Randomize.net User’s 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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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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When Clinical Site logs-in and randomizes a patient on a blinded trial 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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Only Clinical Site accounts can randomize patients. All users, including the primary user, can be enabled to randomize patients.

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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.
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.

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”.

![Create Coordinating Centre](image-url)
To login to the *Coordinating Centre* Account, from [www.randomize.net](http://www.randomize.net) click on “SIGN IN” and provide the login credentials. Then click on “LOGIN”.

![Login page](image-url)
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”.

**Edit Details**

**Coordinating Center Details**

**Login ID:**

**Coordinating Center Name:**

**Contact Person:**

**Address 1:**

**Address 2:**

**City:**

**State:**

**Country:**

**Zip/Postal Code:**

**Phone:**

**Email:**

**Other:**

**Phone:**

**Other:**
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.
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”.
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.
2.1 Create an Auditor Account

To create an Auditor Account, click on “ADMINISTRATORS” from the Coordinating Centre home page.
Click on “CREATE ADMINISTRATOR”.
Provide “Login ID”, “Name”, “Email” address, and tick “Auditor”, as shown on next page.
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.

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.

By default, “ENABLED” is set to “True”. To set it to “False”, click on “Edit Administrator Details”.
The new Auditor account is now shown.
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”.
Provide “Login ID”, “Name”, “Email” address, and tick “Full Admin”, as shown in the screen on the next page.
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.

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.

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.
2.3 Create a Kit Administrator Account

To create a 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.
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*.

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 newly created *Kit Administrator* account is now shown.
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.
Administrator details are shown. Click on “Edit Administrator Details”.
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”.

![Image of EDIT ADMINISTRATOR screen]

- **Login**: demoauditor
- **Name**: Demo Auditor
- **Administrator Email**: demoauditor@randomize.net
- **Enabled**: True
- **Roles**: Full Admin, Audio

Administrator Roles Help:
- **Full Admin**: An full administrator that perform all the same tasks as the Coordinating Center.
- **Auditor**: A reviewer administrator that cannot make any changes to the trials or Clinical Sites.
- **Kit Administrator**: An unblinded administrator that can import/design/view kits and can also view all Vital and Clinical Site Information.

[SAVE CHANGES] [CANCEL]
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.
The changes are now shown. Clicking on “ADMINISTRATORS” takes you to the screen on the next page.
The new settings are shown in the list of Administrators.
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.
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.
Click on “OK”.
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”.
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.
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.
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.
Click on “Edit Trial Details”.
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.
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.

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

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

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1388</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>22/12/2010 21:00:23</td>
<td>1</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial 1</td>
<td>False</td>
<td>22/12/2010 21:00:23</td>
<td>0</td>
</tr>
</tbody>
</table>

Create a trial
Click on “Edit Treatments”.

![Trial Details Table]

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Demo Blinded Trial 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated</td>
<td>No</td>
</tr>
<tr>
<td>No. Active Clinical Sites</td>
<td>0</td>
</tr>
<tr>
<td>Record Patient Initials</td>
<td>No</td>
</tr>
<tr>
<td>Record Patient Birthdate</td>
<td>No</td>
</tr>
<tr>
<td>Record Other Variable</td>
<td>No</td>
</tr>
<tr>
<td>Treatments</td>
<td>None</td>
</tr>
<tr>
<td>Stratify by Clinical Site</td>
<td>Yes</td>
</tr>
<tr>
<td>Blocking Factors</td>
<td>None</td>
</tr>
<tr>
<td>Block Sizes</td>
<td>N/A</td>
</tr>
<tr>
<td>Stratification Variables</td>
<td>None</td>
</tr>
</tbody>
</table>
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.
The process can be repeated to add additional treatment arms.
Adding a Placebo treatment arm.
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 been 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”.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1938</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>22/12/2019 21:30:23</td>
<td>1</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial</td>
<td>False</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
Click on “Edit Inclusion/Exclusion Criteria”.

<table>
<thead>
<tr>
<th>TRIAL DETAILS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIAL ID</td>
<td>1072</td>
</tr>
<tr>
<td>TRIAL NAME</td>
<td>Demo Blinded Trial 1</td>
</tr>
<tr>
<td>ACTIVATED</td>
<td>No</td>
</tr>
<tr>
<td>NUMBER OF ACTIVE CLINICAL SITES</td>
<td>0</td>
</tr>
<tr>
<td>RECORD PATIENT INITIALS</td>
<td>No</td>
</tr>
<tr>
<td>RECORD PATIENT BIRTHDATE</td>
<td>No</td>
</tr>
<tr>
<td>RECORD OTHER VARIABLE</td>
<td>No</td>
</tr>
<tr>
<td>TREATMENTS</td>
<td>None</td>
</tr>
<tr>
<td>STRATIFY BY CLINICAL SITE</td>
<td>Yes</td>
</tr>
<tr>
<td>BLOCKING FACTORS</td>
<td>None</td>
</tr>
<tr>
<td>BLOCK SIZES</td>
<td>N/A</td>
</tr>
<tr>
<td>STRATIFICATION VARIABLES</td>
<td>None</td>
</tr>
</tbody>
</table>
Click on the “+” sign next to “Add Inclusion Criteria”.
Type in the first inclusion criterion and then click on the disk symbol just to the right.
The process can be repeated to add additional inclusion criteria.
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.
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.
3.5 Add / Edit Stratification Information (optional)

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

Note: stratification information CANNOT be changed once the trial is activated.
Click on the trial for which you want to edit stratification information.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1938</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>22/12/2010 21:00:23</td>
<td>1</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial 1</td>
<td>False</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
Click on “Edit Stratification Information”.

[Image of a trial details page with options to edit various aspects of the trial, such as the trial name, number of active clinical sites, number of treatments, and stratification variables.]
When at trial is created “Stratify by Clinical Site” is set to “yes” be 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”.

![Image of the interface showing option to add stratification information including settings for stratify by clinical site and blocking factor.](image-url)
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.
To add a stratification variable, click on the “+” sign just to the left of “Add Stratification Variable”.
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.”
Clicking on the “disk” symbols just to the right will save the variable name and its levels.
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.
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. To change the default settings, see page 82.

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.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1385</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>22/12/2016 21:30:23</td>
<td>1</td>
</tr>
<tr>
<td>1472</td>
<td>Demo Blinded Trial 1</td>
<td>False</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
Click on “Notification Emails”
Click on the “+” sign next to “Add new email”.
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”.
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.
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 users at Clinical Sites from seeing the allocated treatment.
3.7 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.
Click on “Limits”.
By clicking on “Yes” you will then 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.
3.8 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.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1938</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>20/12/2016 21:30:23</td>
<td>1</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial 1</td>
<td>Pseudo</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

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”.

---

**TRIAL DETAILS**

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>12372</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Name</td>
<td>Demo Blinded Trial 1</td>
</tr>
<tr>
<td>Activated</td>
<td>No</td>
</tr>
<tr>
<td>Number of Active Clinical Sites</td>
<td>0</td>
</tr>
<tr>
<td>Record Patient Initials</td>
<td>No</td>
</tr>
<tr>
<td>Record Patient Birthdate</td>
<td>No</td>
</tr>
<tr>
<td>Record Other Variables</td>
<td>No</td>
</tr>
<tr>
<td>Treatments</td>
<td>1. Active 2. Placebo</td>
</tr>
<tr>
<td>Stratify by Clinical Site</td>
<td>Yes</td>
</tr>
<tr>
<td>Blocking Factors</td>
<td>2</td>
</tr>
<tr>
<td>Block Sizes</td>
<td>4</td>
</tr>
<tr>
<td>Stratification Variables</td>
<td>1. Duration since injury a. Less than 2 years b. 2 years or more</td>
</tr>
</tbody>
</table>
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.
To deactivate the trial, click on “Deactivate Trial” and then on “Ok”.

![Deactivate Trial button highlighted on the page.](image)
To activate one or more Clinical Sites, allowing them to randomize patients, click on “Activate Clinical Sites”.

![Randomize.net Trial Details]

- **Trial ID:** 1072
- **Trial Name:** Demo Blinded Trial 1
- **Activated:** Yes
- **Date Activated:** 22/05/2022 19:28:13
- **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.
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”.

![Clinical Site Activation Interface](image-url)
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”.

<table>
<thead>
<tr>
<th>CLINICAL SITE NAME</th>
<th>PATIENT ID PREFIX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concept Medical, Demo 1</td>
<td></td>
</tr>
</tbody>
</table>

![Screen capture showing the CREATE CLINICAL SITE button highlighted.](image-url)
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 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.
Clinical Site details are shown.

<table>
<thead>
<tr>
<th>NAME</th>
<th>Demo Clinical Site 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATIENT ID PREFIX</td>
<td></td>
</tr>
<tr>
<td>NUMBER OF USERS</td>
<td>1</td>
</tr>
<tr>
<td>ACTIVE TRIALS</td>
<td>None (You must activate sites from the Trials menu)</td>
</tr>
</tbody>
</table>
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.
Click on “Edit Clinical Site Details”.
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.
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.

<table>
<thead>
<tr>
<th>Clinical Site Name</th>
<th>Patient ID Prefix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demo Clinical Site 1</td>
<td></td>
</tr>
</tbody>
</table>

![Clinical Site Selection Screenshot](image-url)
Click on “Manage Clinical Site Users”.
Click on “CREATE USER”.
Entre 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 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.
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.
Click on “Manage Clinical Site Users”.

![Clinical Site Details](image-url)
Click on the user whose details you want to edit.

<table>
<thead>
<tr>
<th>LOGIN ID</th>
<th>NAME</th>
<th>EMAIL ADDRESS</th>
<th>ENABLED</th>
</tr>
</thead>
<tbody>
<tr>
<td>DemoUser2</td>
<td>Demo Clin Site 1</td>
<td><a href="mailto:andy@mdjwellis.com">andy@mdjwellis.com</a></td>
<td>True</td>
</tr>
<tr>
<td>DemoUser2</td>
<td>Mary Smith</td>
<td><a href="mailto:mary.smith@mycro.com">mary.smith@mycro.com</a></td>
<td>True</td>
</tr>
</tbody>
</table>
Click on “Edit User Details”.

![User Details](image-url)
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.

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”.

![Randomize.net Interface](image-url)
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.
Click on “Manage Clinical Site Users”.

[Image of a clinical trial management interface with a table showing the name, patient ID prefix, number of users, and active trials for Demo Clinical Site 1.]
Click on the user whose password you want to change.
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.
Entre 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.
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 127.
Click on the trial for which you want to activate a *Clinical Site*.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1388</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>22/12/2016 21:30:23</td>
<td>1</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial 1</td>
<td>True</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>
There currently no active Clinical Sites. To activate one or more Clinical Sites, allowing them to randomize patients, click on “Activate Clinical Sites”
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.
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”.
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 131.

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.
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*.
The “TRIAL DETAILS” are shown.

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

Click on “Manage Kits”.
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 are shown on the next page.
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.

Click on "CANCEL" to return to the screen on the next page.
To import more *Kit Numbers*, click on “Import Kits”.

![Import Kits Screen](image-url)
Click on “Choose file”.
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.
You can click on “View/Edit” to verify the importation procedure.
| Demo Clinical Site | demoSite1 | 1 | Active | A12 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A19 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A47 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A49 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A39 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A32 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A13 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A18 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A63 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A9 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A14 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A26 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A27 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A67 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A17 | False | False |
| Demo Clinical Site | demoSite1 | 1 | Active | A1 | False | False |

**Newly imported Kit Numbers**

**Kits not yet available at the Clinical Site**

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.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1068</td>
<td>Demo Trial 1</td>
<td>False</td>
<td>23-12-2010 22:05:23</td>
<td>0</td>
</tr>
<tr>
<td>1072</td>
<td>Demo Blinded Trial 1</td>
<td>True</td>
<td>01-06-2020 13:02:39</td>
<td>1</td>
</tr>
</tbody>
</table>
The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>1372</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIAL NAME</td>
<td>Demo Blinded Trial 1</td>
</tr>
<tr>
<td>ACTIVATED</td>
<td>Yes</td>
</tr>
<tr>
<td>DATE ACTIVATED</td>
<td>01-08-2020 23:02:39</td>
</tr>
<tr>
<td>NUMBER OF ACTIVE CLINICAL SITES</td>
<td>1</td>
</tr>
<tr>
<td>RECORD PATIENT INITIALS</td>
<td>Yes</td>
</tr>
<tr>
<td>RECORD PATIENT BIRTHDATE</td>
<td>No</td>
</tr>
<tr>
<td>RECORD OTHER VARIABLE</td>
<td>No</td>
</tr>
</tbody>
</table>
| 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* are displayed as on the next page.
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.
Click "SAVE CHANGES" to indicate that the Kits are now available and return to the screen on the next page.

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”.

<table>
<thead>
<tr>
<th>SITE ID</th>
<th>CLINICAL SITE NAME</th>
<th>USED KITS</th>
<th>REMAINING KITS</th>
<th>NOT YET AVAILABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>View/Ed</td>
<td>democlinicalsite1</td>
<td>7</td>
<td>53</td>
<td>0</td>
</tr>
</tbody>
</table>
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 150.

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A61</td>
</tr>
<tr>
<td>2</td>
<td>A62</td>
</tr>
<tr>
<td>3</td>
<td>A63</td>
</tr>
<tr>
<td>4</td>
<td>A64</td>
</tr>
<tr>
<td>5</td>
<td>A65</td>
</tr>
<tr>
<td>6</td>
<td>A66</td>
</tr>
<tr>
<td>7</td>
<td>A67</td>
</tr>
<tr>
<td>8</td>
<td>A68</td>
</tr>
<tr>
<td>9</td>
<td>A69</td>
</tr>
<tr>
<td>10</td>
<td>A70</td>
</tr>
</tbody>
</table>
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*.

<table>
<thead>
<tr>
<th>TRIAL ID</th>
<th>TRIAL NAME</th>
<th>ACTIVE</th>
<th>DATE ACTIVATED</th>
<th>NUMBER OF ACTIVE SITES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1068</td>
<td>Demo Trial 1</td>
<td>False</td>
<td>23-12-2019 22:05:23</td>
<td>0</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial 1</td>
<td>True</td>
<td>01-06-2020 12:02:29</td>
<td>1</td>
</tr>
</tbody>
</table>
The “TRIAL DETAILS” are shown.

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

Click on “Manage Kits”.
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”.

![Image of Randomize.net interface with a table showing the status of kits by clinical site. The table highlights that 7 Kits have been used and 53 are REMAINING at Demo Clinical Site 1, while Demo Clinical Site 2 has no Kits imported or assigned.]
Click on “Choose file”.

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 or Primary User Login ID
  - Treatment ID
  - Kit ID
  - Available at Clinical Site Yes/No (Y=yes, N=no)

Importing unassigned kits:
Please upload a CSV (comma-separated values) file with two columns with the following order:
  - Treatment ID
  - Kit ID
Navigate to the file containing the *Kit Numbers* you want to import. Click on it and then click on “Open”.

![Image of file selection dialog box]

**Importing unassigned kits:**

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

- Treatment ID
- Kit ID
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.

<table>
<thead>
<tr>
<th>Treatment ID</th>
<th>Treatment</th>
<th>Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo</td>
<td>A61</td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A62</td>
</tr>
<tr>
<td></td>
<td>Placebo</td>
<td>A63</td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A64</td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A65</td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A66</td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A67</td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A68</td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A69</td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A70</td>
</tr>
</tbody>
</table>
There are now 10 Unassigned Kits that can be assigned to *Clinical Sites* when appropriate.
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.
The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.

![TRIAL DETAILS screenshot](image)
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”.
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.

<table>
<thead>
<tr>
<th>TREATMENT ID</th>
<th>TREATMENT</th>
<th>KIT</th>
<th>CLINICAL SITE</th>
<th>AVAILABLE</th>
<th>DELETE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A61</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A62</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A63</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A64</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A65</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A66</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A67</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Placebo</td>
<td>A68</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A69</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Active</td>
<td>A70</td>
<td>Pick One</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SAVE CHANGES  CANCEL
*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.

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”.

![Randomize.net dashboard](image)
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.
The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.

![Image of TRIAL DETAILS page with details and 'Manage Kits' highlighted]
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”.

![Manage Kits Table](image)
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.
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 166 and the Kits will not be available for future patients.
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.
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.
The “TRIAL DETAILS” are shown.

Click on “Manage Kits”.

![Trial Details Screenshot]
Click on “Edit Kit Preferences”.
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.

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.

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.

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.
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”.
6.1 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.
Provide the Patient ID number, in this case “104”.

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

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

Click on “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”.
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](#).
6.2 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.
Click on the trial.
Provide the Patient ID number, in this case “104”.

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

You will then be taken to the screen on the next page.
You will receive the message “Email confirmation sent”.

Click on “HOME”.
6.3 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.

<table>
<thead>
<tr>
<th>ID</th>
<th>Trial Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>192</td>
<td>Demo Blinded Trial 1</td>
</tr>
</tbody>
</table>
Provide the Patient ID number, in this case “104”.

Click on “NEXT”.

![Randomization Software Interface](image-url)
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".
A confirmation email message is sent to all individuals who are authorized to received email notifications, see Section 3.6.
6.4 Unblind 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”.

Note warning.
Then click “OK”.
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 received email notifications, see Section 3.6. An example of the email message is given on the next page.
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
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.

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Trial Name</th>
<th>Active</th>
<th>Date Activated</th>
<th>Number of Active Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>1938</td>
<td>Demo Trial 1</td>
<td>True</td>
<td>22/12/2015 21:00:23</td>
<td>1</td>
</tr>
<tr>
<td>1972</td>
<td>Demo Blinded Trial 1</td>
<td>False</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

CREATE A TRIAL
Click on “Reports”.
Click on “Treatment Allocation”.

<table>
<thead>
<tr>
<th>DEMO CLINICAL SITE 1</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEB-2020</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1</td>
</tr>
</tbody>
</table>
Top panel is prior to unblinding.

Bottom is after unblinding.

| Patient with ID 104 was randomized to “Active”.
| This blank prior to unblinding. |
7. Reports

To view the Reports, click on “TRIALS” from the Coordinating Centre home page.
Click on the trial whose reports you want to view.
Click on “Reports”.

<table>
<thead>
<tr>
<th>TRIAL DETAILS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TRIAL ID</td>
<td>3872</td>
</tr>
<tr>
<td>TRIAL NAME</td>
<td>Demo Blinded Trial 1</td>
</tr>
<tr>
<td>ACTIVATED</td>
<td>Yes</td>
</tr>
<tr>
<td>DATE ACTIVATED</td>
<td>11-06-2020 23:02:09</td>
</tr>
<tr>
<td>NUMBER OF ACTIVE CLINICAL SITES</td>
<td>2</td>
</tr>
<tr>
<td>RECORD PATIENT INITIALS</td>
<td>Yes</td>
</tr>
<tr>
<td>RECORD PATIENT BIRTH DATE</td>
<td>No</td>
</tr>
<tr>
<td>RECORD OTHER VARIABLE</td>
<td>No</td>
</tr>
</tbody>
</table>
| TREATMENTS | 1. Active  
2. Placebo |
| STRATIFY BY CLINICAL SITE | Yes |
| BLOCKING FACTORS | 2 |
| BLOCK SIZE | 2 |
| STRATIFICATION VARIABLES | 1. Duration since injury  
   a. Less than 2 years  
   b. 2 years or more |
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.
This report is a cross-tabulation defined by the stratification variables, in this case “DURATION SINCE INJURY”, and Clinical Site.

Clicking on “Treatment Allocation” takes you to the screen on the next page.
This report contains a complete listing of all patients randomized.

Note that a second *Kit Number* (A41) was requested for Patient ID 104, and that Patient ID 922 was unblinded in an emergency.

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

<table>
<thead>
<tr>
<th>PATIENT ID</th>
<th>CLINICAL SITE</th>
<th>USER ID</th>
<th>DATE RANDOMIZED</th>
<th>DURATION SINCE INJURY</th>
<th>TREATMENT</th>
<th>UNBLINDED TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>507</td>
<td>Demo Clinical Site 1</td>
<td>demo123</td>
<td>01-09-2020 23:16:42</td>
<td>en</td>
<td>2 years or more</td>
<td>A33</td>
</tr>
<tr>
<td>103-123</td>
<td>Demo Clinical Site 1</td>
<td>demotestingkit1</td>
<td>01-10-2020 09:13:33</td>
<td>lms</td>
<td>Less than 2 years</td>
<td>A15</td>
</tr>
<tr>
<td>103-124</td>
<td>Demo Clinical Site 1</td>
<td>demotestingkit1</td>
<td>01-10-2020 09:13:37</td>
<td>nic</td>
<td>2 years or more</td>
<td>A15</td>
</tr>
<tr>
<td>103-125</td>
<td>Demo Clinical Site 1</td>
<td>demotestingkit1</td>
<td>01-10-2020 09:13:47</td>
<td>nil</td>
<td>2 years or more</td>
<td>A28</td>
</tr>
<tr>
<td>103-126</td>
<td>Demo Clinical Site 1</td>
<td>demotestingkit1</td>
<td>01-10-2020 09:13:48</td>
<td>ite</td>
<td>Less than 2 years</td>
<td>A14</td>
</tr>
<tr>
<td>120-001</td>
<td>Demo Clinical Site 1</td>
<td>demodemo101</td>
<td>01-10-2020 11:57:09</td>
<td>dem</td>
<td>Less than 2 years</td>
<td>A30</td>
</tr>
<tr>
<td>104</td>
<td>Demo Clinical Site 1</td>
<td>demo123</td>
<td>02-05-2020 23:24:49</td>
<td>der</td>
<td>2 years or more</td>
<td>A40, A41</td>
</tr>
<tr>
<td>922</td>
<td>Demo Clinical Site 1</td>
<td>democlinic12</td>
<td>02-04-2020 19:15:37</td>
<td>lsb</td>
<td>Less than 2 years</td>
<td>A50</td>
</tr>
<tr>
<td>776</td>
<td>Demo Clinical Site 1</td>
<td>democlinic32</td>
<td>02-04-2020 19:15:48</td>
<td>lfi</td>
<td>2 years or more</td>
<td>A34</td>
</tr>
<tr>
<td>143</td>
<td>Demo Clinical Site 2</td>
<td>democlinic32</td>
<td>02-04-2020 19:24:12</td>
<td>hd</td>
<td>Less than 2 years</td>
<td>A65</td>
</tr>
<tr>
<td>511</td>
<td>Demo Clinical Site 2</td>
<td>democlinic12</td>
<td>02-04-2020 19:24:48</td>
<td>ucw</td>
<td>2 years or more</td>
<td>A40</td>
</tr>
</tbody>
</table>
### TRIAL DETAILS

<table>
<thead>
<tr>
<th>ID</th>
<th>Demo Blinded Trial 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIVATED</td>
<td>Yes</td>
</tr>
<tr>
<td>DATE ACTIVATED</td>
<td>2020-08-28 23:02:02</td>
</tr>
<tr>
<td>NUMBER OF ACTIVE CLINICAL SITES</td>
<td>2</td>
</tr>
<tr>
<td>RECORD PATIENT INITIALS</td>
<td>Yes</td>
</tr>
<tr>
<td>RECORD PATIENT BIRTHDATE</td>
<td>No</td>
</tr>
<tr>
<td>RECORD OTHER VARIABLE</td>
<td>No</td>
</tr>
<tr>
<td>TREATMENTS</td>
<td>Active, Placebo</td>
</tr>
<tr>
<td>STRATIFY BY CLINICAL SITE</td>
<td>Yes</td>
</tr>
<tr>
<td>BLOCKING FACTORS</td>
<td>2</td>
</tr>
<tr>
<td>BLOCK SIZE</td>
<td>1</td>
</tr>
<tr>
<td>STRATIFICATION VARIABLES</td>
<td>1. Duration since injury a. Less than 2 years, b. 2 years or more</td>
</tr>
</tbody>
</table>