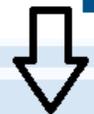


POINT Randomization Instructions

No.	Procedure	Notes/Troubleshooting
1	<p>A. Go to https://webdcu.musc.edu/ B. Enter user name (full email address) and password, click [Login] button. C. Click on [POINT].</p>	<ul style="list-style-type: none"> • If the study website is not accessible, call the WebDCU Randomization Emergency Hotline (1-866-450-2016). • If login failed but you have an active WebDCU account, click “Forgot Password” link to have a password sent to your email address. • If unsuccessful, find another study team member who can login/randomize. • If unsuccessful, call the WebDCU Randomization Emergency Hotline (1-866-450-2016).
2	<p>A. On the home screen you will see the ‘Add New Subject’ heading. B. If you have permissions at more than one spoke/site, select the appropriate spoke/site from the spoke drop-down box. C. Enter the date of enrollment. D. Click [Add Subject] button.</p>	<ul style="list-style-type: none"> • If you do not see the [Add Subject] button, you do not have the proper permissions. Find another team member who can add a subject/randomize. If no other team member is available, call the WebDCU Randomization Emergency Hotline (1-866-450-2016).
3	<p>A. After the above information is submitted, the subject ID will be assigned, the baseline/randomization forms will be posted, and you will be directed to the subject’s CRF collection schedule.</p>	
4	<p>A. Click on the icon for [00 Eligibility Form]. B. Enter Eligibility CRF data and click [Save Record] button. C. Click [Submit CRF] button.</p>	<ul style="list-style-type: none"> • All inclusion criteria questions must be answered ‘Yes’, and all exclusion criteria question must be answered ‘No’ in order to be eligible for the study. • If rule violation flags appear in red next to any question on the CRF after saving data, click [Edit CRF] to make data corrections. Then click [Save Record] again and [Submit CRF].
5	<p>A. Click on the ‘Subject CRF’ tab at the top of the screen, and then click the icon for [10 Randomization Form]. B. Enter Randomization CRF data and click [Save Record] button. C. Click [Submit CRF] button.</p>	<ul style="list-style-type: none"> • If rule violation flags appear in red next to any question on the CRF after data saving, click [Edit CRF] to make data corrections. Then click [Save Record] again and [Submit CRF]. • You must click [Submit CRF] to perform subject randomization. • If all eligibility criteria are not met, randomization will be blocked.
6	<p>A. Print the Randomization Verification Form ( link at top of Randomization Form) and bring to the pharmacy for completion. B. Pick the study drug bottle with the drug ID matching the ID number on the Randomization Verification Form.</p>	<ul style="list-style-type: none"> • If site pharmacist can’t find the study drug with the bottle ID listed on the randomization CRF, check if all study drug bottles received are placed in the correct location. • If problems can’t be resolved, call the WebDCU Randomization Emergency Hotline (1-866-450-2016) for help.
7	<p>A. Treat the subject. B. File Randomization Verification Form in subject record.</p>	<ul style="list-style-type: none"> • If the study drug bottle was found to be damaged before being used, call the WebDCU Randomization Emergency Hotline (1-866-450-2016) for help.
<p>Please print these instructions and post them in a location where study team members will have access while randomizing subjects.</p>		



Enrolled 61% (3569 / 5840) of Projected Subjects

Add New Subject

Harrison - Miguel Servet Hospital, Zaragoza, ESP **Baseline/Randomization** on

- Subject CRF Binder
- Study Progress
- Data Management
- Project Management
- Safety Monitoring
- Site Management
- Drug Tracking
- Data Monitoring
- CRF Data List
- Project Setup
- User Management
- Regulatory Document
- Toolbox
- Alerts



Subject 5471 CRF Binder

Miguel Servet Hospital, Zaragoza, ESP

Aaron PERLMUTTER Sign Out

Help

Hub: All Hubs | Site/Spoke: All Sites/Spokes | Subject: 5471 | Next Visit: | Date:

CRF	Baseline/Randomization	
	16-Apr-2016	Next Visit
F00 Eligibility Form	<input type="checkbox"/>	<input type="checkbox"/>
F10 Randomization Form	<input type="checkbox"/>	<input type="checkbox"/>
F01 Demographics	<input type="checkbox"/>	<input type="checkbox"/>
F02 ABCD ² Score	<input type="checkbox"/>	<input type="checkbox"/>
F04 NIH Stroke Scale	<input type="checkbox"/>	<input type="checkbox"/>
F05 Medical History	<input type="checkbox"/>	<input type="checkbox"/>
F06 Prior Medications	<input type="checkbox"/>	<input type="checkbox"/>
F07 Index TIA/Stroke Symptoms	<input type="checkbox"/>	<input type="checkbox"/>
F08 Vital Signs	<input type="checkbox"/>	<input type="checkbox"/>
F11 Head CT / MRI Scan	<input type="checkbox"/>	<input type="checkbox"/>
F12 Electrocardiogram	<input type="checkbox"/>	<input type="checkbox"/>
F13 Carotid Imaging Results	<input type="checkbox"/>	<input type="checkbox"/>
F19 SAE/Clinical Outcome Reporting Form	<input type="checkbox"/>	<input type="checkbox"/>
F20 Final Diagnosis	<input type="checkbox"/>	<input type="checkbox"/>
F21 Protocol Deviations/Violations	<input type="checkbox"/>	<input type="checkbox"/>
F22 Ancillary Biomarker	<input type="checkbox"/>	<input type="checkbox"/>



The task completed in 1.949219 sec

Edit: **F00 Eligibility Form**

Help

CRF ID: 131879	F00 Eligibility Form			Rule Status:	DCR
Site/Spoke: Miguel Servet Hospital, Zaragoza, ESP	Subject: 5471	Visit: Baseline/Randomization	Submit:	Accept:	Verify:

No.	Item Description	Data Value
This form must be data entered and submitted into WebDCU™ with all eligibility criteria met or randomization will be blocked.		
<p>To randomize a subject:</p> <ol style="list-style-type: none"> 1. Data enter this form. Then click save. Address any rule violations, then click submit. 2. Click on the [Subject CRF] tab at the top of the screen and then click on the Randomization Form (Form 10). Data enter the Randomization Form. Then click save. Address any rule violations, then click submit. 3. WebDCU™ will display the bottle number to be given to that subject. <p style="text-align: center; color: red;">Note: All eligibility criteria must be met or randomization will be blocked.</p>		
Patient's admission orders should be reviewed for POINT prohibited medications. Patient is ineligible for POINT if unwilling or unable to stop use of prohibited concomitant medications.		
40	Which version of the protocol is currently approved by your IRB? Answer the questions corresponding to the protocol version that is currently IRB approved at your site.	<input type="radio"/> Version 2.2 or earlier <input type="radio"/> Version 3 <input type="radio"/> Version 4 or later
1	Age (Study participant must be >= 18 years to be eligible.)	<input type="text"/> Years
3	Date of TIA/minor stroke onset	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd-mmm-yyyy) Complete
4	Time of TIA/minor stroke onset: For subjects where time of onset is not known, enter the time the subject was last known to be free of new ischemic symptoms. Subject must be randomized within 12 hours of symptom onset.	hh <input type="text"/> : mm <input type="text"/> (24hr clock) Complete Time
44	Have the subject's neurologic symptoms associated with the index event completely resolved at the time of randomization?	<input type="radio"/> No <input type="radio"/> Yes
45	Is there evidence on head CT or MRI of acute infarct at the time of randomization?	<input type="radio"/> No <input type="radio"/> Yes
INCLUSION CRITERIA: To be eligible, all questions in this section should be answered YES.		
	Neurologic deficit (based on history or exam) attributed to focal brain ischemia and EITHER:	

	Note: M/CUMM = $10^{12}/L = 10^6/mm^3 = 10^6/uL$		M/CUMM
35	Hemoglobin	<input type="text" value="65"/>	
49	Hemoglobin unit	<input checked="" type="radio"/> g/dL <input type="radio"/> G/L <input type="radio"/> mmol/L	
36	Hematocrit	<input type="text" value="57"/>	
50	Hematocrit unit	<input type="radio"/> % <input checked="" type="radio"/> L/L	
37	Platelet count (must be $\geq 100 \times 10^9/l$ for randomization) Note: K/CUMM = $10^9/L = 10^3/mm^3 = 10^3/uL$	<input type="text" value="112"/>	K/CUMM

Mytrus Video

51	Was the subject shown any portion of the Mytrus video during the consenting process? If no, skip to Question 38.	<input checked="" type="radio"/> No <input type="radio"/> Yes
52	Mytrus ID	<input type="text"/>

This subject's eligibility must be reviewed by a physician investigator or randomization will be blocked.

38	Last name of reviewing physician investigator	<input type="text" value="Perlmutter"/>	(50 char.)
39	Date of physician investigator review	<input type="text" value="16"/> <input type="text" value="Apr"/> <input type="text" value="2016"/> <input type="text"/>	(dd-mmm-yyyy) Complete
c	General Comments	<input type="text"/>	(250 char.)

Reminders:

1. Review the subject's admission orders for POINT prohibited medications.
2. Notify the patient's primary care physician of this subject's participation in this trial.

This form must be data entered and submitted into WebDCU™ with all eligibility criteria met or randomization will be blocked.

To randomize a subject:

1. Data enter this form. Then click save. Address any rule violations, then click submit.
2. Click on the [Subject CRF] tab at the top of the screen and then click on the Randomization Form (Form 10). Data enter the Randomization Form. Then click save. Address any rule violations, then click submit.
3. WebDCU™ will display the bottle number to be given to that subject.

Note: All eligibility criteria must be met or randomization will be blocked.

Last updated by Aaron PERLMUTTER on 20-Apr-2016 12:05PM





Subject
CRF

View: F00 Eligibility Form

Help

Submit CRF

Edit CRF

Delete CRF Data

View Audit trail

CRF ID: 131879	F00 Eligibility Form			Rule Status:	DCR:
Site/Spoke: Miguel Servet Hospital, Zaragoza, ESP	Subject: 5471	Visit: Baseline/Randomization	Submit:	Accept:	Verify:

Ready to Submit

This form has been data entered and has passed all rule checks. Please submit this CRF, if no edits to the data are currently required.

No.	Item Description	Data Value
This form must be data entered and submitted into WebDCU™ with all eligibility criteria met or randomization will be blocked.		
<p>To randomize a subject:</p> <ol style="list-style-type: none"> 1. Data enter this form. Then click save. Address any rule violations, then click submit. 2. Click on the [Subject CRF] tab at the top of the screen and then click on the Randomization Form (Form 10). Data enter the Randomization Form. Then click save. Address any rule violations, then click submit. 3. WebDCU™ will display the bottle number to be given to that subject. <p>Note: All eligibility criteria must be met or randomization will be blocked.</p> <p>Patient's admission orders should be reviewed for POINT prohibited medications. Patient is ineligible for POINT if unwilling or unable to stop use of prohibited concomitant medications.</p>		
40	Which version of the protocol is currently approved by your IRB? Answer the questions corresponding to the protocol version that is currently IRB approved at your site.	<input type="radio"/> Version 2.2 or earlier <input type="radio"/> Version 3 <input checked="" type="radio"/> Version 4 or later
1	Age (Study participant must be >= 18 years to be eligible.)	90 Years <input type="text"/>
3	Date of TIA/minor stroke onset	20-Apr-2016 (dd-mmm-yyyy)
4	Time of TIA/minor stroke onset: For subjects where time of onset is not known, enter the time the subject was last known to be free of new ischemic symptoms. Subject must be randomized within 12 hours of symptom onset.	17:11 (24hr clock) Complete Time
44	Have the subject's neurologic symptoms associated with the index event completely resolved at the time of randomization?	<input type="radio"/> No <input checked="" type="radio"/> Yes
45	Is there evidence on head CT or MRI of acute infarct at the time of randomization?	<input checked="" type="radio"/> No <input type="radio"/> Yes



Subject 5471 CRF Binder

Miguel Servet Hospital, Zaragoza, ESP

Help

Hub: All Hubs | Site/Spoke: All Sites/Spokes | Subject: 5471 | Next Visit: [] | Date: []

CRF	Baseline/Randomization 16-Apr-2016
F00 Eligibility Form	
F10 Randomization Form	
F01 Demographics	
F02 ABCD^2 Score	
F04 NIH Stroke Scale	
F05 Medical History	
F06 Prior Medications	
F07 Index TIA/Stroke Symptoms	
F08 Vital Signs	
F11 Head CT / MRI Scan	
F12 Electrocardiogram	
F13 Carotid Imaging Results	
F19 SAE/Clinical Outcome Reporting Form	
F20 Final Diagnosis	
F21 Protocol Deviations/Violations	
F22 Ancillary Biomarker	



The task completed in 0.9648438 sec



Edit: F10 Randomization Form

Help

CRF ID: 131887	F10 Randomization Form			Rule Status:	DCR
Site/Spoke: Miguel Servet Hospital, Zaragoza, ESP	Subject: 5471	Visit: Baseline/Randomization	Submit:	Accept:	Verify:

No.	Item Description	Data Value
<p>Before this form can be submitted and a randomization number assigned to this subject, the Eligibility Form (Form 00) must be data entered and submitted into WebDCU™ with all eligibility criteria met. A study team member should witness the ingestion of the initial loading dose of 600mg of study drug.</p>		
1	Is this patient deemed to be eligible for randomization?	<input type="radio"/> No <input checked="" type="radio"/> Yes
3	Date of randomization	16 Apr 2016  (dd-mmm-yyyy) Complete
2	Time of randomization (local time)	18 : 04 (24hr clock) Complete Time

The randomization assignment provided by WebDCU™ (or the emergency hotline) must match the Study Drug ID on the bottle dispensed for the subject. Pharmacists and Investigators are responsible for confirming this information **before the loading dose is administered.**

Study drug loading dose must be given within 2 hours of randomization.

This form must be **SUBMITTED** to receive the randomization assignment for this subject.

c	General Comments	<input type="text" value=""/> (250 char.)
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Save Record

Cancel Edit

Be sure to select only the bottle labeled with the randomization number (study drug ID) that matches the number assigned by WebDCU.



POINT Randomization Verification Form

This form should be filed with the other source documents for this subject.

Subject : #####

Study Drug ID assigned by WebDCU™ : 11761

The number on the study drug bottle selected must match this number.

Number on bottle retrieved from the pharmacy/other study drug storage location : _____

Signature of the person verifying WebDCU Study Drug ID matches the number on the bottle retrieved from the pharmacy/other study drug storage location. This verification must take place prior to loading dose administration : _____

Printed name of the person listed above : _____

Date : _____

The POINT WebDCU™ Emergency Randomization Hot Line is: 1-866-450-2016

Bottle Label



Protocol Number: NCT00992019

EudraCT Number: 2013-001185-41

Study Drug Bottle Number: 11761

Matches study drug ID from WebDCU, ok to select.

Lot Number: 5

Expiration Date: 09/2017

Investigator Name: _____

Site: _____



POINT Randomization Verification Form

This form should be filed with the other source documents for this subject.

Subject : #####

Study Drug ID assigned by WebDCU™ : 13310

Number on bottle retrieved from the pharmacy/other study drug storage location : _____

Signature of the person verifying WebDCU Study Drug ID matches the number on the bottle retrieved from the pharmacy/other study drug storage location. This verification must take place prior to loading dose administration : _____

Printed name of the person listed above : _____

Date : _____

The POINT WebDCU™ Emergency Randomization Hot Line is: 1-866-450-2016

Bottle Label

Protocol Number: NCT00992019
EudraCT Number: 2013-001185-41
Study Drug Bottle Number: 13301 ← Does not match.
Lot Number: 5
Expiration Date: 09/2017
Investigator Name: _____
Site: _____

DO NOT SELECT!