calerie Phase 2

Protocol Deviation

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

Protocol Deviation

Please indicate below any deviations from the Calerie Protocol taken for this participant.
Check all that apply *(one participant per form)*:

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Date of deviation: ___ ___ /___ ___ ___/___ ___ ___ ___
day month year

☐ Informed Consent
☐ Inclusion/Exclusion criteria
☐ Randomization/treatment assignment
☐ Concomitant Medications
☐ Study/laboratory procedures *(specify)*: ____________________
☐ Participant non-fasting
☐ Participant safety *(specify)*: ____________________
☐ Other *(specify)*: ____________________

Brief explanation of deviation: ____________________
____

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Date of deviation: ___ ___ /___ ___ ___/___ ___ ___ ___
day month year

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☐ Participant non-fasting
☐ Participant safety *(specify)*: ____________________
☐ Other *(specify)*: ____________________

Brief explanation of deviation: ____________________
____

☐ Baseline 1 ☐ Baseline 2 ☐ Month 1 ☐ Month 3 ☐ Month 6 ☐ Month 9 ☐ Month 12 ☐ Month 18 ☐ Month 24

Date of deviation: ___ ___ /___ ___ ___/___ ___ ___ ___
day month year

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☐ Inclusion/Exclusion criteria
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☐ Concomitant Medications
☐ Study/laboratory procedures *(specify)*: ____________________
☐ Participant non-fasting
☐ Participant safety *(specify)*: ____________________
☐ Other *(specify)*: ____________________

Brief explanation of deviation: ____________________
____

Submission date: ___ ___ /___ ___ ___/___ ___ ___ ___ ___ ___ /___ ___ ___/___ ___ ___ ___ ___ ___ /___ ___ ___/___ ___ ___ ___
day month year day month year day month year

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