

Side Effect Tracking

Record ID

Participant information:

[phone_screen_arm_1][fname]

[phone_screen_arm_1][lname]

[phone_screen_arm_1][phone_number_main]

Max Side Effect Intensity reported by patient was:

(If a Code 3, this is a possible SAE and must be reviewed by the HCP immediately.)

Code 2 Side Effect Endorsements
(symptom interferes with some daily activities)

Code 2 events limited to:

- cardiac symptoms (irregular heartbeat or palpitations, increased heart rate, chest pain),
- dermatologic symptoms (skin swelling, skin rash or redness (not sunburn)),
- depressed mood,
- specific gastrointestinal symptoms (vomiting, indigestion), and
- specific sleep problems (insomnia, abnormal dreams)

Code 3 Side Effect Endorsements
(no normal activities are possible)

-any symptom

Irritability

In: [intake_arm_1][irritability]

V1: [ta_v1_arm_1][irritability]

V2: [ta_v2_tqd_arm_1][irritability]

V3: [ta_v3_arm_1][irritability]

V4: [ta_v4_eot_arm_1][irritability]

V5: [ta_v5_3mth_arm_1][irritability]

☐ None

☐ Does not interfere with daily activities

☐ Interferes with some activities

☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Agitation

In: [intake_arm_1][agitation]

V1: [ta_v1_arm_1][agitation]

V2: [ta_v2_tqd_arm_1][agitation]

V3: [ta_v3_arm_1][agitation]

V4: [ta_v4_eot_arm_1][agitation]

V5: [ta_v5_3mth_arm_1][agitation]

☐ None

☐ Does not interfere with daily activities

☐ Interferes with some activities

☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Hostility

In: [intake_arm_1][hostility]

V1: [ta_v1_arm_1][hostility]

V2: [ta_v2_tqd_arm_1][hostility]

V3: [ta_v3_arm_1][hostility]

V4: [ta_v4_eot_arm_1][hostility]

V5: [ta_v5_3mth_arm_1][hostility]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Irregular heartbeat or palpitations

In: [intake_arm_1][irregular_heartbeat]

V1: [ta_v1_arm_1][irregular_heartbeat]

V2: [ta_v2_tqd_arm_1][irregular_heartbeat]

V3: [ta_v3_arm_1][irregular_heartbeat]

V4: [ta_v4_eot_arm_1][irregular_heartbeat]

V5: [ta_v5_3mth_arm_1][irregular_heartbeat]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Increased Heart Rate

In: [intake_arm_1][incrs_heart_rate]

V1: [ta_v1_arm_1][incrs_heart_rate]

V2: [ta_v2_tqd_arm_1][incrs_heart_rate]

V3: [ta_v3_arm_1][incrs_heart_rate]

V4: [ta_v4_eot_arm_1][incrs_heart_rate]

V5: [ta_v5_3mth_arm_1][incrs_heart_rate]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Chest Pain

In: [intake_arm_1][chest_pain]

V1: [ta_v1_arm_1][chest_pain]

V2: [ta_v2_tqd_arm_1][chest_pain]

V3: [ta_v3_arm_1][chest_pain]

V4: [ta_v4_eot_arm_1][chest_pain]

V5: [ta_v5_3mth_arm_1][chest_pain]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Depressed Mood

In: [intake_arm_1][depressed_mood]

V1: [ta_v1_arm_1][depressed_mood]

V2: [ta_v2_tqd_arm_1][depressed_mood]

V3: [ta_v3_arm_1][depressed_mood]

V4: [ta_v4_eot_arm_1][depressed_mood]

V5: [ta_v5_3mth_arm_1][depressed_mood]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Nausea

In: [intake_arm_1][nausea]

V1: [ta_v1_arm_1][nausea]

V2: [ta_v2_tqd_arm_1][nausea]

V3: [ta_v3_arm_1][nausea]

V4: [ta_v4_eot_arm_1][nausea]

V5: [ta_v5_3mth_arm_1][nausea]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Vomiting

In: [intake_arm_1][vomiting]

V1: [ta_v1_arm_1][vomiting]

V2: [ta_v2_tqd_arm_1][vomiting]

V3: [ta_v3_arm_1][vomiting]

V4: [ta_v4_eot_arm_1][vomiting]

V5: [ta_v5_3mth_arm_1][vomiting]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Abdominal_Pain In: [intake_arm_1][abdominal_pain] V1: [ta_v1_arm_1][abdominal_pain] V2: [ta_v2_tqd_arm_1][abdominal_pain] V3: [ta_v3_arm_1][abdominal_pain] V4: [ta_v4_eot_arm_1][abdominal_pain] V5: [ta_v5_3mth_arm_1][abdominal_pain]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Constipation In: [intake_arm_1][constipation] V1: [ta_v1_arm_1][constipation] V2: [ta_v2_tqd_arm_1][constipation] V3: [ta_v3_arm_1][constipation] V4: [ta_v4_eot_arm_1][constipation] V5: [ta_v5_3mth_arm_1][constipation]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Diarrhea In: [intake_arm_1][diarrhea] V1: [ta_v1_arm_1][diarrhea] V2: [ta_v2_tqd_arm_1][diarrhea] V3: [ta_v3_arm_1][diarrhea] V4: [ta_v4_eot_arm_1][diarrhea] V5: [ta_v5_3mth_arm_1][diarrhea]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Dry_Mouth In: [intake_arm_1][dry_mouth] V1: [ta_v1_arm_1][dry_mouth] V2: [ta_v2_tqd_arm_1][dry_mouth] V3: [ta_v3_arm_1][dry_mouth] V4: [ta_v4_eot_arm_1][dry_mouth] V5: [ta_v5_3mth_arm_1][dry_mouth]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Indigestion In: [intake_arm_1][indigestion] V1: [ta_v1_arm_1][indigestion] V2: [ta_v2_tqd_arm_1][indigestion] V3: [ta_v3_arm_1][indigestion] V4: [ta_v4_eot_arm_1][indigestion] V5: [ta_v5_3mth_arm_1][indigestion]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Gas or Flatulence In: [intake_arm_1][gas] V1: [ta_v1_arm_1][gas] V2: [ta_v2_tqd_arm_1][gas] V3: [ta_v3_arm_1][gas] V4: [ta_v4_eot_arm_1][gas] V5: [ta_v5_3mth_arm_1][gas]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Anxiety In: [intake_arm_1][anxiety] V1: [ta_v1_arm_1][anxiety] V2: [ta_v2_tqd_arm_1][anxiety] V3: [ta_v3_arm_1][anxiety] V4: [ta_v4_eot_arm_1][anxiety] V5: [ta_v5_3mth_arm_1][anxiety]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)

Skin Swelling In: [intake_arm_1][skin_swelling] V1: [ta_v1_arm_1][skin_swelling] V2: [ta_v2_tqd_arm_1][skin_swelling] V3: [ta_v3_arm_1][skin_swelling] V4: [ta_v4_eot_arm_1][skin_swelling] V5: [ta_v5_3mth_arm_1][skin_swelling]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Rash or Skin Redness (not sunburn) In: [intake_arm_1][redness] V1: [ta_v1_arm_1][redness] V2: [ta_v2_tqd_arm_1][redness] V3: [ta_v3_arm_1][redness] V4: [ta_v4_eot_arm_1][redness] V5: [ta_v5_3mth_arm_1][redness]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Headache In: [intake_arm_1][headache] V1: [ta_v1_arm_1][headache] V2: [ta_v2_tqd_arm_1][headache] V3: [ta_v3_arm_1][headache] V4: [ta_v4_eot_arm_1][headache] V5: [ta_v5_3mth_arm_1][headache]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Dizziness In: [intake_arm_1][dizziness] V1: [ta_v1_arm_1][dizziness] V2: [ta_v2_tqd_arm_1][dizziness] V3: [ta_v3_arm_1][dizziness] V4: [ta_v4_eot_arm_1][dizziness] V5: [ta_v5_3mth_arm_1][dizziness]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Insomnia In: [intake_arm_1][insomnia] V1: [ta_v1_arm_1][insomnia] V2: [ta_v2_tqd_arm_1][insomnia] V3: [ta_v3_arm_1][insomnia] V4: [ta_v4_eot_arm_1][insomnia] V5: [ta_v5_3mth_arm_1][insomnia]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Abnormal dreams In: [intake_arm_1][abnormal_dreams] V1: [ta_v1_arm_1][abnormal_dreams] V2: [ta_v2_tqd_arm_1][abnormal_dreams] V3: [ta_v3_arm_1][abnormal_dreams] V4: [ta_v4_eot_arm_1][abnormal_dreams] V5: [ta_v5_3mth_arm_1][abnormal_dreams]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)
Sleepwalking In: [intake_arm_1][sleepwalking] V1: [ta_v1_arm_1][sleepwalking] V2: [ta_v2_tqd_arm_1][sleepwalking] V3: [ta_v3_arm_1][sleepwalking] V4: [ta_v4_eot_arm_1][sleepwalking] V5: [ta_v5_3mth_arm_1][sleepwalking]	☐ None ☐ Does not interfere with daily activities ☐ Interferes with some activities ☐ No normal activities are possible (The HCP can recode the symptom using the radio buttons above)

Other Sleep Problems

In: [intake_arm_1][other_sleep_problems]

V1: [ta_v1_arm_1][other_sleep_problems]

V2: [ta_v2_tqd_arm_1][other_sleep_problems]

V3: [ta_v3_arm_1][other_sleep_problems]

V4: [ta_v4_eot_arm_1][other_sleep_problems]

V5: [ta_v5_3mth_arm_1][other_sleep_problems]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Other Concern or Experience

In: [intake_arm_1][otherseimpact]

V1: [ta_v1_arm_1][otherseimpact]

V2: [ta_v2_tqd_arm_1][otherseimpact]

V3: [ta_v3_arm_1][otherseimpact]

V4: [ta_v4_eot_arm_1][otherseimpact]

V5: [ta_v5_3mth_arm_1][otherseimpact]

☐ None☐ Does not interfere with daily activities☐ Interferes with some activities☐ No normal activities are possible

(The HCP can recode the symptom using the radio buttons above)

Brief descriptions

In: [intake_arm_1][othersetext]

V1: [ta_v1_arm_1][othersetext]

V2: [ta_v2_tqd_arm_1][othersetext]

V3: [ta_v3_arm_1][othersetext]

V4: [ta_v4_eot_arm_1][othersetext]

V5: [ta_v5_3mth_arm_1][othersetext]

STAFF: Are there any symptoms listed above for the current visit?☐ No☐ Yes

(If NO, submit the form as complete. If YES, save as unverified and send the link to HCP/PI per the EvarQuit SE and SAE manual.)

STAFF: You just indicated that you're having [moderate/severe... symptoms noted above].

What would you attribute this to? How long have you been experiencing the symptom? Anything done to treat this symptom? What normal daily activities have been impacted and how?

(Please add your name, the date, and time once you complete this field. Save the instrument as unverified after you are done. Then email Dr. Mahoney to inform him that this participant has a SEC/SAE to be reviewed.)

STAFF: Is participant currently smoking?☐ Yes☐ No

Note: For the fields below, a value of 1 indicates that cigarettes have been used in the past 7 days of the visit, according to the TLFB Set-Up form

Intake: [intake_arm_1][cigs]

T/A 1: [ta_v1_arm_1][cigs]

T/A 2: [ta_v2_tqd_arm_1][cigs]

T/A 3: [ta_v3_arm_1][cigs]

T/A 4: [ta_v4_eot_arm_1][cigs]

T/A 5: [ta_v5_3mth_arm_1][cigs]

STAFF: Is participant currently taking study medication?

- ☐ Yes
☐ No

Note: For the fields below, a value of 1 indicates that NRT patches have been used in the past 7 days, according to the TLFB Set-Up form

Intake: [intake_arm_1][nrtpatch]
T/A 1: [ta_v1_arm_1][nrtpatch]
T/A 2: [ta_v2_tqd_arm_1][nrtpatch]
T/A 3: [ta_v3_arm_1][nrtpatch]
T/A 4: [ta_v4_eot_arm_1][nrtpatch]
T/A 5: [ta_v5_3mth_arm_1][nrtpatch]

Note: For the fields below, a value of 1 indicates that NRT lozenges have been used in the past 7 days, according to the TLFB Set-Up form

Intake: [intake_arm_1][nrtloz]
T/A 1: [ta_v1_arm_1][nrtloz]
T/A 2: [ta_v2_tqd_arm_1][nrtloz]
T/A 3: [ta_v3_arm_1][nrtloz]
T/A 4: [ta_v4_eot_arm_1][nrtloz]
T/A 5: [ta_v5_3mth_arm_1][nrtloz]

HCP/PI - If you made any code changes with the radio buttons above, provide a rationale in the text box below:

HCP/PI - Order/Instructions:

(Please provide instructions to the staff about how the treatment should proceed (e.g., continue medication, discontinue medication, decrease dosage, etc.).)

HCP/PI - Is this an SAE?

- ☐ No
☐ Yes
(An SAE is any adverse event, without regard to causality, that is life-threatening or that results in any of the following outcomes: death; in-patient hospitalization or prolongation of existing hospitalization; persistent or significant disability or incapacity; or a congenital anomaly or birth defect. Any other medical that, in the medical judgment of the Principal Investigator/Study Physician, may jeopardize the subject or may require medical or surgical intervention to prevent one of the outcomes listed above is also considered a SAE. A planned medical or surgical procedure is not, in itself, an SAE, even if hospitalization is necessary.)

HCP/PI - Response re: ppt continuation in study

- ☐ Participant may continue in the trial
☐ Participant may NOT continue in the trial
☐ Participant opts to withdraw from study

HCP/PI - Response re: medication

- ☐ Study medication should be continued
☐ Study medication should NOT be continued
☐ Dose adjustments recommended _____
-

HCP/PI Response Other comments

(HCP will document important SAE chars. here, including attribution.)