

Section 6. Web Randomization

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This section provides information on the process for randomization to study group for MTN-028 study participants using the Frontier Science & Technology Research Foundation (FSTRF) randomization system.

6.1 Participant Randomization Overview

Randomization is the process whereby a participant is assigned to a study treatment arm.

There are two main steps in the randomization process:

- request randomization using the MTN-028 Frontier Science & Technology Research Foundation (FSTRF) Randomization system
- receive and print randomization confirmation notice

6.2 Requesting FSRTF User Accounts

Staff must have FSTRF user account in order to access the system and randomize participants. Follow the below steps in order to create an account.

- Go to the FSTRF Portal:
<https://www.fstrf.org/apps/cfm/apps/common/Portal/index.cfm>
- Click on the link for “Register”

Figure 1. Log in page of the FSTRF Randomization System

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Statistical Data Management for Clinical Trials

Please Log In:

User Name:

Password:

All Data Management Center (DMC) computing systems will be offline between 8PM and midnight, Eastern Time, on the first Saturday of each month. This will be done to perform various system maintenance tasks that contribute to the ongoing stability of DMC computer and communications systems.

All databases at the DMC are offline for maintenance each Friday and Saturday night from 11:50 p.m. to 12:10 a.m. Eastern time.

This is the FSTRF Computer System. This computer system is monitored with privacy accommodations for all lawful purposes, including: ensuring that its use is authorized, for management of the system, to facilitate protection against unauthorized use, and to verify security procedures. Use of this FSTRF system, authorized or unauthorized, constitutes acknowledgment and consent to monitoring by the system.

[Register](#) | [Reset Password](#) | [Login Help](#) | [Email Webmaster](#)

- Enter your information (e.g. first name, last name, institution, e-mail address)
- Create a password
 - **NOTE:** This is the password you will use to access the system moving forward once an account has been created.
- If you are a staff member (for example, the clinic coordinator) requesting an account for one of your staff, please enter your own information under “Person completing this form”. If you are entering information for yourself, you can check the box for “same as above”.
- Click “Next”
- Choose the project “MTN” from the drop down menu and click “Other- Non-Laboratory Staff” for your position from the menu. In the comments, please enter “MTN-028” and your site name.
- Click “Next”
- For “Web/Data Access for Lab(s)”, click “No”
- For “Randomization Access”, click “Yes”
 - Click “Institution number not available”
 - Click both “Access to Randomization Checklists” and “Access to Randomize Patients”
- Review your information for accuracy and click “Submit”

NOTE: If you or your staff member already has a FSTRF account, for example, due to participation in another clinical trial, you must still request an account via the FSTRF Portal in order to randomize for MTN studies. Use the same e-mail and password of the existing account to request the MTN account.

6.3 Requesting Participant Randomization Using the FSTRF System

CRS staff will request randomization for a participant via the MTN-028 FSTRF web-based randomization system once the participant has met all eligibility requirements at the participant’s Enrollment Visit (Visit 2.0).

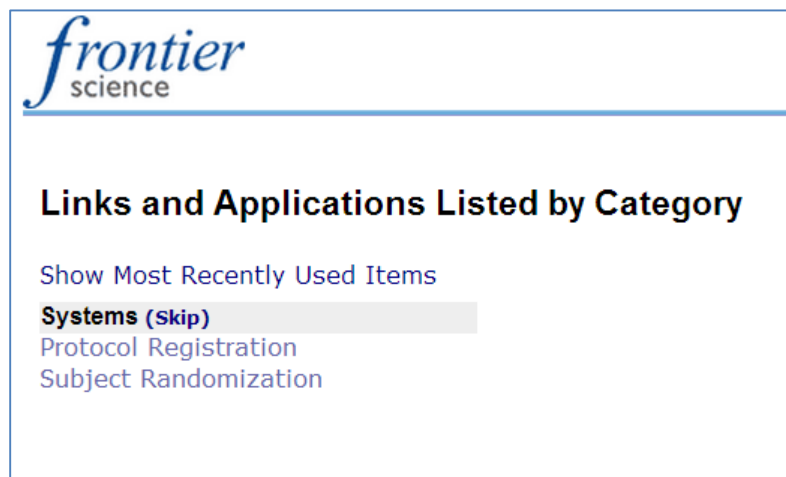
To request randomization for a participant:

1. Log onto the FSTRF system at www.fstrf.org/Portal (see Figure 1) and log in using your FSTRF Randomization System username and password

NOTE: You must request a FSTRF user account – see above section 6.2

2. Once logged on, you will arrive at the welcome page (see Figure 2). From the welcome screen, click on “Subject Randomization”

Figure 2. Links and Applications Listed by Category Page of the FSTRF Randomization System



3. From the Randomization Screen, use the drop down menus provided to select your institution and study, then click “Continue” (see Figure 3a). You can disregard (e.g., leave blank) the check box for “Blank Eligibility Checklist”, since it does not apply to MTN-028. Click “OK” in the confirmation pop-up box (see Figure 3b).

Figure 3a. FSTRF MTN Subject Randomization System Part 1

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MTN Subject Randomization System (Testing Phase)

Enter Institution Code and select a Study

Blank Eligibility Checklist

Institution (for this enrollment) :
335 Pittsburgh

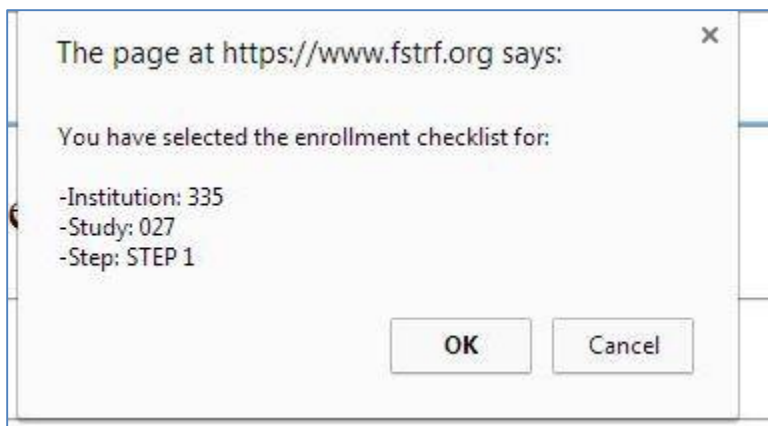
Study:
027

Continue Reset

Contact Information

| | |
|-------|---|
| Email | Randomization Help Desk |
| Tel | +1 716 834-0900 ext. 7301 |
| Fax | +1 716 832-8437 |
| Help | Online Help (.pdf) |

Figure 3b. FSTRF MTN Subject Randomization System Part 1 Pop-up Box



4. The next page is pre-filled so you do not need to edit or complete anything on this page. Click “Continue” (Figure 4a). Click “OK” in the confirmation pop-up box (see Figure 4b).

Figure 4a. FSTRF MTN Subject Randomization System Part 2

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MTN Subject Randomization System (Testing Phase)

Institution: 335
Protocol: 027

Please select a step:

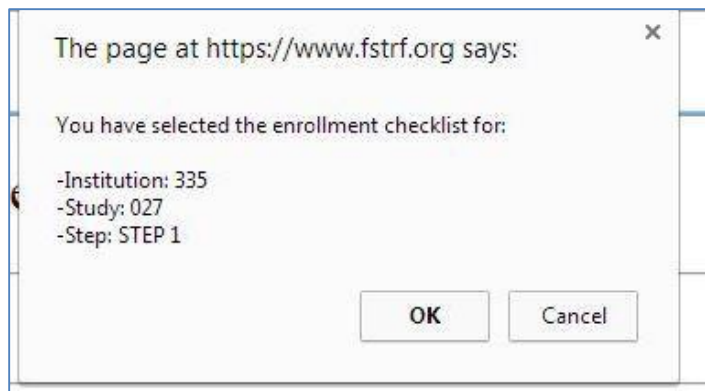
STEP 1

Continue Reset

Contact Information

| | |
|-------|---|
| Email | Randomization Help Desk |
| Tel | +1 716 834-0900 ext. 7301 |
| Fax | +1 716 832-8437 |
| Help | Online Help (.pdf) |

Figure 4b. FSTRF MTN Subject Randomization System part 2. Pop-up Box



5. On the next screen, select the box for “Click here to continue!” Enter the participant’s Participant ID Number (e.g. PTID), without dashes, in the space provided and hit the “Enter” key on your keyboard. You must enter a valid PTID to proceed (See Figure 5a). Click “OK” in the confirmation pop-up box (figure 5b).

Figure 5a. FSTRF MTN Subject Randomization System Randomization Page

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MTN Subject Randomization System

Institution: 335
Protocol: 027
Step 1:

Eligibility Checklist:

Q0001
Protocol MTN 027
A Phase 1 Safety and Pharmacokinetics Study of MK-2048/Vicriviroc (MK-4176)/MK-2048A Intravaginal Rings
Eligibility Checklist Date: February 27, 2015
 Click here to continue!

Q0002
Enter the participant's Patient Number.

Q0003
Select your site.
 Alabama Microbicide [Eligible]
 Pittsburgh [Eligible]

Additional Information:

Comments:

The page at https://www.fstrf.org says:
All criteria have been met. Please click OK to continue.

Figure 5b. FSTRF MTN Subject Enrollment System Randomization Page Pop-up Box

The page at https://www.fstrf.org says:
All criteria have been met. Please click OK to continue.

6. Click “Enroll” at the bottom of the page and “OK” in the confirmation pop-up box (See Figures 6a and 6b). This will confirm the request to randomize the participant.

Figure 6a. FSTRF MTN Subject Enrollment System Randomization Page

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Q0002
Enter the participant's Patient Number.
77777774

Q0003
Select your site.
 Alabama Microbicide [Eligible]
 Pittsburgh [Eligible]

Additional Information:
Comments:
[Text Area]

Enroll | Reset

Download Checklist (No answers will be saved)

[Calculate Time Between Dates](#)

[Return To Main Menu](#)

Figure 6b. FSTRF MTN Subject Enrollment System Randomization Page

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Q0002
Enter the participant's Patient Number.
77777774

Q0003
Select your site.
 Alabama Microbicide [Eligible]
 Pittsburgh [Eligible]

Additional Information:
Comments:
[Text Area]

Enroll | Reset

Download Checklist (No answers will be saved)

[Calculate Time Between Dates](#)

[Return To Main Menu](#)

Contact Information
Email: [Randomization Help Desk](#)
Tel: +1 716 834-0900 ext. 7301
Fax: +1 716 832-8437
Help: [Online Help \(.pdf\)](#)

The page at https://www.fstrf.org says:
Enroll?
OK | Cancel

6.4 Randomization Confirmation Notices

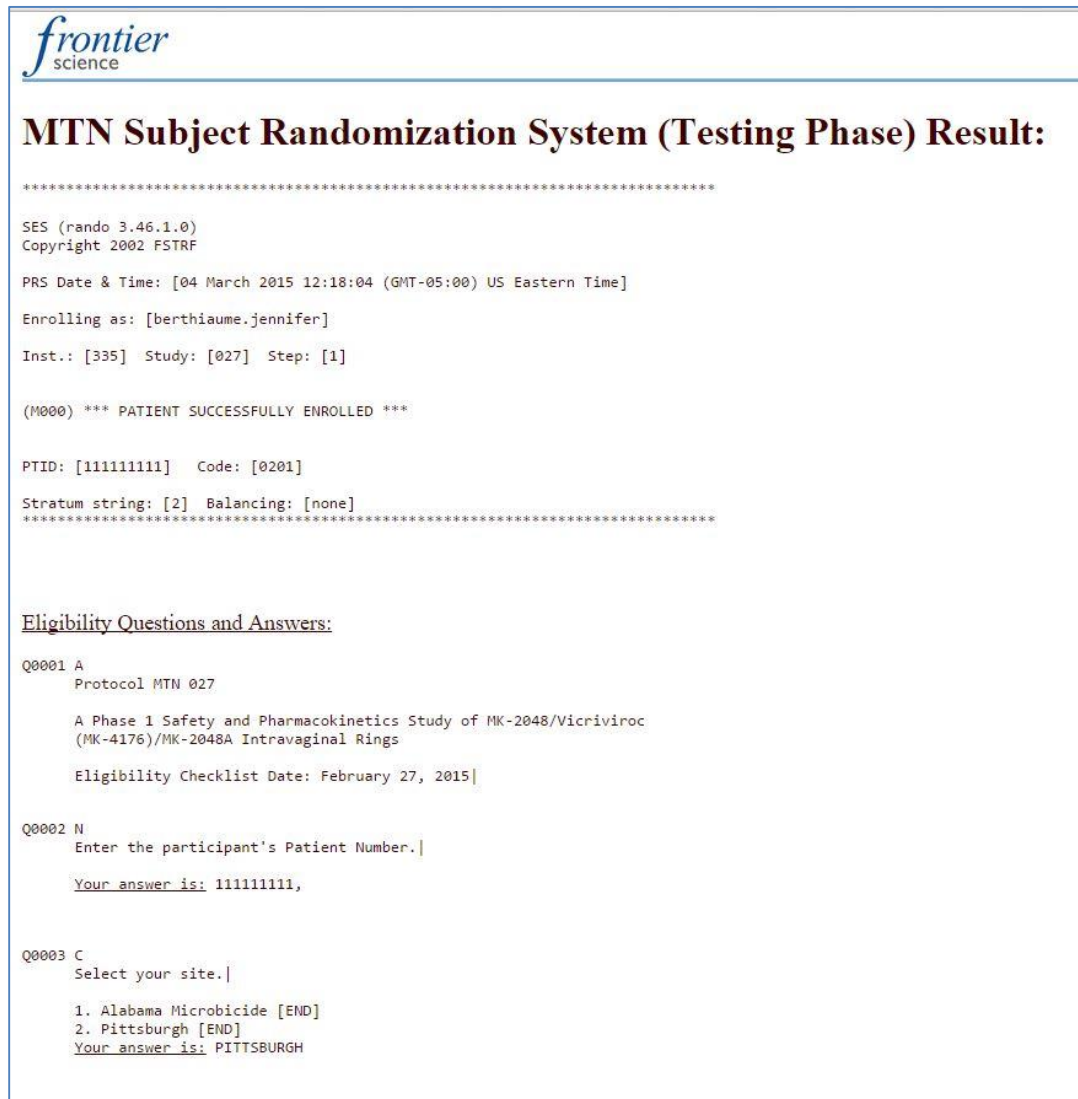
When a participant has been successfully randomized, you will see the following web message (Figure 7). A notification of randomization will also be sent via e-mail to:

- CRS Clinic Coordinator and CRS Pharmacist aliases
- Randomization confirmation notices will include date of randomization, CRS clinic staff member name, DataFax site number (Inst.), study number, PTID, site location, and the randomization number (Code).
- NOTE: The Eligibility Checklist Date listed on the Randomization confirmation notice refers to the date that this item was last modified by FSTRF when configuring the web randomization interface. This date does not signify the date that each participant's eligibility for the study was confirmed. Rather, the date provided on the MTN-028 Eligibility Checklist word document should be used as the date that each participant's eligibility was confirmed.
- Once the randomization confirmation notice is received, CRF staff must complete the following steps:
 1. Write the randomization number (code) on the MTN-028 prescription before sending to the pharmacy.

NOTE: The randomization number (Code) provided by FSTRF will be displayed as a 4-digit number with a leading 0. When transcribing the randomization number onto the MTN-028 Prescription and Enrollment (ENR-1) CRF, the leading "0" should be transcribed.

2. Print two copies of the randomization confirmation email – one to keep in the participant's study binder and the second to send with the study prescription to the pharmacy.
3. All randomization notices should be kept in a secure location
4. Please refer to SSP Section 7 for additional guidance on study product dispensation considerations for clinic staff.

Figure 7. FSTRF MTN Randomization Notice



6.5 Randomization Codes and Randomization Time

- Randomization confirmation notices will include 4-digit randomization number (codes). This 4-digit randomization number will be used by the pharmacist to identify which study product sub-lot code should be dispensed. Randomization numbers (codes) will appear on confirmation notices that are sent to both CRS Pharmacists and Clinic Coordinators.
- The randomization time within the confirmation email is provided in Eastern Standard Time (EST). When completing item 5 on the Enrollment CRF, convert the time of randomization according to the site's local standard time zone.

6.6 Replacing Participants

If a participant discontinues study participation or is placed on hold (and the ring has been out for longer than consecutive three days) the participant needs to be replaced, and the following steps should be completed:

1. Inform the MTN-028 Management Team immediately (mtn028mgmt@mtnstopshiv.org)
2. Once the site receives confirmation from the SCHARP Project Manager that the participant does need to be replaced, the site must contact FSTRF (sdac.random.desk@fstrf.org; user.support@fstrf.org) to let them know that there is a participant that needs to be replaced. The email to FSTRF should include the PTID for the participant that needs to be replaced.
3. Once FSTRF notifies the site that the randomization system is ready to replace the participant, the next eligible participant will be enrolled as a replacement participant. The replacement participant will be assigned a new PTID and the site clinic staff will complete the steps for randomization using the FSTRF website. The replacement participant will be assigned to the same product as the participant being replaced via the FSTRF website.
 - NOTE: FSTRF's operating hours for assistance with randomization are 6AM – 5PM Eastern. If it is determined that a participant must be replaced after 5PM Eastern (2PM Pacific) and another patient is already scheduled to be randomized that afternoon, that patient can be randomized. Site staff should still email FSTRF informing them that a participant needs to be replaced and the next day when FSTRF informs the site that the randomization system is ready to replace the participant, the next eligible patient randomized will be assigned the same product as the discontinued participant.
4. The reason that the participant is being replaced should be recorded on the Participant Replacement Log CRF.
5. The PTID assigned to the participant that is being replaced should be documented on the replacement participant's Enrollment CRF.

6.7 Logging Out

To log out of the FSTRF system, click on “skip to content” in the upper right corner of the screen. This will reveal a menu bar with a logout option (see Figure 8).

Figure 8. Signing out of FSTRF



6.8 Randomization Technical Support

In circumstances where CRS staff need to randomize a participant, but are unable to access the FSTRF system due to technical problems, have any issues with the FSTRF randomization, or do not receive the randomization confirmation email, the CRS staff should contact FSTRF via the contact information provided at the bottom of the portal.

| Contact Information | |
|---------------------|---|
| Email | Randomization Help Desk |
| Tel | +1 716 834-0900 ext. 7301 |
| Fax | +1 716 898-7082 |
| Help | Online Help (.pdf) |

For operational issues, contact the MTN-028 SCHARP Project Manager and the Statistical Research Associate.