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General Overview

At the Enrollment Visit (Visit 2), study staff will provide the participant with general use instructions and train the participant on using the SMS to report on ring use and vaginal bleeding. The training should be done using the cell phone that the participant will use during the study (make sure to remind participants who will be using their own cell phones to bring them to their study visit). Site staff should follow the general use instructions below.

The Population Council team will be available to assist in troubleshooting and resolving any problems as they arise. To facilitate the troubleshooting process, sites should provide a description of the problem, including a copy of the error message(s), if any, date and time of when the problem occurred, and the password and phone number that was used, if available.

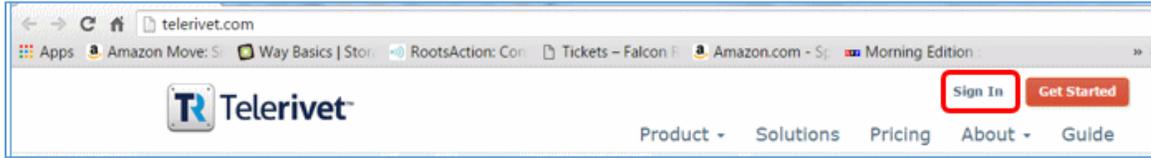
If sites encounter any problems with the SMS, sites should notify the team by sending an email to mtn030behavioralteam@mtncouncil.org.

General Use Instructions:

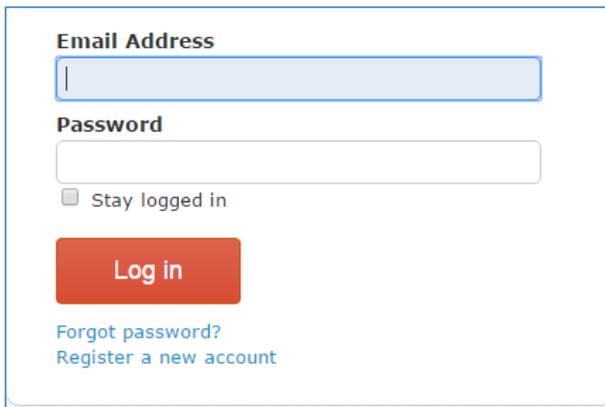
1. Inform the participant that the study procedures include responding to brief text messages about product use and bleeding on a daily basis, and that she will receive compensation per SMS session (compensation varies by site).
2. Determine whether the participant will receive the messages on her phone or a phone provided by the study.
3. Inform the participant that she can choose the most convenient time of the day to get the text message and that this time will be programmed once her information is entered into the system. The time can be changed later on by technical staff at the Population Council, if the participant makes a request that the site staff is not able to fulfill.
4. The participant should respond to an SMS daily immediately after receiving it during the 16 days of follow-up. Inform the participant that if she does not receive the daily SMS for any reason, to let the site staff know.
5. The participant should be informed that site staff will contact her if she has not sent any SMS text messages for 48 consecutive hours, in order to make sure that she is not having problems with the SMS system.
6. The participant should be reminded that her responses should be as honest as possible when answering the questions via SMS. Her responses will help to develop a product that will be useful to people like her.
7. Alert the participant that the SMS should not be used for reporting to the clinic staff any medical problems that may result from the ring. If the participant has any medical problems, she should contact the site clinic staff.
8. If product is permanently discontinued, you can go into the Telerivet portal, click on Messages, and then to Scheduled and edit the scheduled SMS series for the participant. This will allow you to either delete the series of upcoming SMS questions or adjust the schedule.

How to set up a user for SMS questions after enrollment into MTN-030.

1. From a browser, navigate to <https://www.telerivet.com>
2. Click **Sign In** at the top right of the web page.



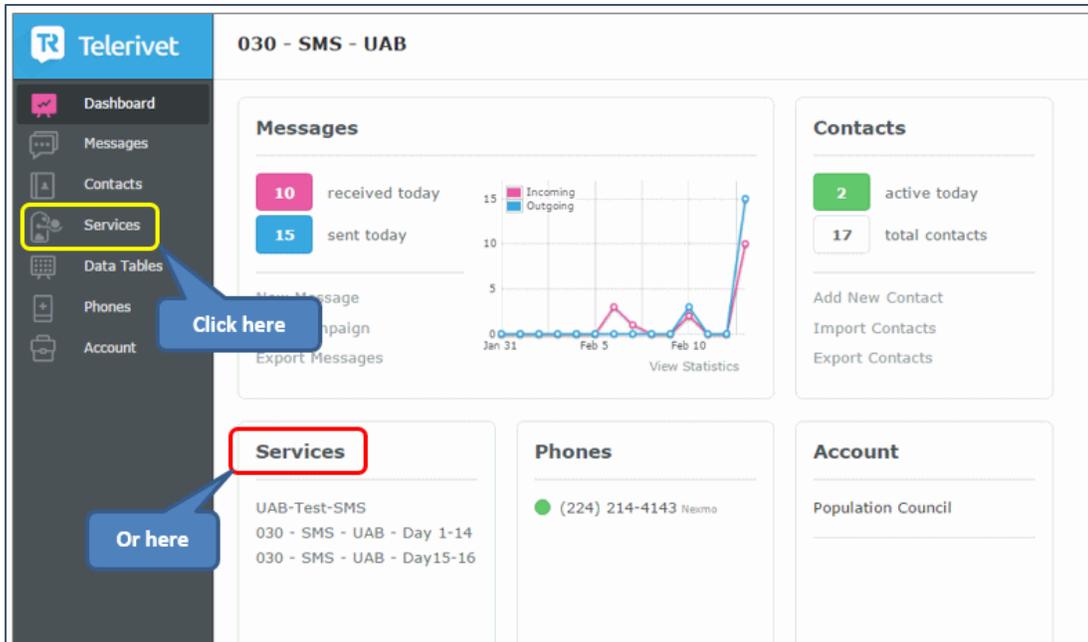
3. Enter the email address that was set up for you to access the SMS web portal.

A screenshot of the Telerivet login form. It contains two input fields: 'Email Address' and 'Password'. Below the password field is a checkbox labeled 'Stay logged in'. A red 'Log in' button is positioned below the checkbox. At the bottom of the form, there are two links: 'Forgot password?' and 'Register a new account'.

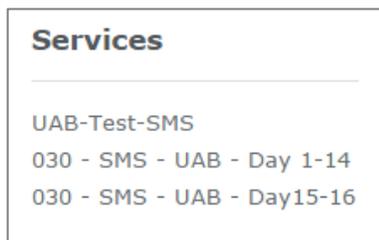
4. Enter the password which was provided to you.

Note: Each site is set up so that at least two staff members have access to the SMS portal. If additional user accounts are required, please contact Stan Mierzwa – smierzwa@popcouncil.org or Craig Savel – csavel@popcouncil.org. When user accounts are created, the user is notified via the email address they have provided that the SMS account has been established.

5. After successful login, you will be presented with a “dashboard” screen. From there you will need to choose **Services**, which you will find either on the gray navigation bar on the left side of the screen or the Services section itself, which is located in the middle portion of the screen (exact location will depend on Zoom value/amount).
6. Once you are in the Services section, select the Day 0-14 option for your site (**030 – SMS – UAB for the UAB site and 030 – SMS – PITT for the PITT site**). Participants/staff at each site will see only the services available for their site.



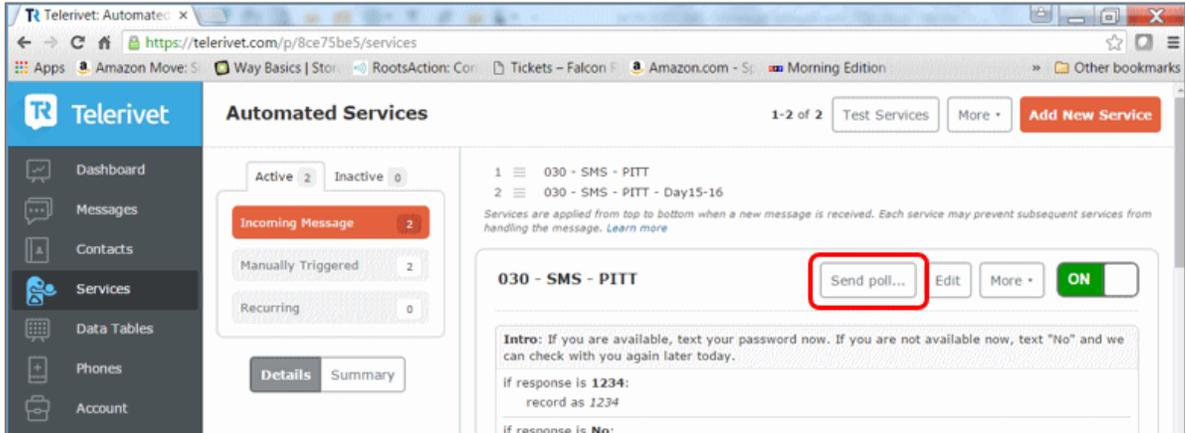
a. Below is an example for the UAB site.



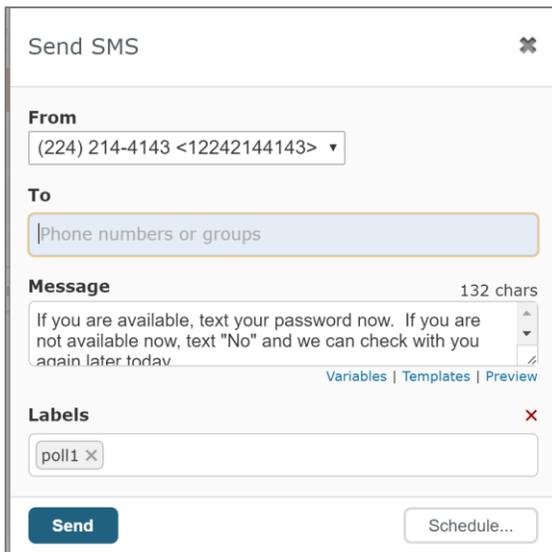
b. Staff at the Population Council will have access to the data for both sites.

Telerivet		Projects 1-2 of 2		
	Project Name	Organization Name	Contacts	Last Active
Projects	030 - SMS - PITT	Population Council	1	June 16
Account	030 - SMS - UAB	Population Council	11	June 16

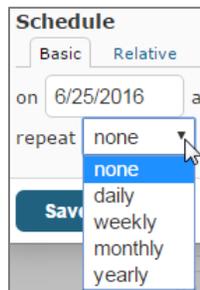
7. Click **Send Poll**.



8. The dialog box below will then allow you to configure the survey for the participant.



- Enter the cell phone number of the participant in the “To” field.
- Click **Schedule**.
- Enter the start date by clicking on the date that is displayed in the “on” field, and then click the drop-down menu next to **repeat** and select “daily” to repeat every 1 day.



- d. Click in the circle to indicate that the survey should end after "X" occurrences, with "X" being the date (within the 13-15 day post-randomization visit window) when the Day 14 Visit is scheduled to occur.

The screenshot shows a 'Send SMS' configuration window. It includes fields for 'From' (a dropdown menu with '(224) 214-4143 <12242144143>' selected), 'To' (a text input field with the placeholder 'Phone numbers or groups'), and 'Message' (a text area with 132 characters, containing the text: 'If you are available, text your password now. If you are not available now, text "No" and we can check with you again later today.'). Below the message are links for 'Variables', 'Templates', and 'Preview'. The 'Labels' section has a dropdown menu with 'UAB1-14' selected. The 'Schedule' section has two tabs: 'Basic' and 'Relative'. Under 'Basic', there are fields for 'start' (6/24/2016), 'at' (12:00 PM), and a time zone dropdown (CDT (UTC-4)). There is also a 'repeat' dropdown (daily) and an 'every' field (1 day(s)). The 'end' section has three radio buttons: 'never', 'after 14 occurrences' (which is selected), and 'on'.

- e. Ask the participant which time she would like the SMS survey to be sent every day and enter that in the "at" field

The screenshot shows a 'Schedule' configuration window. It has two tabs: 'Basic' and 'Relative'. Under 'Basic', there are fields for 'on' (6/16/2016), 'at' (12:00 PM), and a time zone dropdown (CDT (UTC-4)). There is also a 'repeat' dropdown (none). A 'Save' button is at the bottom.

- f. Click **Save**.

2. Next, click on the 030 – SMS – [UAB or PITT] – Day 15-16 Service. Based on your access, you will see either the UAB or PITT available system.
3. Click **Send poll**.
4. Enter the participant’s cell phone number in the “To” field.
5. Click **Schedule** and enter the date for the Day 15 SMS survey (that is, the Day 15 Visit target date) in the “on” field and the time the survey should be sent to the participant. If a participant doesn’t complete her Day 14 visit on her target date, you cannot re-schedule the individual SMS survey. However, it is possible to delay or re-schedule the day 15/16 SMS survey. Adjustments can be made to the number of occurrences necessary for SMS surveys.
6. Click the drop-down for repeat and select “daily,” every **1** day, and end after “Y” occurrences, with “Y” being the date when the Day 16 Visit is scheduled to occur.

repeat daily ▼

every day(s)

end never

after occurrences

on

Save

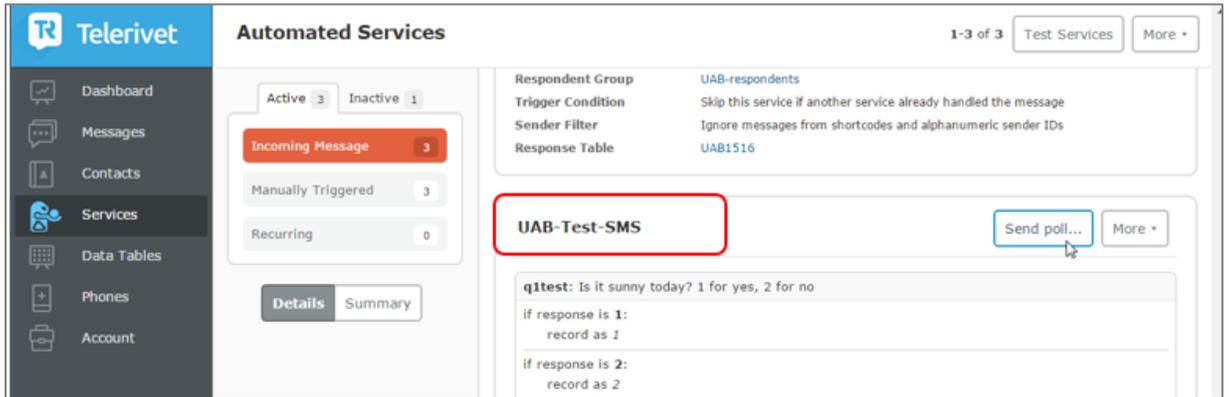
7. Click **Save**.
8. You can review the scheduled SMS for the participant by doing the following
 - a. From the left navigation bar, click “Messages”
 - b. Then click “Scheduled”, under Conversations
 - c. To the right on the screen, you will see all the scheduled SMS surveys, if greyed out, the surveys are completed; if not greyed out, they are still in cycle.

If the participant is not able to answer the survey questions when she receives the initial SMS, she has two options:

- *Enter “No”, and wait to be contacted by the site staff, who will be alerted by email that a survey was rejected. Site staff can then manually log back in to the portal and re-send the survey at different time.*
- *Alternatively, the participant can wait until she is ready to answer the questions and then enter her password, which will trigger the survey to begin.*

Practice with a Test Survey

1. If you would like to practice with a test survey, please use the scroll bar on the right to scroll down to the test SMS survey once you have logged into the Telerivet website. This will also ensure that the SMS surveys are working.



2. After you click “Send poll”, the dialog box below will appear, and will allow you to run the test survey. Enter the mobile phone number you would like to test (yours or the participant’s, for example).

You may choose to “Send” the message right away or Schedule it to be sent at a later time, as you would for the actual survey.

The 'Send SMS' dialog box is shown with the following fields and options:

- From:** (224) 214-4143 <12242144143>
- To:** Phone numbers or groups
- Message:** Is it sunny today? 1 for yes, 2 for no (38 chars). Below the message field are links for 'Variables', 'Templates', and 'Preview'.
- Labels:** UAB-Test
- Buttons:** 'Send' and 'Schedule...'

If you choose the **Schedule** option, you will click **Save** after you entered the time and date.

Send SMS
✕

From

(224) 214-4143 <12242144143> ▾

To

<9172324659> ✕

Message 38 chars

Is it sunny today? 1 for yes, 2 for no

G

[Variables](#) | [Templates](#) | [Preview](#)

Labels ✕

UAB-Test ✕

Schedule ✕

Basic
Relative

start at ▾

repeat ▾

every day(s)

end never

after occurrences

on

Save

SMS phone numbers assigned to the sites

Each of the sites has a pre-established SMS phone number that will be used to send the SMS surveys. Site staff may want to suggest that participants program the appropriate number listed below into their phones so that they are recognized by the participant when she receives the text messages. The numbers are assigned as follows:

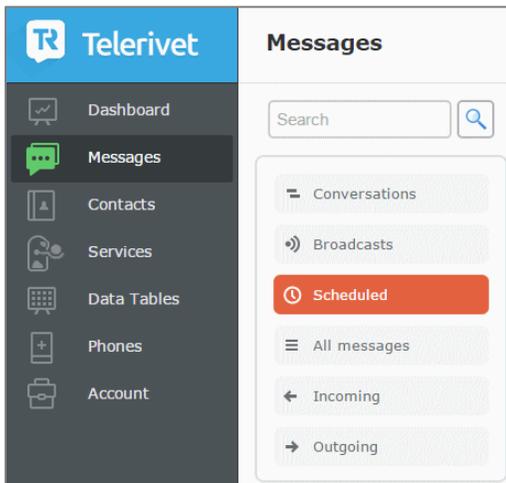
UAB – (224) 214-4143

PITT – (201) 241-3454

View a list of scheduled SMS messages

To view a list of scheduled messages set up as daily surveys, please do the following.

1. Log into the SMS portal.
2. Click on **Messages** in the left navigation bar.
3. Click on **Scheduled** – under the “Conversations”
4. From the **Scheduled** SMS it is possible for you to either delete the series if required, or to make adjustments to the schedule.



End of Day Check-in

Site staff are requested to log back in to the portal at the end of their work day to see if any surveys need to be resent because the participant was not able to complete it at the scheduled time. If any are found, staff should follow steps above to have the survey resent to the participant.

Log out of the SMS portal

1. After completing your analysis or work inside the SMS portal, please click “Log out” at the bottom of the left hand navigation bar to securely logout from the system.



Data Review

1. Login to the SMS dashboard portal at <https://www.telerivet.com>
2. From the left navigation bar, click “Data Tables”
3. Under Table Name – select the survey you wish to review, which would be either the Day 1-14 SMS survey (ex. UAB1-14) or Day 15-16 SMS survey (ex. UAB1516).

Data Tables
Table Name
UAB1-14
UAB1516

4. You are then presented with all collected data and can scroll to the right to see the resulting data. The responses to review include Q1, Q2, Q2a, Q2b, Q2c and the Date/Time the survey was created.
5. You can also quickly filter the SMS resulting data. For example: from the left navigation bar, Click “Contact Name”, select the logic such as “is” and enter a cell phone number and hit “Enter”. You will be presented with all SMS surveys completed from a participant’s specific cell phone.

UAB1-14		Contact Name	Phone Number
<input type="checkbox"/>	2017903556	+12017903556	
<input type="checkbox"/>	2017903556	+12017903556	
<input type="checkbox"/>	2017903556	+12017903556	
<input type="checkbox"/>	2017903556	+12017903556	

Rows Stats

Filters

Contact Name

is

is not

starts with

does not start with

alphabetically before

alphabetically after (or equal)

alphabetically between

has any value

does not have value

Final SMS Surveys

MTN-030/IPM-041

DAILY SMS (TEXT MESSAGE) QUESTIONS

Introduction

If you are available, text your password now.

If you are not available now, text “No” and we can check with you again later today.

Days 0-14

1. Have you had any spotting or bleeding in the last 24 hours? 1) no bleeding, 2) light bleeding, 3) moderate bleeding 4) heavy bleeding
2. Has the ring been out of your vagina (either partially or fully) at any time in the last 24 hours? Yes/no. If no, end of survey.
 - a. If yes to 2: Did you remove it? yes/no
 - b. If yes to 2: Did it fall out? 1. No, 2) yes partially, 3) yes fully
 - c. If yes to 2: Was it out for more than 3 hours? Yes/no

Days 15 and 16.

1. Have you had any spotting or bleeding in the last 24 hours? 1) no bleeding, 2) light bleeding, 3) moderate bleeding 4) heavy bleeding

MTN-030 SMS Codes

Day 1-14

Q Num	Question	Response Option	Response Code
Q1	Have you had any spotting or bleeding in the last 24 hours? 1 for no bleeding, 2 for light bleeding, 3 for moderate bleeding, 4 for heaving bleeding	1, 2, 3, 4	1, 2, 3, 4
Q2	Has the ring been out of your vagina (either partially or fully) at any time in the last 24 hours? Y for yes, n for no	y, n	y, n
Q2A	Did you remove it? Y for yes and n for no	y, n	y, n
Q2B	Did it fall out? 1 for no, 2 for yes partially, 3 for yes fully	1, 2, 3	1, 2, 3
Q2C	Was it out for more than 3 hours? Y for yes, n for no	y, n	y, n

**Day 15-
16**

Q Num	Question	Response Option	Response Code
Q1	Have you had any spotting or bleeding in the last 24 hours? 1 for no bleeding, 2 for light bleeding, 3 for moderate bleeding, 4 for heavy bleeding	1, 2, 3, 4	1, 2, 3, 4

Data Entry into the Bleeding SMS Electronic Case Report Form (eCRF)

At the Day 7, Day 14/PUEV, and Day 16 visits, entry of the bleeding SMS data is required into the Bleeding SMS eCRF in the MTN-030 Medidata Rave study database. Below is an example of completion of the Bleeding SMS eCRF based on the below SMS data output containing data for 4 separate text messages (one per row) from a participant.

Note: completion of this eCRF is required, even if no SMS data is available for the participant (i.e., she did not respond to any of the text messages or given questions).

Contact Name	Phone Number	Intro	Intro_code	q1	q1_code	q2	q2_code	q2a	q2a_code	q2b	q2b_code	q2c	q2c_code	Time Created
<input type="checkbox"/> 2017903556	+12017903556	1234	1234	1	1	N	n							8/10 11:50 am
<input type="checkbox"/> 2017903556	+12017903556	1234	1234	4	4	N	n							8/3 1:07 pm
<input type="checkbox"/> 2017903556	+12017903556	1234	1234	2	2	Y	y	N	n	2	2	Y	y	7/31 11:32 am
<input type="checkbox"/> 2017903556	+12017903556	1234	1234	4	4	N	n							6/28 1:21 pm

Complete one row in the eCRF for each row with a >1 response in the "q1_code" column.

- Enter the "Time Created" date as the "Date SMS Report of Spotting/Bleeding Sent by Participant".
- Enter the "SMS Description of Spotting/Bleeding" on the eCRF based on the code entered in the "q1_code" column (2=light bleeding, 3=moderate bleeding, 4=heavy bleeding).

Count the number of rows with a >1 response in the "q1_code" column and enter this number as the "# of spotting/bleeding" days on the eCRF.

If any responses in the "q1_code" column are >1, answer "Yes" to "Did the participant report any vaginal spotting or bleeding via SMS?"

Subject: 999251834
Page: Bleeding SMS - V6.0 - Day 7

Date of assessment	11 AUG 2017	
Did the participant report any vaginal spotting or bleeding via SMS?	Yes	
On how many days did the participant experience vaginal spotting or bleeding per SMS report?	3 # of spotting/bleeding days	
#	Date SMS Report of Spotting/Bleeding Sent by Participant	SMS Description of Spotting/Bleeding
1	3 AUG 2017	Heavy bleeding (leaked)
2	31 JUL 2017	Light bleeding (used panty liner, toilet paper or no protection)
3	28 JUN 2017	Heavy bleeding (leaked)

Data Entry into the Ring Outage SMS Electronic Case Report Form (eCRF)

At the Day 7 and Day 14/PUEV 16 visits, entry of the ring outage SMS data is required into the Ring Outage SMS eCRF in the MTN-030 Medidata Rave study database. Below is an example of completion of the Ring Outage SMS eCRF based on the below SMS data output containing data for 4 separate text messages from a participant.

Note: completion of this eCRF is required, even if no SMS data is available for the participant (i.e., she did not respond to any of the text messages or given questions).

Contact Name	Phone Number	Intro	Intro_code	q1	q1_code	q2	q2_code	q2a	q2a_code	q2b	q2b_code	q2c	q2c_code	Time Created	
<input type="checkbox"/>	2017903556	+12017903556	1234	1234	1	1	N	n						8/10 11:50 am	
<input type="checkbox"/>	2017903556	+12017903556	1234	1234	4	4	N	n						8/3 1:07 pm	
<input type="checkbox"/>	2017903556	+12017903556	1234	1234	2	2	Y	y	N	n	2	2	Y	y	7/31 11:32 am
<input type="checkbox"/>	2017903556	+12017903556	1234	1234	4	4	N	n						6/28 1:21 pm	

- Complete one row in the eCRF for each row with a yes response in the "q2_code" column.
- Enter the "Time Created" date as the "Date SMS Report of Ring Outage Sent by Participant".
 - Enter the "Did the participant remove the ring?" response on the eCRF based on the "q2a code" entered ("y" or "Y"=yes, "N" or "n"=no).
 - Enter the "Did the ring fall out?" response based on the "q2b_code" entered (1=no, 2=yes partially, 3=yes fully).
 - Enter the "Was the ring out for more than 3 hours?" response based on the "q2c code" entered ("Y" or "y"=yes, "N" or "n"=no).

Review "q2_code" responses for each row ("y" or "Y"=yes, "N" or "n"=no). If all are no, enter "No" for eCRF question "Did the participant report any partial or full ring outages via SMS?" If at least one yes response is present, enter "Yes" on the eCRF.

Count the number of yes rows in the "q2_code" column and enter this number as the "# of Days" with a ring outage on the eCRF.

subject: 999662765
 Page: Ring Outage SMS - V7.0 - Day 14

Date of assessment: 11 Aug 2017

Did the participant report any partial or full ring outages via SMS? Yes

On how many days did the participant report a ring outage (partial or full) via SMS: 1 # of Days

Currently viewing line 1 of 1. Click here to return to "Complete View".

Date SMS Report of Ring Outage Sent by Participant: 31 Jul 2017

Did the participant remove the ring? Yes No

Did the ring fall out? Yes Partially Yes Fully No

Was the ring out for more than 3 hours? Yes No