Randomize.net Kit Manager User Manual

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 at 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 of the Coordinating Center User's Manual for creating a *Kit Administrator*.

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1.1 Import Assigned Kit Numbers

Prior to importing "assigned" *Kit Numbers*, create a comma delimited (*.csv) file as shown on the next page. 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 primary user of the *Clinical Site* to which the *Kit Number* has been "assigned". The Login ID is case sensitive. *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 <u>page 6</u> for illustration.

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 <u>Section 1.2</u> for the procedure to indicate that previously imported *Kit Numbers* are now available.

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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".

RANDOMIZE	NET WELCOME Demo Kit Administ	rator LOGOUT
HOME TRIALS CLINICAL SITES A	MINISTRATORS MY ACCOUNT	HELP
Select Trial » Trial Details		
TRIAL DETAILS		
Edit Trial Details Notification Emails Edit Inclusio	n/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	
TREATMEN'S	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.

	WELCOME Demo Kit Administrator LOGOUT
HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT	HELP
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To import more Kit Numbers, click on "Import Kits".

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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.

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Clicking on "CANCEL" will cancel the importation procedure.

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



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Newly imported <i>Kit</i> <i>Numbers</i>	Demo Clinical Site 1 Demo Clin	democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo	A10 A34 A04 A06 A10 A25 A35 A36 A25 A35 A36 A25 A38 A20 A43 A38 A20 A43 A43 A43 A43 A43 A44 A17 A31 A44 A13 A44 A17 A31 A55 A21 A32 A51 A52 A54 A57	8 5 6 7 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 20 21 22 23 24 22 23 24 25 25 26 27 28 29	False		S S S S S S S S S S S S S S S S S S S	Kits not yet available at the Clinical Site
Newly imported <i>Kit</i> <i>Numbers</i>	Demo Clinical Site 1 Demo Clin	democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo	A10 A34 A04 A06 A10 A11 A25 A38 A20 A43 A08 A43 A08 A43 A08 A43 A04 A11 A31 A34 A13 A44 A17 A31 A36 A21 A32 A51 A52 A51 A52 A51 A52 A51	8 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 20 21 22 23 23 24 22 23 24 25 26 27 28 29 20	False		S S S S S S S S S S S S S S S S S S S	Kits not yet available at the Clinical Site
Newly imported <i>Kit</i> <i>Numbers</i>	Demo Clinical Site 1 Demo Clin	democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo	A10 A34 A04 A06 A10 A11 A25 A35 A35 A36 A20 A43 A08 A43 A44 A17 A36 A51 A54 A57 A59 A60	8 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 21 22 23 24 23 24 25 26 27 28 29 30	False		S S S S S S S S S S S S S S S S S S S	Kits not yet available at the Clinical Site
Newly imported <i>Kit</i> <i>Numbers</i>	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo	A10 A34 A04 A06 A10 A11 A25 A35 A38 A20 A43 A43 A44 A13 A46 A24 A13 A46 A24 A13 A46 A24 A13 A46 A24 A13 A45 A24 A13 A45 A35 A20 A43 A45 A38 A46 A45 A38 A46 A45 A38 A46 A45 A38 A46 A45 A38 A46 A45 A38 A46 A45 A45 A45 A45 A45 A45 A45 A45	8 5 6 7 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 24 25 26 27 28 29 30	False	 <td>S S S S S S S S S S S S S S S S S S S</td><td>Kits not yet available at the Clinical Site</td>	S S S S S S S S S S S S S S S S S S S	Kits not yet available at the Clinical Site
Newly imported <i>Kit</i> <i>Numbers</i>	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo <td< td=""><td>A10 A34 A04 A06 A10 A11 A25 A35 A38 A20 A43 A43 A44 A13 A44 A17 A31 A36 A24 A13 A44 A17 A31 A36 A24 A13 A45 A55 A38 A45 A55 A38 A45 A55 A55 A55 A55 A55 A55 A55</td><td>8 5 6 7 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30</td><td>False False False</td><td> <td>S S S S S S S S S S S S S S S S S S S</td><td>Kits not yet available at the Clinical Site</td></td></td<>	A10 A34 A04 A06 A10 A11 A25 A35 A38 A20 A43 A43 A44 A13 A44 A17 A31 A36 A24 A13 A44 A17 A31 A36 A24 A13 A45 A55 A38 A45 A55 A38 A45 A55 A55 A55 A55 A55 A55 A55	8 5 6 7 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	False	 <td>S S S S S S S S S S S S S S S S S S S</td><td>Kits not yet available at the Clinical Site</td>	S S S S S S S S S S S S S S S S S S S	Kits not yet available at the Clinical Site
Newly imported <i>Kit</i> <i>Numbers</i>	Demo Clinical Site 1 Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Clinical Site 1 Demo Clinical Site 1 Dem	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo <td< td=""><td>A10 A34 A04 A06 A10 A14 A25 A38 A20 A34 A20 A43 A08 A43 A43 A44 A17 A31 A36 A05 A21 A36 A51 A52 A52 A53 A60</td><td>8 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 29 29 29 20 21 28 29 20 20 21 20 20 20 20 20 20 20 20 20 20 20 20 20</td><td>False False False</td><td> <td>S S S S S S S S S S S S S S S S S S S</td><td>Kits not yet available at the Clinical Site</td></td></td<>	A10 A34 A04 A06 A10 A14 A25 A38 A20 A34 A20 A43 A08 A43 A43 A44 A17 A31 A36 A05 A21 A36 A51 A52 A52 A53 A60	8 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 29 29 29 20 21 28 29 20 20 21 20 20 20 20 20 20 20 20 20 20 20 20 20	False	 <td>S S S S S S S S S S S S S S S S S S S</td><td>Kits not yet available at the Clinical Site</td>	S S S S S S S S S S S S S S S S S S S	Kits not yet available at the Clinical Site

1.2 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.

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY A	ACCOUNT HELP
TRIALS Create/manage citized biais and view regins	CLINICAL STEES Createfmanage clinical sites.
ADMINISTRATORS Created-manage trial administrators	MY ACCOUNT VewImodity my account details

Click on the appropriate trial.

RA	NDOMIZE.NET		WELCOME Demo Kit Administrator LOGOUT			
HOME	TRIALS CLINICAL SITES ADMINISTRATORS			HELP		
Select Trial TRIAL Select a trial	.S to manage:					
TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES		
1968 1972	Deme Trial 1 Demo Blinded Trial 1	False True	22-12-2019 22:05:23 01-09-2020 23:02:39	0		

The "TRIAL DETAILS" are shown.

Click on "Manage Kits".

RANDOMIZE	NET WELCOME Demo Kit Administ	rator LOGOUT
HOME TRIALS CLINICAL SITES		HELP
Select Trial » Trial Details		
TRIAL DETAILS		
Edit Trial Details Notification Emails Edit Inclusio	n/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 k	<i>Kits</i> is displayed as on the next page.
		ins is alspia, ea as on the next page.

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 View/Edit democlinsite1 Demo Clinical Site 1 7	REMAINING KITS NOT YET AVAILABLE 48 5

	Demo Clinical Site 1	democlinsite1	1	Active	A33	15	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A18	16	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A03	17	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A09	18	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A14	19	False	✓	v
	Demo Clinical Site 1	democlinsite1	1	Active	A26	20	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A27	21	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A07	22	False		
	Demo Clinical Site 1	democlinsite1	1	Activo	A07	22	False		
		democriminer	1	Active	AST	23	Faise		•
	Demo Clinical Site 1	democlinsite1	1	Active	A01	24	Faise		<u> </u>
	Demo Clinical Site 1	democlinsite1	1	Active	A12	25	False	✓	✓
	Demo Clinical Site 1	democlinsite1	1	Active	A52	26	False	2	Z
	Demo Clinical Site 1	democlinsite1	1	Active	A53	27	False		•
	Demo Clinical Site 1	democlinsite1	1	Active	A55	28	False	\frown	
	Demo Clinical Site 1	democlinsite1	1	Active	A56	29	False		
	Demo Clinical Site 1	democlinsite1	1	Active	A58	30	False	$\backslash \circ /$	
	Demo Clinical Site 1	democlinsite1	2	Placebo	A23	1	True	\smile	
	Demo Clinical Site 1	democlinsite1	2	Placebo	A45	2	True		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A15	3	True		
	Demo Clinical Site 1	demoetinsite1	2	Placebo	A16	4	True		
	Demo Clinical Site	democlinsite1	2	Placebo	A34	5	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A0/	6	False		
	Demo Clinical Site 1	democlineite1	2	Placebo	A06	7	False		
	Domo Clinical Site 4	democlineited	2	Placebo	A10	0	False		
Ticking the boyes in	Demo Clinical Site 1	democlinsite1	2	Placebo	A10	0	Faise		•
ficking the boxes in	Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False	✓	✓
the "Available"	Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False	•	•
column indicatos that	Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False		
column mulcates that	Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False		
the <i>Kits</i> are now	Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False		
available at the	Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False		
<i>Clinical Site</i> identified									
in the first two						-			-
	Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False		V
columns. See the	Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False	2	2
screen on the next	Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False	•	•
220	Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False		
page.	Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False		
	Demo Clinical Site 1	democlinste1	2	Placebo	A43	14	False		
	Demo Clinical Site 1	democlineited	2	Placebo	A09	15	False		
	Demo Clinical Site 4	democlineited	2	Placebo	A00	16	Falco		
	Demo Clinical Site 1	democilinsite1	2	Placebo	A46	10	Faise		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A24	17	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A13	18	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A44	19	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A17	20	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A31	21	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A36	22	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A05	28	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A21	24	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A32	25	False		
	Demo Clinical Site 4	democlineited	2	Placebo	ASZ	26	Falco		
	Demo Clinical Site 1	democrimsite1	2	Placebo	ACT	20	Faise		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A54	2/	False	Y	
	Demo Clinical Site 1	democlinsite1	2	Placebo	A57	28	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A59	29	False		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A60	30	False		
								\bigcirc	
	SAVE CHANGES	ANCEL							

	Demo Clinical Site 1	democlinsite1	1	Active	A09	18	False			
	Demo Clinical Site 1	democlinsite1	1	Active	A14	19	False	•		
	Demo Clinical Site 1	democlinsite1	1	Active	A26	20	False		2	
	Demo Clinical Site 1	democlinsite1	1	Active	A27	21	False	 ✓ 	 ✓ ✓ 	
	Demo Clinical Site 1	democlinsite1	1	Active	A07	22	Faise	•	•	
	Demo Clinical Site 1	democlinsite1	1	Active	A37	23	False	•	•	
	Demo Clinical Site 1	democlinsite1	1	Active	A12	25	False			
	Demo Clinical Site 1	democlinsite1	1	Active	A52	26	False		•	
	Demo Clinical Site 1	democlinsite1	1	Active	A53	27	False		Image: A state of the state	
	Demo Clinical Site 1	democlinsite1	1	Active	A55	28	False	I	✓	
	Demo Clinical Site 1	democlinsite1	1	Active	A56	29	False			
	Demo Clinical Site 1	democlinsite1	1	Active	A58	30	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A23	1	True	\smile		
	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			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A06	7	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A10	8	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A11	9	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A25	10	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A35	11	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A38	12	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A20	13	False		•	
	Demo Clinical Site 1	democlinsite1	2	Placebo	A43	14	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A08	15	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A46	16	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A24	17	False			
	Demo Clinical Site 1	democlinsite1	2	Placebo	A13	18	False	V		
	Demo Clinical Site 1	democlinsite1	2	Placebo	A34	5	False			
	Denne Olivia I Oliv 4		0							
	Demo Clinical Site 1	democlinsite1	2	Placebo	A04	6	False			-
	Demo Clinical Site 1	democlinsite1 democlinsite1	2	Placebo	A04	6 7	False False	×	 ✓ 	
	Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1	2 2 2	Placebo Placebo Placebo	A04 A06 A10	6 7 8	False False False	• •	2 2 2	-
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	Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo	A04 A06 A10 A11 A25	6 7 8 9 10	False False False False False	• • • • • • • •	© © © ©	-
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo	A04 A06 A10 A11 A25 A35	6 7 8 9 10 11	False False False False False False False	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	\$ \$ \$ \$ \$ \$ \$ \$	· · ·
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A10 A11 A25 A35 A38	6 7 8 9 10 11 12	FalseFalseFalseFalseFalseFalseFalseFalse	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	8 8 8 8 8 8 8 8 8	
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo	 A04 A06 A10 A11 A25 A35 A38 A20 	6 7 8 9 10 11 12 13	False	8 8 9 8 8 8 8 8 8 8 8 9	8 8 8 8 8 8 8 8 8 8 8 8 8	
	Demo Cinical Site 1 Demo Cinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	 A04 A06 A10 A11 A25 A35 A38 A20 A43 	6 7 8 9 10 11 12 13 14	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo	 A04 A06 A10 A11 A25 A35 A38 A20 A43 A08 	6 7 8 9 10 11 12 13 14 15	FalseFalseFalseFalseFalseFalseFalseFalseFalseFalseFalseFalse	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A10 A11 A25 A35 A38 A20 A43 A08 A46	6 7 8 9 10 11 12 13 14 15 16	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	 A04 A06 A10 A11 A25 A35 A38 A20 A43 A08 A46 A24 	6 7 8 9 10 11 12 13 14 15 16 17	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A10 A11 A25 A35 A38 A20 A43 A08 A46 A24 A13	6 7 8 9 10 11 12 13 14 15 16 17 18	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A10 A11 A25 A35 A38 A20 A43 A08 A46 A24 A13 A44	6 7 8 9 10 11 12 13 14 15 16 17 18 19	False	3 3 <t< td=""><td></td><td></td></t<>		
	Demo Clinical Site 1 Demo Clinical Site 1	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A06 A10 A11 A11 A25 A35 A35 A36 A43 A43 A46 A24 A13 A44 A13 A44	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A06 A10 A11 A11 A25 A35 A35 A36 A30 A43 A43 A46 A24 A13 A43 A44 A13 A44 A17 A31	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A06 A10 A11 A11 A25 A35 A35 A38 A20 A43 A43 A43 A43 A44 A13 A44 A13 A44 A17 A31	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A06 A06 A10 A11 A25 A35 A35 A38 A20 A43 A43 A43 A43 A44 A13 A44 A13 A44 A17 A31 A36 A05	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 23	False	8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8		
	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A06 A06 A10 A11 A25 A31 A35 A35 A38 A20 A33 A43 A43 A43 A44 A17 A31 A36 A08 A41 A17 A31 A36 A03 A05	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 24	False	S S <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES"	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo	A04 A06 A06 A10 A11 A25 A33 A35 A35 A35 A36 A32 A43 A43 A43 A46 A24 A13 A44 A17 A31 A36 A06 A05 A21 A32	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 22 23 24 25	False	 8 9 9<		
Click "SAVE CHANGES" to indicate that the	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo	A04 A04 A06 A10 A11 A11 A12 A35 A38 A36 A43 A38 A43 A43 A43 A43 A43 A44 A13 A44 A13 A44 A17 A36 A43 A05 A21 A32 A51 A52	6 7 8 9 10 11 12 13 13 14 15 16 17 18 19 20 21 22 23 24 22 23 24 25 26	False	S S <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES" to indicate that the	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo Placebo	A04 A04 A06 A10 A11 A11 A12 A35 A38 A36 A43 A38 A43 A43 A43 A43 A43 A44 A17 A36 A44 A17 A31 A36 A42 A31 A36 A42 A31 A36 A55 A21 A32 A51	6 7 8 9 10 11 12 13 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 27	False	S S <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES" to indicate that the <i>Kits</i> are now available	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo <td< td=""><td>A04 A04 A06 A06 A10 A11 A25 A36 A35 A38 A26 A37 A38 A20 A43 A38 A43 A43 A43 A44 A17 A31 A36 A24 A44 A17 A31 A36 A21 A32 A32 A32 A51 A51 A54 A54</td><td>6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 22 23 24 22 23 24 25 26 27 28</td><td>False False False</td><td>S S <t< td=""><td></td><td></td></t<></td></td<>	A04 A04 A06 A06 A10 A11 A25 A36 A35 A38 A26 A37 A38 A20 A43 A38 A43 A43 A43 A44 A17 A31 A36 A24 A44 A17 A31 A36 A21 A32 A32 A32 A51 A51 A54 A54	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 22 23 24 22 23 24 25 26 27 28	False	S S <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES" to indicate that the <i>Kits</i> are now available and return to the	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo <td< td=""><td>A04 A04 A06 A06 A10 A11 A25 A36 A35 A38 A20 A33 A38 A20 A43 A38 A43 A43 A43 A44 A17 A31 A36 A24 A44 A17 A31 A36 A21 A32 A32 A32 A51 A54 A57 A59</td><td>6 7 8 9 10 11 12 13 14 15 16 17 18 17 18 20 21 22 22 23 22 23 22 24 25 26 27 28 29 20</td><td>False False False</td><td>3 3 <t< td=""><td></td><td></td></t<></td></td<>	A04 A04 A06 A06 A10 A11 A25 A36 A35 A38 A20 A33 A38 A20 A43 A38 A43 A43 A43 A44 A17 A31 A36 A24 A44 A17 A31 A36 A21 A32 A32 A32 A51 A54 A57 A59	6 7 8 9 10 11 12 13 14 15 16 17 18 17 18 20 21 22 22 23 22 23 22 24 25 26 27 28 29 20	False	3 3 <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES" to indicate that the <i>Kits</i> are now available and return to the screen on the pext	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo <td< td=""><td>A04 A04 A06 A06 A10 A11 A25 A35 A35 A36 A20 A33 A36 A24 A44 A17 A31 A36 A24 A44 A47 A31 A36 A21 A37 A36 A36 A35 A37 A36 A36 A36 A44 A44 A31 A36 A32 A31 A36 A35 A37 A36 A36 A36 A37 A36 A36 A36 A37 A36 A36 A37 A37 A36 A37 A37 A37 A37 A37 A37 A37 A37 A37 A37</td><td>6 7 8 9 10 11 12 13 14 15 15 16 17 18 19 20 21 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 23</td><td>False False False</td><td>3 3 <t< td=""><td></td><td></td></t<></td></td<>	A04 A04 A06 A06 A10 A11 A25 A35 A35 A36 A20 A33 A36 A24 A44 A17 A31 A36 A24 A44 A47 A31 A36 A21 A37 A36 A36 A35 A37 A36 A36 A36 A44 A44 A31 A36 A32 A31 A36 A35 A37 A36 A36 A36 A37 A36 A36 A36 A37 A36 A36 A37 A37 A36 A37 A37 A37 A37 A37 A37 A37 A37 A37 A37	6 7 8 9 10 11 12 13 14 15 15 16 17 18 19 20 21 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 23	False False	3 3 <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES" to indicate that the <i>Kits</i> are now available and return to the screen on the next	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo	A04 A04 A06 A10 A11 A12 A31 A32 A43 A43 A43 A43 A43 A43 A43 A44 A17 A31 A36 A02 A31 A36 A51 A52 A51 A52 A51 A52 A51 A52 A51 A52 A53 A54 A55 A50	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 22 23 23	False False	3 3 <t< td=""><td></td><td></td></t<>		
Click "SAVE CHANGES" to indicate that the <i>Kits</i> are now available and return to the screen on the next page.	Demo Clinical Site 1 Demo Clin	democlinsite1 democlinsite1	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Placebo Placebo <td< td=""><td>A04 A04 A06 A10 A11 A21 A35 A35 A36 A20 A38 A38 A43 A43 A43 A43 A43 A43 A43 A43 A44 A17 A31 A36 A21 A36 A37 A38 A39 A44 A17 A31 A36 A37 A36 A32 A31 A32 A32 A34 A51 A52 A51 A52 A50 A50</td><td>6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30</td><td>False False False</td><td>0 0 <t< td=""><td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td><td>previous</td></t<></td></td<>	A04 A04 A06 A10 A11 A21 A35 A35 A36 A20 A38 A38 A43 A43 A43 A43 A43 A43 A43 A43 A44 A17 A31 A36 A21 A36 A37 A38 A39 A44 A17 A31 A36 A37 A36 A32 A31 A32 A32 A34 A51 A52 A51 A52 A50 A50	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30	False False	0 0 <t< td=""><td>0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0</td><td>previous</td></t<>	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	previous

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".

	WELCOME Demo Kit Administrator LOC
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 K	TS REMAINING KITS NOT YET AVAILABLE
View/Edit democlinsite1 Demo Clinical Site 1 7	53 0

1.3 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 <u>page 25</u>.

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

×≣	5 0	€			Demo Kits 61 to	70 Unassigned.csv - I	Excel			? 🗈 -	- 8	×
FILE	HOME INSERT	PAGE LAYOUT	FORMULAS DATA	A REVIEW VIE	W ACROBAT					Ar	ndy Willan 👻	
Normal	Page Break Page Cus Preview Layout Vi	stom ews	✓ Formula Bar✓ Headings✓ Zoo	m 100% Zoom to Selection	New Arrange Freez Window All Panes	Split Split	 ○ View Side by Side △ Synchronous Scrolling ▲ Reset Window Position 	Switch Macros Yindows *				
Δ1	Workbook Views	Sh	ow	Zoom		Window		Macros				^
AI		₩ J ^x Z										^
	Α	В	С	D	E	F	G	Н	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	Demo Kits 61 to	o 70 Unassigned	(+)				: •					• •
READY										<u> </u>	+ 20	00%



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

WELCOME Demo Kit Administrator | LOGOUT Select Trial TRIALS Select a trial to manage: NUMBER OF ACTIVE SITES TRIAL ID TRIAL NAME ACTIVE DATE ACTIVATED 1968 Demo Trial 1 False 22-12-2019 22:05:23 0 1972 Demo Blinded Trial 1 01-09-2020 23:02:39 True 1

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

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 Administ	rator LOGOUT
HOME TRIALS CLINICAL SITES AL	MINISTRATORS MY ACCOUNT	HELP
Select Trial » Trial Details		
TRIAL DETAILS		
Edit Trial Details Notification Emails Edit Inclusio	n/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".

RAI	NDON				WELCOME	IOUT		
Номе Т	RIALS CLINIC	AL SITES ADMINISTRATORS	MY AG	CCOUNT	HELP			
Select Trial » MANA Edit Kit Prefer	Trial Details » N GE KITS ence: Import Kits	tanage Kits Assign Kits						
	SITE ID	CLINICAL SITE NAME		USED KITS	REMAINING NITS	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".

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:	
Culnical Site Frimary User Login ID Treatment ID Kit 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.

HOME TRIALS CLINICAL SITES	HELP	
Select Trial » Trial Details » Manage Kits	>> Manage Kits For Site	
IMPORT KITS		
Choose file		
TREATMENT ID	TREATMENT	КІТ
TREATMENT ID	TREATMENT	КІТ
2	Placebo	A61
1	Active	A62
1 2	Active Placebo	A62 A63
1 2 1	Active Placebo Active	A62 A63 A64
1 2 1 1	Active Placebo Active Active	A62 A63 A64 A65
1 2 1 1 1	Active Placebo Active Active Active	A62 A63 A64 A65 A66
1 2 1 1 1 2 2	Active Placebo Active Active Active Active Placebo	A62 A63 A64 A65 A66 A66
1 2 1 1 1 2 2	Active Placebo Active Active Active Active Placebo Placebo Placebo	A62 A63 A64 A65 A66 A67 A68
1 2 1 1 1 2 2 2 2	Active Placebo Active Active Active Active Placebo Placebo Placebo Placebo Placebo	A62 A63 A64 A65 A66 A67 A68 A69

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

R A	NDO	MIZE.NET	WELCOME Demo Kit Administrator LO		
HOME		CAL SITES ADMINISTRATORS			HELP
Select Tria	» Trial Details »	Manage Kits			
O Kits in	ported successfully.				
MAN Edit Kit Pr	AGE KITS	s Assign Kits			
	SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE
View/Ed	it democlinsite1	Demo Clinical Site 1	7	53	0
		Demo Clinical Site 2	0	0	0

1.4 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.

	WELCOME Demo Kit Administrator LOGOUT
HOME TRIALS CLINICAL SITES ADMINISTRATORS MY	ACCOUNT
TRIALS Create/manage diriced trials and view reports	CLINICAL STEES Create/manage clinical sites.
ADMINISTRATORS Create/manage trial administrators	MY ACCOUNT Verwimodity my account details

Click on the appropriate trial.

RA	NDOMIZE.NET		WELCOM	E Demo Kit Administrator LOG	OUT
номе	TRIALS CLINICAL SITES ADMINISTRATORS			HELP	
Select Trial TRIAI Select a tria	_S				
TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES	
1968 1972 (Demo Trial 1 Demo Blinded Trial 1	False True	22-12-2019 22:05:23 01-09-2020 23:02:39	0	

The "TRIAL DETAILS" are shown.

Click on "Manage Kits".

RANDOMIZE	NET WELCOME Demo Kit Admi	nistrator LOGOUT
	MINISTRATORS MY ACCOUNT	HELP
Select Trial » Trial Details		
TRIAL DETAILS		
Edit Trial Details Notification Emails Edit Inclusio	n/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".

RANDO	MIZE.NET		WELCOM	E Demo Kit Administrator LOC	BOUT
HOME TRIALS CLINI				HELP	
Select Trial » Trial Details » MANAGE KITS Edit Kit Preferences Import Kit	Manage Kits				
SITE ID	CLINICAL SITE NAME	USED KITS	REMAINING KITS	NOT YET AVAILABLE	
View/Edit democlinsite1 View/Edit democlinsite2	Demo Clinical Site 1 Demo Clinical Site 2	7	53 0	0	
UNASSIGNED KIT COU	NT 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.

RANDO		г		WELCO	ME Dem	o Kit Administrator LOGOUT	
HOME TRIALS						HELP	
Select Trial » Trial Details	s » Manage Kits » Assign Kits S	5					
TREATMENT ID	TREATMENT	КІТ	CLINICAL SITE	4 VAILA	BLE	DELETE	
2	Placebo	A61	Pick One	Y			
1	Active	A62	Pick One	•		D	
2	Placebo	A63	Pick One	•			
1	Active	A64	Pick One	•		0	
1	Active	A65	Pick One	•			
1	Active	A66	Pick One	•			
2	Placebo	A67	Pick One	•			
2	Placebo	A68	Pick One	•			
2	Placebo	A69	Pick One	•			
4	Active	A70	Pick One	•			

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.

		T STRATORS M	Y ACCOUNT	WE	LCOME Demo	Kit Administrator LOG4	TUC
Select Trial » Trial Details	» Manage Kits » Assign Ki	ts					
TREATMENT ID	TREATMENT	КІТ	CLINICAL SITE		VAILABLE	DELETE	
2	Placebo	A61	Demo Clinical Site 1	T	0	0	
1	Active	A62	Demo Clinical Site 1	•		D	
2	Placebo	A63	Demo Clinical Site 1	•			
1	Active	A64	Demo Clinical Site 1	T			
1	Active	A65	Demo Clinical Site 2	•			
1	Active	A66	Demo Clinical Site 2		0		
2	Placebo	A67	Demo Clinical Site 2	T	۲		
2	Placebo	A68	Demo Clinical Site 2	T		٥	
2	Placebo	A69	Pick One	*			
1	Active	A70	Pick One	•		D	
SAVE CHANGES	CANCEL		 	Ticking the AVAILABLI Indicate the are physica	boxes und E" will at the <i>Kits</i> Ily availabl	er Tickin "DELE the <i>Kii</i> remov	g the boxes unde TE" will delete <i>t Number</i> and ve it from the

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 "<u>Make Assigned Kits available</u>".

RA	NDOMIZE.NET		WELCOM	E Demo Kit Administrator LOG	DUT
номе	TRIALS CLINICAL SITES ADMINISTRATORS			HELP	
Select Trial	» Trial Details » Manage Kits				
Kits alloc	ated successfully.				
MANA Edit Kit Prefe	GE KITS rrences 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	
UNASS	IGNED KIT COULT			<u> </u>	

1.5 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.

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY	ACCOUNT
TRIALS Create/manage clinical tials and view reports	CLINICAL STRES Create/manage clinical states.
ADMINISTRATORS Create/manage trial administrators	My Account Vewimodity my account details

Click on the appropriate trial.

RA	NDOMIZE.NET		WELCOME Der	no Kit Administrator LOG	OUT
номе	TRIALS CLINICAL SITES ADMINISTRATORS			HELP	
Select Trial TRIAL Select a trial	.S to manage:				
TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES	
1968	Demo Trial 1 Demo Blinded Trial 1	False True	22-12-2019 22:05:23 01-09-2020 23:02:39	0 1	

The "TRIAL DETAILS" are shown.

Click on "Manage Kits".

RANDOMIZE	.NET WELCOME Demo Kit Adminis	trator LOGOUT
HOME TRIALS CLINICAL SITES A		HELP
Select Trial » Trial Details		
TRIAL DETAILS		
Edit Trial Details Notification Emails Edit Inclusio	n/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-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".

	WELCOME Demo Kit Administrator LOGO
HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT	HELP
Select Trial » Trial Details » Manage Kits C Kits allocated successfully. MANAGE KITS Edit Kit Preferences Import Kits Assign Kits	
SITE ID CLINICAL SITE NAME USEC NITS ViewlEdit democlinsite1 Demo Clinical Site 1 7 ViewlEdit tlemoclinsite2 Demo Clinical Site 2 0	REMAINING KITS NOT YET AVAILABLE 53 4 0 4

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.

					v	/ELCO	Demo Kit A	Administrator L
HOME TRIALS	LINICAL SITES AD	MINISTRATORS MY	ACCOUNT					HELP
Select Trial » Trial Details	» Manage Kits » Ma	nage Kits For Site						
	SITE ID	TREATMENT ID	TREATMENT	KIT	NUMBER	IS USED		ASSIGNED
CUNICAL SUF NAME		THE STATE IN THE	THE ACTURE OF		DEIX	IS SOLL		TOORED
Demo Clinical Site 2	democlinsite2	1	Active	A65	1	False		
Demo Clinical Site 2 Demo Clinical Site 2	democlinsite2 democlinsite2	1	Active Active	A65 A66	1 2	False False		 ✓
Demo Clinical Site 2 Demo Clinical Site 2 Demo Clinical Site 2	democlinsite2 democlinsite2 democlinsite2	1 1 2	Active Active Placebo	A65 A66 A67	1 2 1	False False False		9 9 9

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 <u>page 167</u> and the *Kits* will not be available for future patients.

					WELCOME Demo Kit Administrator Log				
HOME TRIALS CLI	NICAL SITES ADI	MINISTRATORS MY	ACCOUNT					HELP	
CLINICAL SITE NAME	S for Demo Clinic	TREATMENT ID	TREATMENT	КІТ	NUMBER	IS USED	AVAILABLE	ASSIGNED	
Demo Clinical Site 2	democlinsite2	1	Active	A65	1	False		2	
		1 2015						-	
Demo Clinical Site 2	democlinsite2	1	Active	A66	2	Faise		2	
Demo Clinical Site 2 Demo Clinical Site 2	democlinsite2 democlinsite2	2	Active Placebo	A66 A67	2	False	$\mathbf{\bigcirc}$	e e	

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 ye	et assigned to a Clinical Site.	

RA	NDO			WELCOME	E Demo Kit Administrator LOG	OUT
HOME	TRIALS CLINIC	AL SITES ADMINISTRATORS MY A	CCOUNT		HELP	
Select Trial	» Trial Details » A	Aanage Kits				
 Kits save 	d successfully.					
Edit Kit Pref	SITE ID	Assign Kits CLINICAL SITE NAME	Jused Kits	REMAINING KITS	NOT YET AVAILABLE	
View/Edit	democlinsite1	Demo Clinical Site 1	7	53	4	
	dama alimatica O		0			
View/Edit	democlinsitez	Demo Clinical Site 2	0	2	2	

1.6 *Kit* Preferences

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

	WELCOME Demo Kit Administrator LOGOUT
HOME TRIALS CLINICAL SITES ADMINISTRATORS MY A	ACCOUNT
TRIALS Create/manage clinice/ thais and view report	CLINICAL SITES Create/manage clinical sites.
ADMINISTRATORS Create/manage trial administrators	MY ACCOUNT Vew/modily my account details

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

RA	NDOMIZE.NET				
номе	TRIALS CLINICAL SITES ADMINISTRATORS		HELP		
Select Trial TRIAL Select a trial	_S				
TRIAL ID	TRIAL NAME	ACTIVE	DATE ACTIVATED	NUMBER OF ACTIVE SITES	
1968 1972 (Demo Trial 1 Demo Blinded Trial 1	False True	22-12-2019 22:05:23 01-09-2020 23:02:39	0	

The "TRIAL DETAILS" are shown.

Click on "Manage Kits".

RANDOMIZE	.NET WELCOME Demo Kit Admi			
HOME TRIALS CLINICAL SITES AL	DMINISTRATORS MY ACCOUNT	HELP		
Select Trial » Trial Details TRIAL DETAILS Edit Trial Details Notification Emails Edit Inclusio	n/Exclusion Criteria Activate Clinical Sites Limits Reports Manage Kits			
TRIAL ID TRIAL NAME	1972 Demo Blinded Trial 1			
	Yes 01-09-2020 23-02-39			
NUMBER OF ACTIVE CLINICAL SITES	1			
RECORD PATIENT INITIALS RECORD PATIENT BIRTHDATE	No			
RECORD OTHER VARIABLE	No 1. Active 2. Placebo			
STRATIFY BY CLINICAL SITE	Yes			
BLOCKING FACTORS BLOCK SIZES	2 4			
STRATIFICATION VARIABLES	1. Duration since injury a. Less than 2 years b. 2 years or more			

Click on "Edit Kit Preferences".

R A	NDO	MIZE.NET		WELCON	E Demo Kit Administrator LOG
HOME		CAL SITES ADMINISTRATORS			HELP
Select Trial	» Trial Details » ated successfully. GE KITS erences mport Kit	Aanage 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

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.

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT	If "No", all <i>Kit Numbers</i> must be available at all <i>Clinical Sites</i> . If "Yes", <i>Kit Numbers</i> must be assigned to one <i>Clinical Site</i> only.		
KITS PREFERENCES	The default is "Yes" and cannot be reset after trial is activated.		
Allow Reflii/Replacement Of Kits: Ves No Low Kit Email Alert Level per Treatment Arm: Off V All Kit Administrators Send Email Alert to : Coordinating Celliner Clinical Site	If "Yes", a <i>Clinical Site</i> can request another <i>Kit Number</i> containing the same treatment for a previously randomized patient. The default is "No" and can be reset anytime.		
SAVE CHANGES CANCEL	Low <i>Kit</i> 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.

HOME TRIALS CLINICAL SITES ADMINISTRATORS MY ACCOUNT Select Trial * Trial Details * Manage Kits * Kits Preferences KIT S PREFERENCES KIT List Per Clinical Site: * Yes * No Allow Reflin/Replacement Of Kits: * Yes * No Low Kit Email Alert Level per Treatment Of * * * * * * * * * * * * * * * * * * *	HELP
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".

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 5 ▼ ummer 5 ▼ wmmer 5 ▼ wmmer 6 Coordinating Center wmmer Clinical Site CANCEL	