

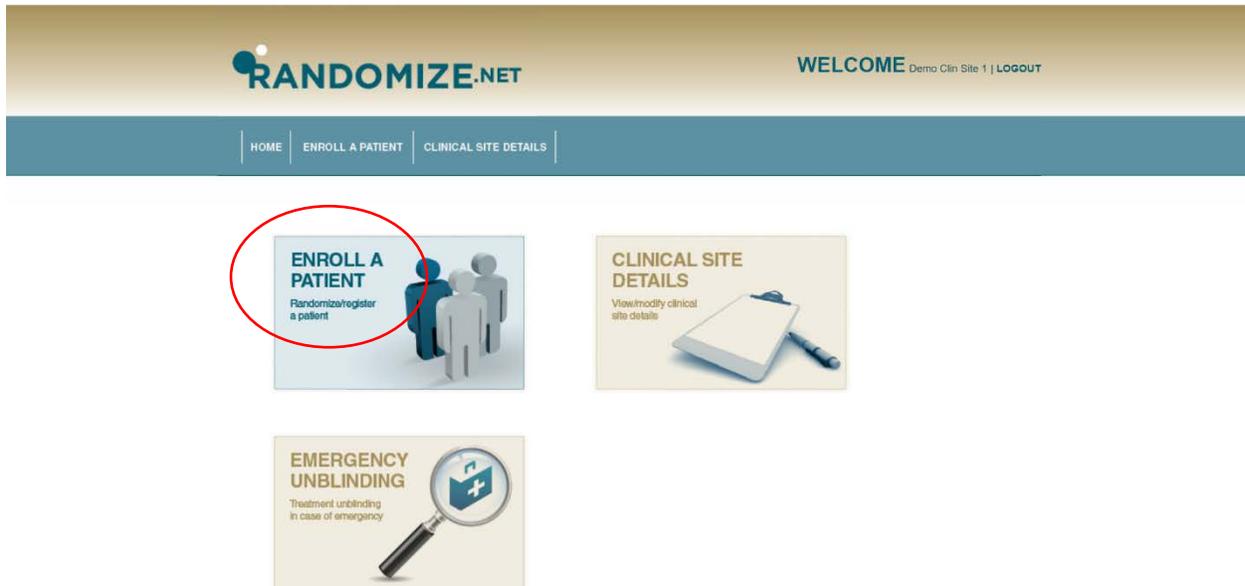
# Randomize.net Clinical Site User Manual

## Table of Contents

<a href="#">1 To Randomize a Patient</a> .....	2
<a href="#">2 To Resend Confirmation Email Message</a> .....	11
<a href="#">3 To Get New <i>Kit Number</i> with Same Treatment</a> .....	16
<a href="#">4 To Unblind a Patient in an Emergency</a> .....	21

## 1 To Randomize a Patient

Login using your login ID and password. Then click on “ENROL A PATIENT” from the home page.



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

Click on the name of the trial to which you want to randomize a patient.

The screenshot shows the RANDOMIZE.NET website interface. At the top, there is a navigation bar with the logo and the text 'WELCOME Demo Clin Site 1 | LOGOUT'. Below this is a secondary navigation bar with links for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main content area is titled 'STEP 1: SELECT A TRIAL' and contains a table with two columns: 'ID' and 'TRIAL NAME'. The table has one row with the ID '1972' and the trial name 'Demo Blinded Trial 1', which is circled in red.

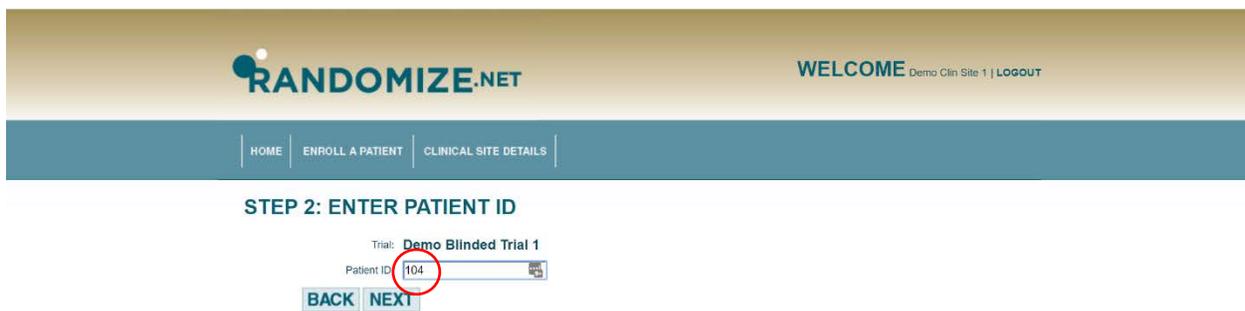
ID	TRIAL NAME
1972	Demo Blinded Trial 1

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

Click on “NEXT”.

Your *Coordinating Centre* might have configured the trial to prefill a Patient ID prefix.

Your *Coordinating Centre* might have configured the trial to prefill the Patient ID number. In which case just click on “NEXT”.



The screenshot shows the RANDOMIZE.NET interface. At the top, there is a navigation bar with the logo and a 'WELCOME' message for 'Demo Clin Site 1' with a 'LOGOUT' link. Below this is a menu with 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main heading is 'STEP 2: ENTER PATIENT ID'. The trial name is 'Demo Blinded Trial 1'. The 'Patient ID' field contains the value '104', which is circled in red. Below the field are two buttons: 'BACK' and 'NEXT'.

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

Click on “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.

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

Click on “NEXT”.

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 "HOME", "ENROLL A PATIENT", and "CLINICAL SITE DETAILS". The main content area is titled "STEP 4: ANSWER INCLUSION/EXCLUSION CRITERIA". It displays "Trial: Demo Blinded Trial 1" and "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 <sup>2</sup> or body weight $<$ 50 kg?	<input type="radio"/> Yes	<input checked="" type="radio"/> No

At the bottom, there are "BACK" and "NEXT" buttons. Red circles in the original image highlight the selected "Yes" and "No" radio buttons in the inclusion and exclusion criteria sections.

If requested, 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 requested, 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 your 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.

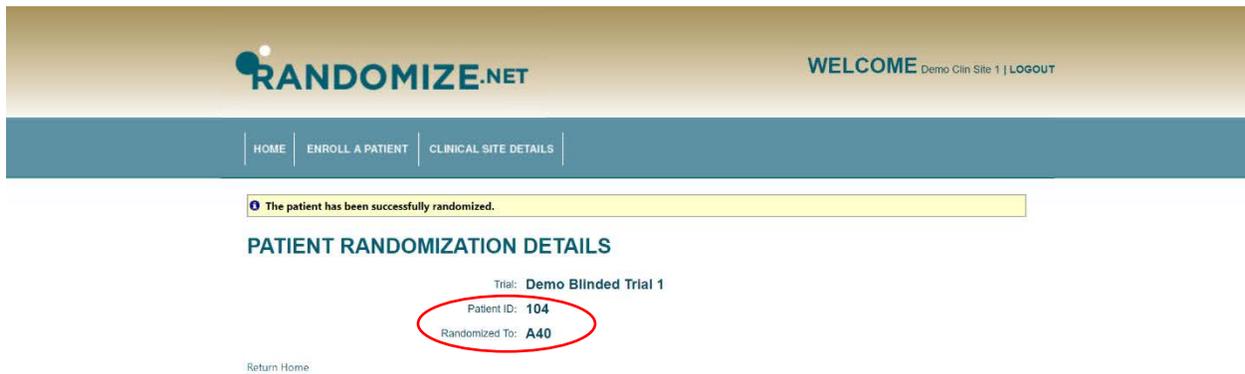
**BACK** **RANDOMIZE**

You will be shown the following below. Since this is a blinded trial, the patient has been randomized to a *Kit Number*. If the trial is unblinded, you will be shown the allocated treatment.

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

The *Kit Number*, either

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



The screenshot shows the RANDOMIZE.NET interface. At the top, the logo "RANDOMIZE.NET" is on the left, and "WELCOME Demo Clin Site 1 | LOGOUT" is on the right. Below the logo is a navigation bar with "HOME", "ENROLL A PATIENT", and "CLINICAL SITE DETAILS". A yellow notification bar states "The patient has been successfully randomized." Below this is the section "PATIENT RANDOMIZATION DETAILS". Underneath, it says "Trial: Demo Blinded Trial 1". The "Patient ID: 104" and "Randomized To: A40" are circled in red. A "Return Home" link is at the bottom left.

**RANDOMIZE.NET** WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

The patient has been successfully randomized.

**PATIENT RANDOMIZATION DETAILS**

Trial: Demo Blinded Trial 1

Patient ID: 104

Randomized To: A40

Return Home

You will be sent the email message shown below.

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.

---

Randomize.NET - Patient Randomization Confirmation Inbox x



**Randomize.Net Notifications** <notify@randomize.net>

### PATIENT RANDOMIZATION CONFIRMATION

Coordinating Center: **Demo Coordinating Centre**

Trial: **Demo Blinded Trial 1**

Clinical Site: **Demo Clinical Site 1 (democlinsite1)**

Patient ID: **104**

Randomized To: **A40**

Date Randomized: **02/05/2020 23:24:49**

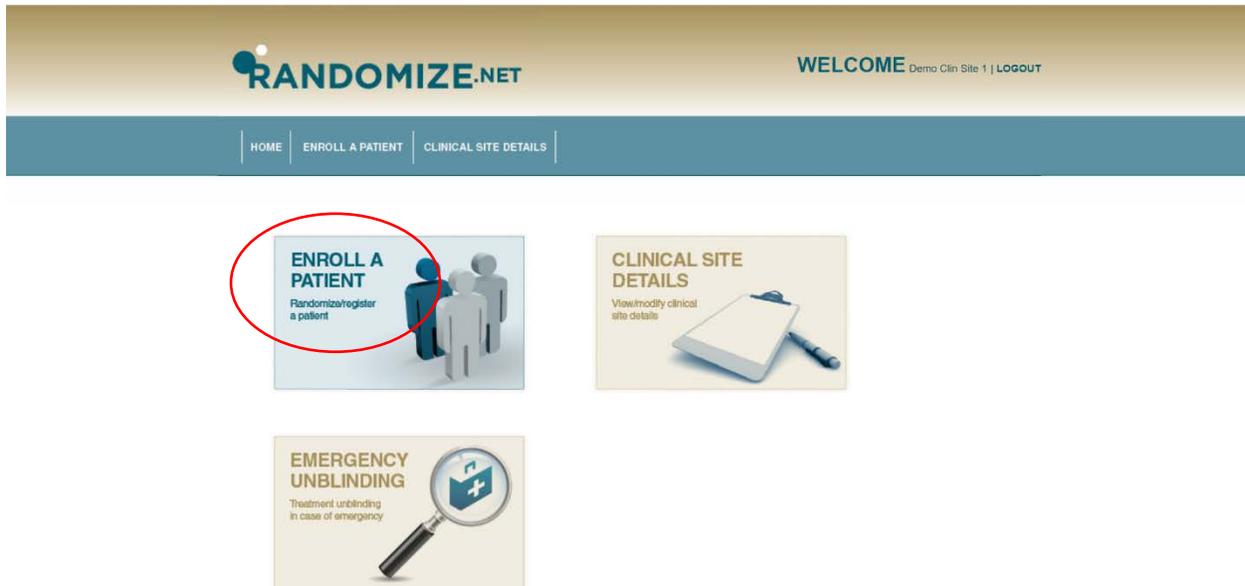
Reply

Reply all

Forward

## 2 To Resend Confirmation Email Message

Login using your login ID and password. Then click on “ENROLL A PATIENT” from the home page.



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

Click on the name of the trial.

The screenshot shows the Randomize.net website interface. At the top, there is a navigation bar with the logo 'RANDOMIZE.NET' on the left and 'WELCOME Demo Clin Site 1 | LOGOUT' on the right. Below the navigation bar, there are three menu items: 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main content area is titled 'STEP 1: SELECT A TRIAL'. Below this title is a table with two columns: 'ID' and 'TRIAL NAME'. The table contains one row with the ID '1972' and the trial name 'Demo Blinded Trial 1'. The trial name is circled in red.

ID	TRIAL NAME
1972	Demo Blinded Trial 1

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

If the trial is configured to prefill the Patient ID number, the resend email confirmation feature is not yet available.

Click on “NEXT”.



The screenshot shows the Randomize.net website interface. At the top, there is a navigation bar with the logo "RANDOMIZE.NET" on the left and "WELCOME Demo Clin Site 1 | LOGOUT" on the right. Below the navigation bar, there are three menu items: "HOME", "ENROLL A PATIENT", and "CLINICAL SITE DETAILS". The main content area is titled "STEP 2: ENTER PATIENT ID". Underneath this title, it says "Trial: Demo Blinded Trial 1". There is a "Patient ID:" label followed by a text input field containing the number "104". The input field is circled in red. Below the input field, there are two buttons: "BACK" and "NEXT".

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.

**RANDOMIZE.NET** WELCOME Demo Clin Site 1 | LOGOUT

HOME | ENROLL A PATIENT | CLINICAL SITE DETAILS

**⚠ This patient has already been randomized. Re-send Email Confirmation**

**STEP 2: ENTER PATIENT ID**

Trial: Demo Blinded Trial 1

Patient ID: 104

BACK NEXT

You will receive the message “Email confirmation sent”.

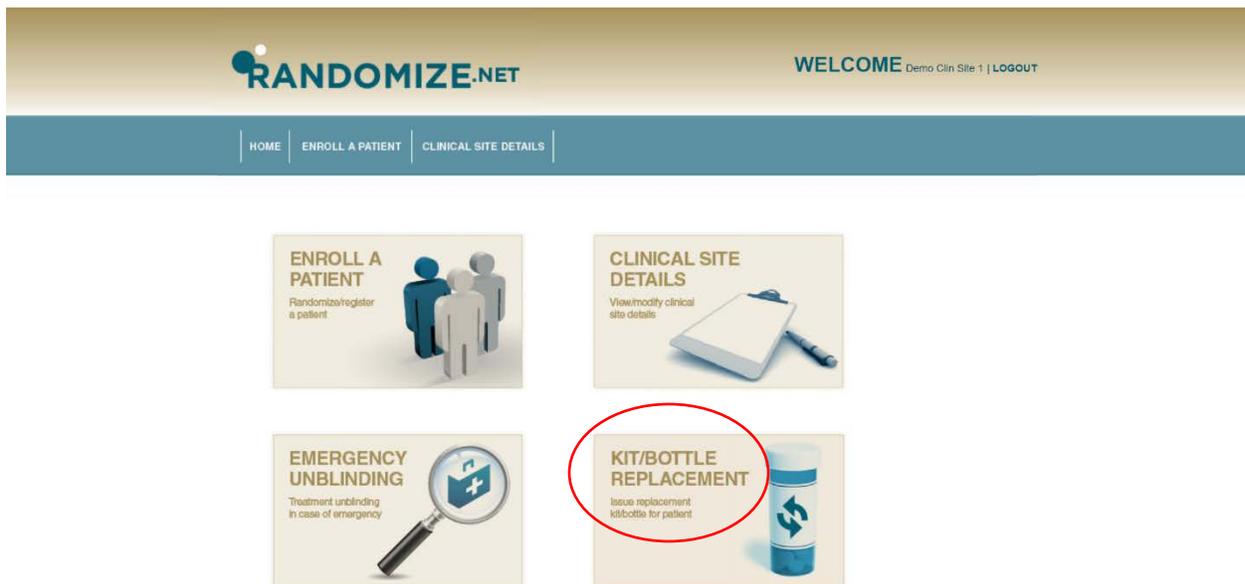
Click on “HOME”.

The screenshot shows the RANDOMIZE.NET website interface. At the top, the logo "RANDOMIZE.NET" is on the left, and "WELCOME Mary Smith | LOGOUT" is on the right. Below the logo, a navigation bar contains "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". Below this title, it shows "Trial: Demo Blinded Trial 1" and "Patient ID: 104" in a text input field. At the bottom of the form are "BACK" and "NEXT" buttons.

### 3 To 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.

Login using your login ID and password. Then click on “KIT/BOTTLE REPLACEMENT” from the home page.



Click on the name of the trial.

The screenshot shows the Randomize.net interface. At the top, there is a navigation bar with the logo 'RANDOMIZE.NET' on the left and 'WELCOME Demo Clin Site 1 | LOGOUT' on the right. Below this is a secondary navigation bar with links for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main content area is titled 'STEP 1: SELECT A TRIAL' and contains a table with the following data:

ID	TRIAL NAME
1972	Demo Blinded Trial 1

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

Click on “NEXT”.

The screenshot shows the RANDOMIZE.NET 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 for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main heading is 'STEP 2: KIT/BOTTLE REPLACEMENT'. Underneath, it says 'Trial: Demo Blinded Trial 1'. A text input field for 'Patient ID' contains the value '104', which is circled in red. Below the input field 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".



The screenshot shows the Randomize.net website interface. At the top, there is a navigation bar with the logo 'RANDOMIZE.NET' on the left and 'WELCOME Demo Clin Site 1 | LOGOUT' on the right. Below this is a secondary navigation bar with links for 'HOME', 'ENROLL A PATIENT', and 'CLINICAL SITE DETAILS'. The main content area displays the title 'BOTTLE REPLACEMENT RESULT' followed by 'Trial: Demo Blinded Trial 1'. Below that, it shows 'Patient ID: 104' and 'Replacement Bottle Number: A41'. A 'Return Home' button is located at the bottom of this section. Red circles are drawn around the patient ID '104', the replacement bottle number 'A41', and the 'Return Home' button.

A confirmation email message is sent to all individuals who are authorized to receive email notifications.

The screenshot shows an email client interface. At the top, there is a navigation bar with icons for back, forward, search, and other functions. The email title is "Kit Replacement Notification" with a small "Inbox x" indicator. The sender is "Randomize.Net Notifications" with the email address "<notify@randomize.net>" and the recipient is "to Andy, me, Mary". The time is "3:41 PM (0 minutes ago)".

The main content of the email is titled "KIT REPLACEMENT" in bold blue text. Below this, the following information is listed:

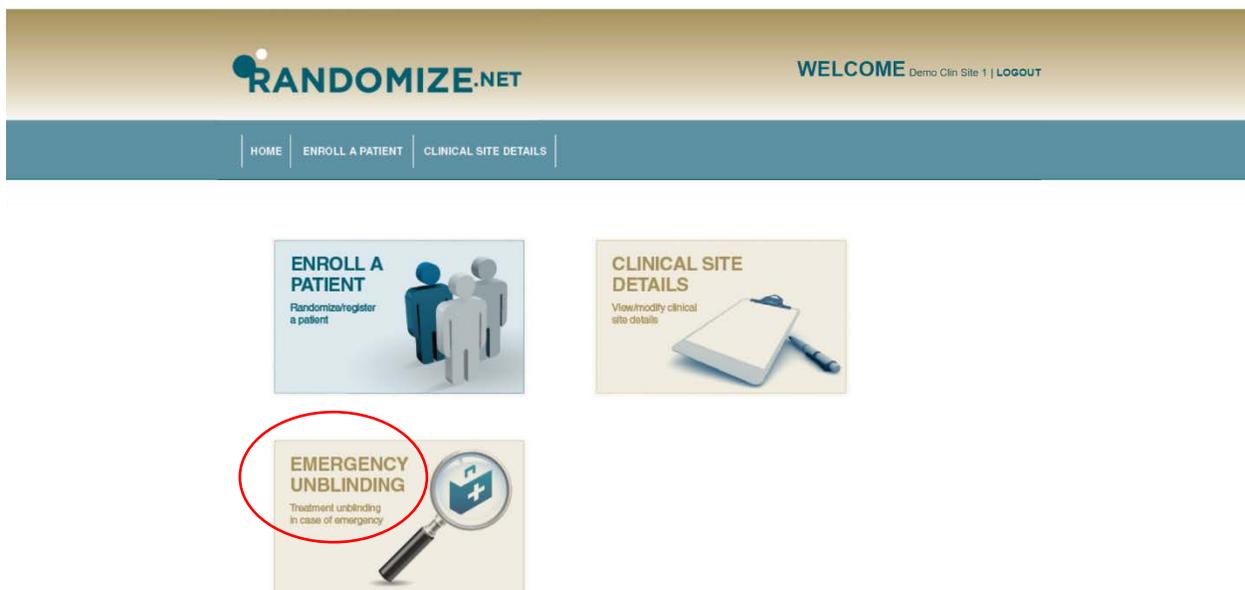
- Coordinating Center: **Demo Coordinating Centre**
- Trial: **Demo Blinded Trial 1**
- Clinical Site: **democlinsite1 - Demo Clinical Site 1**
- Patient ID: **104**
- Date: **02-18-2020 00:11:31**
- Replacement Randomized To: **A41**

At the bottom of the email content, there are three buttons: "Reply", "Reply all", and "Forward".

## 4 To Unblind a Patient in an Emergency

Login using your login ID and password. Then click on “EMERGENCY UNBLINDING” from the home page.

Any enabled user from your *Clinical Site* can unblind a patient that was previously randomized by a user at your *Clinical Site*.



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

Select the trial from the pull-down menu and provide the Patient ID number.

Click on “NEXT”.



⚠ 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:

Note warning.

Then click “OK”.



### EMERGENCY TREATMENT UNBLINDING

Trial:

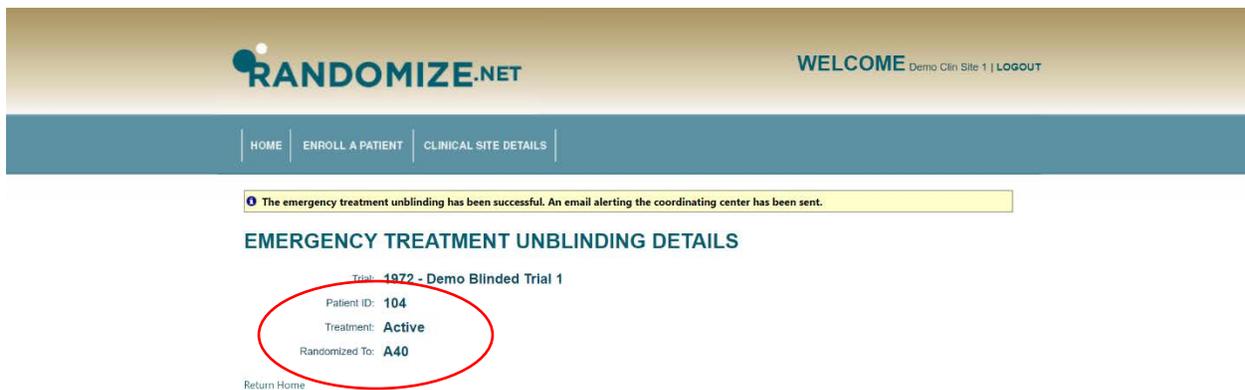
Patient ID:

OR

Randomized To:

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. An example of the email message is given on the next page.



The screenshot shows the RANDOMIZE.NET interface. At the top, the logo "RANDOMIZE.NET" is on the left and "WELCOME Demo Clin Site 1 | LOGOUT" is on the right. Below the logo is a navigation bar with "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 heading is "EMERGENCY TREATMENT UNBLINDING DETAILS". Below this, the trial name "Trial: 1972 - Demo Blinded Trial 1" is shown. The patient information is listed as "Patient ID: 104", "Treatment: Active", and "Randomized To: A40". A red circle highlights the "Patient ID: 104", "Treatment: Active", and "Randomized To: A40" text. A "Return Home" link is located below the patient information.

## 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