SAP MODULE 1 – DETAILED STATISTICAL METHODOLOGY

STUDY EN3835-401

MOBI: A PHASE 4, OPEN-LABEL STUDY TO ASSESS EFFECTS OF MITIGATION TREATMENTS ON BRUISING OF CCH-AAES TREATMENT OF BUTTOCK CELLULITE IN ADULT FEMALES

Version 1.0

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LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
AE	Adverse event
ATC	Anatomical therapeutic chemical
BID	Twice daily
BIS	Bruising Improvement Scale
BMI	Body mass index
CCH	Collagenase clostridium histolyticum
cm	centimeters
CR-PCSS	Clinician Reported Photonumeric Cellulite Severity Scale
CSS	Cellulite Severity Scale
eCRF	Electronic case report form
ET	Early termination
EN3835	Purified lyophilized clostridial collagenase
GAIS	Global Aesthetic Improvement Scale
IA	Interim Analysis
I-BIS	Investigator – Bruising Improvement Scale
ICF	Informed consent form
ICH	International Council on Harmonisation
I-GAIS	Investigator Global Aesthetic Improvement Scale
kg	kilogram
m	meters
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligrams
mL	milliliters
NSAIDS	Non-steroidal anti-inflammatory drugs
PDL	Pulse Dye Laser
PR-PCSS	Patient Reported Photonumeric Cellulite Severity Scale
QID	Four times daily
SAE	Serious adverse event
SAP	Statistical Analysis Plan
S-BIS	Subject – Bruising Improvement Scale
SD	Standard deviation
TEAE	Treatment-emergent adverse event
WHO	World Health Organization

1. STUDY OBJECTIVE

The primary objective of this study is to assess the effect of mitigation treatments on bruising in the buttocks of subjects with cellulite after the first treatment of QWO (CCH-aaes).

The secondary objectives of this study are:

- To assess both investigator and subject assessment of bruising with mitigation treatments in subjects with cellulite after the first treatment of QWO (CCH-aaes);
- To assess the level of aesthetic improvement of cellulite after treatment of QWO (CCH-aaes) with and/or without bruising mitigation treatment;
- To assess the safety of QWO (CCH-aaes) with mitigation treatment in subjects with cellulite.

[redacted]

2. STUDY DESIGN AND MEASURES

This study is a Phase 4, multicenter, open-label, multiple dose study to assess the effect of mitigation treatments on injection site bruising and safety in adult women with moderate cellulite in the buttocks treated with QWO (CCH-aaes). Approximately 75 subjects will be screened in order to enroll approximately 48 subjects in 6 cohorts.

At the Screening Visit, subjects who meet all inclusion criteria and have no exclusion criteria according to the investigator's assessment will be assigned to 1 of 6 treatment cohorts. Subjects will be allocated to cohorts using a site-specific Mitigation Treatment Assignment Table provided by the sponsor.

Pending site capabilities and available mitigation treatments, each site will administer each mitigation treatment, with approximately 1-3 subjects assigned to each mitigation treatment as shown in Table 1. Mitigation treatments will be administered at or after the initial treatment session of QWO (CCH-aaes).

Table 1: Distribution of Mitigation Treatments

		QWO (CCH-aaes)[a]		Mitigation Treatment	
	N	Left Buttock	Right Buttock	Left Buttock	Right Buttock
Cohort 1	8	Up to 0.84 mg	Up to 0.84 mg	None	
Cohort 2	8	Up to 0.84 mg	Up to 0.84 mg	Compression garment	
Cohort 3	8	Up to 0.84 mg	Up to 0.84 mg	None	Instant cold packs
Cohort 4	8	Up to 0.84 mg	Up to 0.84 mg	None	Arnica patches
Cohort 5	8	Up to 0.84 mg	Up to 0.84 mg	None	INhance Post-Injection Serum with TriHex Technology
Cohort 6	8	Up to 0.84 mg	Up to 0.84 mg	None	PDL Treatment[b]

[a]For each subject, an identical dose and injection count of QWO (CCH-aaes) should be administered for the first treatment session to each buttock. The number of injections may differ among subjects.
[b]Pulse dye laser (PDL) may be used at the settings selected according to the investigator's discretion.

Eligible subjects will receive up to 0.84 mg of QWO (CCH-aaes) per buttock in both buttocks for a total dose of 1.68 mg per treatment session for 3 treatment sessions (Day 1, Day 21 ±3 days, and Day 43 ±3 days). To reduce variance in the bruising observed on the left and right buttock of a subject after the first treatment session of QWO (CCH-aaes), each buttock should be treated with the same number of QWO (CCH-aaes) injections on Day 1, of up to 12 injections per buttock. The number of injections may differ between treatment sessions; 12 injections per buttock may be administered during the first treatment session followed by fewer injections per buttock during the second and third treatment sessions. The number of injections per buttock per subject may differ among subjects.

Subjects will return to the site on Days 2, 4, 7, and 14 (ie, 1, 3, 6, and 13 days after injection on Day 1) for additional evaluations and digital photography obtained with standardized parameters. After the first mitigation treatment session, on Days 4 and 7, the effect of mitigation treatments on the severity of bruising will be assessed using the Investigator Bruising Improvement Scale (I-BIS) and the Investigator Assessment of Bruising Severity Scale. The effect of mitigation treatments on the severity of bruising will be assessed by subjects on the Subject Bruising Improvement Scale (S-BIS) and the Patient Bother by Bruising Scale. Safety will be assessed by collecting adverse events (AEs) and treatment-emergent adverse events (TEAEs) and assessing injection site reactions in the buttocks throughout the study. [redacted]

At the investigator's discretion, for the second and third QWO (CCH-aaes) treatment sessions on Days 22 and 43, subjects will be permitted to receive the same mitigation treatment to the right buttock as received during the first QWO (CCH-aaes) treatment session. The severity of bruising will be assessed at each visit. Subject and investigator assessments of satisfaction, aesthetic improvement, and digital photography will also be conducted on Days 22 (± 3 days) and 43 (±3 days). Subjects will return to the site for last study visit on Day 71 for additional investigator assessments of bruising and digital photography.

Subjects will participate in the study for approximately 92 days.

Table 2 contains the schedule of assessments.

Table 2: Study EN3835-401 Schedule of Assessments

	Screening Period	Treatment Period							Follow-Up Period
Procedures	**Day -14**	**Day 1 (Baseline)**	**Day 2**	**Day 4**	**Day 7**	**Day 14**	**Day 22 (± 3d)**	**Day 43 (± 3d)**	**Day 71/ET (+7d)**
Informed consent	X								
Inclusion/exclusion criteria	X								
Medical history/surgical history/cellulite history including previous treatments	X								
Prior/concomitant medications/procedures (including all prior medications/procedures for cellulite)	X	X	X	X	X	X	X	X	X
Physical examination (including height)	X								
Weight	X								X
Fitzpatrick skin type	X [a]								
Vital signs	X	X [b]							
Digital photography[c]		X	X	X	X	X	X [d]	X [d]	X
Cohort assignment	X [e]								
QWO (CCH-aaes) administration		X					X	X	
Subject Assessments									
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]		
Subject-Bruising Improvement Scale (S-BIS)			X	X	X	X	X [d]		
Patient Bother by Bruising Scale [g]				X	X		X [d]		
Investigator Assessments									
Hexsel Cellulite Severity Scale (CSS) Subsection D	X [h]								
Clinician-Reported Photonumeric Cellulite Severity Scale (CR-PCSS)	X [i]								
Selection and marking of dimples to be treated with both buttocks		X [c]					X [d]	X [d]	
Investigator Assessment of Bruising Severity Scale		X	X	X	X	X	X [d]		
Investigator- Bruising Improvement Scale (I-BIS) [j]			X	X	X	X	X [d]		
Investigator- Global Aesthetic Improvement Scale (I-GAIS)							X [d]	X	X

Table 2: Study EN3835-401 Assessments (Continued)

Procedures	Screening Period	Treatment Period							Follow-Up Period
	Day -14	Day 1 (Baseline)	Day 2	Day 4	Day 7	Day 14	Day 22 (± 3d)	Day 43 (± 3d)	Day 71/ET (+7d)
Mitigation Treatment Cohorts									
Compression garments		X [k,p]							
Instant cold packs to the right buttock only		X [l,p]							
Arnica patches (OcuMend®) to the right buttock only		X [m,p]							
INhance Post-Injection Serum with TriHex Technology® to the right buttock only		X [n,p]							
Pulse dye laser (PDL) treatment to the right buttock only		X [o,p]							
Injection site reactions/local tolerability in each buttock treated		X	X	X	X	X	X	X	X
Adverse events (AEs)		X [q]							

[a] Subjects with a Fitzpatrick skin rating of I-III will be included.
[b] Before injection and approximately 30 minutes after injection. Pulse and blood pressure should be collected after the subject has been sitting for 5 minutes.
[c] Buttocks will be photographed before and after injection site and dimple marking on Days 1, 22, and 43. Buttocks will also be photographed during the Days 2, 4, 7, 14, and 71 visits (ET) (no dimple or injection site markings).
[d]. Before injection.
[e] Subjects will be assigned to 1 of 6 cohorts according to a site specific Mitigation Treatment Assignment Table. Cohort 1 = no mitigation treatment; Cohorts 2-6 = mitigation treatments
[f] Before QWO (CCH-aaes) injection, and 5 and 15 minutes after injection.
[g] Using mirrors, or photographs captured either by the subject or another person with the subject's imaging device (ie, cell phone, digital camera), or images captured by the investigator or designee using the site's digital photography system.
[h] Baseline Hexsel CSS Subsection D must be '0' (absence of flaccidity or sagging skin) or '1' (slightly draped appearance) on each buttock.
[i] Baseline CR-PCSS rating must be a '3' (moderate) on each buttock.
[j] Based on live assessments while the subject is in front of the investigator.
[k] Compression garments will be worn after QWO (CCH-aaes) injection on Day 1 and worn 24 hours a day for the next 7 days.
[l] Apply instant cold packs immediately after QWO (CCH-aaes) injection for 5-10 minutes immediately after CCH-aaes injection while subject is in a prone position.
[m] Arnica patches applied BID for 2 days immediately after QWO (CCH-aaes) injection on Day 1.
[n] Inhance Post-Injection Serum is applied QID directly on and around the injections site for up to 7 days after QWO (CCH-aaes) injection on Day 1, until resolution of bruising.
[o] PDL treatment between Days 1 (same day of QWO [CCH-aaes] injection) and Day 7 after QWO (CCH-aaes) treatment. PDL settings are according to the investigator's discretion.
[p] For the second and third QWO (CCH-aaes) treatment sessions, at the investigator's discretion, subjects will be allowed to use the same mitigation treatment in the same buttock (as applicable) that received mitigation treatment for the first CCH-aaes treatment session.
[q] AEs will be collected from the time the subject signed the ICF until end of the study or early termination.
BID = twice daily, d = Days, ET = early termination, ICF = informed consent form, QID = Four times daily

2.1. Inclusion Criteria

In order to be eligible to participate in the study, subjects must meet the following criteria at Screening and/or Day 1 visit:

1. Voluntarily sign and date an informed consent agreement.
2. Be a female ≥18 years of age and ≤ 50 years of age.
3. Have both buttocks with:
    a. A CR-PCSS score of 3 (moderate) as reported by the Investigator, and
    b. A Hexsel CSS Subsection D "Grade of laxity, flaccidity, or sagging skin" score of 0 (absence of laxity, flaccidity, or sagging skin) or 1 (slightly draped appearance).
4. Have a body mass index between ≥18 and ≤ 30 kg/m^2, and intends to maintain stable body weight throughout the duration of the study (a variation of ≤ 10% from baseline body weight is permitted).
5. Have a Fitzpatrick skin rating of I-III.
6. Be willing to apply sunscreen before each exposure to the sun while participating in the study (ie, Baseline through end of study).
7. Be judged to be in good health, based upon the investigator's medical judgment and the results of a medical history and physical examination at Screening.
8. Be willing and able to cooperate with the requirements of the study.
9. Be able to read, complete and understand the patient reported outcomes rating instruments in English.

2.2. Exclusion Criteria

A subject will be excluded from study participation if the subject:

1. Has any of the following systemic conditions:
    a. Coagulation disorder including but not limited to a Factor II, V, VII, or X deficiency.
    b. Skin pigmentation disorder.
    c. Evidence or history of malignancy (other than excised basal-cell carcinoma) unless there has been no recurrence in at least 5 years.
    d. History of keloidal scarring or abnormal wound healing.
    e. Concurrent diseases or conditions that might interfere with the conduct of the study, confound the interpretation of the study results, or endanger the subject's well-being, including but not limited to rheumatoid arthritis and/or other rheumatoid disease(s), Vitamin K deficiency, or liver diseases. Any questions about concurrent diseases should be discussed with the Medical Monitor.
    f. Evidence of clinically significant abnormalities on physical examination or vital signs.
2. Has any of the following local conditions in the buttocks:

a. History of lower extremity thrombosis or post-thrombosis syndrome.
b. Vascular disorder (eg, varicose veins, telangiectasia, vasculitis) in area to be treated.
c. Inflammation or active infection in the buttocks.
d. Active cutaneous alteration including rash, eczema, or psoriasis.
e. Has a tattoo in the buttocks, visible in clinical photographs.

3. Has skin laxity or linear undulations on either buttock that can be effaced by lifting skin.
4. Requires the following concomitant medications during the study and cannot discontinue these medications within the time specified before QWO (CCH-aaes) treatment:
   a. Antiplatelet medication (clopidogrel [Plavix®]) including aspirin at any dose within 14 days of treatment.
   b. Anticoagulants, such as warfarin (Coumadin®); heparin analogues within 14 days of treatment.
   c. Non-steroidal anti-inflammatory drugs (NSAIDS), such as ibuprofen (Motrin®, Advil®) and naproxen (Aleve®) 7 days before the study.
   d. Any medications (eg, corticosteroids, certain antidepressants [eg, citalopram, fluoxetine], nutritional/homeopathic supplements [eg, fish oil, Vitamin E, omega 3, ginko biloba, ginger, St John's Wart, green tea, ginseng, feverfew, saw palmetto, turmeric, bromelain]) or foods (eg, pineapple) that have, or have been reported to have anticoagulant effects within 14 days of treatment.
   e. Antibiotics, such as penicillin and cephalosporin within 48 hours of treatment.
5. Has used any of the following for the treatment of cellulite on a buttock within the timelines identified below or intends to use any of the following at any time during the study:
   a. Liposuction in a buttock during the 12-month period before injection of QWO (CCH-aaes).
   b. Injections (eg, mesotherapy, derma fillers, biostimulatory fillers); radiofrequency device treatments; laser treatment; buttock implant treatment; cryolipolysis; or surgery (including subcision and/or powered subcision) within a buttock during the 12-month period before QWO (CCH-aaes) injection.
   c. Any investigational treatment for cellulite on the buttock during the 12-month period before the injection of QWO (CCH-aaes).
   d. Endermologie™ or similar treatments within a buttock during the 6-month period before injection of QWO (CCH-aaes).
   e. Massage therapy for cellulite within a buttock during the 3-month period before injection of QWO (CCH-aaes).
   f. Creams (eg, Celluvera™, TriLastin®) and/or home therapies to prevent or mitigate cellulite within a buttock during the 2-week period before QWO (CCH-aaes) injection.
6. Is presently nursing or providing breast milk or intends to do so during the study.
7. Intends to become pregnant during the study.

8. Intends to initiate an intensive sport program regimen, exercise program regimen, or intensive weight reduction program during the study.
9. Has recently tanned or intends to use tanning spray or tanning booths during the study.
10. Intends to engage in strenuous activity within 48 hours after the first injection of QWO (CCH-aaes).
11. Has received an investigational drug or treatment within 30 days prior to injection of QWO (CCH-aaes).
12. Has a known systemic allergy to collagenase or any other excipient of QWO (CCH-aaes).
13. Has a known systemic allergy or local sensitivity to any of the mitigation treatments or included excipients (ie, arnica patches, INhance post-injection serum).
14. Has received any collagenase treatments at any time prior to treatment in this study.
15. Was a subject in a previous cellulite clinical trial of CCH: (EN3835, QWO [CCH-aaes]).
16. For subjects allocated to PDL treatment:

    Subjects will be excluded from PDL treatment if they have any contraindications to PDL as indicated in the manufacturer's documentation, for example but not limited to:

    a. previous exposure to photosensitizing medications, food and/or supplements or other photosensitizing agents within 2 weeks of QWO (CCH-aaes) treatment.
    b. exposure to Accutane® (isotretinoin) within 6 months of QWO (CCH-aaes) treatment.

2.3. Selecting and Marking of Dimples

To ensure that the contralateral buttock that does not receive mitigation treatment can serve as the subject's own control, and that a similar level of injection site bruising will be induced, subjects should have a similar number of dimples requiring treatment. Subjects can be treated with up to 12 injections of QWO (CCH-aaes) on each buttock. The number of injections of QWO (CCH-aaes) administered to the right and left buttocks should be identical on Day 1. The number of injections may differ between treatment sessions, eg, 12 injections in each buttock in the first treatment session followed by fewer injections per buttock at the second and third treatment sessions as dimples improve.

For treatment, the investigator or qualified designee will select up to 12 dimples within each treatment area (each buttock) that are well-defined, evident when the subject is standing, and suitable for treatment.

For each dimple selected for treatment, the investigator or qualified designee will choose injection sites (injection sites within a dimple should be spaced approximately 2 cm apart, if a dimple requires more than 1 injection; locating at least 1 injection site at the nadir, if present, of the dimple). Each injection site will be marked with a "dot" using a surgical marker. For round dimples, the "dot" will be placed in the center of the dimple; for elongated dimples, "dots" will be spaced out approximately 2 cm along the longer axis of the dimple. The investigator or qualified designee will then use a surgical marker to circle each of the dimples selected for treatment.

2.4. Treatment Administration

2.4.1. QWO (CCH-aaes)

QWO will be provided by Endo Pharmaceuticals Inc.

Dosage and Mode of Administration: QWO (CCH-aaes), 0.84 mg, injected subcutaneously per buttock with both buttocks treated for a total dose of 1.68 mg. For each buttock, a dose of up to 0.84 mg of QWO (CCH-aaes) in 3.6 mL will be administered as up to 12 subcutaneous injections (0.3-mL injection administered as three 0.1-mL aliquots per injection). There will be 3 treatment visits at intervals of approximately 21 days as described in schedule of assessments.

To induce a similar extent and severity of bruising in each buttock, approximately the same number of injections should be administered to the left and to the right buttock. However, the number of injections per buttock may differ among treatments. The number of injections administered to each buttock on Day 1 must be recorded. The volume and dose of injection at each treatment visit will be injected per the QWO Prescribing Information. QWO will be provided in cartons containing 1 QWO 1.84-mg single-dose vial and 1 diluent for QWO 8-mL single-dose vial.

2.4.2. Mitigation Treatments

Mitigation treatments will be provided locally by each investigator/subject.

At the investigator's discretion and with consent of the subject, mitigation treatments provided after the first treatment session of QWO (CCH-aaes), can be administered after the second and third QWO (CCH-aaes) treatment sessions. Mitigation treatments administered after each treatment session with QWO (CCH-aaes) may be recorded as concomitant medications.

Cohort 1 will serve as a control and no mitigation treatment will be administered.

2.4.2.1. Compression Garments (Cohort 2)

Subjects will be instructed to wear a commercially available compression garment (ie, SPANX Grade 3) after the injection on Day 1, for 24 hours per day for 7 days after the injection (Day 1 – Day 8). Garments may be removed for personal hygiene and when the subject is being evaluated at the investigator's office during study visits. Subjects should be informed that ill-fitting compression garments may contribute to pain.

2.4.2.2. Instant cold packs (Cohort 3)

Instant cold packs should be applied **to the right buttock only** for 5-10 minutes immediately after the injection of QWO (CCH-aaes) while the subject is lying in prone position.

2.4.2.3. Arnica Gel Patches (OcuMend) (Cohort 4)

Subjects will be instructed to apply OcuMend gel patches (arnica montana 50% and ledum palustre) immediately after the CCH-aaes injection **to the right buttock only** BID on Days 1 and 2 for a total of 4 doses. One or two patches per application may be required depending on the extent of the bruising.

2.4.2.4. INhance Post-Injection Serum with TriHex Technology (Cohort 5)

INhance Post-injection Serum will be applied by investigators at the site of injections on Day 1 **on the right buttock only** and then by the subject or subject's associate QID for up to 7 days after injection or until resolution of bruising according to the product instructions. The serum is available in a small 10-mL tube with a chilled tip. A small amount of the serum will be applied on the skin and around the injection site and gently rubbed in using the cooling applicator.

2.4.2.5. Pulse Dye Laser Treatment (Cohort 6)

Investigators will apply laser treatment with PDL to the bruising observed **on the right buttock only** as a single treatment between Day 1 (same day of QWO [CCH-aaes) injection) and Day 7 after QWO (CCH-aaes) treatment.

The investigator can adjust laser settings at his/her discretion. Laser settings will be recorded in detail to allow comparability across sites. Only select sites will be administering laser treatment.

2.5. Measures to Minimize Bias

This is an open label study, however, the mitigation treatment for each subject will be assigned in a 1:1:1:1:1:1 ratio using a Mitigation Treatment Assignment Table. To ensure a balanced approach in the application of mitigation treatments and the assessment of bruising among the sites and investigators, 1-3 subjects per site will be assigned to each mitigation treatment (pending site capabilities, subjects available, and available mitigation equipment).

At Screening, the investigator or designee will refer to the Mitigation Treatment Assignment Table to determine which mitigation treatment should be administered.

The investigator must maintain a subject master log linking the subject identification number to the subject's name. The subject identification number will not be reassigned to another subject in this study in the case of study withdrawal.

2.6. Digital Photographs

At the time points indicated on the schedule of assessments, the investigator or qualified designee will photograph bilateral buttocks in a single photograph while the subjects is standing in a consistent, standard relaxed pose, with relaxed gluteus muscles using the investigator's digital camera. Photographs of bilateral buttocks will be obtained:

- Before and after marking dimples and injection sites (prior to injections) on Days 1, 22, and 43.
- During the Days 2, 4, 7, 14, and 71 visits (end of study/ET) (no dimple or injection site markings).

2.7. Investigator Assessment Ratings

2.7.1. Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS)

Investigators will rate the severity of the cellulite of each buttock, independently, at the Screening visit using the 5-level Clinician-Reported Photonumeric Cellulite Severity Scale (CR-PCSS).

The following labels and descriptions are associated with each level of severity on the CR-PCSS Buttock scale (Table 3):

Table 3: Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS)

Rating	Response Option
0	None: No dimples or evident cellulite
1	Almost None: Few dimples that are mostly superficial in depth
2	Mild: Several dimples of which most are shallow in depth
3	Moderate: Many dimples of which most are moderate in depth
4	Severe: A lot of dimples with some of more severe depth

Investigators will be instructed to look at each buttock under evaluation 'live' with the subject standing in front of him/her with relaxed gluteus muscles. Investigators who are physicians will be trained and qualified on the use of the CR-PCSS prior to assessing any subjects.

Subjects must have a baseline CR-PCSS rating of '3' (moderate) on each buttock at the Screening visit to be included in the study.

2.7.2. Hexsel Cellulite Severity Scale (CSS)

The Hexsel CSS is a photonumeric scale that looks at 5 key morphologic features of cellulite[3,4]:

- A - Number of evident depressions.
- B - Depth of depressions.
- C - Morphological appearance of skin surface alterations.
- D - Laxity, flaccidity or sagging of skin.
- E - Current classification scale based on medical literature.

Each of these features is evaluated on a 4-point scale from a low of 0 to a high of 3. For this study, only "D - laxity, flaccidity or sagging of skin" will be assessed for eligibility.

Investigators who are physicians will use the Hexsel CSS Subsection D (laxity, flaccidity or sagging of skin) to assess the severity of laxity in each buttock at the Screening Visit (Table 4). The assessment will be made while the subject is in the standing position with relaxed gluteus muscles.

Table 4: Hexsel CSS (D) laxity, flaccidity or sagging of skin

Rating	Description
0	Absence
1	Slight
2	Moderate
3	Severe

To participate in the study, for each buttock, subjects must have a Baseline Hexsel CSS Subsection D rating of '0' (absence of flaccidity or sagging skin) or '1' (slightly draped appearance) at the Screening Visit.

2.7.3. Investigator Assessment of Bruising Severity Scale

Severity of bruising for each buttock will be documented on the Investigator Assessment of Bruising Severity Scale on Days 1, 2, 4, 7, 14, and 22 (before injection). Investigators will be asked to rate the level of subject bruising using a 5-point photonumeric scale (Table 5):

Table 5: Investigator Bruising Severity Scale

Rating	Response Option
0	None or almost no bruising
1	Mild Bruising
2	Moderate Bruising
3	Severe Bruising
4	Very Severe Bruising

Investigators will document their responses on the corresponding page of the eCRF.

2.7.4. Investigator Bruising Improvement Scale (I-BIS)

On Days 2, 4, 7, 14, and 22 (before injection), the investigator will rate the bruising of the mitigation-treated buttock when compared to the untreated (with mitigation treatment) buttock using the 3-point Likert scale (Table 6). Scores on the higher end of the range indicate greater improvement of bruising with treatment.

Table 6: Investigator Bruising Improvement Scale (I-BIS)

Rating	Response Option
1	Worse (more bruising)
2	Similar
3	Improved (less bruising)

The I-BIS evaluations will be based on live assessments while the subject is in front of the investigator. Note that the I-BIS assessment cannot be completed for subjects that either do not receive mitigation treatment (Cohort 1) or subjects that receive bilateral mitigation treatment (as in Cohort 2), as there is no untreated buttock for comparison.

2.7.5. Investigator-Global Aesthetic Improvement Scale (I-GAIS)

On Days 22, 43, and 71, the investigator will determine the degree of improvement of each of the buttocks by comparing the cellulite by live assessment on Days 22, 43, and 71 to the Day 1 pre-treatment (Baseline) image of that buttock (Table 7). The investigator will provide a separate rating for each buttock from the I-GAIS and enter the results on the corresponding page of the eCRF.

Table 7: Investigator Global Aesthetic Improvement Scale (I-GAIS)

Rating	Response Option	Description
+3	Very much improved	Optimal cosmetic result from treatment of the treated dimples
+2	Much improved	Marked improvement in the treated area appearance from before treatment, but not completely optimal
+1	Improved	Obvious improvement in the treated area appearance from before treatment, but additional treatment is indicated
0	No change	The treated area appearance is essentially the same as before treatment
−1	Worse	The treated area appearance is worse than before treatment
−2	Much worse	Marked worsening in appearance from the initial condition
−3	Very much worse	Obvious worsening in appearance from the initial condition

2.8. Subject Assessment Ratings

2.8.1. [redacted]

[redacted]

2.8.2. Subject Bruising Improvement Scale (S-BIS)

On Days 2, 4, 7, 14, and 22 (before injection), the subject will rate the bruising of the mitigation-treated buttock when compared to the untreated (with mitigation treatment) buttock using the 3-point Likert scale (Table 8). Scores on the higher end of the range indicate greater improvement of bruising with treatment.

Table 8: Subject Bruising Improvement Scale (S-BIS)

Rating	Response Option
1	Worse (more bruising)
2	Similar
3	Improved (less bruising)

Note that the S-BIS assessment cannot be completed for subjects that either do not receive mitigation treatment (Cohort 1) or subjects that receive bilateral mitigation treatment (as in Cohort 2), as there is no untreated buttock for comparison.

2.8.3. Patient Bother by Bruising Scale

On Days 4, 7, and 22 (before injection), subjects will indicate their level of bother by bruising for each buttock using a 4-point scale. Subjects were asked “Thinking about the bruising on your

left/right buttock, how bothered are you with the appearance of the bruising on your left/right buttock?" and asked to respond using one of the following ratings (Table 9):

Table 9: Patient Bother by Bruising Scale

Rating	Description
1	Not at all bothered
2	A little bothered
3	Moderately bothered
4	Extremely bothered

Subjects may use a mirror, or photographs captured by the subject or another person with the subject's imaging device (ie cell phone, digital cameras) or images captured by the investigator or designee using the site's digital photography system.

2.9. Skin Assessment (Fitzpatrick Scale)

At the Screening Visit, subject skin type will be evaluated by the Investigator using the Fitzpatrick Scale (Table 10). Only subjects with a Fitzpatrick skin rating of I-III at the Screening Visit will be included in the study.

Table 10: Fitzpatrick Scale

Rating	Response Option	Description
I	Pale white skin, blue/hazel eyes, blond/red hair	Always burns, does not tan
II	Fair skin, blue eyes	Burns easily, tans poorly
III	Darker white skin	Tans after initial burn
IV	Light brown skin	Burns minimally, tans easily
V	Brown skin	Rarely burns, tans darkly easily
VI	Dark brown or black skin	Never burns, always tans darkly

2.10. Weight, Height, and BMI

At the Screening Visit, height and weight measurements will be taken. Baseline body mass index (BMI) will be computed from these measurements as the weight in kilograms (kg) divided by height in meters squared (m^2).

Body weight will also be measured at the Day 71/ET visit; BMI will be computed from this measurement using the height at Screening.

2.11. Adverse Events

Adverse Events (AEs), including both observed or volunteered problems, complaints, signs or symptoms must be recorded, regardless of whether associated with the use of study treatment. Study treatment includes QWO (CCH-aaes) and mitigation treatments.

The following information will be collected for all AEs:

- Verbatim description
- Injection Site Reaction (Yes/No)
- Date of Onset

- Date of Resolution/or Ongoing
- Severity (Mild, Moderate, Severe)
- Relationship to QWO (CCH-aaes) (Not Related, Unlikely Related, Possibly Related, Probably Related)
- Action taken with QWO (CCH-aaes) (None, Interrupted, Withdrawn)
- Relationship to Mitigation Treatment (Not Related, Unlikely Related, Possibly Related, Probably Related)
- Action taken with Mitigation Treatment (None, Interrupted, Withdrawn)
- Outcome (Recovered/Resolved, Recovered/Resolved w/Sequelae, Recovering/ Resolving, Not Recovered/Not Resolved, Fatal, Unknown)
- Whether or not a concomitant medication or procedure was required
- Classified as a serious adverse event (SAE) or not
- SAE Code (Death, Life-threatening, Inpatient or prolonged hospitalization, Persistent or significant disability/incapacity, Congenital anomaly or birth defect, Other medically important event)

2.12. Medical History

Medical history and cellulite history, including all prior procedures to treat cellulite, will be obtained at the Screening Visit. Medical history will include a review of the following systems: general, dermatological, respiratory, cardiovascular, gastrointestinal, genitourinary, gynecological, endocrine, musculoskeletal, hematological, neuropsychological, immune (allergies), and head, eyes, ears, nose, and throat. Historical and current medical conditions including date of last menstrual period will be recorded.

History of tobacco and alcohol use (never, current, former) will also be collected.

Surgical history will include a review of all surgical procedures completed in the prior 5 years and any surgery completed at any time in the treatment area.

2.13. Physical Examination

A limited physical examination will include evaluation of height, weight, lungs, heart, abdomen, and extremities will be conducted at the Screening Visit. Weight will also be recorded at the Day 71/ET visit.

2.14. Vital Signs

Temperature, pulse, systolic blood pressure, and diastolic blood pressures will be collected at the Screening Visit, and before the first QWO (CCH-aaes) injection and approximately 30 minutes after injection on Day 1. Pulse and blood pressure will be collected after the subject has been sitting for 5 minutes.

The investigator will review all vital sign values for clinical significance. Any vital sign value meeting the investigator's criteria for clinical significance will be recorded as an AE (or SAE, if appropriate).

2.15. Pregnancy

All pregnancies in subjects identified during or after this study, where the estimated date of conception is determined to have occurred during the study or within 28 days of the last study treatment in subjects who terminate the study early, must be reported, followed to conclusion, and the outcome reported, even if the subject is discontinued from the study.

Subjects will be instructed to immediately notify the investigator of any pregnancies.

Pregnancy itself is not regarded as an AE unless there is suspicion that the investigational product under study may have interfered with the effectiveness of a contraceptive medication. Likewise, elective abortions without complications are not considered AEs. Any SAEs associated with pregnancy, including spontaneous miscarriages, must additionally be reported and handled as SAEs.

A subject who becomes pregnant must be withdrawn from the study.

2.16. Prior and Concomitant Medications and Procedures

Any prior medications and nondrug therapies (eg, blood transfusions, oxygen supplementation, physical therapy, etc.), including all prior medications and/or procedures for cellulite, taken within the 30 days prior to the Baseline Visit will be recorded. Any concomitant medications and/or nondrug therapies received from the Baseline Visit through the Day 71 Visit will also be recorded. Mitigation treatments administered after each treatment session of QWO (CCH-aaes) may be recorded as concomitant medications or procedures, as appropriate.

2.16.1. Prohibited Medications

During the study, the following treatments are prohibited:

- Anticoagulants (ie, warfarin [Coumadin] heparin analogues)
- Antiplatelet medications (eg, clopidogrel [Plavix], aspirin)

2.16.2. Suggested Concomitant Medications and Procedures

During the study, acetaminophen will be permitted to treat pain at the injection site as needed.

Other required concomitant medications may be administered at the investigator's discretion.

2.17. COVID-19 Related Protocol Deviations

All study assessments conducted outside of the allowed windows outlined in the schedule of assessments due to a COVID-19 interruption will be documented as a protocol deviation. COVID-19 will be recorded as the reason for these out-of-window assessments.

3. STUDY PARAMETERS

3.1. Subject Disposition

Subjects will be considered as completing the study if they complete the Day 71 visit. Subjects who do not complete the study will report their reason for early discontinuation.

Time in the study (days) will be computed as the date of last visit minus the date of Day 1 + 1, where the date of the last visit is determined as the following:

- The date of Day 71 if the subject completes the study
- The date of early termination visit if the subject is terminated early from study at a non-scheduled visit
- The date of the latest scheduled visit if the subject is terminated early from study at a scheduled visit or lost to follow-up

3.2. Early Termination Visit Assessments

Subjects who discontinue study treatment (QWO [CCH-aaes] or mitigation treatment) or are withdrawn from the study will be encouraged to complete the remaining study visits and evaluations, including providing any additional follow-up information, unless the subject specifically indicates that they will not participate in any further evaluations.

Subjects who discontinue or are withdrawn from the study at any time after the first dose of the study treatment (QWO [CCH-aaes] and mitigation treatments) will not be replaced.

Permanent study discontinuation is required if the subject becomes pregnant during the study.

3.3. Study Treatment

Subjects will be divided into 1 of 6 treatment cohorts (different mitigation treatments along with the same QWO treatment). Subjects will first receive up to 0.84 mg of QWO (CCH-aaes) injected subcutaneously per buttock with both buttocks treated. There will be 3 treatment visits at intervals of 21 days as described in the schedule of assessments. Mitigation treatments will be provided locally by each investigator/subject, and can be administered after each treatment session of QWO (CCH-aaes).

3.3.1. QWO (CCH-aaes) Assessments

To induce a similar extent and severity of bruising in each buttock, approximately the same number of injections (up to 12 per buttock) will be administered to the left and right buttock; however, the number of injections per buttock may differ among treatments as dimples improve.

The number of injections administered at each treatment session will be recorded for each buttock. The difference in the number of injections administered will be computed for each subject for each QWO treatment session as (number of QWO injections in left buttock) – (number of QWO injections in right buttock). A positive difference is indicative of more injections in the left buttock, while a negative difference is indicative of more injections in the right buttock.

3.3.2. Mitigation Assessments

Mitigation treatments administered after each treatment session of QWO (CCH-aaes) will be recorded on the Study Mitigation Treatment page of the eCRF. The start and stop date, type of mitigation treatment, and location (left and/or right buttock) will be recorded and assessed.

Mitigation treatments may also be recorded as concomitant medications or procedures; these treatment records will be included in corresponding assessments (see section 3.6.2).

3.3.3. Cohorts

The cohorts will be structured as described in Table 1, and will be summarized by the mitigation treatment used:

- Cohort 1: No mitigation treatment (control)
- Cohort 2: Compression garments
- Cohort 3: Instant cold packs
- Cohort 4: Arnica gel patches (OcuMend)
- Cohort 5: INhance post-injection serum with TriHex technology
- Cohort 6: Pulse Dye Laser (PDL) treatment

Once subjects are assigned to a particular cohort using the site-specific Mitigation Treatment Assignment Table, the cohort assignments will remain regardless of the actual treatment received. Subjects who receive a different mitigation treatment at any time from the mitigation treatment to which they were assigned will be reported as a protocol deviation.

3.4. Efficacy Parameters

3.4.1. Investigator Bruising Severity Scale

3.4.1.1. Investigator Bruising Severity Scale Rating

The Investigator Bruising Severity Scale Rating is directly obtained from the investigator's assessments of each buttock at an evaluation visit.

3.4.1.2. Baseline Investigator Bruising Severity Scale Rating

The Baseline Investigator Bruising Severity Scale Rating is the rating obtained for this item from the investigator's assessments on Day 1.

3.4.1.3. Change from Baseline Investigator Bruising Severity Scale Rating

The change from baseline Investigator Bruising Severity Scale Rating will be the visit rating minus the baseline rating. A negative change in score indicates a reduction in subject bruising severity, while a positive change in score indicates an increase in subject bruising severity.

3.4.2. I-GAIS

3.4.2.1. I-GAIS Rating

The I-GAIS rating is directly obtained from the investigator's assessments of each buttock at an evaluation visit.

3.4.2.2. One-Level I-GAIS Responder

One-level I-GAIS Responder is defined as any subject with an improved (+1, +2 or +3) score on the I-GAIS at an evaluation visit.

3.4.3. I-BIS Rating

The I-BIS rating is directly obtained from the investigator's assessment rating comparing the bruising of the mitigation-treated buttock to the untreated (with mitigation treatment) buttock at an evaluation visit. Note that this assessment cannot be completed in either subjects that do not receive mitigation treatment (Cohort 1) or subjects that receive bilateral mitigation treatment (eg, Cohort 2 – compression garments) since the subjects in those two cohorts do not have a untreated buttock as a comparator.

3.4.4. S-BIS Rating

The S-BIS rating is directly obtained from the subject's assessment rating comparing the bruising of the mitigation-treated buttock to the untreated (with mitigation treatment) buttock. Note that this assessment cannot be completed in either subjects that do not receive mitigation treatment (Cohort 1) or subjects that receive bilateral mitigation treatment (eg, Cohort 2 – compression garments) since the subjects in those two cohorts do not have a untreated buttock as a comparator.

3.4.5. Patient Bothered by Bruising Scale Rating

The Patient Bothered by Bruising Scale rating is directly obtained from the subject's answer to the question "how bothered are you with the appearance of the bruising on your left/right buttock?" for each buttock. To complete this assessment, subjects may use either a mirror or photographs captured by the subject or another person with the subject's imaging device, or images captured by the investigator or designee using the site's digital photography system.

[redacted]

[redacted]

3.5. Safety Parameters

3.5.1. Adverse Events and Treatment-Emergent Adverse Events

Adverse events will be mapped to system organ class and preferred term using the Medical Dictionary for Regulatory Activities (MedDRA). Treatment-emergent adverse events (TEAEs) are any AEs with a start date equal to or after the date of the first injection of QWO (CCH-aaes).

3.5.1.1. Adverse Event Duration

Duration of an AE will be the AE end date minus the AE start date + 1. If AEs are still ongoing at the end of the study or AEs have partial start or stop dates, durations of those AEs are not determined.

3.5.1.2. Intensity of Adverse Events

Intensity (or severity) of AEs will be graded as "mild", "moderate" or "severe". For AEs with missing severity, the most severe assessment will be imputed for analyses, following worst-case principle. If the intensity of an AE changes, then the most severe intensity during the continuous episode will be recorded.

3.5.1.3. Relationship to QWO (CCH-aaes)

The causal relationship with study drug (QWO [CCH-aaes]) will be classified by the investigator and will be reported as follows:

- Not related.
- Unlikely related.
- Possibly related.
- Probably related.

QWO-related adverse events are AEs with the relationship described by the investigator as "probably related" or "possibly related". "Not related" or "unlikely related" causality assessments are considered as not related.

Any missing relationship of an AE to QWO (CCH-aaes) will be considered as related for the analyses, following worst-case principle.

3.5.1.4. Relationship to Mitigation Treatment

The causal relationship with mitigation treatment will be classified by the investigator and will be reported as follows:

- Not related.

- Unlikely related.
- Possibly related.
- Probably related.

Mitigation-related adverse events are AEs with the relationship described by the investigator as "probably related" or "possibly related". "Not related" or "unlikely related" causality assessments are considered as not related.

Any missing relationship of an AE to mitigation treatment will be considered as related for the analyses, following worst-case principle.

3.5.1.5. Action Taken with QWO (CCH-aaes) and Mitigation Treatments

The action taken with QWO (CCH-aaes) treatment and/or the mitigation treatment will be reported by the investigator as follows:

- Not changed
- Interrupted.
- Withdrawn.

Actions taken with QWO (CCH-aaes) will be reported separately from actions taken with mitigation treatment.

3.5.2. Vital Signs

The baseline values for vital signs (study baseline) will be those taken at Day 1 pre-dose for the by-visit analyses.

Vital signs will be analyzed for Day 1, with pre-dose value as baseline and post-baseline measurement taken approximately 30 minutes after injection. Change from baseline will be the post-baseline value minus the baseline value.

3.6. Other Parameters

3.6.1. Medical History

Medical history will be mapped to preferred term using MedDRA. All medical history terms will be reviewed by the study medical monitor to determine if any other terms should be included.

3.6.2. Prior/Concomitant Medications and Procedures

A concomitant medication is any medication with a stop date on or after the date of the first QWO (CCH-aaes) injection, or a medication reported as ongoing. A prior medication is any medication taken prior to the date of the first QWO (CCH-aaes) injection. All medications will be coded with the World Health Organization (WHO) drug dictionary, by active ingredient and WHO anatomical therapeutic chemical (ATC) classification of ingredients.

A concomitant procedure is any procedure and/or nondrug therapy with a stop date on or after the date of the first QWO (CCH-aaes) injection, or a procedure and/or nondrug therapy reported as ongoing. A prior procedure is any procedure and/or nondrug therapy administered prior to the date of the first QWO (CCH-aaes) injection. Procedures will be reported using the "Additional Concomitant Procedure/Therapy" page of the eCRF.

For all previous and concomitant medications, the following information will be collected: medication name, start date, stop date or ongoing, dose and dose unit, route of administration, frequency, indication, and whether the medication is used to treat an adverse event (Yes/No).

For all previous and concomitant procedures, the following information will be collected: description of procedure/surgery/non-drug therapy, start date, stop date or ongoing, indication, and whether the therapy/procedure is used to treat an adverse event (Yes/No).

4. ANALYSIS POPULATIONS

4.1. Safety Population

The Safety Population is defined as all subjects allocated to treatment who receive at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment. All demographic and baseline characteristics, as well as safety parameters, will be summarized based on this population.

4.2. Evaluable Population

The Evaluable Population is defined as all subjects allocated to treatment who receive at least 1 injection of QWO (CCH-aaes) and have at least 1 bruising assessment after the first dose of QWO (CCH-aaes). The primary and key secondary efficacy parameters will be summarized based on this population.

5. STATISTICAL METHODS

5.1. Overview

The primary efficacy endpoint will be summarized as frequency counts and percentages based on the Evaluable Population by cohort. Mean and standard deviation (SD) will also be provided.

The secondary and supportive efficacy endpoints except for change from baseline measures will be summarized as frequency counts and percentages based on the Evaluable Population by cohort and by buttock, where appropriate. The change from baseline measures will be summarized using descriptive statistics (n, mean, SD, median, minimum and maximum).

TEAEs will be summarized as frequency counts and percentages by preferred term and by cohort. The results and change from baseline for vital signs will be summarized using descriptive statistics.

Subject listings of all data from the eCRFs as well as any derived variables will be presented.

5.2. Missing Data Handling

Missing efficacy data will not be imputed for analysis unless otherwise specified.

5.3. Subject Disposition

The number of subjects included in each study population will be summarized by cohort and overall. Subjects excluded from the Safety Population or Evaluable Population will be listed.

The number and percentages of subjects screened, enrolled, completed, and withdrawn from the study, as well as the reason for withdrawal from study will be summarized by cohort and overall. The number and percentage of screen failures will also be shown.

A listing of disposition data will be provided. Screen failure reasons will also be listed. In addition, a listing for inclusion/exclusion criteria will also be presented.

5.4. Protocol Deviations

Protocol deviations will be divided in categories and severity (major/minor) will be determined. Protocol deviations will not be summarized; however, a subject listing will be presented.

5.5. Demographics and Baseline Characteristics

Demographics and baseline characteristics will be summarized by cohort and overall using the Safety Population. Age, height (at Screening), body weight (at Screening), and BMI in kg/m^2 (at Screening) will be summarized as continuous variables using descriptive statistics (n, mean, standard deviation (SD), median, minimum and maximum).

Gender, race and ethnicity will be summarized as categorical variables using frequency counts and percentages. In addition, age group and BMI group will be summarized as categorical variables using frequency counts and percentages.

The following baseline characteristics will be summarized using frequency counts and percentages:

- CR-PCSS cellulite severity ratings for each buttock at Screening.
- Hexsel CSS Section D (laxity, flaccidity or sagging of skin) scores for each buttock at Screening.
- Skin category based on Fitzpatrick Skin Scale assessment.
- Report of tobacco and alcohol use
  - Alcohol use (Never, Current, and Former).
  - Tobacco use (Never, Current, and Former).

All demographic and baseline characteristics will be presented in subject listings.

5.6. Medical and Surgical History

Medical and surgical history, including cellulite history and previous treatments, will be coded using MedDRA. Medical and surgical history data will not be summarized; however, a subject listing will be provided.

5.7. Efficacy Evaluation

Efficacy parameters will be summarized for each mitigation group based on the Evaluable Population, unless otherwise stated. Missing values will not be imputed, and only observed data will be summarized.

For mitigation treatments that are bilaterally administered (e.g. compression garments in cohort 2), efficacy parameters will be compared to the control arm (cohort 1). For mitigation treatments that are unilaterally applied (e.g. instant cold packs, arnica patches, INhance, and PDL treatment in cohorts 3-6, which are applied to the right buttock only), subjects will serve as their own control. In these cases, efficacy parameters from mitigation treatment (right buttock) will be compared to contralateral buttock with no mitigation treatment (left buttock). There will be no formal comparison of efficacy parameters between mitigation treatments.

5.7.1. Overview of Treatment

Summaries for both QWO (CCH-aaes) and mitigation treatments will be provided for the Safety Population.

5.7.1.1. QWO (CCH-aaes)

The following information regarding QWO (CCH-aaes) treatment will be summarized for each buttock by cohort:

- Number of QWO (CCH-aaes) treatment sessions per subject
- Number of subjects who received QWO (CCH-aaes) treatment or did not receive QWO (CCH-aaes) treatment each treatment visit
- For subjects who had the QWO (CCH-aaes) treatment done, the number of injections given at each treatment visit
- For subjects who had the QWO (CCH-aaes) treatment done, the subject-level difference in the number of injections given at each treatment visit (left buttock – right buttock).

A subject listing containing all QWO (CCH-aaes) treatment administration information will be provided.

5.7.1.2. Mitigation

The following information regarding mitigation treatments will be summarized for the treated buttock(s), by cohort:

- Number of mitigation treatment sessions per subject per QWO treatment cycle

- For subjects who had mitigation treatment done, the type of mitigation treatment received, by treatment visit

Note that for Cohort 2, mitigation treatment was administered to both left and right buttocks. For Cohorts 3-6, mitigation treatment was administered to right buttock only. Cohort 1 did not receive mitigation treatment and therefore will not be included in mitigation treatment summaries.

A subject listing containing mitigation treatment administration information will be provided.

5.7.2. Primary Endpoint and Secondary Endpoints – Bruising Level

For each cohort, results at each level of bruising on the Investigator Assessment of Bruising Severity Scale (see section 2.7.1) will be summarized by visit and by buttock for each subject using counts and percentages. Results and changes from baseline evaluation rating will also be summarized using descriptive statistics (mean and SD).

A listing of Investigator Assessment of Bruising Severity ratings will be provided.

5.7.3. Secondary Endpoints – Improvement of Bruising

For each cohort, results at each rating level of the I-GAIS (see section 2.7.5) will be summarized by visit and by buttock for each subject using counts and percentages, along with mean and SD. Additionally, the 1-level I-GAIS responders (as defined in section 3.4.2.2) will be summarized by cohort and by buttock for each subject using counts and percentages of subjects. A listing of I-GAIS ratings will be provided.

For subjects that receive unilateral mitigation treatments (cohorts 3-6), results at each rating level of the I-BIS (see section 2.7.4) will also be summarized by visit using counts and percentages. A listing of I-BIS ratings will be provided.

For subjects that receive unilateral mitigation treatments (cohorts 3-6), results at each rating level of the S-BIS (see section 2.8.2), as determined by the subject's self-assessment, will be summarized by visit using counts and percentages. A listing of S-BIS ratings will be provided.

5.7.4. Secondary Endpoints – Patient Bothered by Bruising

For each cohort, results at each rating level of the Patient Bother by Bruising Scale (see section 2.8.3) will be summarized by visit and by buttock for each subject using counts and percentages.

A listing of Patient Bother by Bruising ratings will be provided.

5.7.5. Exploratory Endpoints – [redacted]

[redacted]

5.8. Safety Evaluation

5.8.1. Adverse Events

The following listings will be provided based on **all AEs**:

- Listing of deaths.
- Listing of non-fatal SAEs.
- Listing of non-serious AEs leading to discontinuation from study.

Listing of non-serious AEs leading to interruption or discontinuation of either QWO (CCH-aaes) or mitigation treatment. The following summary tables of AEs will be presented by cohort:

- TEAEs
  - Overall summary
  - By preferred term
  - By preferred term and severity
  - By frequency of SAEs
  - By frequency of most common non-SAE
- QWO-related AEs
  - Overall summary
  - By preferred term
  - By preferred term and severity
- Mitigation-related AEs
  - Overall summary
  - By preferred term
  - By preferred term and severity

The overall summary will consist of the following items:

- Total number of AEs
  - All AEs
  - Mild AEs
  - Moderate AEs
  - Severe AEs
  - Related to QWO (CCH-aaes) Only (TEAEs overall summary only)
  - Related to Mitigation Only (TEAEs overall summary only)
  - Related to both QWO (CCH-aaes) and Mitigation (TEAEs overall summary only)
- Total number of subjects with
  - At least 1 AE

- At least 1 SAE
- At least 1 severe AE
- No severe AEs but at least 1 moderate AE
- No severe/moderate AEs but at least 1 mild AE
- At least 1 AE leading to discontinuation from study
- At least 1 AE leading to interruption or discontinuation of QWO (CCH-aaes) only (TEAE overall summary only)
- At least 1 AE leading to interruption or discontinuation of Mitigation Treatment only (TEAE overall summary only)
- At least 1 AE leading to interruption or discontinuation of both QWO (CCH-aaes) and Mitigation Treatment (TEAE overall summary only)
- Total number of subjects who died (TEAEs overall summary only)

Percentages for the total number of mild, moderate, and severe AEs will be based on the total number of all AEs in the cohort.

The by frequency summaries will also include the total number of occurrences the AE preferred term was reported as well the number of subjects with at least 1 report of the AE. Most common non-SAEs are any preferred term AE that at least 5% of the subjects in any cohort report at least once.

5.8.1.1. Adverse Event Conventions

The following conventions will be followed:

- Table by preferred term - If an AE preferred term occurred multiple times within a body system for the same subject, the preferred term will only be counted once for the subject for the summary of preferred terms. If an AE body system occurred multiple times for the same subject, the body system will only be counted once for the subject for the summary of body systems. If a subject has any AE, the subject will be counted once in the summary of subjects with at least 1 AE.
- Table by preferred term and severity - If an AE preferred term occurred multiple times within a body system for the same subject, only the most severe one will be used. If the most severe preferred term of an AE occurred multiple times within a body system for the same subject, only 1 will be counted. In addition, this summary will also contain the total number of subjects with at least 1 mild, 1 moderate, or 1 severe. If a subject has at least 1 severe AE, then the subject will be counted in the severe category. If the subject has no severe AEs, but at least 1 moderate AE, then the subject will be counted in the moderate category, and if the subject has no severe and no moderate AEs, but has at least 1 mild AE, then the subject will be counted in the mild category.
- Table of frequency of preferred terms – Preferred terms will be ordered by their descending frequency within the treatment cohort. If 2 or more preferred terms are tied in their frequency, then the preferred terms will be ordered alphabetically.

5.8.2. Weight and BMI

Weight and BMI at baseline, Day 71/ET, and change from baseline will be summarized by treatment cohort.

5.8.3. Vital Signs

Vital signs on injection day will be summarized at baseline (pre-injection) and post-injection time points (30 minutes after injection) and change from baseline by treatment cohort. The baseline value will be based on the pre-injection measurement at each treatment session. A listing of all vital sign information will be provided.

5.8.4. Prior and Concomitant Medications and Procedures

Prior and concomitant medications will be summarized by cohort and overall using frequency counts and percentages by active ingredient within each ATC, with ATC and active ingredients ordered alphabetically. Prior and concomitant procedures (nondrug therapies) will be summarized by cohort and overall using frequency counts and percentages with name of the procedures ordered alphabetically. Multiple uses of the same medication/procedure by a subject will be counted only once.

Subject listings of medications (indicating prior and concomitant medications) and procedures (indicating prior and concomitant procedures) will be provided.

Mitigation treatments recorded as concomitant medications or concomitant procedures will be included in associated summaries and listings.

6. DERIVED VARIABLES

6.1. Subject Level Variables

The following variables will be determined for each subject (see Table 11).

Table 11: Subject Level Derived Dataset Variables

Variable	Definition
Age Group	18 – <25 years 25 – <35 years 35 – 50 years
Height (cm)	If height unit is inches, then height is equal to the recorded value multiplied by 2.54 and then rounded to 1 decimal point.
Weight (kg)	If weight unit is pounds, then weight is equal to the recorded value multiplied by 0.454 and then rounded to 1 decimal point.
BMI (kg/m^2)	$Weight/(Height/100)^2$
BMI Group	Normal Weight (<25.0 kg/m^2) Overweight (≥25.0 kg/m^2)
Baseline	For Investigator Assessment of Bruising Severity Scale: Day 1 measurement. Otherwise: Last evaluable measurement before first QWO (CCH-aaes) injection on Day 1.
Date of First QWO Injection	Day 1 visit date

Table 11: Subject Level Derived Dataset Variables (Continued)

Variable	Definition
Difference in number of QWO injections	(number of QWO injections in left buttock) – (number of QWO injections in right buttock).
Last Date in Study	Date of last visit where subject was seen by the investigator. If subject was lost to follow-up, then last date of contact. If the subject had contact with the site after the final visit (eg, to follow-up on an AE), the last visit date will still be used as last date in the study.
Time in Study	Last Date in Study – Date of First Injection + 1

AE=Adverse event; BMI=Body mass index

6.2. Safety Variables

6.2.1. Adverse Events

Adverse events will be organized in 2 different ways: by event and by subject. The by event dataset will include all the characteristics of the event obtained on the eCRF plus the derived variables presented in Table 12. A second by event dataset will be created for the AE duration analysis. This duration dataset will contain only the subject number, treatment session, body system classification, preferred term, and duration.

Table 12: Adverse Event Variables by Event

Variable	Values/Definition
Treatment-Emergent	AE with a start date after the first dose of study medication
QWO-Related	If relationship to QWO (CCH-aaes) is reported as possible, probable or missing; 'unlikely related' AE will be classified as not a drug-related AE.
Mitigation-Related	If relationship to study mitigation only is reported as possible, probable or missing; 'unlikely related' AE will be classified as not a mitigation-related AE.
Onset Day	AE Start Date - Date of First Injection + 1
Duration	AE Stop Date - AE Start Date + 1

AE=Adverse event

The by-subject dataset will summarize all the AE events for a subject and will include the variables presented in Table 13. The same variables will be computed for TEAEs and treatment-related AEs.

Table 13: Adverse Event Variables by Subject

Variable	Values/Definition
Total AEs	Sum of number of AEs the subject reported
Total Mild AEs	Sum of number of mild AEs the subject reported
Total Moderate AEs	Sum of number of moderate AEs the subject reported
Total Severe AEs	Sum of number of severe AEs the subject reported
Had AE	Flag (Y/N) to indicate subject had at least 1 AE
Had Severe AE	Flag (Y/N) to indicate subject had at least 1 AE of moderate or severe severity
Had SAE	Flag (Y/N) to indicate subject had at least 1 serious AE

Table 13: Adverse Event Variables by Subject (Continued)

Variable	Values/Definition
Had AE Leading to Discontinuation	Flag (Y/N) to indicate subject had at least 1 AE that led to discontinuation from the study
Had AE Leading to Interruption/Withdrawal of QWO (CCH-aaes)	Flag (Y/N) to indicate subject had at least 1 AE that led to interruption/withdrawal of QWO (CCH-aaes)
Had AE Leading to Interruption/Withdrawal of Mitigation	Flag (Y/N) to indicate subject had at least 1 AE that led to interruption/withdrawal of Mitigation treatment

AE=Adverse event; SAE=Serious adverse event; Y/N=Yes/No

6.3. Imputation of Partial Dates

Study visit dates, birthdates, informed consent date, injection dates/times, all assessment dates, and date of completion/last contact date must be complete dates; no imputations will be done. No imputations will be done for partial medical history onset/resolution dates, partial alcohol/tobacco stop dates, missing date of last menstrual period, partial AEs onset/end dates and partial concomitant medication/procedure start/stop dates. All AEs with a missing onset day will be considered treatment-emergent except if the onset month/year is prior to the first injection date. All medications/procedures with a missing onset and stop day will be considered concomitant except if the stop month/year is prior to the first injection date.

6.4. Relative Study Day

Relative study day will be computed for each visit and for each AE. For visits or events occurring on or after the Day 1 visit, relative study day will be the date of visit (event) minus the date of first QWO (CCH-aaes) injection + 1. For visits or events that occur prior to the Day 1 visit, the relative study day will be the date of visit (event) minus the date of first QWO (CCH-aaes) injection.

6.5. Conventions and Algorithms

6.5.1. Summary Tables/Subject Listings Conventions

Summary tables, subject listings, graphs and any supportive SAS output will include a "footer" of explanatory notes that will indicate, when applicable:

- Date of data extraction
- Date and time of output generation
- SAS program name, including the path, that generates the output

Null summary tables will be presented with a note stating that "No Subjects Met Criteria."

The summary tables will clearly indicate the effective sample size per treatment group. All summary tables involving percentages will round the percentages off to 1 decimal place. All summary tables involving descriptive statistics of continuous variables will round the mean and median to 1 decimal place more than the variable's standard form and round the standard

deviation to 2 decimal places more than the variable's standard form. The standard form of a percent change variable is one decimal place.

When calculating percentages, the denominator will be based on the number of non-missing responses. The number of missing responses will be presented as a count only. If the denominator is expected to change over time, then the denominator used to calculate the percentage should be presented on the table. Any subject and/or buttock record removed from an analysis will be noted at the bottom of the table along with the reason for removal. These subjects and/or buttock records will also be listed.

When summarizing AEs, and vital signs, subjects with multiple occurrences of an event will be counted only once in the summary. When AEs are summarized by severity, if the subject has multiple occurrences of the same AE, the most severe will be used for the summary.

By-subject listings for AEs and vital signs will be provided. Other by-subject listings will be provided as support for summary tables and serve as a data source substitute when a summary table is deemed either inappropriate or unnecessary. All subject listings will be organized by investigational site and cohort, sorted by subject number. When applicable, the subject listings will include the visit date, and days relative to the start of first treatment and start of treatment session.

7. INTERIM ANALYSES

An interim analysis (IA) will be conducted at a time point to be determined after at least 25% of subjects of the count of total planned subjects have received treatment and completed Day 22 Visit assessments.

8. SAMPLE SIZE DETERMINATIONS

The proposed sample size is approximately 48 subjects. The sample size is based on evaluation of mitigation treatment in 6 cohorts of approximately 8 subjects each. Five (5) treatment cohorts will receive mitigation treatments and 1 treatment cohort will not receive mitigation treatment.

9. TABLES, LISTINGS, AND GRAPH SHELLS

The layouts of the summary tables, subject listings, and graphs are presented in SAP Module 2. These layouts incorporate all the appropriate table titles, table numbers, and footnotes.

10. CHANGE FROM PROTOCOL

Table 14 lists any significant changes in the SAP from what is proposed in the protocol.

Table 14: Changes from Protocol

Text in Protocol	Change in SAP	Justification

11. REVISION HISTORY

Non-editorial changes made to any of the sections of this SAP will be recorded in Table 15. All significant changes require a new signature page be completed.

Table 15: Revision History

Description of Change/Reason for Change	Document Version Number Before Change	Date of Change
Original	N/A	N/A

12. REFERENCES

1. US Food and Drug Administration. Guidance for Industry, E9 Statistical Principles for Clinical Studies (ICH E9); 1998:30.
2. Clinical Study Protocol: MOBI: A Phase 4, Open-Label Study to Assess Effects of Mitigation Treatments on Bruising of CCH-aaes Treatment of Buttock Cellulite in Females. Dated: November 18, 2020.
3. Hexsel DM, Dal'Forno T, Hexsel CL. A validated photonumeric cellulite severity scale. *J Eur Acad Dermatol Venereol*. 2009;23 (5):523-8.
4. Nürnberger F, Müller G. So-called cellulite: an invented disease. *J Dermatol Surg Oncol*. 1978;4(3):221-9.

13. TABLES, LISTINGS, AND GRAPH SHELLS

The layouts of the summary tables, subject listings, and graphs are presented in SAP Module 2.

These layouts incorporate all the appropriate table titles, table numbers, and footnotes.

SAP MODULE 2 – TABLE, LISTING AND GRAPH SHELLS

Protocol No. EN3835-401

MOBI: A PHASE 4, OPEN-LABEL STUDY TO ASSESS EFFECTS OF MITIGATION TREATMENTS ON BRUISING OF CCH-AAES TREATMENT OF BUTTOCK CELLULITE IN ADULT FEMALES

Version 1.0

February 10, 2021

Endo Pharmaceuticals Inc.
1400 Atwater Drive
Malvern, PA 19355
USA

LIST OF TABLES

LIST OF DATA LISTINGS

Table 14.1.1
Subject Disposition

	Statistic	Cohort 1 No Mitigation	Cohort 2 Compression	...	Cohort 6 PDL Treatment	Overall
Screened Subjects [1]	n					xx
Screen Failures [2]	n (%)					xx (xx.x)
Enrolled Subjects [3]	n	xx	Xx	…	xx	xx
Safety Population [4]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Evaluable Population [5]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Study Completion Status						
Completed Study [6]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Withdrawn from Study	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Adverse Event	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Death	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Protocol Non-compliance	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Withdrawal by Subject	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Investigator Decision	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Sponsor Decision	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Subject Moved	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Pregnancy	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Lost to Follow-Up	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] All subjects who signed informed consent.
[2] Percentages for screen failure subjects are based on the number of screened subjects in each column.
[3] All subjects who were enrolled and allocated to one of the 6 mitigation cohorts. Percentages were based on all enrolled subjects.
[4] All enrolled subjects who received at least one injection of QWO (CCH-aaes) with or without mitigation treatment.
[5] All enrolled subjects who received at least one injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).
[6] Received at least one injection of QWO (CCH-aaes) with or without mitigation treatment and completed the Day 71 visit.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.1.2
Demographic and Baseline Characteristics
Safety Population

	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Age (Years)	n	xx	Xx		xx	xx
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx
	Median	xx.x	xx.x	…	xx.x	xx.x
	Min	xx	Xx		xx	xx
	Max	xx	Xx		xx	xx
Age Group						
18-<25 Years	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
25-<35 Years	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
35-50 Years	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Gender						
Female	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Race						
American Indian/Alaskan Native	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Black of African American	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
White	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Ethnicity						
Hispanic or Latino	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Not Hispanic and Non-Latino	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Table 14.1.2
Demographic and Baseline Characteristics
Safety Population

	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Body Weight (kg)	n	xx	Xx		xx	xx
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx
	Median	xx.x	xx.x	…	xx.x	xx.x
	Min	xx	Xx		xx	xx
	Max	xx	Xx		xx	xx
Body Height (cm)	n	xx	Xx		xx	xx
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx
	Median	xx.x	xx.x	…	xx.x	xx.x
	Min	xx	Xx		xx	xx
	Max	xx	Xx		xx	xx
BMI (kg/m^2)	n	xx	Xx		xx	xx
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx
	Median	xx.x	xx.x	…	xx.x	xx.x
	Min	xx	Xx		xx	xx
	Max	xx	Xx		xx	xx
BMI Group						
Normal Weight (< 25.0 kg/m^2)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Overweight (>= 25.0 kg/m^2)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Table 14.1.2
Demographic and Baseline Characteristics
Safety Population

	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Skin Category (Fitzpatrick Scale) [1]						
I (Pale White)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
II (Fair)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
III (Darker White)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Alcohol Use						
Never	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Current	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Former	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Tobacco Use						
Never	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Current	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Former	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] Only subjects with a Fitzpatrick skin rating of I-III at the Screening Visit were eligible for the study as per the protocol inclusion criteria.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.1.3
CR-PCSS Cellulite Severity Rating and Hexsel CSS Subsection D Score of Left/Right Buttock at Screening
Safety Population

Buttock	Parameter	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Left	CR-PCSS Rating [1]						
	3 (Moderate)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Hexsel CSS Subsection D Score [2]						
	0 (Absence of flaccidity or sagging of skin)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	1 (Slightly draped appearance)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Right	CR-PCSS Rating [1]						
	3 (Moderate)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Hexsel CSS Subsection D Score [2]						
	0 (Absence of flaccidity or sagging of skin)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	1 (Slightly draped appearance)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] CR-PCSS = Clinician-Reported Photonumeric Cellulite Severity Scale. Only subjects with a baseline CR-PCSS rating of 3 (Moderate) on each buttock at the Screening Visit were included in the study as per the protocol inclusion criteria.
[2] CSS = Cellulite Severity Scale. Only subjects with a baseline Hexsel CSS Subsection D score of 0 or 1 on each buttock at the Screening Visit were included in the study as per the protocol inclusion criteria.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.1.4.1.1
Prior Medications
Safety Population

Drug Class/ Preferred Term [1]	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Number of subjects with at least one prior medication [2]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Drug Class 1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 3	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Drug Class 2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 4	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 5	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 6	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 7	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] Drug class and preferred term were coded using WHO-drug dictionary (Version xxxxx).
[2] Prior medications are any medication reported as taken prior to Day 1.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment". Table should be sorted alphabetically by Drug Class/Preferred Term.

Table 14.1.4.1.2
Concomitant Medications
Safety Population

Drug Class/ Preferred Term [1]	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Number of subjects with at least one concomitant medication [2]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Drug Class 1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 3	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Drug Class 2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 4	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 5	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 6	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Preferred Term 7	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] Drug class and preferred term were coded using WHO-drug dictionary (Version xxxxx).
[2] Concomitant medications are any medication reported as taken on or after Day 1 (Baseline Visit) through Day 71/Early Termination Visit. Mitigation medications provided after each QWO (CCH-aaes) treatment session may also be included as concomitant medications.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment". Table should be sorted alphabetically by Drug Class/Preferred Term.

Table 14.1.4.2.1
Prior Procedures
Safety Population

Procedure	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Number of subjects with at least one prior procedure [1]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] A prior procedure is any procedure/nondrug therapy reported as received prior to Day 1.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment". Table should be sorted alphabetically by Drug Class/Preferred Term.

Table 14.1.4.2.2
Concomitant Procedures
Safety Population

Procedure	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)	Overall (N=xxx)
Number of subjects with at least one concomitant procedure [1]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
xxxxxxxxxxxx	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] A concomitant procedure is any procedure/nondrug therapy received on or after Day 1 (Baseline Visit) through Day 71/Early Termination Visit. Mitigation procedures administered after each QWO (CCH-aaes) treatment session may also be included as concomitant procedures.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment". Table should be sorted alphabetically by Drug Class/Preferred Term.

[redacted]

Table 14.2.1.1
Treatment Exposure – QWO (CCH-aaes)
Safety Population

		Cohort 1 No Mitigation (N=xxx)		...	Cohort 6 PDL Treatment (N=xxx)	
Parameter	Statistic	Left	Right		Left	Right
Treatment Sessions Per Subject						
One QWO Treatment Session	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Two QWO Treatment Sessions	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Three QWO Treatment Sessions	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Treatment Session 1 (Day 1)						
QWO Treatment Done	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
QWO Treatment Not Done	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Treatment Session 2 (Day 22)						
QWO Treatment Done	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
QWO Treatment Not Done	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Treatment Session 3 (Day 43)						
QWO Treatment Done	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
QWO Treatment Not Done	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.2.1.2
Overview of Treatment – QWO (CCH-aaes)
Safety Population

Visit / Parameter	Statistic	Cohort 1 No Mitigation (N=xxx) Left	Right	Difference [1]	...	Cohort 6 PDL Treatment (N=xxx) Left	Right	Difference [1]
QWO Treatment Session 1 (Day 1)								
Number of QWO Injections	n	Xx	xx	xx	…	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	…	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	…	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	…	xx.x	xx.x	xx.x
	Min	Xx	xx	xx		xx	xx	xx
	Max	Xx	xx	xx		xx	xx	xx
QWO Treatment Session 2 (Day 22)								
Number of QWO Injections	n	Xx	xx	xx	…	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	…	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	…	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	…	xx.x	xx.x	xx.x
	Min	Xx	xx	xx		xx	xx	xx
	Max	Xx	xx	xx		xx	xx	xx
QWO Treatment Session 3 (Day 43)								
Number of QWO Injections	n	Xx	xx	xx	…	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	…	xx.x	xx.x	xx.x
	SD	xx.xx	xx.xx	xx.xx	…	xx.xx	xx.xx	xx.xx
	Median	xx.x	xx.x	xx.x	…	xx.x	xx.x	xx.x
	Min	Xx	xx	xx		xx	xx	xx
	Max	Xx	xx	xx		xx	xx	xx

[1] Difference = (number of QWO injections in left buttock) – (number of QWO injections in right buttock). Difference was calculated for each subject for each QWO treatment session.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.2.2
Treatment Exposure – Mitigation Treatment, Treated Buttock [1]
Safety Population

Visit Mitigation Treatment Type	Statistic	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)
Mitigation Treatment Sessions Per Subject				
One Mitigation Treatment Session	n (%)	xx (xx.x)	…	xx (xx.x)
Two Mitigation Treatment Sessions	n (%)	xx (xx.x)	…	xx (xx.x)
Three Mitigation Treatment Sessions	n (%)	xx (xx.x)	…	xx (xx.x)
Treatment Session 1 (Day 1)				
Compression garment	n (%)	xx (xx.x)	…	xx (xx.x)
Instant cold packs	n (%)	xx (xx.x)	…	xx (xx.x)
Arnica patches	n (%)	xx (xx.x)	…	xx (xx.x)
INhance post-injection serum [2]	n (%)	xx (xx.x)	…	xx (xx.x)
PDL Treatment [3]	n (%)	xx (xx.x)	…	xx (xx.x)
Treatment Session 2 (Day 22)				
Compression garment	n (%)	xx (xx.x)	…	xx (xx.x)
Instant cold packs	n (%)	xx (xx.x)	…	xx (xx.x)
Arnica patches	n (%)	xx (xx.x)	…	xx (xx.x)
INhance post-injection serum [2]	n (%)	xx (xx.x)	…	xx (xx.x)
PDL Treatment [3]	n (%)	xx (xx.x)	…	xx (xx.x)
Treatment Session 3 (Day 43)				
Compression garment	n (%)	xx (xx.x)	…	xx (xx.x)
Instant cold packs	n (%)	xx (xx.x)	…	xx (xx.x)
Arnica patches	n (%)	xx (xx.x)	…	xx (xx.x)
INhance post-injection serum [2]	n (%)	xx (xx.x)	…	xx (xx.x)
PDL Treatment [3]	n (%)	xx (xx.x)	…	xx (xx.x)

[1] For Cohort 2, mitigation treatment was administered to both left and right buttocks. For Cohorts 3-6, mitigation treatment was administered to right buttock only.
[2] INhance post-injection serum with TriHex technology.
[3] PDL = pulse dye laser.
Note: By design, Cohort 1 did not receive any mitigation treatment.
Safety Population includes all subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 2-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.2.3.1
Observed and Change from Baseline in Investigator Assessment of Bruising Severity, by Visit
Evaluable Population

Visit		Cohort 1 No Mitigation (N=xxx)		...	Cohort 6 PDL Treatment (N=xxx)	
Bruising Severity Rating [1]	Statistic [2]	Left	Right		Left	Right
Baseline [3]						
Number of Subjects Evaluated	n	xx	xx	…	xx	xx
0 (None or almost none)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
1 (Mild)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
2 (Moderate)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
3 (Severe)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
4 (Very Severe)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx
Day 2						
Number of Subjects Evaluated	n	xx	xx	…	xx	xx
0 (None or almost none)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
1 (Mild)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
2 (Moderate)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
3 (Severe)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
4 (Very Severe)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx
Change from Baseline at Day 2						
Number of Subjects Evaluated	n	xx	xx	…	xx	xx
-4	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-3	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
0	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+3	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+4	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Mean	xx.x	xx.x	…	xx.x	xx.x
	SD	xx.xx	xx.xx	…	xx.xx	xx.xx

[1] Results as reported using the Investigator Assessment of Bruising Severity Scale.
[2] Percentages are based on number of subjects with non-missing assessments at an evaluation visit.
[3] Based on results recorded at the Baseline Visit (Day 1).
[4] Based on results recorded at the Day 22 Visit, before injection.
Note: By design, Cohort 1 did not receive any mitigation treatment. For Cohort 2, mitigation treatment was administered to both left and right buttocks. For Cohorts 3-6, mitigation treatment was administered to right buttock only.
Evaluable Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).

Table 14.2.3.1
Observed and Change from Baseline in Investigator Assessment of Bruising Severity, by Visit
Evaluable Population

Visit			Cohort 1 No Mitigation (N=xxx)		...	Cohort 6 PDL Treatment (N=xxx)	
Bruising Severity Rating [1]		Statistic [2]	Left	Right		Left	Right

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-2 on page 1, columns for cohorts 3-4 on page 2, and columns for cohorts 5-6 on page 3. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".
Repeat this table for Bruising Level ratings for days 4, 7, 14, and 22, and change from baseline at days 4, 7, 14 and 22. For Day 22, please include footnote [4] (i.e. display should be "Day 22 [4]" and "Change from Baseline at Day 22 [4]").

Table 14.2.3.2
Summary of Investigator-Global Aesthetic Improvement Scale (I-GAIS) Ratings and 1-Level Responders by Visit
Evaluable Population

Visit		Cohort 1 No Mitigation (N=xxx)		...	Cohort 6 PDL Treatment (N=xxx)	
Parameter	Statistic [1]	Left	Right		Left	Right
Day 22 [2]						
I-GAIS Rating [3]						
Number of Subjects Evaluated	n	xx	xx		xx	xx
+3 (Very much improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+2 (Much improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+1 (Improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
0 (No change)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-1 (Worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-2 (Much worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-3 (Very much worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Mean	xx.x	xx.x		xx.x	xx.x
	SD	xx.xx	xx.xx		xx.xx	xx.xx
1-level I-GAIS Responder [4]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Day 43						
I-GAIS Rating [3]						
Number of Subjects Evaluated	n	xx	xx		xx	xx
+3 (Very much improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+2 (Much improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+1 (Improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
0 (No change)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-1 (Worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-2 (Much worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-3 (Very much worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Mean	xx.x	xx.x		xx.x	xx.x
	SD	xx.xx	xx.xx		xx.xx	xx.xx
1-level I-GAIS Responder [4]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Day 71						
I-GAIS Rating [3]						
Number of Subjects Evaluated	n	xx	xx		xx	xx
+3 (Very much improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+2 (Much improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
+1 (Improved)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
0 (No change)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-1 (Worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-2 (Much worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
-3 (Very much worse)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
	Mean	xx.x	xx.x		xx.x	xx.x
	SD	xx.xx	xx.xx		xx.xx	xx.xx

Table 14.2.3.2
Summary of Investigator-Global Aesthetic Improvement Scale (I-GAIS) Ratings and 1-Level Responders by Visit
Evaluable Population

Visit			Cohort 1 No Mitigation (N=xxx)		...	Cohort 6 PDL Treatment (N=xxx)	
Parameter		Statistic [1]	Left	Right		Left	Right
1-level I-GAIS Responder [4]		n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] Percentages are based on number of subjects with non-missing assessments at an evaluation visit.
[2] Based on results recorded at the Day 22 visit, before injection.
[3] I-GAIS = Investigator-Global Aesthetic Improvement Scale.
[4] A subject is considered a 1-level I-GAIS Responder if they have an improved (+1, +2, +3) rating on the I-GAIS at an evaluation visit.
Note: By design, Cohort 1 did not receive any mitigation treatment. For Cohort 2, mitigation treatment was administered to both left and right buttocks. For Cohorts 3-6, mitigation treatment was administered to right buttock only.
Evaluable Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-2 on page 1, columns for cohorts 3-4 on page 2, and columns for cohorts 5-6 on page 3. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.2.3.3
Summary of Investigator-Bruising Improvement Scale (I-BIS) Ratings by Visit
Evaluable Population

Visit I-BIS Rating [1]	Statistic [2]	Cohort 3 Cold Packs (N=xxx)	Cohort 4 Arnica Patches (N=xxx)	Cohort 5 INhance Serum (N=xxx)	Cohort 6 PDL Treatment (N=xxx)
Day 2					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 4					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 7					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 14					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 22 [3]					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] I-BIS = Investigator-Bruising Improvement Scale. I-BIS Rating was directly obtained from the investigator's assessment rating comparing the bruising of the mitigation-treated buttock to the untreated (with mitigation treatment) buttock. The I-BIS assessment was not completed for subjects that did not receive mitigation treatment (Cohort 1) or subjects that received bilateral mitigation treatment (Cohort 2), as these subjects did not have an untreated buttock as a comparator.
[2] Percentages are based on number of subjects with non-missing assessments at an evaluation visit.
[3] Based on results recorded at the Day 22 visit, before injection.
Note: Evaluable Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Table 14.2.3.4
Summary of Subject-Bruising Improvement Scale (S-BIS) Ratings by Visit
Evaluable Population

Visit S-BIS Rating [1]	Statistic [2]	Cohort 3 Cold Packs (N=xxx)	Cohort 4 Arnica Patches (N=xxx)	Cohort 5 INhance Serum (N=xxx)	Cohort 6 PDL Treatment (N=xxx)
Day 2					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 4					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 7					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 14					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Day 22 [3]					
Number of Subjects Evaluated	n	xx	xx	xx	xx
1 (Worse – more bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2 (Similar)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3 (Improved – less bruising)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] S-BIS = Subject-Bruising Improvement Scale. S-BIS Rating was directly obtained from the subject's assessment rating comparing the bruising of the mitigation-treated buttock to the untreated (with mitigation treatment) buttock. The S-BIS assessment was not completed for subjects that did not receive mitigation treatment (Cohort 1) or subjects that received bilateral mitigation treatment (Cohort 2), as these subjects did not have an untreated buttock as a comparator.
[2] Percentages are based on number of subjects with non-missing assessments at an evaluation visit.
[3] Based on results recorded at the Day 22 visit, before injection.
Note: Evaluable Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Table 14.2.3.5
Summary of Patient Bothered by Bruising Ratings by Visit
Evaluable Population

Visit / Patient Bother Rating [1]	Statistic [2]	Cohort 1 No Mitigation (N=xxx) Left	Cohort 1 No Mitigation (N=xxx) Right	…	Cohort 6 PDL Treatment (N=xxx) Left	Cohort 6 PDL Treatment (N=xxx) Right
Day 4						
Number of Subjects Evaluated	n	xx	xx		xx	xx
1 (Not at all bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
2 (A little bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
3 (Moderately bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
4 (Extremely bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Day 7						
Number of Subjects Evaluated	n	xx	xx		xx	xx
1 (Not at all bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
2 (A little bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
3 (Moderately bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
4 (Extremely bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
Day 22 [3]						
Number of Subjects Evaluated	n	xx	xx		xx	xx
1 (Not at all bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
2 (A little bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
3 (Moderately bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)
4 (Extremely bothered)	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)	xx (xx.x)

[1] Results as reported using the Patient Bothered by Bruising Scale.
[2] Percentages are based on number of subjects with non-missing assessments at an evaluation visit.
[3] Based on results recorded at the Day 22 visit, before injection.
Note: By design, Cohort 1 did not receive any mitigation treatment. For Cohort 2, mitigation treatment was administered to both left and right buttocks. For Cohorts 3-6, mitigation treatment was administered to right buttock only.
Evaluable Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-2 on page 1, columns for cohorts 3-4 on page 2, and columns for cohorts 5-6 on page 3. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

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Datasets (extraction):  status(ddmmmyyyy),                                    ddmmmmyyyy:HHMM
Source:  ...\xxxxxxx.sas
```

Programming note: please include columns for cohorts 1-2 on page 1, columns for cohorts 3-4 on page 2, and columns for cohorts 5-6 on page 3. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.3.1.1
Overall Summary of Treatment-Emergent Adverse Events
Safety Population

Parameter	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	…	Cohort 6 PDL Treatment (N=xxx)
Total Number of TEAEs Reported [1]	n	xx	Xx	…	xx
Total Number of Mild TEAEs [1]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Total Number of Moderate TEAEs [1]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Total Number of Severe TEAEs [1]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Total Number of TEAEs related to QWO only [2]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Total Number of TEAEs related to Mitigation only [2]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Total Number of TEAEs related to both QWO and Mitigation [2]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Number of Subjects Reporting TEAEs:					
At least one TEAE	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
At least one Serious TEAE	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
At least one Severe TEAE	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
No Severe TEAE, but at least one Moderate TEAE	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
No Severe/Moderate TEAEs, but at least one Mild TEAE	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
At least one TEAE Leading to Withdrawal from Study	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
At least one TEAE Leading to Interruption/Discontinuation of QWO (CCH-aaes) only	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
At least one TEAE Leading Interruption/Discontinuation of Mitigation Treatment only	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
At least one TEAE Leading to Interruption/Discontinuation of both QWO (CCH-aaes) and Mitigation Treatment	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Number of Subjects with TEAEs Resulting in Death	n	xx	xx	…	xx

[1] Treatment emergent adverse events (TEAEs) are adverse events with a start date after the first dose of QWO (CCH-aaes). Total number of adverse events reported includes the same adverse event occurring multiple times for a subject being counted at each occurrence. Percentages were based on the overall total number of all adverse events within the cohort.
[2] Treatment emergent adverse events (TEAEs) reported as having possibly or probably related to either QWO, or mitigation treatment, or both. Missing relationships were considered as related.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.3.1.2
Overall Summary of QWO-Related Adverse Events
Safety Population

[1] QWO-related adverse events (QWO-related AEs) are treatment-emergent adverse events reported as having possibly or probably related to QWO (CCH-aaes). Missing relationships were considered as related. Total number of adverse events reported includes the same adverse event occurring multiple times for a subject being counted at each occurrence. Percentages were based on the overall total number of all adverse events within the cohort.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.3.1.1 with QWO- Related Adverse Events only. Replace TEAE with QWO-Related AEs. Do not include rows "Related to xxx" and "At least 1 AE leading to interruption or discontinuation of xxx".

Table 14.3.1.3
Overall Summary of Mitigation-Related Adverse Events
Safety Population

[1] Mitigation-related adverse events (Mitigation-related AEs) are treatment-emergent adverse events reported as having possibly or probably related to the mitigation treatment. Missing relationships were considered as related. Total number of adverse events reported includes the same adverse event occurring multiple times for a subject being counted at each occurrence. Percentages were based on the overall total number of all adverse events within the cohort.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.3.1.1 with Mitigation-Related Adverse Events only. Replace TEAE with Mitigation-Related AEs.. Do not include rows "Related to xxx" and "At least 1 AE leading to interruption or discontinuation of xxx".

Table 14.3.2.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class Preferred Term [1]	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	…	Cohort 6 PDL Treatment (N=xxx)
Number of Subjects with at least one TEAE [2]	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
System Organ Class 1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 1	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 3	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
System Organ Class 2	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 4	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 5	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 6	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 7	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple adverse events were reported within a given system organ class and/or preferred term, only one event was counted per subject.
[2] Treatment-emergent adverse events (TEAEs) are adverse events with a start date after the first dose of QWO (CCH-aaes).
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.3.2.2
QWO-Related Adverse Events by System Organ Class and Preferred Term
Safety Population

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple adverse events were reported within a given system organ class and/or preferred term, only one event was counted per subject.
[2] QWO-related adverse events (QWO-related AEs) are treatment-emergent adverse events reported as having possibly or probably related to QWO (CCH-aaes). Missing relationships were considered as related.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.3.2.1 with QWO-Related events only. Replace TEAE with QWO-Related AEs..

Table 14.3.2.3
Mitigation-Related Adverse Events by System Organ Class and Preferred Term
Safety Population

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple adverse events were reported within a given system organ class and/or preferred term, only one event was counted per subject.
[2] Mitigation-related adverse events (Mitigation-related AEs) are treatment-emergent adverse events reported as having possibly or probably related to the mitigation treatment. Missing relationships were considered as related.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.3.2.1 with Mitigation-Related events only. Replace TEAE with Mitigation-Related AEs.

Table 14.3.3.1
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class\ Preferred Term [1]	Severity	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	…	Cohort 6 PDL Treatment (N=xxx)
Number of Subjects whose most severe TEAE [2] is	Mild	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Moderate	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Severe	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
System Organ Class 1	Mild	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Moderate	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Severe	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 1	Mild	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Moderate	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Severe	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Preferred Term 2	Mild	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Moderate	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
	Severe	n (%)	xx (xx.x)	xx (xx.x)	…	xx (xx.x)

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple adverse events were reported within a given system organ class and/or preferred term, only the most severe event was counted per subject.
[2] Treatment-emergent adverse events (TEAEs) are adverse events with a start date after the first dose of QWO (CCH-aaes).
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, and columns for cohorts 4-6 and Overall on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.3.3.2
QWO-Related Adverse Events by System Organ Class, Preferred Term, and Severity
Safety Population

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple adverse events were reported within a given system organ class and/or preferred term, only the most severe event was counted per subject.
[2] QWO-related adverse events (QWO-related AEs) are treatment-emergent adverse events reported as having possibly or probably related to the QWO (CCH-aaes). Missing relationships were considered as related.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.3.2.1 with QWO-Related events only. Replace TEAE with QWO-Related AEs.

Table 14.3.3.3
Mitigation-Related Adverse Events by System Organ Class, Preferred Term, and Severity
Safety Population

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple adverse events were reported within a given system organ class and/or preferred term, only the most severe event was counted per subject.
[2] Mitigation-related adverse events (Mitigation-related AEs) are treatment-emergent adverse events reported as having possibly or probably related to the mitigation treatment. Missing relationships were considered as related.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.3.3.1 with Mitigation-Related events only. Replace TEAE with Mitigation-Related AEs.

Table 14.3.4.1
Summary of Serious Adverse Events by Frequency
Safety Population

Preferred Term [1]	System Organ Class [1]	Cohort 1 No Mitigation (N=xxx) Subjects n (%)	Cohort 1 No Mitigation (N=xxx) Occurrence [3] n	…	Cohort 6 PDL Treatment (N=xxx)
Any Serious TEAE [2]		xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Most Frequent Preferred Term	System Organ Class	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
2nd Most Frequent Preferred Term	System Organ Class	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
3rd Most Frequent Preferred Term	System Organ Class	xx (xx.x)	xx (xx.x)	…	xx (xx.x)

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple serious adverse events were reported within a given system organ class and/or preferred term, only one event was counted per subject.
[2] Serious adverse events (SAEs) were determined by the investigator and marked as SAE on eCRF.
[3] Occurrence is the total number of times the serious adverse event was reported in the study.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-2 on page 1, columns for cohorts 3-4 on page 2, and columns for cohorts 5-6 on page 3. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.3.5.1
Summary of Most Common (>=5%) Non-Serious Treatment-Emergent Adverse Events by Frequency
Safety Population

Preferred Term [1]	System Organ Class [1]	Cohort 1 No Mitigation (N=xxx) Subjects n (%)	Cohort 1 No Mitigation (N=xxx) Occurrence [3] n	…	Cohort 6 PDL Treatment (N=xxx)
Any Most Common Non-Serious TEAE [2]		xx (xx.x)	xx (xx.x)	…	xx (xx.x)
Most Frequent Preferred Term	System Organ Class	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
2nd Most Frequent Preferred Term	System Organ Class	xx (xx.x)	xx (xx.x)	…	xx (xx.x)
3rd Most Frequent Preferred Term	System Organ Class	xx (xx.x)	xx (xx.x)	…	xx (xx.x)

[1] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x). If multiple serious adverse events were reported within a given system organ class and/or preferred term, only one event was counted per subject.
[2] Any non-serious TEAEs (adverse events with a start date after the first dose of QWO [CCH-aaes]) reported at least 5% of subjects in any cohort at least once.
[3] Occurrence is the total number of times the non-serious TEAE was reported in the study.
Note: Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-2 on page 1, columns for cohorts 3-4 on page 2, and columns for cohorts 5-6 on page 3. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.4.1.1
Body Weight (kg) and BMI (kg/m^2)
Safety Population

Parameter Timepoint	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)
Body Weight (kg)					
Baseline [1]	n	xx	xx		xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	xx		xx
	Max	xx	xx		xx
Day 71/ET					
Value	n	xx	xx		xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	xx		xx
	Max	xx	xx		xx
Change from Baseline	n	xx	xx		xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	xx		xx
	Max	xx	xx		xx
BMI (kg/m^2)					
Baseline [1]	n	xx	xx	…	xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	xx		xx
	Max	xx	xx		xx
…	…	…	…	…	…

[1] Based on the last evaluable measurement before first QWO (CCH-aaes) injection at the Baseline Visit (Day 1).
Note: BMI = Body Mass Index; ET = Early Termination.
Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Table 14.4.1.1
Body Weight (kg) and BMI (kg/m^2)
Safety Population

Parameter Timepoint	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)

Programming note: please include columns for cohorts 1-3 on page 1, columns for cohorts 4-6 on page 2 if it is impossible to put all columns in one page. Repeat for BMI Day 71/ET Value and Change from Baseline. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.4.2.1
Vital Signs: Systolic Blood Pressure (mmHg)
Safety Population

Timepoint	Statistic	Cohort 1 No Mitigation (N=xxx)	Cohort 2 Compression (N=xxx)	...	Cohort 6 PDL Treatment (N=xxx)
Baseline [1]	n	xx	Xx		xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	Xx		xx
	Max	xx	Xx		xx
30 Minutes After Injection					
Value	n	xx	Xx		xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	Xx		xx
	Max	xx	Xx		xx
Change from Baseline	n	xx	Xx		xx
	Mean	xx.x	xx.x	…	xx.x
	SD	xx.xx	xx.xx	…	xx.xx
	Median	xx.x	xx.x	…	xx.x
	Min	xx	Xx		xx
	Max	xx	Xx		xx

[1] Based on the last evaluable measurement before first QWO (CCH-aaes) injection at the Baseline Visit (Day 1).
Notes: ET = Early Termination.
Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: please include columns for cohorts 1-3 on page 1, columns for cohorts 4-6 on page 2 if it is impossible to put all columns in one page. Cohort column headers should read: "Cohort 1 No Mitigation", "Cohort 2 Compression", "Cohort 3 Cold Packs", "Cohort 4 Arnica Patches", "Cohort 5 INhance Serum", "Cohort 6 PDL Treatment".

Table 14.4.2.2
Vital Signs: Diastolic Blood Pressure (mmHg)
Safety Population

[1] Based on the last evaluable measurement before first QWO (CCH-aaes) injection at the Baseline Visit (Day 1).
Notes: ET = Early Termination.
Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programming note: Use same format as Table 14.4.2.1. Replace Systolic BP with Diastolic BP.

Repeat Table 14.4.2.1 format for the following tables:

Table 14.4.2.3
Vital Signs: Body Temperature (oC)
Safety Population

Table 14.4.2.4
Vital Signs: Pulse Rate (beats per minute)
Safety Population

Listing 16.2.1.1
Subject Visits and Disposition

Subject ID	Cohort [1]	Visit	Visit Date (Study Day [2])	Visit Done?/If no, Reason	Visit Type	Completed Study?	Reason for Early Termination/Withdrawal
XXXX-XXXX	Cohort 1	Screening	yyyy-mm-dd (-xx)	Yes	Remote		
		Day 1	yyyy-mm-dd (xx)	Yes	Remote		
		Day 2	yyyy-mm-dd (xx)	No/xxxx	Remote		
		Day 4	yyyy-mm-dd (xx)	Yes	Remote		
		…	…	…	…	…	…
		Day 43	yyyy-mm-dd (xx)	Yes	Remote	No	Pregnancy (xxxx)
		Unscheduled (if any)	yyyy-mm-dd (xx)	Yes	In-Person		
XXXX-XXXX	Cohort 2	Screening	yyyy-mm-dd (-xx)	Yes			
		Day 1	yyyy-mm-dd (xx)	Yes			
		Day 2	yyyy-mm-dd (xx)	Yes			
		Day 4	yyyy-mm-dd (xx)	Yes			
		…	…	…	…	…	…
		Day 71/ET	yyyy-mm-dd (xx)	Yes		Yes	

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Study day is relative to the day of first QWO (CCH-aaes) injection (i.e. Date of Day 1).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Listing 16.2.1.2
Discontinued Subjects
All Subjects

Subject ID	Cohort [1]	First Injection Date	Last Visit Date	Time in Study (days)[2]	Reason for Early Termination/Withdrawal
XXXX-XXXX	Cohort 1	yyyy-mm-dd	yyyy-mm-dd	xx	xxxxxxxxxxxxxxxxx
XXXX-XXXX	Cohort 1	yyyy-mm-dd	yyyy-mm-dd	xx	Xxxxxxxxxxxxxxxxx
XXXX-XXXX	Cohort 2	yyyy-mm-dd	yyyy-mm-dd	xx	xxxxxxxxxxxxxxxxx
XXXX-XXXX	Cohort 4	yyyy-mm-dd	yyyy-mm-dd	xx	xxxxxxxxxxxxxxxxx
…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Time in Study (days) = (Last Visit Date) – (First Injection Date) + 1.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: Keep only discontinued subjects who are not screen failures.

Listing 16.2.1.3
Screen Failures
All Subjects

Subject ID	Cohort [1]	Screening Type	Screen Failure Date	Reason for Screen Failure	Specify
XXXX-XXXX	Cohort 1	Initial	yyyy-mm-dd	xxxxxxxxxxxxxxxxx	xxxxxxxxx
XXXX-XXXX	Cohort 1	Initial	yyyy-mm-dd	Xxxxxxxxxxxxxxxxx	Xxxxxxxxx
XXXX-XXXX	Cohort 2	Initial	yyyy-mm-dd	xxxxxxxxxxxxxxxxx	xxxxxxxxx
XXXX-XXXX	Cohort 4	Rescreening	yyyy-mm-dd	xxxxxxxxxxxxxxxxx	xxxxxxxxx
…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID.

Listing 16.2.1.4
Inclusion/Exclusion Criteria
All Subjects

Subject ID	Cohort [1]	Inclusion Criteria Not Met/ Exclusion Criteria Met	Inclusion/Exclusion Criterion
XXXX-XXXX	Cohort 1	INC01	xxxxxxxxxxxxxxxxx
XXXX-XXXX	Cohort 1	EXCL02	Xxxxxxxxxxxxxxxxx
XXXX-XXXX	Cohort 2	xxxxx	xxxxxxxxxxxxxxxxx
XXXX-XXXX	Cohort 4	xxxxx	xxxxxxxxxxxxxxxxx
…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID.

Listing 16.2.2
Protocol Deviations
All Subjects

Subject ID	Cohort [1]	Date of Deviation (Study Day [2])	Protocol Deviation Number/Category	Description of Protocol Deviation	Severity of Protocol Deviation
XXXX-XXXX	Cohort 1	yyyy-mm-dd (-xx)	xx/xxxxxxxxx	xxxxxxxxxxxxxxxxx	Major
XXXX-XXXX	Cohort 1	yyyy-mm-dd (xx)	xx/xxxxxxxxx	Xxxxxxxxxxxxxxxxx	Minor
XXXX-XXXX	Cohort 2	yyyy-mm-dd (-xx)	xx/xxxxxxxxx	xxxxxxxxxxxxxxxxx	xxxxxxxxx
XXXX-XXXX	Cohort 4	yyyy-mm-dd (xx)	xx/xxxxxxxxx	xxxxxxxxxxxxxxxxx	xxxxxxxxx
…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Study day is relative to the day of first QWO (CCH-aaes) injection (i.e. Date of Day 1).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID.

Listing 16.2.3
Exclusion from Analysis Population
All Enrolled Subjects

Subject ID	Cohort [1]	Population from Which Subject was Excluded [2]	Reason for Exclusion
XXXX-XXXX	Cohort 1	Evaluable	xxxxxxxxx
XXXX-XXXX	Cohort 1	Evaluable	xxxxxxxxx
XXXX-XXXX	Cohort 2	Safety	xxxxxxxxx
XXXX-XXXX	Cohort 4	Evaluable	xxxxxxxxx
…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Safety Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment. Evaluable Population includes all enrolled subjects who received at least 1 injection of QWO (CCH-aaes) with or without mitigation treatment and have at least one bruising assessment after the first dose of QWO (CCH-aaes).

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID.

Listing 16.2.4.1
Demographics
All Enrolled Subjects

Subject ID	Cohort [1]	Age (yrs)	Sex	Race (Specify)	Ethnicity	Fitzpatrick Skin Scale [2]	Child-bearing Potential? [3]	Date of Last Menstrual Period	Reason Cannot Bear Children (Specify)
XXXX-XXXX	Cohort 1	xx	Female	White	Hispanic	I	Yes	yyyy-mm-dd	
XXXX-XXXX	Cohort 1	xx	Female	Black	Not Hispanic	II	Yes	yyyy-mm-dd	
XXXX-XXXX	Cohort 2	xx	Female	Other(xxx)	xxxxxxxx	I	No		Other(xxxxxx)
XXXX-XXXX	Cohort 4	xx	Female	xxxxxxxxx	xxxxxxxx	III	Yes	yyyy-mm-dd	
…	…	…	…	…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Fitzpatrick Scale: I: Pale white skin, blue/hazel eyes, blond/red hair; II: Fair skin, blue eyes; III: Darker white skin; IV: Light brown skin; V: Brown skin; VI: Dark brown or black skin. Only subjects with a Fitzpatrick skin rating of I-III at the Screening Visit were eligible for the study per the protocol inclusion criteria.
[3] If yes, date of last menstrual period was collected. If no, reason cannot bear children was collected.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID.

Listing 16.2.4.2
Baseline Characteristics
All Enrolled Subjects

Subject ID	Cohort [1]	Height (cm)	Weight (kg)	BMI (kg/m^2)	Alcohol Use	Tobacco Use	Left/Right CR-PCSS Score at Screening [2]	Left/Right Hexsel CSS Score at Screening [3]
XXXX-XXXX	Cohort 1	xx	xx	xx	No	No	L: 3 R: 3	L: 0 R: 0
XXXX-XXXX	Cohort 1	xx	xx	xx	No	Current	L: 3 R: 3	L: xx R: xx
XXXX-XXXX	Cohort 2	xx	xx	xx	Current	Current	L: 3 R: 3	L: xx R: xx
XXXX-XXXX	Cohort 4	xx	xx	xx	Former	No	L: 3 R: 3	L: xx R: xx
…	…	…	…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] CR-PCSS = Clinician-Reported Photonumeric Cellulite Severity Scale. Only subjects with a baseline CR-PCSS rating of 3 (Moderate) on each buttock at the Screening Visit were included in the study.
[3] CSS = Cellulite Severity Scale. Only subjects with a baseline Hexsel CSS Subsection D score of 0 (Absence of flaccidity or sagging of skin) or 1 (Slightly draped appearance) on each buttock were included in the study.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID.

Listing 16.2.4.3
Medical and Surgical History
All Enrolled Subjects

Subject ID	Cohort [1]	Term	Start Date	Stop Date	Ongoing?
XXXX-XXXX	Cohort 1	Xxxxxxxxxxxxx	yyyy-mm-dd	yyyy-mm-dd	No
		Xxxxxxxxxxxxx	yyyy-mm-dd	yyyy-mm-dd	No
XXXX-XXXX	Cohort 2	Xxxxxxxxxxxxx	yyyy-mm-dd		Yes
		Xxxxxxxxxxxxx	yyyy-mm-dd	yyyy-mm-dd	No
…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by start date within a subject.

Listing 16.2.4.4
Prior and Concomitant Medications
All Enrolled Subjects

Subject ID	Cohort [1]	Prior or Concomitant [2]	S: System Organ Class P: Preferred Term V: Verbatim [3]	Start Date (Study Day)/ Stop Date (Study Day) [4]	Indication	D: Dose Unit R: Route F: Frequency	For AE?
XXXX-XXXX	Cohort 1	Prior	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	(yyyy-mm-dd (-xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	D: xx Unit R: xxxxxx F: xxxxxx	Yes
		Concomitant	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (xx)/ Ongoing	xxxxxxxxxx	D: xx Unit R: xxxxxx F: xxxxxx	Yes
XXXX-XXXX	Cohort 2	Prior	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (-xx)/ yyyy-mm-dd (xx)	xxxxxxxxxx	D: xx Unit R: xxxxxx F: xxxxxx	No
		Concomitant	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (xx)/ Ongoing	xxxxxxxxxx	D: xx Unit R: xxxxxx F: xxxxxx	Yes
…	…		…	…		…	

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Prior medications are any medication reported as taken prior to Day 1. Concomitant medications are any medication reported as taken on or after Day 1 (Baseline Visit) through Day 71/Early Termination Visit.
[3] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x).
[4] Study day is relative to the day of first QWO (CCH-aaes) injection (i.e. Date of Day 1).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all drugs will be sorted by start date within a subject.

Listing 16.2.4.5
Prior and Concomitant Procedures
All Enrolled Subjects

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Prior procedures are any procedure reported as administered prior to Day 1. Concomitant procedures are any procedures reported as administered on or after Day 1 (B Visit) through Day 71/Early Termination Visit.
[3] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x).
[4] Study day is relative to the day of first QWO (CCH-aaes) injection (i.e. Date of Day 1).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all drugs will be sorted by start date within a subject. Use same format as Listing 16.2.4.4. Remove column concerning dose/unit/frequency as this is not collected for procedures/therapies.

Listing 16.2.5.1
Treatment Administration: QWO (CCH-aaes)
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Visit Date	Visit Time	Treatment Area	Number of Injections
XXXX-XXXX	Cohort 1	Screening	yyyy-mm-dd	00:00	Left Buttock	xx
					Right Buttock	xx
		Day 1	yyyy-mm-dd	00:00	Left Buttock	xx
					Right Buttock	xx
XXXX-XXXX	Cohort 2	Screening	yyyy-mm-dd	00:00	Left Buttock	xx
					Right Buttock	xx
		Day 1	yyyy-mm-dd	00:00	Left Buttock	xx
					Right Buttock	xx
		Day 22	yyyy-mm-dd	00:00	Left Buttock	Xx
…	…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by visit date within a subject.

Listing 16.2.5.2
Treatment Administration: Mitigation Treatment
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Start Date (Study Day) [2]	End Date (Study Day) [2]	Mitigation Treatment	Administered Location(s)
XXXX-XXXX	Cohort 2	Day 1	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Compression Garment	Left Buttock, Right Buttock
		Day 2	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Compression Garment	Left Buttock, Right Buttock
XXXX-XXXX	Cohort 6	xxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Pulse Dye Laser Treatment	Right Buttock
		xxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Pulse Dye Laser Treatment	Right Buttock
		Xxxxx	yyyy-mm-dd (xx)	yyyy-mm-dd (xx)	Pulse Dye Laser Treatment	Right Buttock
…	…		…	…		…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Study day is relative to the day of first QWO (CCH-aaes) injection (i.e. Date of Day 1).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by visit date within a subject.

Listing 16.2.6.1
Investigator Assessment of Bruising Severity
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Assessment Date	Assessment Complete? If no, Reason	Treatment Area	Bruising Severity Rating [2]
XXXX-XXXX	Cohort 1	Day 1	yyyy-mm-dd	Yes	Left Buttock	4 (Very severe bruising)
					Right Buttock	2 (Moderate bruising)
		Day 2	yyyy-mm-dd	Yes	Left Buttock	xxxxxxxxx
					Right Buttock	Xxxxxxxxx
XXXX-XXXX	Cohort 2	Day 1	yyyy-mm-dd	No(xxxxxxxxxx)		
		Day 2	yyyy-mm-dd	xxxx	Left Buttock	xxxxxxxxx
					Right Buttock	Xxxxxxxxx
		Day 4	yyyy-mm-dd	xxxx	Left Buttock	xxxxxxxxx
…	…	…	…		…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Bruising severity rating was based on the following scale: 0 (None or almost no bruising), 1 (Mild bruising), 2 (Moderate bruising), 3 (Severe bruising), 4 (Very severe bruising).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Listing 16.2.6.2
Investigator Global Aesthetic Improvement Scale (I-GAIS) Assessment
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Assessment Date	Assessment Complete? If no, Reason	Treatment Area	I-GAIS Rating [2]
XXXX-XXXX	Cohort 1	Day 22	yyyy-mm-dd	Yes	Left Buttock	+3 (Very much improved)
					Right Buttock	+2 (Much improved)
		Day 43	yyyy-mm-dd	Yes	Left Buttock	xxxxxxxxx
					Right Buttock	Xxxxxxxxx
XXXX-XXXX	Cohort 2	Day 22	yyyy-mm-dd	No(xxxxxxxxxx)		
		Day 43	yyyy-mm-dd	xxxx	Left Buttock	xxxxxxxxx
					Right Buttock	Xxxxxxxxx
		Day 71	yyyy-mm-dd	xxxx	Left Buttock	xxxxxxxxx
…	…	…	…		…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] I-GAIS rating was based on the following scale: +3 (Very much improved), +2 (Much improved), +1 (Improved), 0 (No change), -1 (Worse), -2 (Much worse), -3 (Very much worse)
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Listing 16.2.6.3
Investigator Bruising Improvement Scale (I-BIS) Assessment
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Assessment Date	Assessment Complete? If no, Reason	I-BIS Rating [2]
XXXX-XXXX	Cohort 3	Day 2	yyyy-mm-dd	Yes	1 (Worse – more bruising)
		Day 4	yyyy-mm-dd	Yes	2 (Similar)
XXXX-XXXX	Cohort 4	Day 2	yyyy-mm-dd	Yes	xxxxxxxxx
		Day 4	yyyy-mm-dd	No(xxxxxxxxxx)	xxxxxxxxx
		Day 7	yyyy-mm-dd	xxxx	xxxxxxxxx
…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] I-BIS rating was based on the following scale: 1 (Worse – more bruising), 2 (Similar), 3 (Improved – less bruising). I-BIS Rating is directly obtained from the investigator's assessment rating comparing the bruising of the mitigation-treated buttock to the untreated (with mitigation treatment) buttock. The I-BIS assessment was not completed for subjects that did not receive mitigation treatment (Cohort 1) or subjects that received bilateral mitigation treatment (Cohort 2), as these subjects did not have an untreated buttock as a comparator.

Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Listing 16.2.6.4
Subject Bruising Improvement Scale (S-BIS) Assessment
All Enrolled Subjects

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] S-BIS rating was based on the following scale: 1 (Worse – more bruising), 2 (Similar), 3 (Improved – less bruising). S-BIS Rating is directly obtained from the subject's assessment rating comparing the bruising of the mitigation-treated buttock to the untreated (with mitigation treatment) buttock. The S-BIS assessment was not completed in subjects that did not receive mitigation treatment (Cohort 1) or subjects that received bilateral mitigation treatment (Cohort 2), as these subjects did not have an untreated buttock as a comparator.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject. Use same format as Listing 16.2.6.3.

Listing 16.2.6.5
Patient Bother by Bruising Assessment
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Assessment Date	Assessment Complete? If no, Reason	Treatment Area	Patient Bother by Bruising Rating [2]
XXXX-XXXX	Cohort 1	Day 22	yyyy-mm-dd	Yes	Left Buttock	3 (Moderately bothered)
					Right Buttock	1 (Not at all bothered)
		Day 43	yyyy-mm-dd	Yes	Left Buttock	xxxxxxxxx
					Right Buttock	Xxxxxxxxx
XXXX-XXXX	Cohort 2	Day 22	yyyy-mm-dd	No(xxxxxxxxxx)		
		Day 43	yyyy-mm-dd	xxxx	Left Buttock	xxxxxxxxx
					Right Buttock	Xxxxxxxxx
		Day 71	yyyy-mm-dd	xxxx	Left Buttock	xxxxxxxxx
…	…	…	…		…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Patient bothered by bruising rating was based on the following scale: 1 (Not at all bothered), 2 (A little bothered), 3 (Moderately bothered), 4 (Extremely bothered).
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Listing 16.2.6.7
Digital Photography
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Assessment Date	Timepoint [2]	Photos Taken? If no, Reason
XXXX-XXXX	Cohort 1	Day 1	yyyy-mm-dd	Before marking dimples and injection sites	Yes
		Day 2	yyyy-mm-dd	N/A	Yes
XXXX-XXXX	Cohort 2	Day 1	yyyy-mm-dd	xxxxxxxxxxx	No(xxxxxxxxxx)
		Day 2	yyyy-mm-dd	xxxxxxxxxxx	xxxx
…	…	…	…		

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Timepoint = N/A: no dimple or injection site markings were made at this visit; only 1 set of photos was required.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Listing 16.2.7.1
Adverse Events
All Enrolled Subjects

Subject ID	Cohort [1]	S: System Organ Class P: Preferred Term V: Verbatim [2]	Start Date (Study Day)/ Stop Date (Study Day)/ Duration [3]	T: TEAE? I: Injection Site Reaction? S: SAE? [4]	S: Severity T: Treatment O: Outcome	Relation to QWO/ Action Taken	Relation to Mitigation Treatment/ Action Taken
XXXX-XXXX	Cohort 1	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (-xx)/ yyyy-mm-dd (xx)/ xx	T: Yes I: No S: No	S: Mild T: None O: Recovered/ Resolved	Not Related/ Not Changed	Not Related/ Not Changed
		S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (xx)/ Ongoing	T: Yes I: No S: No	S: Moderate T: Medication O: Recovered/ Resolved	Probable/ Withdrawn	Not Related/ Not Changed
XXXX-XXXX	Cohort 2	S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (-xx)/ yyyy-mm-dd (xx)/ xx	T: Yes I: No S: No	S: xxx T: xxxx O: xxxx	xxxxx/xxxxx	xxxxx/xxxxx
		S: xxxxxxxxxxxxxx P: xxxxxxxxxxxxxx V: xxxxxxxxxxxxxx	yyyy-mm-dd (xx)/ Ongoing	T: Yes I: No S: No	S: xxxx T: xxxx O: xxxx	xxxxx/xxxxx	xxxxx/xxxxx
…	…	…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] System organ class and preferred term were coded using MedDRA dictionary (Version xx.x).
[3] Study day is relative to the day of first QWO (CCH-aaes) injection (i.e. Date of Day 1). Duration = (Stop Date) – (Start Date) + 1.
[4] TEAE = treatment-emergent adverse event; SAE = serious adverse event.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all AEs will be sorted by start date within a subject.

Repeat Listing 16.2.7.1 for the following listings:

Listing 16.2.7.2
Deaths
All Enrolled Subjects

Programmer's note: Include only death events.

Listing 16.2.7.3
Non-fatal Serious Adverse Events
All Enrolled Subjects

Programmer's note: Include only non-fatal serious adverse events.

Listing 16.2.7.4
Non-serious AEs Leading to either QWO or Mitigation Treatment Interruption or Discontinuation
All Enrolled Subjects

Programmer's note: Include only AEs where either QWO Action Taken or Mitigation Action Taken = Interrupted.

Listing 16.2.7.5
Non-serious AEs Leading to either QWO or Mitigation Treatment Withdrawn
All Enrolled Subjects

Programmer's note: Include only AEs where either QWO Action Taken or Mitigation Action Taken = Withdrawn.

Listing 16.2.8.1
Vital Signs
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Timepoint [2]	Assessment Date	Assessment Time	Assessment Complete? If no, Reason	Systolic BP (mmHg)	Diastolic BP (mmHg)	Pulse Rate (bpm)	Temp (°C)
XXXX-XXXX	Cohort 1	Screening	N/A	yyyy-mm-dd	00:00	Yes	xx	xx	xx	xx
		Day 1	Pre-injection			Yes	xx	xx	xx	xx
			15 minutes	yyyy-mm-dd	00:00	No(xxxxxxxxxx)				
			30 minutes	yyyy-mm-dd	00:00	xxxx	Xx	Xx	Xx	Xx
				yyyy-mm-dd	00:00					
XXXX-XXXX	Cohort 2	xxxxxx	xxxxxx	…	…	xxxx	xx	xx	xx	xx
		xxxxxx	xxxxxx			xxxx	xx	xx	xx	xx
		xxxxxx	xxxxxx			xxxx	xx	xx	xx	xx
…	…	…	…			…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
[2] Timepoint = N/A: no injections were administered at this visit; only 1 set of vital measurements were collected.

Note: BP = blood pressure; bpm = beats per minute.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Listing 16.2.8.2
Physical Examinations
All Enrolled Subjects

Subject ID	Cohort [1]	Visit	Assessment Date	Assessment Time	Assessment Complete? If no, Reason	Body System	Finding	Specify (if Abnormal)
XXXX-XXXX	Cohort 1	Screening	yyyy-mm-dd	00:00	Yes	Lungs	Normal	
		Day 1			No(xxxxxxxxxx)			
		Day 2	yyyy-mm-dd	00:00	xxxx	Heart	Abnormal	xxxxxxxxx
XXXX-XXXX	Cohort 2	xxxxxx	yyyy-mm-dd	00:00	xxxx	Other(xxxxx)	Abnormal	xxxxxxxxx
		xxxxxx	yyyy-mm-dd	00:00	xxxx	xxxxx	xxxxxx	
		xxxxxx	yyyy-mm-dd	00:00	xxxx	xxxxx	xxxxxx	
…	…	…	…	…	…	…	…	…

[1] Cohort 1 = No mitigation treatment; Cohort 2 = Compression garment on both buttocks; Cohort 3 = Instant cold packs on right buttock only; Cohort 4 = Arnica patches on right buttock only; Cohort 5 = INhance post-injection serum with TreHex technology on right buttock only; Cohort 6 = pulse dye laser treatment on right buttock only.
Datasets (extraction): status(ddmmmyyyy), ddmmmmyyyy:HHMM
Source: ...\xxxxxxx.sas

Programmer's Note: sort by subject ID first and all entries will be sorted by assessment date within a subject.

Signature Manifest

Document Number: RDM-CLIN-DOC-02000 **Revision:** 1

Title: EN3835-401 Statistical Analysis Plan - Module 1

All dates and times are in Eastern Time.

EN3835-401 SAP approval

RDM Approval Step

Name/Signature	Title	Date	Meaning/Reason
[redacted]	[redacted]	11 Feb 2021, 04:52:38 PM	Approved
		11 Feb 2021, 06:43:06 PM	Approved
		12 Feb 2021, 12:36:23 PM	Approved
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