

Dataset name: adev_v2.0

Participant ID pid Acrostic acrostic
Interviewer compby Visit Code vc
Date of Notification vis_dat (mm/dd/yyyy)

Adverse Event Form

CRF 2.0

1. Date of Event eventdate_adev (mm/dd/yyyy) (events marked below occurred on this date)

(Interviewer Note: All adverse events occurring on the same date but that do not have the same underlying pathophysiological cause must have a separate Adverse Event Form.)

2. Who is reporting the event?

reporter_adev

-9
1 Participant
2 Spouse/Proxy
3 Other
-6 Permanently Missing

Other (specify) othreport_adev

3. Did the event occur to a randomized participant?

randomized_adev

-9
1 Yes
0 No
-6 Permanently Missing

4. Were any of the following mentioned?

a. Death	death_adev value="1" <input type="checkbox"/>
b. In-patient hospitalization	hospital_adev value="1" <input type="checkbox"/>
c. Emergency Room or Urgent Care Visit	emroom_adev value="1" <input type="checkbox"/>
d. Fracture	fracture_adev value="1" <input type="checkbox"/>
e. Outpatient surgery	outpsurg_adev value="1" <input type="checkbox"/>
f. Life threatening illness or accident	lte_adev value="1" <input type="checkbox"/>
g. Permanent disability or incapacity	disability_adev value="1" <input type="checkbox"/>

h. Abnormal laboratory or diagnostic test result requiring immediate medical attention	sigclinic_adev value="1" <input type="checkbox"/>
i. Other serious illness that might have resulted in an SAE without aggressive medical intervention	otherevent_adev value="1" <input type="checkbox"/>

j. Restricted activity due to health problem potentially related to the study activity that led to an inability to leave home for at least ONE week	restrict_adev value="1" <input type="checkbox"/>
1. Foot Ulcer	footulcr_adev value="1" <input type="checkbox"/>
2. Muscle or Joint aching	musache_adev value="1" <input type="checkbox"/>
3. Muscle or Joint stiffness	musstif_adev value="1" <input type="checkbox"/>
4. Back pain	backinj_adev value="1" <input type="checkbox"/>
5. Foot Pain	footpain_adev value="1" <input type="checkbox"/>
6. Dizziness	dizznes_adev value="1" <input type="checkbox"/>
7. Fatigue	fatigue_adev value="1" <input type="checkbox"/>
8. Fainting or loss of consciousness	fainting_adev value="1" <input type="checkbox"/>
9. Shortness of breath or asthma	shrtbrth_adev value="1" <input type="checkbox"/>
10. Abnormal heart rhythm	hrtrhyth_adev value="1" <input type="checkbox"/>
11. Fall	fall_adev value="1" <input type="checkbox"/>
12. Any other health problem or symptom	othprb_adev value="1" <input type="checkbox"/>

Please specify: othprbsp_adev

k. Unexpected event that may be related to study procedures	unexpected_adev value="1" <input type="checkbox"/>
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Please specify: unexpspc_adev

l. Adverse event occurred while under the supervision or guidance of study related personnel	atsite_adev value="1" <input type="checkbox"/>
1. Adverse event that meets criteria (A-J above) for SAE	aesae_adev value="1" <input type="checkbox"/>

2. Event requiring active intervention by research staff to reduce potential harm	actint_adev value="1" <input type="checkbox"/>
3. Chest pain for more than two minutes after stopping exercise	chest2_adev value="1" <input type="checkbox"/>
4. Dyspnea for more than two minutes after stopping exercise	dysp2_adev value="1" <input type="checkbox"/>
5. Vital signs out of range (systolic BP >= 250 or diastolic >= 115) for more than two minutes after stopping exercise	vital2_adev value="1" <input type="checkbox"/>
6. A fall during study recommended activity	falldur_adev value="1" <input type="checkbox"/>
7. A symptom or illness that developed and required medical management or attention	sympmed_adev value="1" <input type="checkbox"/>
8. Other	atother_adev value="1" <input type="checkbox"/>

Please specify: atotherspc_adev

Event Number: eventnum_adev

05260



Source Form Language: lang

-9 -
1 English
2 Spanish

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<div style="border: 1px solid black; padding: 5px; margin: 0 auto; width: 80%;"> <div style="text-align: center; margin-bottom: 5px;">Participant ID</div> <div style="border: 1px solid black; display: inline-block; width: 100px; height: 20px; margin: 0 auto;"></div> <div style="text-align: center; margin-top: 5px;">(affix ID label here)</div> </div>	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="font-size: 2em; font-weight: bold; letter-spacing: 0.5em;">LIFE</div> <div style="text-align: right;"> Acrostic <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> </div> </div> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 10px;"> <div style="text-align: center;"> Interviewer <div style="border: 1px solid black; display: inline-block; width: 60px; height: 20px;"></div> </div> <div style="text-align: center;"> Visit Code <div style="border: 1px solid black; display: inline-block; width: 60px; height: 20px; text-align: center; font-weight: bold; font-size: 0.8em;">N S V</div> </div> </div> <div style="display: flex; justify-content: space-between; align-items: center; margin-top: 10px;"> <div style="text-align: center;"> Date of Notification <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> </div> <div style="text-align: center;"> <div style="border: 1px solid black; display: inline-block; width: 40px; height: 20px;"></div> </div> <div style="text-align: center;"> <div style="border: 1px solid black; display: inline-block; width: 60px; height: 20px;"></div> </div> </div> <div style="display: flex; justify-content: space-around; font-size: 0.7em; margin-top: 5px;"> month day year </div>
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Adverse Event Form

1. Date of Event: / / (events marked below occurred on this date)

(Interviewer Note: All adverse events occurring on the same date but that do not have the same underlying pathophysiological cause must have a separate Adverse Event Form.)

2. Who is reporting the event?

- ☐ Participant
- ☐ Spouse/Proxy
- ☐ Other (specify) _____

3. Did the event occur to a randomized participant? ☐ Yes ☐ No

4. Were any of the following mentioned?

A. Death	<input type="checkbox"/>	
B. In-patient hospitalization	<input type="checkbox"/>	
C. Emergency Room or Urgent Care Visit	<input type="checkbox"/>	
D. Fracture	<input type="checkbox"/>	
E. Outpatient surgery	<input type="checkbox"/>	
F. Life threatening illness or accident	<input type="checkbox"/>	
G. Permanent disability or incapacity	<input type="checkbox"/>	
H. Abnormal laboratory or diagnostic test result requiring immediate medical attention	<input type="checkbox"/>	
I. Other serious illness that might have resulted in an SAE without aggressive medical intervention	<input type="checkbox"/>	

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Participant ID
(affix ID label here)

LIFE

Acrostic

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Visit
Code

N	S	V
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J. Restricted activity due to health problem potentially related to the study activity that led to an inability to leave home for at least ONE week

1. Foot ulcer	<input type="checkbox"/>
2. Muscle or joint aching	<input type="checkbox"/>
3. Muscle or joint stiffness	<input type="checkbox"/>
4. Back pain	<input type="checkbox"/>
5. Foot pain	<input type="checkbox"/>
6. Dizziness	<input type="checkbox"/>
7. Fatigue	<input type="checkbox"/>
8. Fainting or loss of consciousness	<input type="checkbox"/>
9. Shortness of breath or asthma	<input type="checkbox"/>
10. Abnormal heart rhythm	<input type="checkbox"/>
11. Fall	<input type="checkbox"/>
12. Any other health problem or symptom Please specify: <input type="text"/>	<input type="checkbox"/>

K. Unexpected event that may be related to study procedures
Please specify:

L. Adverse event occurred while under the supervision or guidance of study related personnel

1. Adverse event that meets criteria (A-J above) for SAE	<input type="checkbox"/>
2. Event requiring active intervention by research staff to reduce potential harm	<input type="checkbox"/>
3. Chest pain for more than two minutes after stopping exercise	<input type="checkbox"/>
4. Dyspnea for more than two minutes after stopping exercise	<input type="checkbox"/>
5. Vital signs out of range (systolic BP \geq 250 or diastolic \geq 115) for more than two minutes after stopping exercise	<input type="checkbox"/>
6. A fall during study recommended activity	<input type="checkbox"/>
7. A symptom or illness that developed and required medical management or attention	<input type="checkbox"/>
8. Other Please specify: <input type="text"/>	<input type="checkbox"/>