *csv file is ready, click on “TRIALS” from the *Kit Administrator* home page.



Click on the trial to which you want to import unassigned *Kit Numbers*.



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Select Trial

TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1

The “TRIAL DETAILS” are shown.

Note the Treatment IDs are displayed “1” for active and “2” for Placebo.

Click on “Manage Kits”.

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Select Trial » Trial Details

TRIAL DETAILS

Edit Trial Details | Notification Emails | Edit Inclusion/Exclusion Criteria | Activate Clinical Sites | Limits | Reports | **Manage Kits**

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Sixty Kits have been imported and assigned to “Demo Clinical Site 1”. Seven have been used and 53 “REMAINING KITS” are available for future patients. No Kits have been imported and assigned to “Demo Clinical Site 2”.

Click on “Import Kits”.

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Select Trial » Trial Details » Manage Kits

MANAGE KITS

[Edit Kit Preferences](#) | [Import Kits](#) | [Assign Kits](#)

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	0
View/Edit	democlinsite2	Demo Clinical Site 2	0	0	0

Click on “Choose file”.

RANDOMIZE.NET WELCOME Demo KIT Administrator | LOGOUT

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Select Trial » Trial Details » Manage Kits » Manage Kits For Site

IMPORT KITS

Choose file

Kit Upload Help

Importing assigned kits:
Please upload a CSV (comma-separated values) file with four columns with the following order:

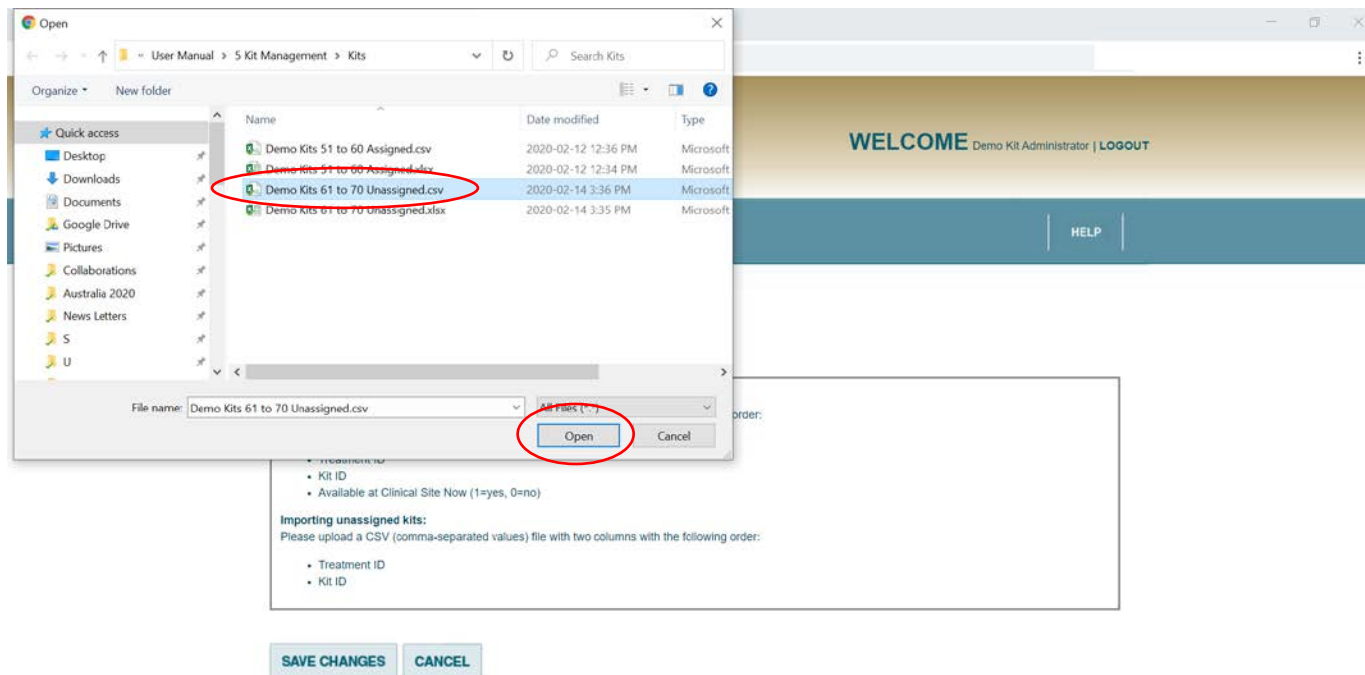
- Clinical Site Primary User Login ID
- Treatment ID
- Kit ID
- Available at Clinical Site Now (1=yes, 0=no)

Importing unassigned kits:
Please upload a CSV (comma-separated values) file with two columns with the following order:

- Treatment ID
- Kit ID

SAVE CHANGES **CANCEL**

Navigate to the file containing the *Kit Numbers* you want to import. Click on it and then click on “Open”.



The 10 Unassigned Kits are displayed.

Clicking on “SAVE CHANGES” will import the *Kits* and take you to the screen on the next page.

Clicking on “CANCEL” will not import the *Kits*.

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Select Trial » Trial Details » Manage Kits » Manage Kits For Site

IMPORT KITS


[Choose file](#)

Unassigned (No Clinical Site):

TREATMENT ID	TREATMENT	KIT
2	Placebo	A61
1	Active	A62
2	Placebo	A63
1	Active	A64
1	Active	A65
1	Active	A66
2	Placebo	A67
2	Placebo	A68
2	Placebo	A69
1	Active	A70

[SAVE CHANGES](#) [CANCEL](#)


There are now 10 Unassigned Kits that can be assigned to *Clinical Sites* when appropriate.



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[Select Trial](#) » [Trial Details](#) » [Manage Kits](#)

 Kits imported successfully.

MANAGE KITS

[Edit Kit Preferences](#) | [Import Kits](#) | [Assign Kits](#)

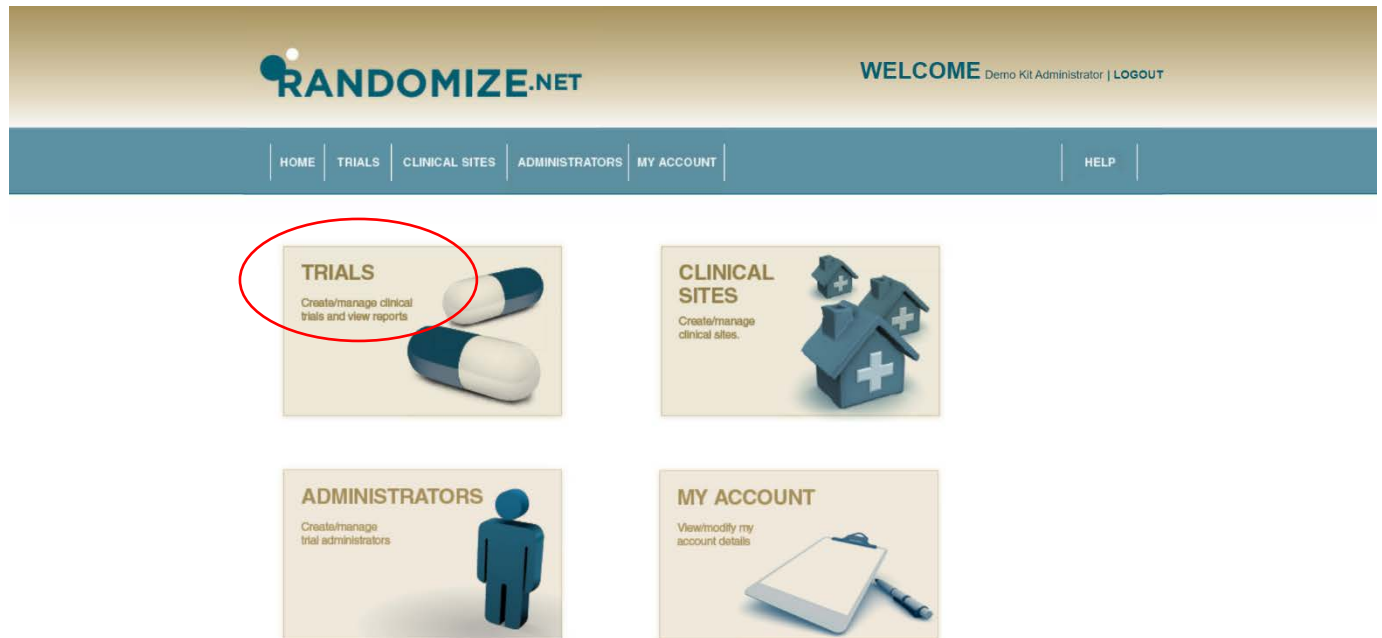
	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	0
View/Edit	democlinsite2	Demo Clinical Site 2	0	0	0

UNASSIGNED KIT COUNT


10

5.4 Assign *Kit Numbers* to *Clinical Sites*

To indicate that previously imported *Kit Numbers* are now available at specific *Clinical Sites*, click on “TRIALS” from the Kit Administrator home page.



Click on the appropriate trial.



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Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1

The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.



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Select Trial » Trial Details

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Limits](#) | [Reports](#) | [Manage Kits](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Sixty *Kits* have been imported and assigned to “Demo Clinical Site 1”. Seven have been used and there are 53 “REMAINING KITS” for future patients. No *Kits* have been imported and assigned to “Demo Clinical Site 2”.

Ten *Kits* have been imported but not yet assigned to a *Clinical Site*.

Click on “Assign Kits”.

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Select Trial » Trial Details » Manage Kits


MANAGE KITS

Edit Kit Preferences | Import Kits | **Assign Kits**

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	0
View/Edit	democlinsite2	Demo Clinical Site 2	0	0	0

UNASSIGNED KIT COUNT 10

Click on the drop-down menus under “CLINICAL SITE” to select the *Clinical Site* you want to assign each *Kit* to. See the screen on the next page.


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[Select Trial](#) » [Trial Details](#) » [Manage Kits](#) » [Assign Kits](#)

ASSIGN KITS

TREATMENT ID	TREATMENT	KIT	CLINICAL SITE	AVAILABLE	DELETE
2	Placebo	A61	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A62	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A63	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A64	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A65	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A66	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A67	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A68	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A69	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A70	<input type="text" value="Pick One"/>	<input type="checkbox"/>	<input type="checkbox"/>

Kit Numbers A61 to A64 are to be assigned to “Demo Clinical Site 1” and A65 to A68 are to be assigned to “Demo Clinical Site 2”.

Clicking on “SAVE CHANGES” will assign the *Kits* and take you to the screen on the next page.

Clicking on “CANCEL” will not assign the *Kits* and take you back to the screen on the previous page.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Manage Kits » Assign Kits

ASSIGN KITS

TREATMENT ID	TREATMENT	KIT	CLINICAL SITE	AVAILABLE	DELETE
2	Placebo	A61	Demo Clinical Site 1 ▼	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A62	Demo Clinical Site 1 ▼	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A63	Demo Clinical Site 1 ▼	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A64	Demo Clinical Site 1 ▼	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A65	Demo Clinical Site 2 ▼	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A66	Demo Clinical Site 2 ▼	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A67	Demo Clinical Site 2 ▼	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A68	Demo Clinical Site 2 ▼	<input type="checkbox"/>	<input type="checkbox"/>
2	Placebo	A69	Pick One ▼	<input type="checkbox"/>	<input type="checkbox"/>
1	Active	A70	Pick One ▼	<input type="checkbox"/>	<input type="checkbox"/>


SAVE CHANGES **CANCEL**

Ticking the boxes under "AVAILABLE" will indicate that the *Kits* are physically available at the *Clinical Site* now.

Ticking the boxes under "DELETE" will delete the *Kit Number* and remove it from the database.

Four “NOT YET AVAILABLE” Kits have been added to each *Clinical Site*. This means the *Kits* have been assigned to these *Clinical Sites* but are not yet physically available. Two *Kits* are still unassigned.


The *Kits* can be made available once they are assigned to the *Clinical Sites* (see screen on previous page) or at a later date, see the next section, entitled “[Make Assigned Kits available](#)”.



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Select Trial » Trial Details » Manage Kits

 Kits allocated successfully.

MANAGE KITS

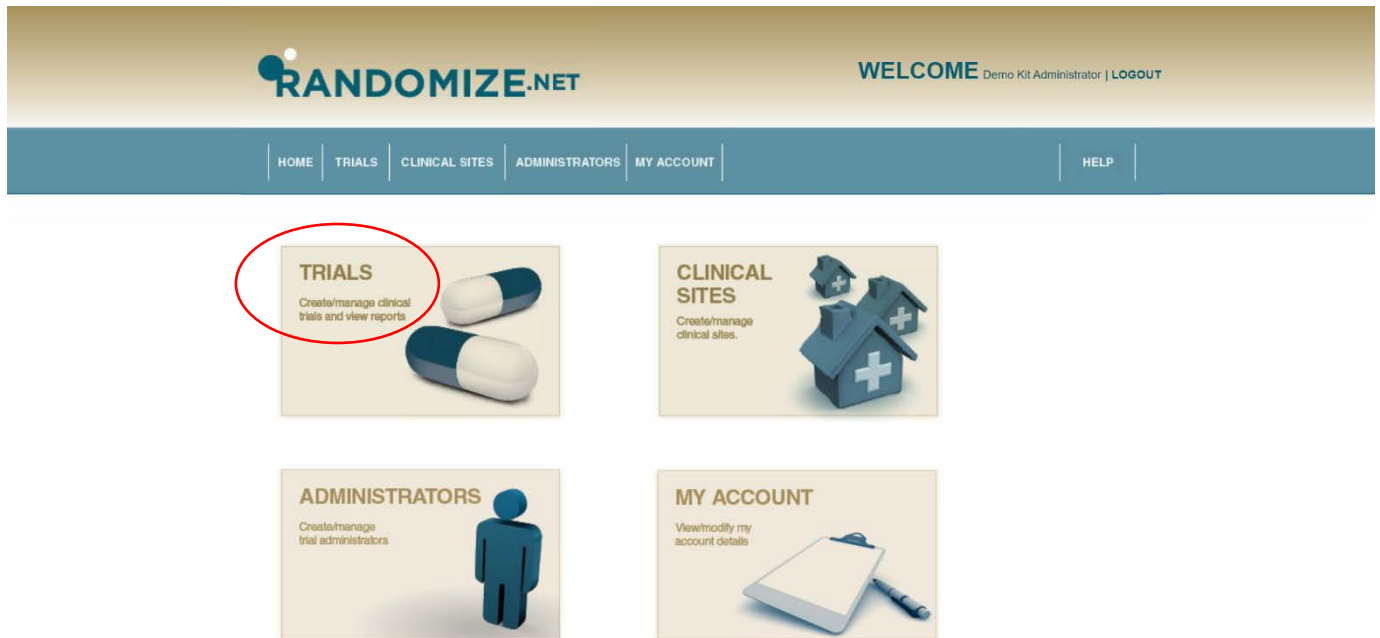
[Edit Kit Preferences](#) | [Import Kits](#) | [Assign Kits](#)

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	4
View/Edit	democlinsite2	Demo Clinical Site 2	0	0	4


UNASSIGNED KIT COUNT 2

5.5 Make Assigned *Kits* available

To indicate that *Kits* are available for future patients at the *Clinical Site* to which they have been previously assigned, click on “TRIALS” from the *Kit Administrator* home page.



Click on the appropriate trial.



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Select Trial

TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1

The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.

The screenshot shows the RANDOMIZE.NET web application. The header includes the logo and a welcome message for the Demo Kit Administrator. The navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled 'TRIAL DETAILS' and includes a breadcrumb trail: 'Select Trial > Trial Details'. The 'Manage Kits' link in the breadcrumb trail is circled in red. Below the breadcrumb trail is a table of trial details.

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Sixty-four *Kits* have been imported and assigned to “Demo Clinical Site 1”. Seven have been used, 53 “REMAINING KITS” are available for future patients, and 4 are “NOT YET AVAILABLE”.

Four *Kits* have been imported and assigned to “Demo Clinical Site 2” but are “NOT YET AVAILABLE”.

Two *Kits* have been imported but not yet assigned to a *Clinical Site*.

To indicate that 2 *Kits* (A65 and A66) at “Demo Clinical Site 2” are now available, click on “View/Edit” on the line entry for “Demo Clinical Site 2”.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Manage Kits

Kits allocated successfully.

MANAGE KITS

Edit Kit Preferences | Import Kits | Assign Kits

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	4
View/Edit	democlinsite2	Demo Clinical Site 2	0	0	4

UNASSIGNED KIT COUNT 2

The 4 *Kits* are listed. They have been “ASSIGNED” to “Demo Clinical Site 2” but not yet indicated as “AVAILABLE”.

To indicate that *Kits* A65 and A66 are now available at the *Clinical Site* tick the boxes under “AVAILABLE”. See the screen on the next page.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT HELP

Select Trial » Trial Details » Manage Kits » Manage Kits For Site


MANAGE KITS for Demo Clinical Site 2

CLINICAL SITE NAME	SITE ID	TREATMENT ID	TREATMENT	KIT	NUMBER	IS USED	AVAILABLE	ASSIGNED
Demo Clinical Site 2	democlinsite2	1	Active	A65	1	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 2	democlinsite2	1	Active	A66	2	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 2	democlinsite2	2	Placebo	A67	1	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 2	democlinsite2	2	Placebo	A68	2	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Click on the boxes under “AVAILABLE” for *Kit Numbers* A65 and A66.

Clicking on “SAVE CHANGES” will make the *Kits* available for future patients and take you to the screen on the next page.

Clicking on “CANCEL” will take you back to the screen on [page 167](#) and the *Kits* will not be available for future patients.

WELCOME Demo Kit Administrator | [LOGOUT](#)

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | [HELP](#)

Select Trial » Trial Details » Manage Kits » Manage Kits For Site

MANAGE KITS for Demo Clinical Site 2


CLINICAL SITE NAME	SITE ID	TREATMENT ID	TREATMENT	KIT	NUMBER	IS USED	AVAILABLE	ASSIGNED
Demo Clinical Site 2	democlinsite2	1	Active	A65	1	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 2	democlinsite2	1	Active	A66	2	False	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 2	democlinsite2	2	Placebo	A67	1	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Demo Clinical Site 2	democlinsite2	2	Placebo	A68	2	False	<input type="checkbox"/>	<input checked="" type="checkbox"/>

[SAVE CHANGES](#)[CANCEL](#)

Sixty-four *Kits* have been imported and assigned to “Demo Clinical Site 1”. Seven have been used, 53 are “REMAINING KITS” and are available for future patients, and 4 are “NOT YET AVAILABLE”.

Four *Kits* have been imported and assigned to “Demo Clinical Site 2”. Two (A65 and A66) are “REMAINING KITS” and are available for future patients and 2 are “NOT YET AVAILABLE”.


Two *Kits* have been imported but not yet assigned to a Clinical Site.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial » Trial Details » Manage Kits

 Kits saved successfully.

MANAGE KITS

[Edit Kit Preferences](#) | [Import Kits](#) | [Assign Kits](#)

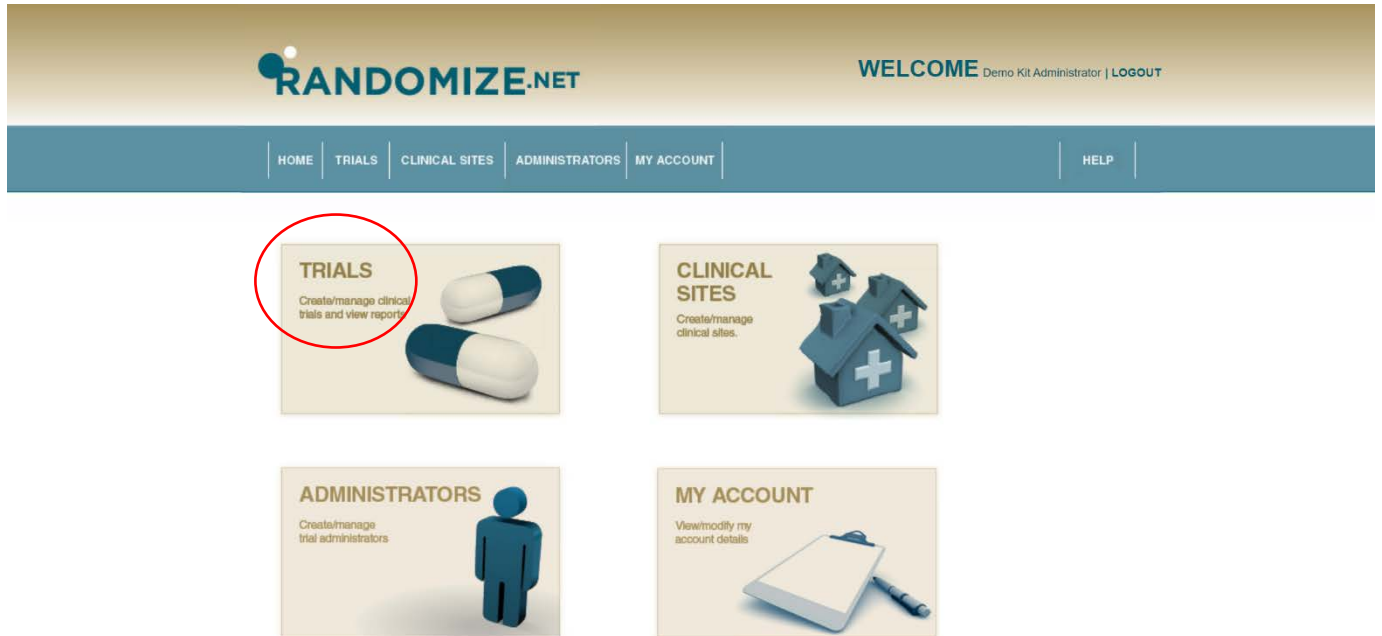
	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	4
View/Edit	democlinsite2	Demo Clinical Site 2	0	2	2

UNASSIGNED KIT COUNT


2

5.6 Kit Preferences

To View/Edit the *Kit* Preferences for a specific trial, click on “TRIALS” from the *Kit Administrator* home page.



Click on the trial for which you want to View/Edit the *Kit* Preferences.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1

The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)


Select Trial » Trial Details

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Limits](#) | [Reports](#) | [Manage Kits](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more


Click on “Edit Kit Preferences”.



WELCOME Demo Kit Administrator | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial » Trial Details » Manage Kits

 Kits allocated successfully.

MANAGE KITS

[Edit Kit Preferences](#) | [Import Kits](#) | [Assign Kits](#)

	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	4
View/Edit	democlinsite2	Demo Clinical Site 2	0	0	4

UNASSIGNED KIT COUNT

2

An explanation of *Kit Preference* is given below.

Clicking on “SAVE CHANGES” saves all changes made during the session and takes you to screen on the previous page.

Clicking on “CANCEL” removes all changes made during the session and takes you to screen on the previous page.

The screenshot shows the 'RANDOMIZE.NET' interface. At the top, there's a navigation bar with 'HOME', 'TRIALS', 'CLINICAL SITES', 'ADMINISTRATORS', and 'MY ACCOUNT'. Below this is a breadcrumb trail: 'Select Trial » Trial Details » Manage Kits » Kits Preferences'. The main heading is 'KITS PREFERENCES'. The settings include:

- Kit List Per Clinical Site:** Radio buttons for 'Yes' (selected) and 'No'.
- Allow Refill/Replacement Of Kits:** Radio buttons for 'Yes' and 'No' (selected).
- Low Kit Email Alert Level per Treatment Arm:** A dropdown menu set to 'Off'.
- Send Email Alert to:** Checkboxes for 'All Kit Administrators', 'Coordinating Center', and 'Clinical Site'.
- Buttons:** 'SAVE CHANGES' and 'CANCEL'.

Three red callout boxes provide additional information:

- Callout 1 (points to 'Kit List Per Clinical Site' 'No' option):** If "No", all *Kit Numbers* must be available at all *Clinical Sites*. If "Yes", *Kit Numbers* must be assigned to one *Clinical Site* only. The default is "Yes" and cannot be reset after trial is activated.
- Callout 2 (points to 'Allow Refill/Replacement Of Kits' 'No' option):** If "Yes", a *Clinical Site* can request another *Kit Number* containing the same treatment for a previously randomized patient. The default is "No" and can be reset anytime.
- Callout 3 (points to 'Low Kit Email Alert Level per Treatment Arm' dropdown):** Low *Kit* alert settings. These are explained in the next 2 pages.

Click on the desired Low *Kit* Alert value. For example, if “5” is chosen, when there are only 5 available *Kits* left for a treatment arm at a *Clinical Site*, the alert email will be sent.

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Manage Kits » Kits Preferences

KITS PREFERENCES

Kit List Per Clinical Site: ☒ Yes ☐ No

Allow Refill/Replacement Of Kits: ☐ Yes ☒ No

Low Kit Email Alert Level per Treatment Arm:

Send Email Alert to :

1
2
3
4
5
6
7
8
9
10

The alert level is now set to "5". When there are only 5 available *Kits* left for a treatment arm at a *Clinical Site*, the alert email will be sent. You can choose to whom the alert emails are sent. In this example, it is "All Kit Administrators" and the "Clinical Site".

RANDOMIZE.NET WELCOME Demo Kit Administrator | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Manage Kits » Kits Preferences

KITS PREFERENCES

Kit List Per Clinical Site: ☒ Yes ☐ No

Allow Refill/Replacement Of Kits: ☐ Yes ☒ No

Low Kit Email Alert Level per Treatment Arm: 5 ▼

Send Email Alert to :

- ☒ All Kit Administrators
- ☐ Coordinating Center
- ☒ Clinical Site

SAVE CHANGES **CANCEL**

6. Blinded Trials Without Using *Kit Numbers*

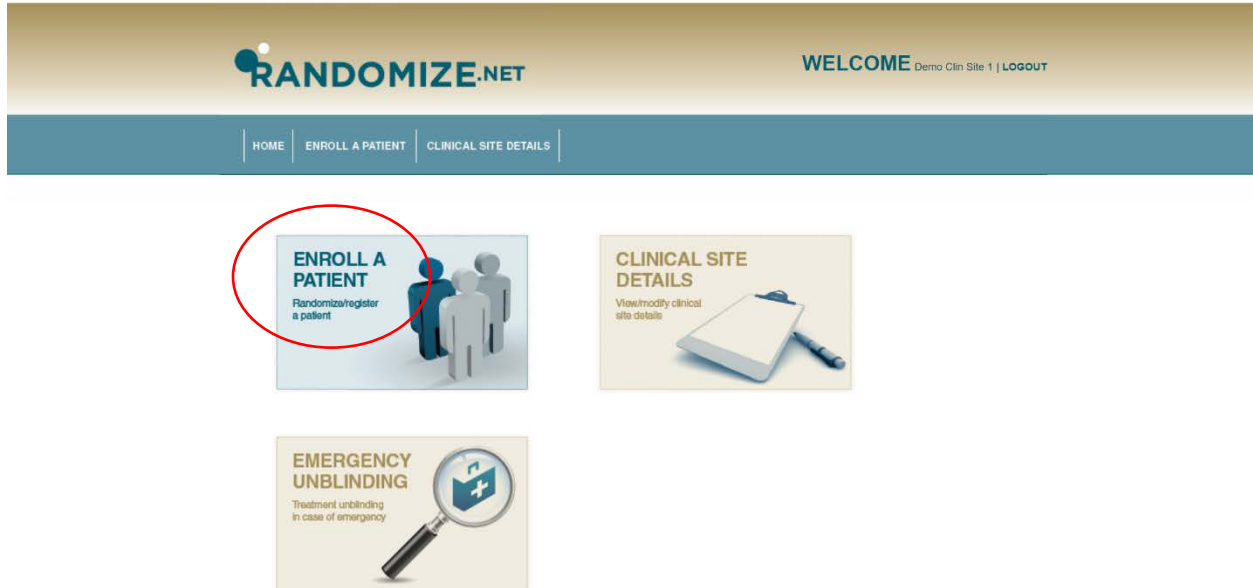
A trial can be blinded without using *Kit Numbers*. There must be an unblinded person (often a pharmacist) at each *Clinical Site*. The unblinded person receives an email confirmation, sent at the time of randomization, that includes the unblinded treatment allocation. The treatment allocation is excluded from the email confirmations sent to the *Clinical Site* users and is not shown on the screen at the time of randomization. The unblinded person is responsible for the patient receiving the allocated treatment while maintaining blinding for everyone else.

To accomplish this, please follow these steps.


1. From “Edit Trial Details”, see [page 50](#), make sure “Double Blind Trial” is set to “No”, even though the trial is blinded. By setting this to “No”, *Kit Numbers* will not be required.
2. From “Notification Emails”, see [page 80](#), tick the box next to “Exclude Treatment for Clinical Sites”. If you want the *Coordination Centre* to remain blinded, untick the box next to “Send Email to Coordinating Centre”. A blinded email notification can be sent to the *Coordinating Centre* by adding them under “Add new email”, see step 4.
3. “Add new email” for the unblinded person at each *Clinical Site*. There can be more than one at each *Clinical Site*. Be sure that the box next to “Exclude treatment” is not ticked. You can choose which *Clinical Site* (or “All Sites”) you want the unblinded person to receive the email confirmation for.
4. To send a blinded email confirmation to the *Coordinating Centre*, add them as in step 3 and choose “All Sites”, but be sure the box next to “Exclude treatment” is ticked to keep them blinded.
5. Prior to activating the trial, notify us at info@randomize.net from the *Coordinating Centre*’s email account that the trial is to be blinded without the use of *Kit Numbers*, and we will activate a setting to prevent the allocated treatment from being shown on the screen at the time of randomization. Be sure to include the *Coordinating Centre* login ID and the trial name and ID number.

7.1 Randomize a Patient

To randomize a patient at a *Clinical Site*, click on “ENROL A PATIENT” from the home page of any enabled user for that *Clinical Site*.



Click on the trial.



WELCOME Demo Clin Site 1 | [LOGOUT](#)

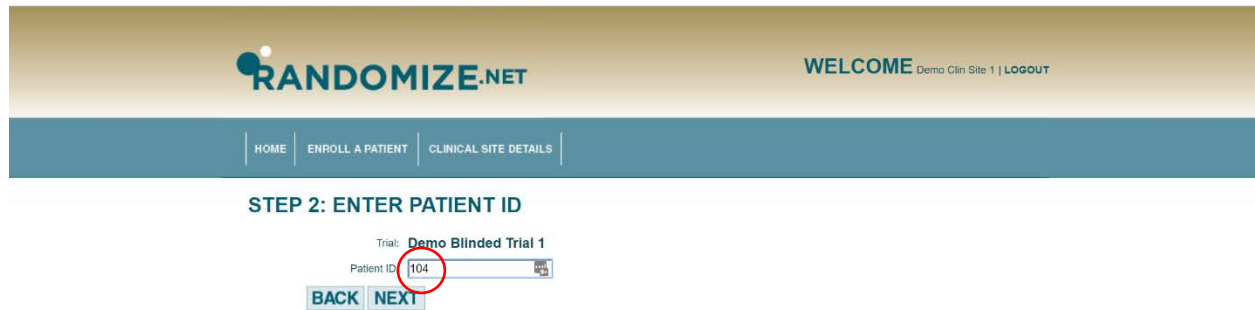
[HOME](#) | [ENROLL A PATIENT](#) | [CLINICAL SITE DETAILS](#)

STEP 1: SELECT A TRIAL

ID	TRIAL NAME
1972	Demo Blinded Trial 1

Provide the Patient ID number, in this case “104”.

Click on “NEXT”.



The screenshot displays the RANDOMIZE.NET website interface. At the top, the logo "RANDOMIZE.NET" is on the left, and "WELCOME Demo Clin Site 1 | LOGOUT" is on the right. Below this is a navigation bar with links: HOME, ENROLL A PATIENT, and CLINICAL SITE DETAILS. The main content area is titled "STEP 2: ENTER PATIENT ID". Under this title, it says "Trial: Demo Blinded Trial 1". There is a text input field labeled "Patient ID" containing the number "104". A red circle is drawn around the input field. Below the input field are two buttons: "BACK" and "NEXT".

Entre any required fields, in this case the “Patient Initials”, given by “der”.

Click on “NEXT”.

The screenshot displays the Randomize.NET web application interface. At the top, there is a header with the Randomize.NET logo on the left and a welcome message "WELCOME Demo Clin Site 1 | LOGOUT" on the right. Below the header is a navigation bar with links for "HOME", "ENROLL A PATIENT", and "CLINICAL SITE DETAILS". The main content area is titled "STEP 3: ENTER PATIENT INFORMATION". Under this title, it shows "Trial: Demo Blinded Trial 1" and "Patient ID: 104". The "Patient Initials" field contains the text "der", which is circled in red. At the bottom of the form, there are two buttons: "BACK" and "NEXT".

RANDOMIZE.NET WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

STEP 3: ENTER PATIENT INFORMATION

Trial: Demo Blinded Trial 1

Patient ID: 104


Patient Initials: der

BACK NEXT

If requested, answer the inclusion and exclusion criteria questions.

The answer to the inclusion criteria questions must be “Yes” and the answer to the exclusion criteria questions must be “No”.

Click on “NEXT”.



WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

STEP 4: ANSWER INCLUSION/EXCLUSION CRITERIA

Trial: **Demo Blinded Trial 1**
Patient ID: **104**

Inclusion Criteria (All answers must be YES for randomization)

1. Does the patient have a traumatic spinal cord injury that occurred \geq 1 year ago?	<input checked="" type="radio"/> Yes	<input type="radio"/> No
2. Does the patient have chronic SCI (persistent spinal cord lesion) confirmed by MRI?	<input checked="" type="radio"/> Yes	<input type="radio"/> No

Exclusion Criteria (All answers must be NO for randomization)

1. Does the patient have a history of stroke, cerebrovascular injury, or elevated intracranial pressure?	<input type="radio"/> Yes	<input checked="" type="radio"/> No
2. Does the patient have a body mass index (BMI) \geq 35 kg/m ² or body weight $<$ 50 kg?	<input type="radio"/> Yes	<input checked="" type="radio"/> No

BACK NEXT

If required, select the appropriate stratification levels. In this case the “Duration of Injury” is “2 years or more”.

Click on “NEXT”.

RANDOMIZE.NET WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

STEP 5: ENTER STRATIFICATION LEVEL(S)

Trial: **Demo Blinded Trial 1**
Patient ID: **104**

Duration since injury

☐ Less than 2 years

☒ 2 years or more

BACK **NEXT**

If required, and if it is true, tick “The above information is correct, proceed with randomization.” This is an optional setting and may not be required for a particular trial.

Click on “RANDOMIZE”.



RANDOMIZE.NET WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

CONFIRM RANDOMIZATION

Trial: **Demo Blinded Trial 1**

Patient ID: **104**

Initials **der**

Duration since injury **2 years or more**

☒ The above information is correct, proceed with randomization.

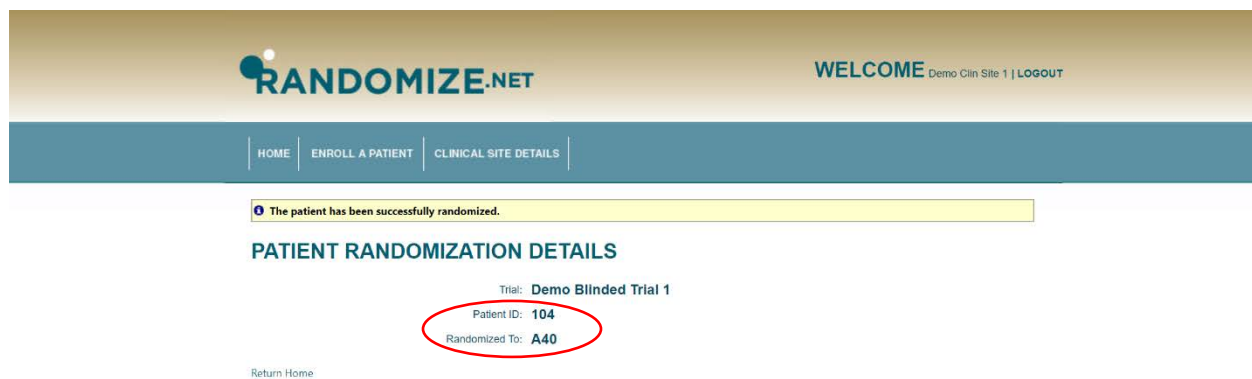
BACK **RANDOMIZE**

The user will be shown the following screen. Since this is a blinded trial, the patient has been randomized to a *Kit Number*.

Patient 104 has now been randomized to *Kit Number* A40.

The *Kit Number*, either

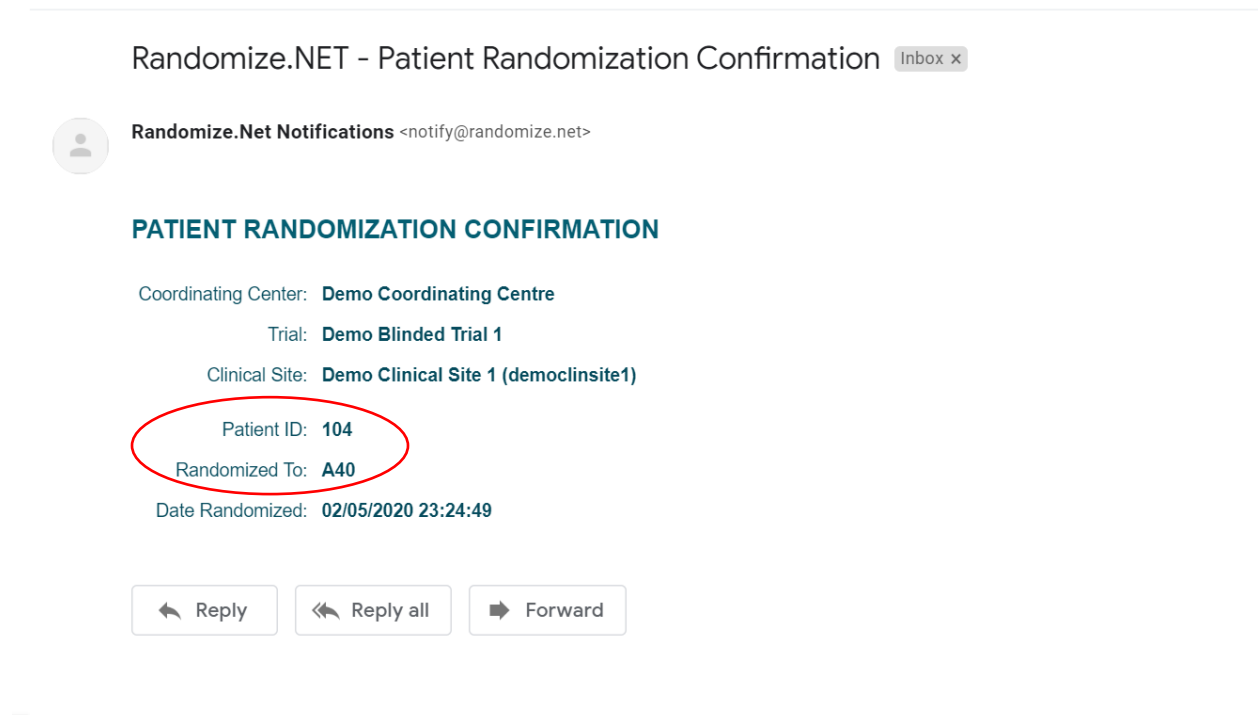
- iii. corresponds to an actual physical kit containing the allocated treatment, located somewhere in the *Clinical Site*, or
- iv. appears on a list, together with the allocated treatment, most likely held by a pharmacist located at the *Clinical Site*.



The following email message will be sent.

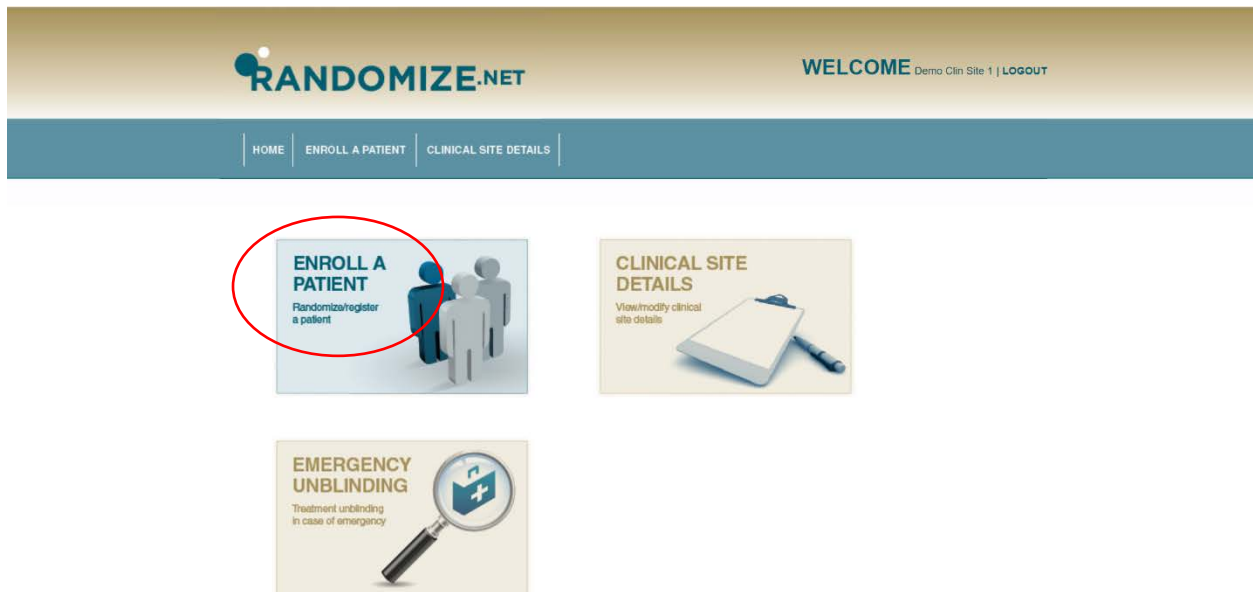
By default, the email message is sent to the *Coordinating Centre*, the primary user at the *Clinical Site* and to the user who randomized the patient, if it is other than the primary user.

The recipients of the confirmation email message can be modified, see [Section 3.6](#).




7.2 Resend Confirmation Email Message

To resend the confirmation email message of a previously randomized patient, click on “ENROLL A PATIENT” from the home page of any user from the *Clinical Site* that randomized the patient.



<https://www.randomize.net/Randomize/ClinicalSite/EnrollPatient.aspx>

Click on the trial.



WELCOME Demo Clin Site 1 | LOGOUT

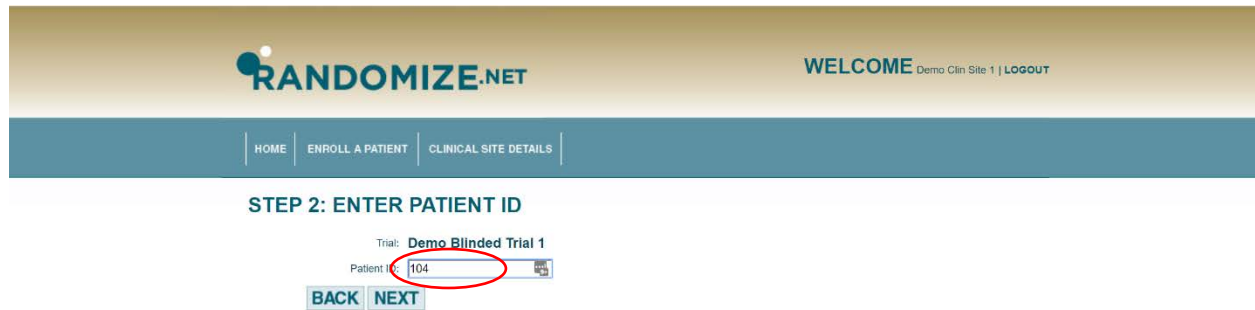
HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

STEP 1: SELECT A TRIAL

ID	TRIAL NAME
1972	Demo Blinded Trial 1

Provide the Patient ID number, in this case “104”.

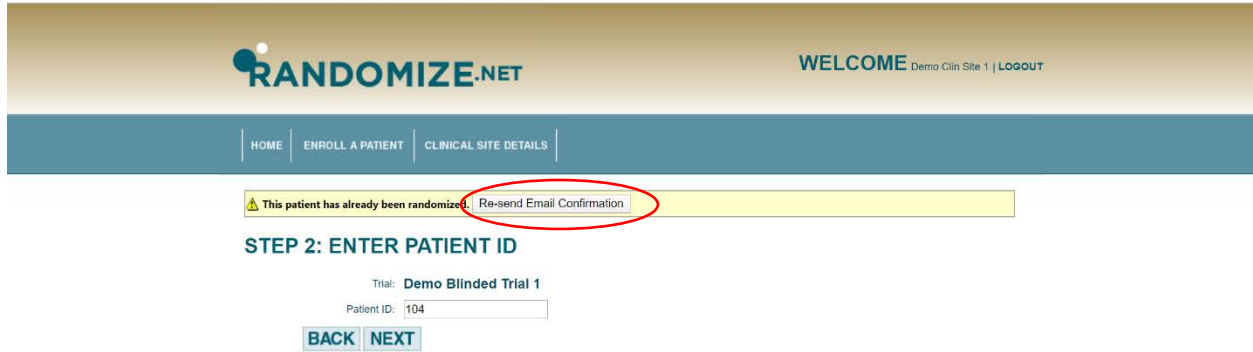
Click on “NEXT”.



The screenshot displays the RANDOMIZE.NET web application. The header features the site logo and a 'WELCOME' message for 'Demo Clin Site 1' with a 'LOGOUT' link. A navigation bar includes links for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main content area is titled 'STEP 2: ENTER PATIENT ID'. It shows the trial name 'Demo Blinded Trial 1' and a 'Patient ID' input field containing the value '104'. A red circle highlights the input field. Below the input field are 'BACK' and 'NEXT' buttons.

The screen below will appear. Click on “Re-send Email Confirmation” and the confirmation email message will be resent to all email addresses that received the original.

You will then be taken to the screen on the next page.



The screenshot displays the RANDOMIZE.NET web application interface. At the top, there is a header with the logo on the left and 'WELCOME Demo Clin Site 1 | LOGOUT' on the right. Below the header is a navigation bar with links for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. A yellow warning banner is present, stating 'This patient has already been randomized.' followed by a red-outlined button labeled 'Re-send Email Confirmation'. Below the banner, the section is titled 'STEP 2: ENTER PATIENT ID'. It includes a 'Trial:' label with the value 'Demo Blinded Trial 1' and a 'Patient ID:' label with the value '104' entered in a text field. At the bottom of this section are two buttons: 'BACK' and 'NEXT'.

You will receive the message “Email confirmation sent”.

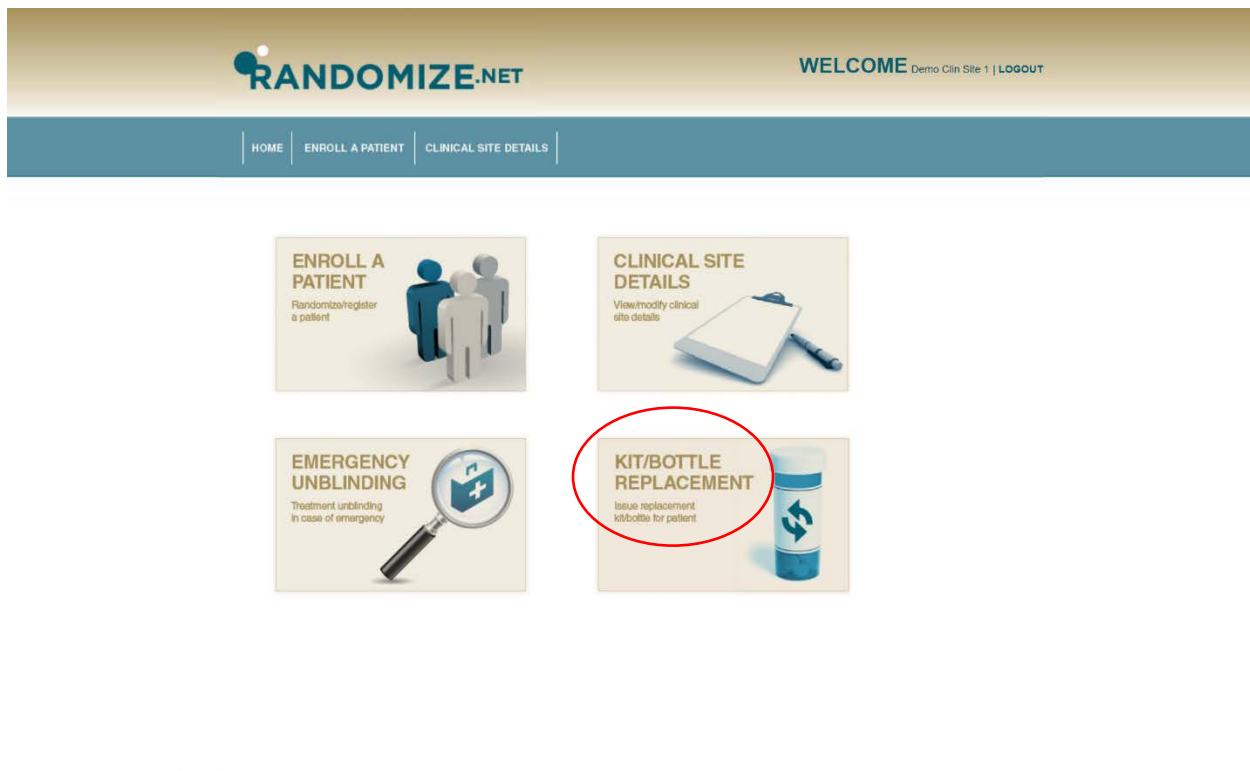
Click on “HOME”.

The screenshot shows the RANDOMIZE.NET website interface. At the top, there is a header with the logo and a welcome message: "WELCOME Mary Smith | LOGOUT". Below the header is a navigation bar with three links: "HOME", "ENROLL A PATIENT", and "CLINICAL SITE DETAILS". The "HOME" link is circled in red. Below the navigation bar, a yellow message box displays "Email confirmation sent.", which is also circled in red. The main content area is titled "STEP 2: ENTER PATIENT ID". It includes a trial name "Demo Blinded Trial 1" and a patient ID input field containing "104". At the bottom of the form are two buttons: "BACK" and "NEXT".


7.3 Get New a *Kit Number* with Same Treatment

In some circumstances it is necessary to get an additional *Kit Number* that contains the same treatment for a previously randomized patient. The *Kit* may have been defective or accidentally destroyed. Also, in some trials, patients can receive repeat doses and therefore need a series of *Kits* containing the same treatment.

To get an additional *Kit Number* that contains the same treatment for a previously randomized patient, click on “KIT/BOTTLE REPLACEMENT” from an enabled *Clinical Site* user home page.



Click on the trial.



WELCOME Demo Clin Site 1 | [LOGOUT](#)

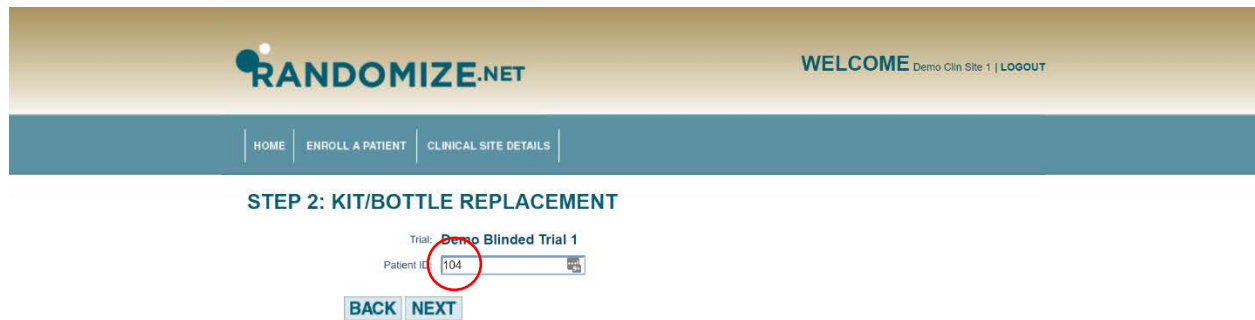
[HOME](#) | [ENROLL A PATIENT](#) | [CLINICAL SITE DETAILS](#)

STEP 1: SELECT A TRIAL

ID	TRIAL NAME
1972	Demo Blinded Trial 1

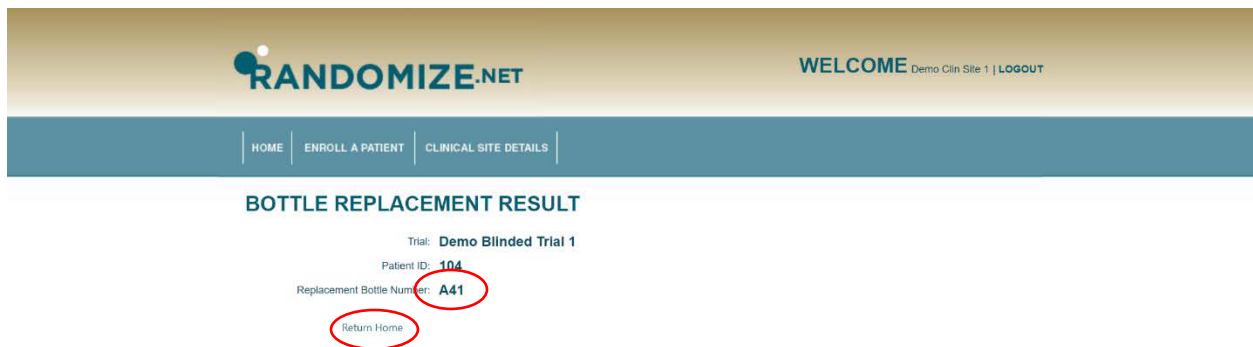
Provide the Patient ID number, in this case “104”.

Click on “NEXT”.



The screenshot displays the RANDOMIZE.NET web application interface. At the top, there is a header bar with the RANDOMIZE.NET logo on the left and "WELCOME Demo Clin Site 1 | LOGOUT" on the right. Below the header is a navigation bar with links for HOME, ENROLL A PATIENT, and CLINICAL SITE DETAILS. The main content area is titled "STEP 2: KIT/BOTTLE REPLACEMENT". Under this title, the trial name "Trial: Demo Blinded Trial 1" is shown. Below the trial name is a form field labeled "Patient ID:" containing the value "104". This field is circled in red. At the bottom of the form are two buttons: "BACK" and "NEXT".

The replacement *Kit Number* is A41. It will contain the same treatment as the *Kit* that was originally assigned to patient 104. To return to the home page click on "Return Home".



RANDOMIZE.NET WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

BOTTLE REPLACEMENT RESULT

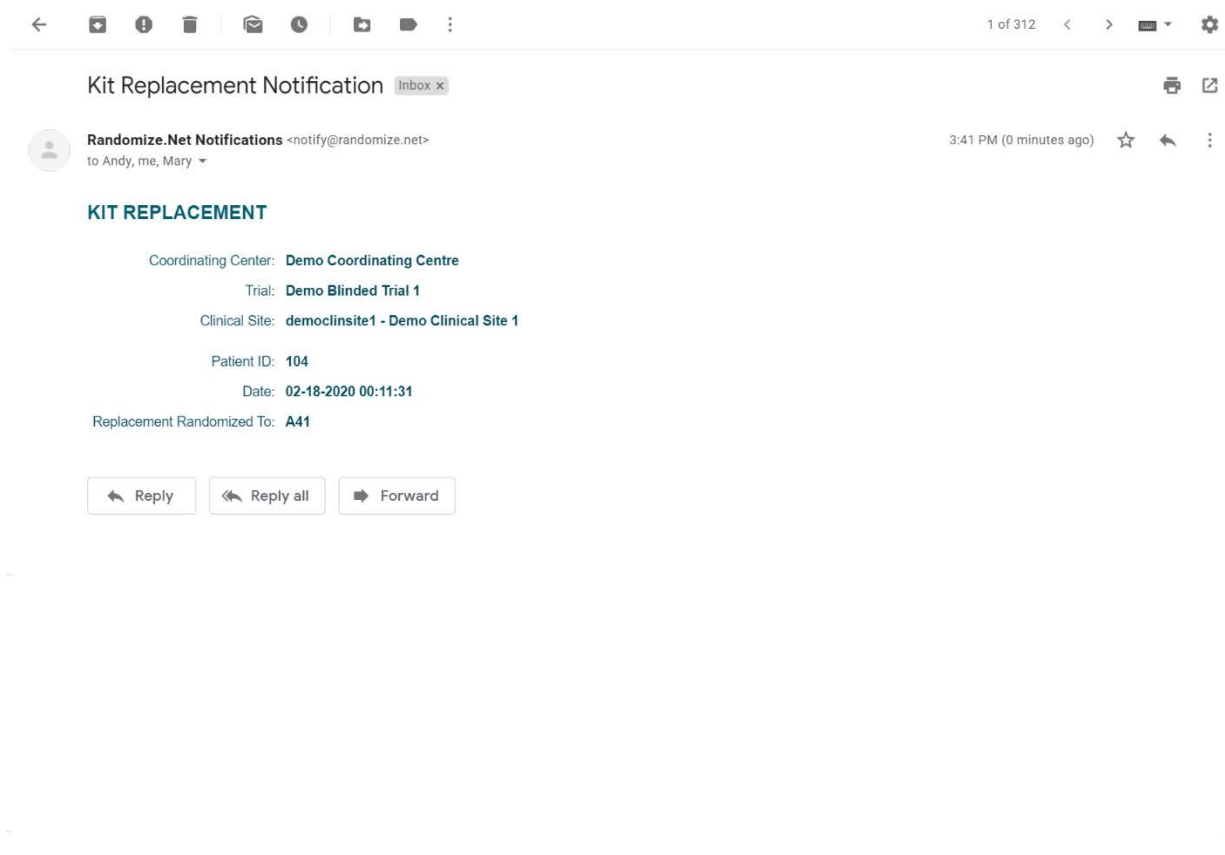
Trial: **Demo Blinded Trial 1**

Patient ID: **104**

Replacement Bottle Number: **A41**

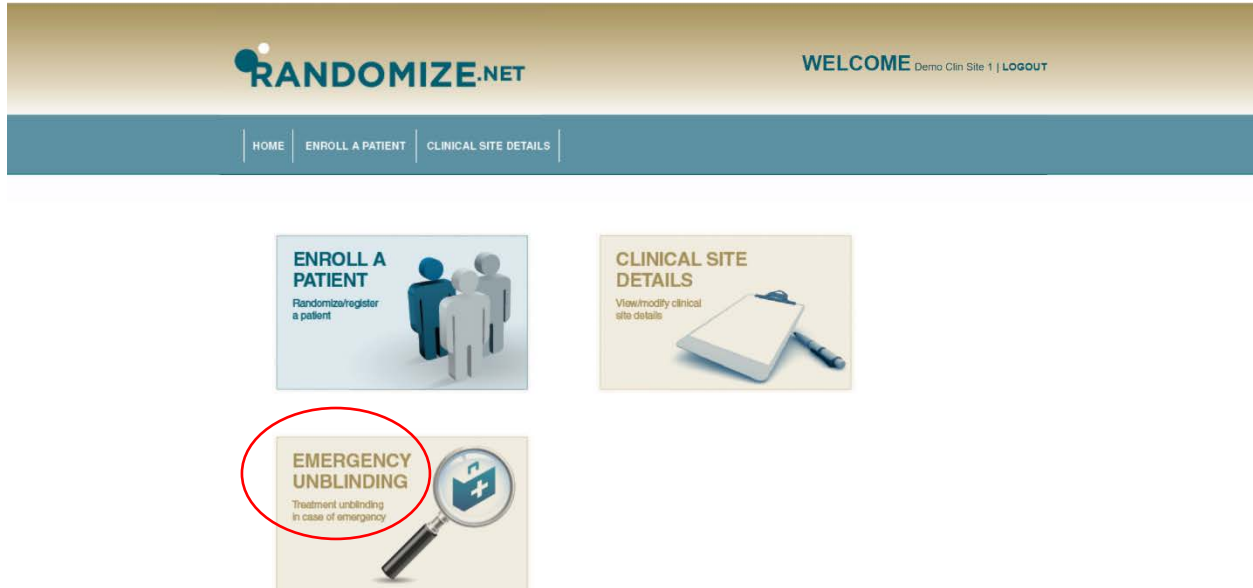
[Return Home](#)

A confirmation email message is sent to all individuals who are authorized to receive email notifications, see [Section 3.6](#).



7.4 Unblind a Patient in an Emergency

To unblind a previously randomized patient, click on “EMERGENCY UNBLINDING” from the home page of any enabled user from the *Clinical Site* that randomized the patient.



Select the trial. Enter Patient ID. Click on “NEXT”.

RANDOMIZE.NET WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

⚠ Emergency treatment unblinding will display the treatment. This should only be done in case of emergency.

EMERGENCY TREATMENT UNBLINDING

Trial: 1972 - Demo Blinded Trial 1 ▼

Patient ID: 104

OR

Randomized To:

BACK NEXT

Note warning.

Then click “OK”.

www.randomize.net says
Are you sure you want to unblind the treatment for this patient or kit number?

OK Cancel

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

WELCOME Demo Clin Site 1 | LOGOUT

⚠ Emergency treatment unblinding will display the <# GetTrialResource().PatientLabel %>'s treatment. This should only be done in case of emergency.

EMERGENCY TREATMENT UNBLINDING

Trial: 1972 - Demo Blinded Trial 1 ▼

Patient ID: 104

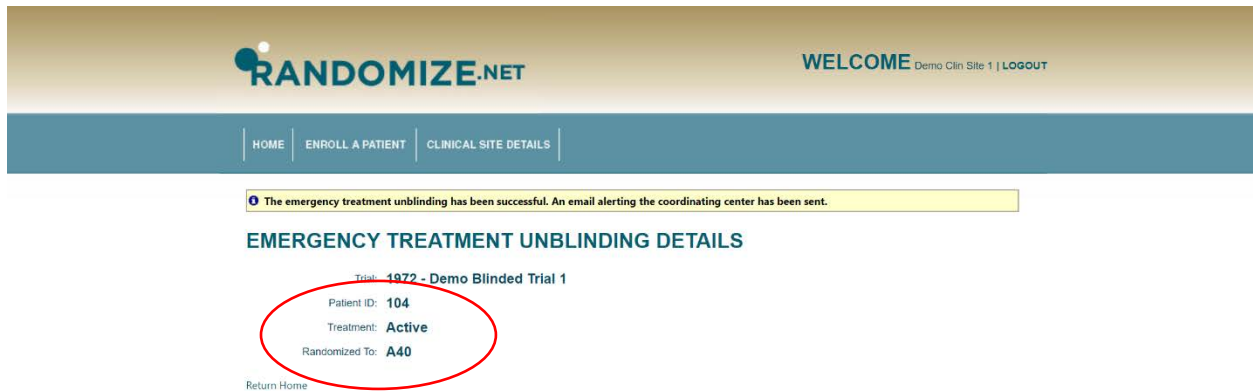
OR

Randomized To:

BACK NEXT

You will be shown a screen indicating that Patient ID “104” was randomized to *Kit Number* “A40” containing the treatment “Active”.

An email message will be sent to all individuals who are authorized to receive email notifications, see [Section 3.6](#). An example of the email message is given on the next page.



The screenshot shows the RANDOMIZE.NET interface. At the top, there is a header with the logo and a 'WELCOME' message for 'Demo Clin Site 1' with a 'LOGOUT' link. Below the header is a navigation bar with links for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. A yellow notification bar states: 'The emergency treatment unblinding has been successful. An email alerting the coordinating center has been sent.' The main section is titled 'EMERGENCY TREATMENT UNBLINDING DETAILS'. It displays the following information: 'Trial: 1972 - Demo Blinded Trial 1', 'Patient ID: 104', 'Treatment: Active', and 'Randomized To: A40'. The 'Patient ID: 104', 'Treatment: Active', and 'Randomized To: A40' are circled in red. A 'Return Home' link is located at the bottom left of the details section.

RANDOMIZE.NET WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

The emergency treatment unblinding has been successful. An email alerting the coordinating center has been sent.

EMERGENCY TREATMENT UNBLINDING DETAILS

Trial: 1972 - Demo Blinded Trial 1

Patient ID: 104

Treatment: Active

Randomized To: A40


Return Home


Emergency Treatment Unblinding: 1972 - Demo Blinded Trial 1 Inbox x


Randomize.Net Notifications <notify@randomize.net>

Emergency treatment unblinding has occurred.

Clinical Site Login ID: democlinsite1
Clinical Site Name: Demo Clinical Site 1
Contact Person: Demo Clin Site 1
Trial: 1972 - Demo Blinded Trial 1
Patient ID: 104
Randomized To: Active

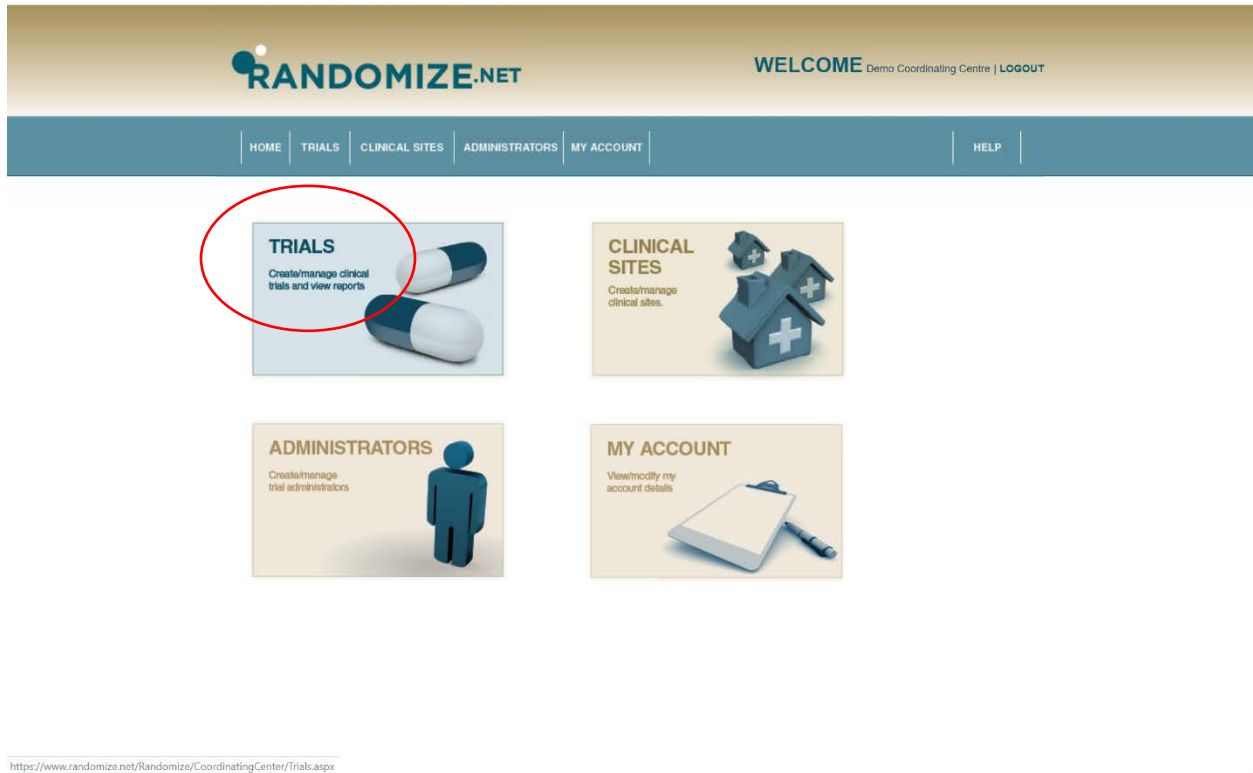
 Reply

 Reply all


 Forward

Unblinding a patient will alter the “Treatment Allocation” report.

To view the “Treatment Allocation” report, click on “TRIALS” from the *Coordinating Centre* home page.



Click on the name of the trial.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial


TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	True	22/12/2019 21:05:23	1
1972	Demo Blinded Trial 1	False		0

CREATE A TRIAL

Click on “Reports”.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)


Select Trial > Trial Details

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Links](#) | [Reports](#) | [Deactivate Trial](#)

TRIAL ID	1972
TRIAL NAME	Demo Blinded Trial 1
ACTIVATED	Yes
DATE ACTIVATED	01-09-2020 23:02:39
NUMBER OF ACTIVE CLINICAL SITES	1
RECORD PATIENT INITIALS	Yes
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Active 2. Placebo
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2
BLOCK SIZES	4
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more

Click on “Treatment Allocation”.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

[Select Trial](#) » [Trial Details](#) » [Reports](#)

REPORTS

To view reports for **Demo Blinded Trial 1**, select a report type.

Accrual Report | [Accrual By Site](#) | [Treatment Allocation](#)

	DEMO CLINICAL SITE 1	TOTAL
FEB-2020	1	1
TOTAL	1	1

[Download report](#)

[BACK](#)

Top panel is prior to unblinding.

Bottom is after unblinding.

The screenshot shows the Randomize.NET interface. The top header includes the logo and a welcome message. The navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area is titled 'REPORTS' and shows a table of patient data. A red callout box points to the 'UNBLINDED TREATMENT' column, which is currently blank.

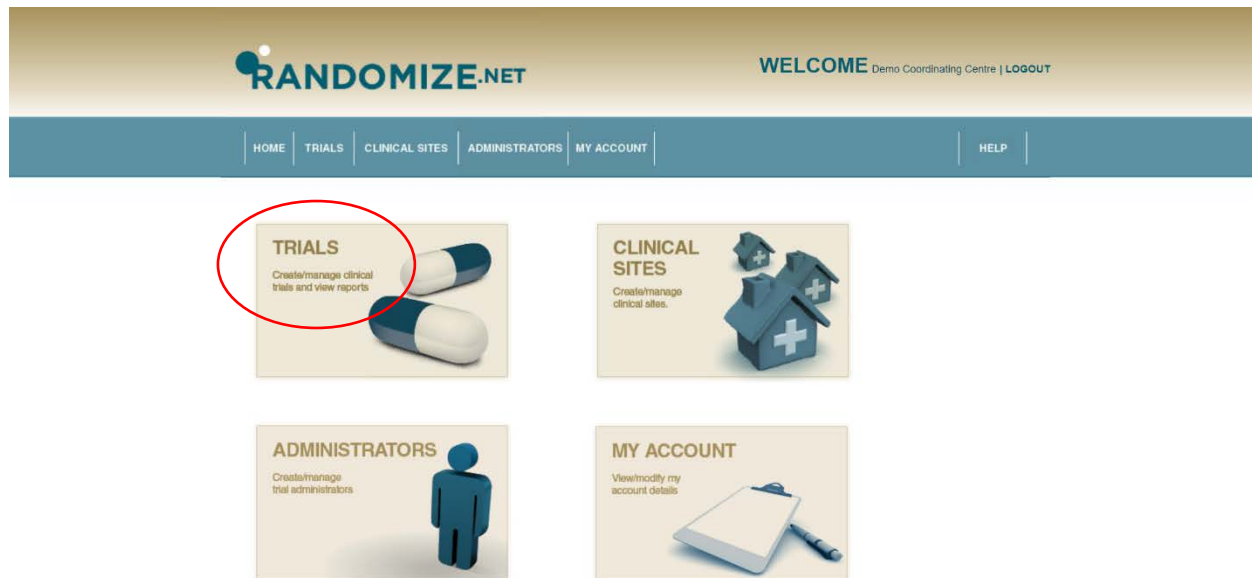
PATIENT ID	CLINICAL SITE	USER ID	DATE RANDOMIZED	INITIALS	DURATION SINCE INJURY	TREATMENT	UNBLINDED TREATMENT
104	Demo Clinical Site 1	democlin-site1	02-05-2020 23:24:49	der	2 years or more	A40	

The screenshot shows the same Randomize.NET interface, but now the 'UNBLINDED TREATMENT' column for patient ID 104 contains the value 'Active'. A red callout box points to this cell.


PATIENT ID	CLINICAL SITE	USER ID	DATE RANDOMIZED	INITIALS	DURATION SINCE INJURY	TREATMENT	UNBLINDED TREATMENT
104	Demo Clinical Site 1	democlin-site1	02-05-2020 23:24:49	der	2 years or more	A40	Active

8. Reports

To view the Reports, click on “TRIALS” from the *Coordinating Centre* home page.



Click on the trial whose reports you want to view.



WELCOME Demo Coordinating Centre | [LOGOUT](#)

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial

TRIALS

Select a trial to manage:

TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES
1968	Demo Trial 1	False	22-12-2019 22:05:23	0
1972	Demo Blinded Trial 1	True	01-09-2020 23:02:39	1
1974	Demo Blinded Trial 2	True	22-01-2020 20:06:43	0
2131	Home-based Exercise	True	01-09-2021 10:18:59	2
2151	MM Demo	True	31-10-2021 13:11:19	2

CREATE A TRIAL

Click on “Reports”.

The screenshot shows the Randomize.NET website interface. At the top, there is a header with the logo and a welcome message. Below the header is a navigation bar with links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area displays the 'TRIAL DETAILS' for trial ID 2131, titled 'Home-based Exercise'. A breadcrumb navigation path is shown: 'Select Trial > Trial Details > Edit Trial Details > Notification Emails > Edit Inclusion/Exclusion Criteria > Activate Clinical Sites > Limits > Reports > Reactivate Trial'. The 'Reports' link is circled in red. Below the breadcrumb, a table lists various trial parameters.

PARAMETER	VALUE
TRIAL ID	2131
TRIAL NAME	Home-based Exercise
ACTIVATED	Yes
DATE ACTIVATED	01-09-2021 10:18:59
NUMBER OF ACTIVE CLINICAL SITES	2
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Home-based exercise program 2. Usual care
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2, 3
BLOCK SIZES	4, 6
STRATIFICATION VARIABLES	1. Sex a. male b. female 2. Age a. 70 to 85

The “Accrual Report” is shown first. It is a cross-tabulation of month of accrual by *Clinical Site*.

Clicking on “Accrual By Strata” takes you to the screen on the next page.

“Accrual By Strata” is not available for blinded studies as it could lead to unblinding.

The screenshot shows the RANDOMIZE.NET web application. The header includes the logo and a welcome message for a 'Demo Coordinating Centre' with a 'LOGOUT' link. A navigation bar contains links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. Below the navigation bar, a breadcrumb trail reads 'Select Trial > Trial Details > Reports'. The main section is titled 'REPORTS' and includes a sub-header 'To view reports for Home-based Exercise, select a report type.' Under this, the 'Accrual Report' is highlighted with a red circle. Other options listed are 'Accrual By Strata', 'Treatment Allocation', and 'User Report'. The 'Accrual Report' displays a table with columns for 'DEMO CLINICAL SITE 1', 'DEMO CLINICAL SITE 2', and 'TOTAL'. The rows show data for SEPT-2021, OCT-2021, NOV-2021, and a TOTAL row. Below the table, there is a 'Download report' link and a 'BACK' button.

	DEMO CLINICAL SITE 1	DEMO CLINICAL SITE 2	TOTAL
SEPT-2021	1	0	1
OCT-2021	0	1	1
NOV-2021	0	0	0
TOTAL	1	1	2

This report is a cross-tabulation defined by the stratification variables, in this case “SEX”, “AGE” and *Clinical Site*.

This table is not available for blinded studies as it could lead to unblinding.

Clicking on “Treatment Allocation” takes you to the screen on the next page.

WELCOME Demo Coordinating Centre | LOGOUT

HOME | TRIALS | CLINICAL SITES | ADMINISTRATORS | MY ACCOUNT | HELP

Select Trial » Trial Details » Reports

REPORTS

To view reports for **Home-based Exercise**, select a report type.

Accrual Report
Accrual By Strata
Treatment Allocation | User Report

		DEMO CLINICAL SITE 1		DEMO CLINICAL SITE 2		TOTAL	
		HOME-BASED EXERCISE PROGRAM	USUAL CARE	HOME-BASED EXERCISE PROGRAM	USUAL CARE	HOME-BASED EXERCISE PROGRAM	USUAL CARE
SEX	MALE	0	0	1	0	1	0
	FEMALE	0	1	0	0	0	1
AGE	70 TO 85	0	0	0	0	0	0
	86 OR OLDER	0	1	1	0	1	1

BACK

This report contains a complete listing of all patients randomized.

Clicking of “User Report” takes you to the screen on the next page.

The screenshot shows the RANDOMIZE.NET web application interface. At the top, there is a header with the logo and a welcome message for the Demo Coordinating Centre, including a LOGOUT link. Below the header is a navigation bar with links for HOME, TRIALS, CLINICAL SITES, ADMINISTRATORS, MY ACCOUNT, and HELP. The main content area shows a breadcrumb trail: Select Trial > Trial Details > Reports. The section is titled "REPORTS" and includes a sub-header "To view reports for Home-based Exercise, select a report type." Below this, there are four report type links: Accrual Report, Accrual By Strat, Treatment Allocation (which is circled in red), and User Report. A table displays patient data for two clinical sites. The table has columns for Patient ID, Clinical Site, User ID, Date Randomized, Sex, Age, and Treatment. Two rows of data are shown. Below the table, there is a "Download report" link and a "BACK" button.

Select Trial > Trial Details > Reports

REPORTS

To view reports for **Home-based Exercise**, select a report type.

[Accrual Report](#) | [Accrual By Strat](#) | [Treatment Allocation](#) | [User Report](#)


PATIENT ID	CLINICAL SITE	USER ID	DATE RANDOMIZED	SEX	AGE	TREATMENT
778	Demo Clinical Site 1	democlinsite1	01-09-2021 10:21:22	female	86 or older	Usual care
456	Demo Clinical Site 2	democlinsite2	31-10-2021 12:35:24	male	86 or older	Home-based exercise program

[Download report](#)

[BACK](#)

This report provides the details for all of the Users associated with the trial.

Clicking on “BACK” at any time takes you to the screen on the next page.



WELCOME Demo Coordinating Centre | LOGOUT

[HOME](#) | [TRIALS](#) | [CLINICAL SITES](#) | [ADMINISTRATORS](#) | [MY ACCOUNT](#) | [HELP](#)

Select Trial » Trial Details » Reports

REPORTS

To view reports for **Home-based Exercise**, select a report type.

Accrual Report | Accrual By Strata | Treatment Allocation | **User Report**

USER ID	SITE NAME	NAME	EMAIL	ENABLED	ROLE
democc		Andy Willan	andy+100@randomize.net	True	Coordinating Center
demoauditor		Demo Auditor	demoaud@randomize.net	True	Auditor
demofa		Demo Full Admin	demofa@randomize.net	True	Full Admin
demoka		Demo Kit Administrator	andy@randomize.net	True	Kit Administrator
democlinsite1	Demo Clinical Site 1	Demo Clin Site 1	democlinsite1@randomize.net	True	Clinical Site
democsuser2	Demo Clinical Site 1	Mary Smith	andywillan.phd@gmail.com	False	Clinical Site
democlinsite2	Demo Clinical Site 2	Demo Clin Site 2	andy+2@randomize.net	True	Clinical Site
democs2user2	Demo Clinical Site 2	Andy Willan	andy@andywillan.com	False	Clinical Site

Download report

BACK

Select Trial » Trial Details

TRIAL DETAILS

[Edit Trial Details](#) | [Notification Emails](#) | [Edit Inclusion/Exclusion Criteria](#) | [Activate Clinical Sites](#) | [Limits](#) | [Reports](#) | [Deactivate Trial](#)

TRIAL ID	2131
TRIAL NAME	Home-based Exercise
ACTIVATED	Yes
DATE ACTIVATED	01-09-2021 10:18:59
NUMBER OF ACTIVE CLINICAL SITES	2
RECORD PATIENT INITIALS	No
RECORD PATIENT BIRTHDATE	No
RECORD OTHER VARIABLE	No
TREATMENTS	1. Home-based exercise program 2. Usual care
STRATIFY BY CLINICAL SITE	Yes
BLOCKING FACTORS	2, 3
BLOCK SIZES	4, 6
STRATIFICATION VARIABLES	1. Sex a. male b. female 2. Age a. 70 to 85

Appendix I: Algorithm for treatment allocation using minimization

Prepared by
Andrew R. Willan, PhD
Professor of Biostatistics, University of Toronto

Consider a trial with t treatment arms and s stratification variables for which balance in treatment allocation is desired. Consider the allocation of the “next” patient. Let n_{ri} be the number of patients currently in the trial with the same level of stratification variable i ($i = 1$ to s) as the “next” patient that have been allocated to treatment r ($r = 1$ to t).

		Stratification Variable (indexed by i)				
		1	2	3	...	s
Treatments (indexed by r)	1	n_{11}	n_{12}	n_{13}	...	n_{1s}
	2	n_{21}	n_{22}	n_{23}	...	n_{2s}
	3	n_{31}	n_{32}	n_{33}	...	n_{3s}

	t	n_{t1}	n_{t2}	n_{t3}	...	n_{ts}

Suppose the “next” patient is allocated to treatment j then $m_{jri} = n_{ri} + I(j = r)$ would be the number of patients in the trial with the same level of stratification variable i as the “next” patient, that are allocated to treatment r .

$$\text{Let } a_{ri} = \pi_r \left\{ 1 + \sum_{q=1}^t n_{qi} \right\},$$

where π_r is the overall desired proportion of patients to be allocated to treatment r . Their sum must equal 1. For equal allocation $\pi_r = 1/t$.

Following the allocation of the “next” patient, a_{ri} is the “expected” number of patients per treatment, assuming perfect balance, that have the same level of stratification variable i as the “next” patient.

$$\text{Let } d_{ji} = \sum_{r=1}^t |m_{jri} - a_{ri}|.$$

d_{ji} is a measure of the deviation from perfect balance for stratification variable i , if the “next” patient is allocated to treatment j .

$$\text{Let } D_j = \sum_{i=1}^s w_i d_{ji}^k, \quad k > 0.$$

D_j is the overall measure of the deviation from perfect balance, if the “next” patient is allocated to treatment j .

The larger the value of k , the more the balanced is forced. The value of k is user specified but is usually set to 2.

The values of w_i are user specified and allow for placing different weights on the stratification variables. Their sum does not have to equal 1.

$$\text{For equal weighting (e.g., } w_i = 1): D_j = \sum_{i=1}^s d_{ji}^k.$$

If $D_j > 0$ for all j , let $C_j = \pi_j / D_j$

The “next” patient is allocated to treatment j with probability $P_j = C_j / C_+$, where $C_+ = \sum_{j=1}^t C_j$.

If $D_j = 0$, then allocating the “next” patient to treatment j results in perfect balance. (This is only possible for one treatment.) In this situation the “next” patient is allocated to treatment j with probability 1.

References

- McEntegart DJ. The pursuit of balance using stratified and dynamic randomization techniques: An overview. *Drug Information Journal* 2003; **37**(3):293-308.
- Scott NW, *et al.* The method of minimization for allocation to clinical trials: A review. *Controlled Clinical Trials* 2002; **23**(6):662-674.
- Zielhuis GA, *et al.* The choice of a balanced allocation method for a clinical trial in otitis media with effusion. *Statistics in Medicine* 1990; **9**(3):237-246.