calerie Phase 2

Signs, Symptoms and Adverse Events Log

Center Number: ___ ___ Participant Number: ___ ___ ___ ___ Participant's Initials: ___ ___ ___ (first middle last)

Signs, Symptoms and Adverse Events

Update form for each visit and mark corresponding additional box. Send copies of this form with each submission starting with baseline:
☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

AE #	Adverse Event	Serious	Intensity	Causality (check only one)	Action Taken Due to AE (check all that apply)	Outcome	Start/End Date OR Check if Continuing
___		☐$_0$ No ☐$_1$ Yes*	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ None ☐$_2$ Doubtful ☐$_3$ Possibly ☐$_4$ Probably ☐$_5$ Very likely	☐$_1$ None ☐$_2$ Intervention temporarily discontinued ☐$_3$ Medical therapy required ☐$_4$ Intervention permanently discontinued ☐$_{98}$ Other (specify): _____	☐$_1$ Still present and unchanged ☐$_2$ Improving ☐$_3$ Resolved ☐$_4$ Resolved with sequelae ☐$_5$ Death	Start Date: __ __/__ __ __/__ __ __ __ day month year End Date: __ __/__ __ __/__ __ __ __ day month year OR ☐$_1$ Continuing
___		☐$_0$ No ☐$_1$ Yes*	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ None ☐$_2$ Doubtful ☐$_3$ Possibly ☐$_4$ Probably ☐$_5$ Very likely	☐$_1$ None ☐$_2$ Intervention temporarily discontinued ☐$_3$ Medical therapy required ☐$_4$ Intervention permanently discontinued ☐$_{98}$ Other (specify): _____	☐$_1$ Still present and unchanged ☐$_2$ Improving ☐$_3$ Resolved ☐$_4$ Resolved with sequelae ☐$_5$ Death	Start Date: __ __/__ __ __/__ __ __ __ day month year End Date: __ __/__ __ __/__ __ __ __ day month year OR ☐$_1$ Continuing
___		☐$_0$ No ☐$_1$ Yes*	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ None ☐$_2$ Doubtful ☐$_3$ Possibly ☐$_4$ Probably ☐$_5$ Very likely	☐$_1$ None ☐$_2$ Intervention temporarily discontinued ☐$_3$ Medical therapy required ☐$_4$ Intervention permanently discontinued ☐$_{98}$ Other (specify): _____	☐$_1$ Still present and unchanged ☐$_2$ Improving ☐$_3$ Resolved ☐$_4$ Resolved with sequelae ☐$_5$ Death	Start Date: __ __/__ __ __/__ __ __ __ day month year End Date: __ __/__ __ __/__ __ __ __ day month year OR ☐$_1$ Continuing
___		☐$_0$ No ☐$_1$ Yes*	☐$_1$ Mild ☐$_2$ Moderate ☐$_3$ Severe	☐$_1$ None ☐$_2$ Doubtful ☐$_3$ Possibly ☐$_4$ Probably ☐$_5$ Very likely	☐$_1$ None ☐$_2$ Intervention temporarily discontinued ☐$_3$ Medical therapy required ☐$_4$ Intervention permanently discontinued ☐$_{98}$ Other (specify): _____	☐$_1$ Still present and unchanged ☐$_2$ Improving ☐$_3$ Resolved ☐$_4$ Resolved with sequelae ☐$_5$ Death	Start Date: __ __/__ __ __/__ __ __ __ day month year End Date: __ __/__ __ __/__ __ __ __ day month year OR ☐$_1$ Continuing

*If Serious is Yes, submit expedited SAE form.

SAE Reporting Criteria: **1** Death **2** Life threatening **3** Persistent or significant disability/incapacity **4** Prolonged or required hospitalization **5** Congenital anomaly or birth defect **6** Other significant medical event