	FORM	
	DOCUMENT #:	FM GP007.1
	REVISION:	E
Study Specific Document Review & Approval Form	PAGE 1 OF 1	

Sponsor: Therm Project Title: Therm RF 005

Document Type: Statistical Analysis Plan (SAP) Document Version: B

Text and Table Validation Required? ☐ Yes ☒ No					
If Yes, Performed by:		Signature:		Date	
Document Owner	Mark McIlduff	Signature:	Mark McIlduff	Date	19SEP2017

Functional Role	Name	Date	Signature	N/A
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BBA SAS Programmer Lead	Mark McIlduff	19SEP2017	Mark McIlduff	☐
BBA Stats Lead	Mark McIlduff	19SEP2017	Mark McIlduff	☐
BBA Clinical Lead				☒
BBA Regulatory Lead				☒
BBA Safety Lead				☒
BBA Medical Lead				☒
Sponsor Representative	Toni Fournier	9/18/17	Toni Fournier	☐
Sponsor Representative	Claudia Jennings	9/18/17	Claudia Jennings	☐
Sponsor Representative	Sam Dickson			☐

Comments:

BBA BOSTON BIOMEDICAL ASSOCIATES	FORM	
	DOCUMENT #:	FM GP007.1
	REVISION:	E
Study Specific Document Review & Approval Form	PAGE 1 OF 1	

Sponsor: Thermi Project Title: Thermi RF 005

Document Type: Statistical Analysis Plan (SAP) Document Version: B

Text and Table Validation Required? ☐ Yes ☒ No					
If Yes, Performed by:		Signature:		Date:	
Document Owner:	Mark McIlduff	Signature:		Date:	

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BBA Stats Lead	Mark McIlduff			☐
BBA Clinical Lead				☒
BBA Regulatory Lead				☒
BBA Safety Lead				☒
BBA Medical Lead				☒
Sponsor Representative	Toni Fournier			☐
Sponsor Representative	Claudia Jennings			☐
Sponsor Representative	Sam Dickson	15 Sep 2017		☐

Comments:

STATISTICAL ANALYSIS PLAN

Protocol Title (Number):

An Open-Label, Single-Center, Single-Treatment, Safety and Effectiveness Evaluation of Percutaneous Radiofrequency in Achieving Submental Lift

Thermi_0005

Sponsor: ThermiGen, LLC

Boston Biomedical Associates
100 Crowley Drive, Suite 216
Marlborough, MA 01752

Effective Date:

SEP 20 2017

Initials MM Date 19Sep2017

TABLE OF CONTENTS

1 ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
BBA	Boston Biomedical Associates
CRF	Case Report Forms
CSR	Clinical Study Report
FDA	United States Food and Drug Administration
ITT	Intent-To-Treat Population
MedDRA	Medical Dictionary for Regulatory Activities
NRS	Numerical Rating Scale
P-GAIS	Physician Global Aesthetic Improvement Scale
P-GSQ	Physician Global Satisfaction Questionnaire
PPP	Per-Protocol Population
PRA	Percutaneous Radiofrequency Ablation
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
S-GAIS	Subject Global Aesthetic Improvement Scale
S-GSQ	Subject Global Satisfaction Questionnaire
SOC	System Organ Class
SOP	Standard Operating Procedure
TEAE	Treatment Emergent AEs

2 SUMMARY

TITLE	An open-label, single-center, single-treatment, safety and effectiveness evaluation of percutaneous radiofrequency in achieving submental lift
PREFACE	This Statistical Analysis Plan (SAP) describes the planned analysis and reporting for ThermiGen, LLC protocol Thermi_0005 (An open-label, single-center, single-treatment, safety and effectiveness evaluation of percutaneous radiofrequency in achieving submental lift). This study is being conducted to assess the safety and effectiveness of the ThermiRF in the treatment of submental skin laxity. The following documents were reviewed in preparation of this SAP: • Clinical Research Protocol Thermi_0005, issued 10MAY2016 • Case report forms (CRFs) issued 18AUG2016 for Protocol Thermi_0005
PURPOSE	The purpose of this SAP is to outline the planned analyses in support of the Clinical Study Report (CSR) for protocol Thermi_0005. Exploratory analyses not necessarily identified in this SAP may be performed to support the clinical development program. Any post-hoc, or unplanned, analyses not identified in this SAP will be clearly identified in the respective CSR.
STUDY OBJECTIVES	The objective of this study is to assess the improvement in overall lift of the submental area at 90 days as determined by a quantitative assessment based on 3D photography.
ENDPOINTS	**Primary Efficacy:** The primary efficacy endpoint is the improvement in overall lift of the submental area at 90 days as determined by a quantitative assessment based on 3D photography. **Secondary Efficacy:** The secondary endpoint is overall aesthetic improvement of the submental area and jawline definition at Days 90 and 180 evaluated by the investigator and subject using the following subjective assessments: 1. Qualitative assessment based on 2D photography performed by blinded panel 2. Physician – Global Aesthetic Improvement Scale Scores (P-GAIS) 3. Subject – Global Aesthetic Improvement Scale Scores (S-GAIS) 4. Physician – Global Satisfaction Questionnaire (P-GSQ) 5. Subject – Global Satisfaction Questionnaire (S-GSQ) Each individual endpoint will be based on study subject population response for each individual endpoint. **Safety:** Safety will be evaluated using the following measures: 1. Numerical Rating Scale (NRS), a 10-point pain scale 2. Self-reported and observed adverse events **Exploratory:** Also of interest is the elasticity measurement at Days 90 and 180.
STUDY DESIGN	This study is a prospective, single-center, open-label study for the evaluation of the ThermiRF device in the treatment of submental skin laxity.
INTERIM ANALYSES	No annual reports for the FDA are anticipated prior to the end of data collection and database lock due to the short nature of this study. A single interim analysis is planned to support a manuscript and presentation. Final study results will not be made available until post database lock.
FINAL ANALYSES	All final planned analyses identified in this SAP will be completed after the last subject has completed their 6 month follow up.

3 SEQUENCE OF PLANNED ANALYSES

3.1 INTERIM ANALYSES

3.1.1 ANNUAL REPORTS

As this study is expected to be completed within one year, no annual reports are anticipated at this time.

3.1.2 OTHER INTERIM REPORTS

An aggregate review of data to support a publication and/or presentation is anticipated at this time. The timing of the interim report is expected to occur prior to database lock and prior to the final analysis.

3.2 FINAL ANALYSES AND REPORTING

All final, planned, analyses identified in the protocol and in this SAP will be performed only after the last subject has completed the Day 180 follow-up visit. Key statistics and study results will be made available to ThermiGen, LLC following database lock. Any post-hoc, exploratory analyses completed to support planned study analyses, which were not identified in this SAP, will be documented and reported as necessary. Any results from these unplanned analyses will also be clearly identified as post-hoc analyses.

4 STUDY OBJECTIVES AND ENDPOINTS

4.1 STUDY OBJECTIVES

4.1.1 PRIMARY OBJECTIVE/ENDPOINT

The primary endpoint is an improvement of at least 20 mm^2 in overall lift of the submental area at Day 90 as determined by a quantitative assessment based on 3D photography.

4.1.2 SECONDARY OBJECTIVE/ENDPOINTS

The secondary endpoint is overall aesthetic improvement of the submental area and jawline definition at Days 90 and 180 evaluated by the investigator and subject using the following subjective assessments:

1. Qualitative assessment based on 2D photography performed by blinded panel
2. Physician – Global Aesthetic Improvement Scale Scores (P-GAIS)
3. Subject – Global Aesthetic Improvement Scale Scores (S-GAIS)
4. Physician – Global Satisfaction Questionnaire (P-GSQ)
5. Subject – Global Satisfaction Questionnaire (S-GSQ)

Each individual endpoint will be based on study subject population response for each individual endpoint.

4.1.3 SAFETY ENDPOINTS

The safety endpoints will be self-reported and observed adverse events along with the reporting of the Numerical Rating Scale (NRS) as a 10-point pain scale.

5 SAMPLE SIZE

The null and alternative hypotheses are:

$$H_0: \pi \leq 0.45 \text{ (or 45\%) vs.}$$
$$H_a: \pi > 0.45$$

where π is the true proportion of subjects with at least 20 mm^2 lift. Under the assumptions that

1. $\pi = 0.70$ (or 70%) for subjects not prematurely withdrawing from the study; and
2. The dropout rate is 12.5% and all dropouts will be considered as non-responders

a sample of size 70 enrolled subjects provides approximately 85% power to reject the null hypothesis in favor of the alternative at a one-sided α=0.05.

6 ANALYSIS POPULATIONS

6.1 INTENT TO TREAT POPULATION (ITT)

The intent-to-treat (ITT) population for this study includes all subjects that signed the informed consent form, meet inclusion/exclusion criteria, and are enrolled in the study. The primary efficacy analysis will be performed using this population.

6.2 PER-PROTOCOL POPULATION (PP)

The per-protocol population (PP) for this study will include all subjects who have completed the Day 90 visit, have an evaluable photograph to measure the area of lift from the Day 90 visit, have not used an excluded medication, and do not have a major protocol violation (see Attachment 1).

6.3 SAFETY

The safety population of this study will include all enrolled subjects who received at least one treatment.

For clarification purposes of the analysis populations described in sections 6.1 – 6.3, the following table from section 8.6.2 of the clinical protocol has been included here for reference (Table 1).

Table 1. Subject Status Classification

Classification	Criteria
Screen Failure	Signs the ICD but does not meet entry criteria or withdraws prior to Visit 2.
Enrolled	Signs the ICD and met all inclusion/exclusion criteria
Treated	Signs the ICD and successfully completes V2
Discontinued/Withdrawal	Signed the ICD but does not successfully complete any visits
Completed	Signs the ICD and successfully completes all study visits

6.4 Rater Agreement Population

Thirty subjects, chosen in sequential order of enrollment, will have 2D photos taken at Day 60 in addition to those taken at baseline and days 90 and 180. These photos will be used to test inter and intra rater reliability among two unblinded clinicians and three blinded clinicians. For more details, see section 10.2.1.

7 General Issues for Statistical Analysis

7.1 Analysis Software

Analysis data sets, statistical analyses and associated output generated by Boston Biomedical Associates (BBA) will be programmed using SAS® Software version 9.4 or later or R version 3.2.3 or later. BBA Standard Operating Procedures (SOPs) will be followed in the creation and validation of all analysis datasets, tables, listings, figures and analyses.

7.2 Disposition of Subjects and Withdrawals

All subjects who provide written informed consent will be accounted for, and for purposes of subject accountability completeness, screen failures will also be presented. The frequency and percent of subjects in each analysis population (percentages will be based on number of enrolled subjects). The number and percent of ITT subjects who completed each scheduled assessment will be presented in a table. The number and percent of ITT subjects who prematurely withdrew from the study will be presented overall and by reason for discontinuation (subject withdrew consent, subject terminated prematurely by sponsor, subject non-compliance, adverse event/serious adverse event, other).

A flow chart and listing will also summarize subject accountability.

7.3 Methods for Withdrawals, Missing Data, and Outliers

All reasonable efforts will be made to obtain complete data for all subjects; however, missing observations most likely will occur. For the primary analysis on the primary efficacy endpoint, missing data will be imputed as a non-responder (i.e., imputed as "less than 20 mm^2 lift"). In the case that a subject has a Day 60 image evaluation but is missing the Day 90 image evaluation, the Day 60 evaluation will be carried forward in the primary endpoint analysis. As a sensitivity analysis, the primary analysis on the primary efficacy endpoint will also be carried out only on subjects with available data. For all remaining efficacy endpoints and for safety endpoints, there will be no imputation of missing data prior to analysis.

Tables detailing missing data and analysis populations will be provided in the final report.

7.4 Protocol Violations

Protocol violations will be summarized in the CSR. This summary will include the number and percent of subjects (overall and by site) with each violation type. Major protocol violations that may exclude a subject from the PP analysis population are identified in a study evaluability checklist and are included in Attachment 1.

7.5 Multiple Comparisons and Multiplicity

No adjustments for multiple comparison will be made, as secondary endpoints will not undergo formal statistical testing in support of labeling claims.

7.6 Assessment of Homogeneity

As this is a single-site study, no analysis will be performed for site homogeneity. Assessment of homogeneity across sex, age groups, and condition types will be performed as outlined in Section 12.

8 Demographics and Other Baseline Characteristics

8.1 Demographics

Age at screening (in years), sex (Male, Female), race (Not Done, White, Black or African American, American Indian/Alaskan Native, Asian, Native Hawaiian or Other Pacific Islander, Unknown, Other), ethnicity, height (inches), weight (lbs), BMI, heart rate (bpm), as well as systolic and diastolic blood pressure (mmHg) for all ITT subjects will be summarized in a table. For continuous variables, the summary will include sample size, mean, median, standard deviation, minimum and maximum. For categorical variables, the summary will include number and percent of ITT subjects.

8.2 Prior and Concurrent Medications

A listing will be provided detailing subjects' medications, but no table is planned at this time.

8.3 Baseline Medical History

The medical history of all ITT subjects will be summarized in a table. For each condition, the number and percent of subjects who do not have any history of the condition, who currently have the condition, and who have a resolved history of the condition will be presented.

8.4 Screening Physical Exam

All subjects will undergo a physical examination for examination of various body systems. For each body system, the number and percentage of ITT subjects considered normal and abnormal will be presented.

9 Treatment Details

For the ITT population, descriptive statistics of number of incisions made, number of RF passes, maximum temperature reached, average temperature reached, surface temperature, and time per unit area will be presented. Descriptive statistics consist of sample size, mean, median, standard deviation, minimum and maximum. These will be presented for right-lateral, frontal, left-lateral, and total.

10 EFFECTIVENESS ANALYSES

The following analyses will be carried out on the ITT and PP populations.

10.1 PRIMARY EFFECTIVENESS VARIABLE

The primary endpoint is an evaluation of the proportion of subjects with greater than 20 mm^2 lift at Day 90. The following hypothesis will be tested:

$$H_o: \pi \leq 0.45 \text{ (or 45\%)}$$
$$Ha: \pi > 0.45 \text{ (or 45\%)}$$

where π is the proportion of subjects with greater than 20 mm^2 lift at Day 90. Statistical summaries will include the number and percentage of subjects with greater than 20 mm^2 lift at Day 90 and a two-sided 90% confidence interval of the percentage based on the exact binomial distribution. A one-sided exact binomial proportion test will be performed at α=0.05. For the ITT population, the analysis will be carried out twice as follows:

1. Any subject with missing data at Day 60 and Day 90 will be treated as non-response to the photography (primary analysis). In the case that a subject has a Day 60 image evaluation but is missing the Day 90 image evaluation, the Day 60 evaluation will be carried forward in the primary endpoint analysis.
2. Any subject with missing data at Day 60 and Day 90 will be removed. In the case that a subject has a Day 60 image evaluation but is missing the Day 90 image evaluation, the Day 60 evaluation will be carried forward in the primary endpoint analysis.

10.2 SECONDARY EFFECTIVENESS VARIABLES

There will be no imputation of missing data before analyses on the following variables. Subjects with missing data for a given variable will be excluded from analysis on that variable.

10.2.1 VALIDATION OF RATER'S ASSESSMENT

To assess the rater's assessment of improvement, a total of five clinicians will review the 2D photography at both baseline and Day 60. Two of the five will be unblinded and will have knowledge of which photos are from which visit. The other three will remain blinded to the visit. All raters will be compared using Cohen's unweighted kappa statistic. Based on the Landis et al. scale, a substantial or almost perfect agreement among raters will validate the method.

10.2.2 PHYSICIAN – GLOBAL AESTHETIC IMPROVEMENT SCALE SCORES (P-GAIS)

Physician will report P-GAIS on a scale of 1-5 at Days 60, 90 and 180. Tables will summarize this in both the ITT and PP populations at each visit. The summary will include the number and percentage of subjects in each of the 5 categories and the two-sided Clopper-Pearson 95% CI of the percentages. A binomial test of proportions will be carried out for those scoring 3 or greater verse those scoring 2 and lower.

10.2.3 Subject – Global Aesthetic Improvement Scale Scores (S-GAIS)

As in section 10.2.2, subjects will report S-GAIS on a scale of 1-5 at Days 60, 90 and 180. Tables will summarize this in both the ITT and PP populations at each visit. The summary will include the number and percentage of subjects in each of the 5 categories and the two-sided Clopper-Pearson 95% CI of the percentages. A binomial test of proportions will be carried out for those scoring 3 or greater verse those scoring 2 and lower.

10.2.4 Physician – Global Satisfaction Questionnaire (P-GSQ)

Physician will fill out the P-GSQ at Days 60, 90 and 180. Tables will summarize this in both the ITT and PP populations at each visit. The summary will include the number and percentage of subjects in each of the categories and the two-sided Clopper-Pearson 95% CI of the percentages. A binomial test of proportions will be carried out to compare those assessed with improvement versus no improvement. Additionally, a binomial test of proportions will test satisfaction, by testing those grouped as "Satisfied" or "Very Satisfied" verse all others. Further, likelihood of recommendation will be tested amongst those responding "Likely" or "Very Likely" verse all others.

10.2.5 Subject – Global Satisfaction Questionnaire (S-GSQ)

Subjects will fill out the S-GSQ at Days 60, 90 and 180. Tables will summarize this in both the ITT and PP populations at each visit. The summary will include the number and percentage of subjects in each of the categories and the two-sided Clopper-Pearson 95% CI of the percentages. A binomial test of proportions will be carried out to compare those assessed with improvement versus no improvement. Additionally, a binomial test of proportions will test satisfaction, by testing those grouped as "Satisfied" or "Very Satisfied" verse all others. Further, likelihood of recommendation will be tested amongst those responding "Likely" or "Very Likely" verse all others.

10.2.6 Qualitative Assessment Based on 2D Photography

Subjects will have 2D photographs taken at screening, Day 90 and Day 180. A blinded panel will compare photographs and provide a qualitative assessment of overall improvement in submental area between the photos using a five-point scale (1= "Much Improved", 2= "Minimally Improved", 3= "No Change from Baseline", 4= "Minimally Worse", 5= "Much Worse"). Tables will summarize the ratings by reader and the median of the three readers by subject in both the ITT and PP populations at each visit. The summary will include the number and percentage of subjects in each of the categories and the two-sided Clopper-Pearson 95% CI of the percentages. Additionally, a binomial test of proportions will test improvement, by testing those grouped as "Much Improved" or "Minimally Improved" verse all others.

10.3 Exploratory Efficacy Variable - Elasticity

Elasticity is collected at baseline and Days 90 and 180. Descriptive statistics (sample size, mean, median, standard deviation, minimum, maximum) of elasticity and of the change from baseline will be presented at each visit. The two-sided 95% confidence interval of the means will be presented.

11 SAFETY ANALYSIS

All adverse events (AEs) will be coded using the standardized Medical Dictionary for Regulatory Activities (MedDRA) central coding dictionary, version 19.1 or greater. All analyses described below will be performed on the Safety Population.

11.1 NUMERICAL RATING SCALE (NRS)

NRS will be summarized for the Safety Population at Days 30, 60 (on the sample of size 30), 90, and 180. Change from Day 30 to Days 60, 90 and 180, and change from Day 90 to Day 180 will also be summarized. The summary consists of the sample size, mean, median, standard deviation, minimum and maximum.

11.2 ALL ADVERSE EVENTS

Summaries of incidence rates and relationship to the investigational device of individual treatment emergent AEs (TEAE) by System Organ Class (SOC) and Preferred Term (PT) will be prepared. A treatment emergent adverse event is defined as an event that started or worsened in severity at or after the first attempt at treatment. Because a subject may experience more than one TEAE, summaries will provide both the number of subjects and the number of events within a reporting period. Percentages provided will be the percent of subjects in the Safety Population experiencing one or more adverse events.

A listing of all adverse events will include the subject number, AE number, days since procedure, the AE SOC and PT, the severity of AE, whether or not the AE is classified as serious (SAE), the relationship of the AE to the investigational device or procedure, the action taken, the outcome, and the adjudication status.

AEs will be recorded for all enrolled subjects to time of withdrawal, and reported in a table for all Safety subjects.

11.3 ADVERSE EVENTS LEADING TO WITHDRAWAL

A summary of incidence rates (frequencies and percentages) of TEAEs leading to study withdrawal, by SOC and PT will be prepared for the Safety Population. A data listing of AEs leading to withdrawal will also be provided, displaying details of the event(s) captured on the CRF.

11.4 SERIOUS ADVERSE EVENTS (SAE)

Summaries of incidence rates and relationship to the investigational device/procedure of individual serious TEAEs SAEs by SOC and PT will be prepared. Summaries will provide both the number of subjects and the number of events within a reporting period. Percentages provided will be the percent of subjects experiencing one or more serious adverse events. A data listing of SAEs will also be provided, displaying details of the event(s) captured on the CRF.

11.5 DEVICE OR PROCEDURE RELATED ADVERSE EVENTS

Summaries of incidence rates of device and procedure related AEs and SAEs by SOC and PT will be prepared. Summaries will provide both the number of subjects and the number of events within a reporting period. Percentages provided will be the percent of subjects experiencing one or more device or

procedure related adverse events. Data listings of device and procedure related AEs and SAEs will also be provided, displaying details of the event(s) captured on the CRF.

11.6 Deaths

Should any subjects die during the course of this study, relevant information will be supplied in a data listing.

12 Planned Subgroup Analyses

12.1 Sex

To understand any potential sex differences which may be relevant to this study, the primary and secondary efficacy endpoints will be evaluated for each sex separately with the results side by side and presented in a table for the ITT analysis set. The purpose of this analysis is to assess consistency across the subgroups of sex.

12.2 Age

To understand any potential differences amongst age groups which may be relevant to this study, the primary and secondary efficacy endpoints will be evaluated for age groupings (to be determined at time of analysis that creates an even dichotomous split) separately with the results side by side and presented in a table for the ITT analysis set. The purpose of this analysis is to assess consistency across the subgroups of age.

12.3 Per-Protocol

As stated in previous sections, all secondary endpoint analysis will be reported in both the ITT and PP populations.

Additional subgroup or exploratory analyses may be completed following database lock.

13 Reporting Conventions

All reporting will meet the standards of BBA SOP BS002 and its associated work instructions. The planned shells of output for the study report is provided in Attachment 2.

13.1 Other Reporting Conventions

- All tables, figures, and data listings will be presented in Portrait Orientation, unless dimensions are such that Landscape orientation would be easier to interpret. Tables, figures, and listings will be presented on a single page whenever possible.
- Each table will have a supporting data listing.
- Legends will be used for all figures with more than one variable or item displayed.
- All date values will be presented as DDMMMYYYY (e.g., 29AUG2001) format. A four-digit year is preferred for all dates.
- All tables, figures, and data listings will have a version identifier and date/time stamp on the bottom of each page of output. The analysis population will be identified at the top of all tables, figures, and listings.
- The margins of all tables, figures, and listings will be 0.5-1 inch overall.

- The text of tables and listings will be Times New Roman, 8-12 point.
- Unless otherwise specified in this SAP, all categorical variable summaries will include % (n/N) of each category if >2 categories, of most important category if 2 categories.
- Unless otherwise specified in this SAP, all continuous variable summaries will include the mean, standard deviation, N, median, minimum, and maximum.
- Minimum and maximum will be reported with the number of significant figures as was reported on the CRF, while median, mean and standard deviation will be reported with have one more decimal place than the data.
- Percentages will be reported to one decimal place, unless more precision is required for accuracy.
- P-values will be reported to three decimal places with a leading zero (for example, 0.032). Any p-values that are less than 0.001 will be reported as <0.001.

ATTACHMENT 1. MAJOR PROTOCOL DEVIATIONS EVALUABILITY CHECKLIST

Attached to SAP as a reference.

ATTACHMENT 2. TABLE, FIGURE, AND LISTING SHELLS

Attached to SAP as a reference.

Appendix 1: Evaluability Checklist for Definition of Deviations (Major vs. Minor)

DEVIATION CATEGORY	DEVIATION SUBCATEGORY	Selected for study? Yes/No	MEETS THE DEFINITION OF MAJOR?	EXCLUDED FROM PER PROTOCOL ANALYSIS?
INFORMED CONSENT		**Yes**		
Role Responsible for Identification and Tracking: **Sponsor Clinical** **Method of Identification:** Direct review of each subject's signed ICF	a. Signed informed consent/assent not available on site	**Yes**	Y	Y
	b. Wrong informed consent/assent version signed	**Yes**	Y	Y
	c. Informed consent not signed and/or dated by subject (or parent/Legally Acceptable representative, if applicable)	**Yes**	Y	Y
	d. Informed consent/assent not signed and/or dated by appropriate site staff.	**Yes**	Y	N
	e. Informed consent/assent not signed prior or at Visit 1 following any study procedure	**Yes**	Y	Y
	f. Other informed consent/assent deviations	**Yes**	Y	
Study Specific Details and Rationale: A. Site to contact subject for copy of ICF for files If subject not provided copy of ICF or copy not available, follow instructions for C. B. Assess follow-up and signing of correct version. C. Follow-up and document reason for oversight, inform IRB as required. Counsel site. D. Assess impact with study team.				
ELIGIBILITY CRITERIA NOT MET	**NA**	**Yes**	Yes	

DEVIATION CATEGORY	DEVIATION SUBCATEGORY	Selected for study? Yes/No	MEETS THE DEFINITION OF MAJOR?	EXCLUDED FROM PER PROTOCOL ANALYSIS?
Role Responsible for Identification and Tracking: **Sponsor Clinical** **Method of Identification:** Direct review of each subject's source records when able. Direct review of electronic data file (remote desk monitoring)	All eligibility criteria	**Yes**	Y	N
	Select eligibility criteria not met	**N**	Y	Y
Study Specific Details and Rationale: **All eligibility criteria deviations are to be reviewed for consideration of important status.**				
NOT WITHDRAWN AFTER DEVELOPING WITHDRAWAL CRITERIA		**Yes**		
Role Responsible for Identification and Tracking: **Sponsor Clinical** **Method of Identification:** During monitoring visits, review of data.	a. Not withdrawn from study	**Yes**	Y	Y
	b. Not discontinued from study treatment	**Yes**	Y	NA
	c. Other deviation of not being withdrawn after developing withdrawal criteria	**Yes**	Y	NA
Study Specific Details and Rationale: All protocol specified withdrawal criteria should be reviewed to determine the status of "important" and if documentation exists supporting the non-withdrawal of the subject as well as discussions between the investigator and the sponsor.				
EXCLUDED MEDICATION OR DEVICE		**Yes**		

DEVIATION CATEGORY	DEVIATION SUBCATEGORY	Selected for study? Yes/No	MEETS THE DEFINITION OF MAJOR?	EXCLUDED FROM PER PROTOCOL ANALYSIS?
Role Responsible for Identification and Tracking: Sponsor Clinical	a. Medication or dose of medication, excluded by the protocol, was administered	**Yes**	Y	N
	b. Device, excluded by the protocol, was administered (***Example: received another device treatment during study conduct***)	**Yes**	Y	Y
Study Specific Details and Rationale: **All medication deviations should be reviewed to determine if documentation exists supporting the non-withdrawal of the subject as well as discussions between the investigator and the sponsor.**				
VISIT COMPLETION		**Yes**		
Role Responsible for Identification and Tracking: Sponsor Clinical **Method of Identification:** Data review.	a. Missed visit at critical data point	**Yes**	Y	Y
	b. Missed any visit other than critical data point	**Yes**	Y	N
	c. Out of window visit/phone contact	**Yes**	N	N
Study Specific Details and Rationale: A. Missed visits will be reviewed for importance as follows: is there a pattern of non-compliance, was the visit missed due to an AE/SAE, or because of safety management guidance. Multiple missed consecutive visits/phone contact will be assessed. Team will review these categories during reviews and determine importance.				
ASSESSMENT OR TIME POINT COMPLETION		**Yes**		
Role Responsible for Identification and/or Tracking:	a. Missed critical assessment (e.g., Photos for critical timepoint, questionnaires)	**Yes**	Y	Y
	b. Incomplete assessment	**Yes**	Y	N
	c. Assessment not properly performed	**Yes**	Y	N

DEVIATION CATEGORY	DEVIATION SUBCATEGORY	Selected for study? Yes/No	MEETS THE DEFINITION OF MAJOR?	EXCLUDED FROM PER PROTOCOL ANALYSIS?
Sponsor clinical team **Method of Identification:** Data review	d. Out of window assessment (***optional***)	**Yes**	N	N
	e. Out of Window efficacy assessment (***optional***)	**Yes**	Y	N
	f. Out of Window safety assessment (***optional***)	**Yes**	Y	N
	g. Out of Window treatment administration (***optional***)	**N/A**	Y	N
Study Specific Details and Rationale: Part 1: Overall, assessments will be reviewed to determine if there is a general pattern of non-compliance which may be determined by the team to be Important. Missed VS and physical exam may impact subject safety if changes in these assessments cannot be evaluated. AEs must be assessed to determine safety of IP. Missed efficacy evaluations (i.e., questionnaires) will impact the data analysis and integrity of the study.				
FAILURE TO REPORT SAFETY EVENTS PER PROTOCOL		**Yes**		
Role Responsible for Identification and Tracking: Investigator, sponsor clinical team **Method of Identification:** Review of safety reports (spontaneous or voluntary reports)	a. SAE Occurred but was not reported. SAE warranted subject be discontinued but subject was not discontinued	**Yes**	Yes	N
	b. AEs of special interest not reported or not properly qualified by the PI for causality	**Yes**	No	N
	c. Pregnancy occured	**Yes**	Yes	N
	d. Other: Define: RASH (specific eCRF page)	**Yes**	Yes	N
Study Specific Details and Rationale:				

Table 1
Analysis Populations

	% (n/N)
All Enrolled	XX
Intention to Treat Population (ITT)	XX.X (X/XX)
Per Protocol Population (PPP)	XX.X (X/XX)
Safety Population (SAF)	XX.X (X/XX)
Note: Percentages are based on "All Enrolled"	

Listing 1
Analysis Populations

Subject ID	**Enrolled**	**ITT**	**PP**	**SAF**
XX-XXX	Yes/No	Yes/No	Yes/No	Yes/No

Table 2 **Subject Accountability** **ITT Population**				
Visit	**Eligible** **N**	**Missed** **% (n/N)**	**Complete** **% (n/N)**	**Early Exit** **% (n/N)**
Screening	XXX			
Procedure	XX	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Day 30	XX	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Day 60	XX	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Day 90	XX	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Day 180	XX	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)

Note: Percentages are based on the number of subjects in the ITT Population.

Listing 2 **Subject Accountability**								
Subject ID	**Screening Date**	**Procedure Date**	**30 Day Visit**	**60 Day Visit**	**90 Day Visit**	**180 Day Visit**	**Study Exit**	**Exit Reason**
XX-XXX	Date9.	Date9.	Date9.	Date9.	Date9.	Date9.	Date9.	

Figure 1. Subject Accountability Flowchart

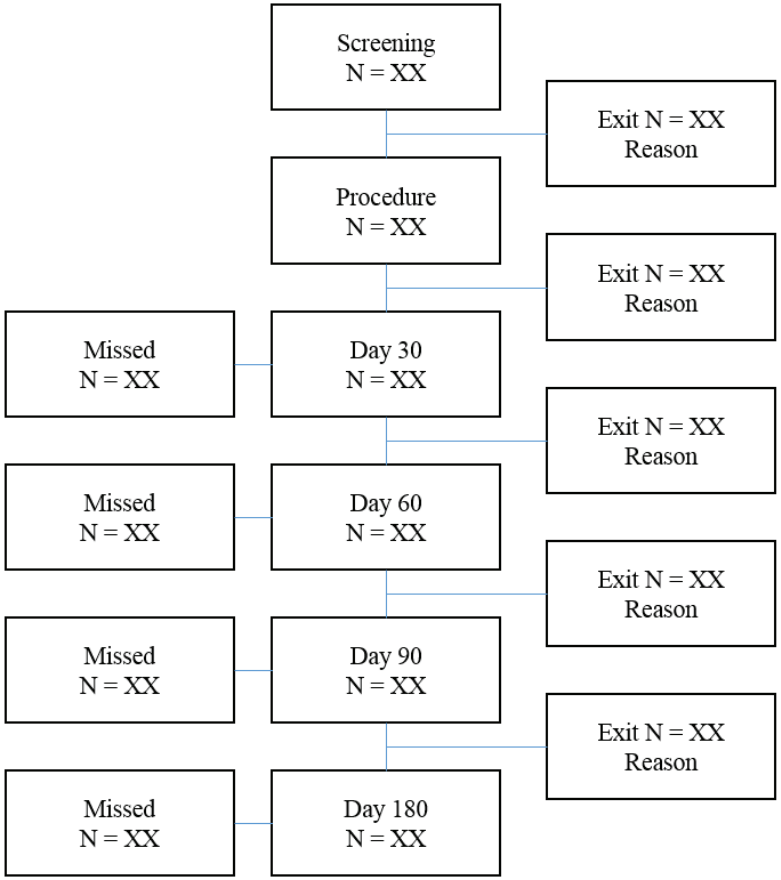

Table 3
Subject Demographics and Baseline Characteristics
ITT Population

	N=XX
Age (years)	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)
Sex	
Male	XX.X (X/XX)
Female	XX.X (X/XX)
Race	
White	XX.X (X/XX)
Black or African American	XX.X (X/XX)
American Indian/Alaskan Native	XX.X (X/XX)
Asian	XX.X (X/XX)
Native Hawaiian or Other Pacific Islander	XX.X (X/XX)
Other [1]	XX.X (X/XX)
Unknown/Not done	XX.X (X/XX)
Ethnicity	
Hispanic	XX.X (X/XX)
Non Hispanic	XX.X (X/XX)
Height (inches)	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)
Weight (lbs)	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)
BMI	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)
Heart Rate (bpm)	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)
Blood Pressure - Systolic (mmHg)	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)
Blood Pressure - Diastolic (mmHg)	
Mean ±SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)

[1] See supportive listing for specific details

Listing 3
Subject Demographics and Baseline Characteristics

Subject ID	Age	Sex	Race	Ethnicity	Height (in.)	Weight (lb.)	BMI	Heart Rate (BPM)	SBP	DBP
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 4
Medical History
ITT Population

	% (n/N)
Aesthetic Procedures to the Lower Part of the Face and Neck	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Injury to the Head	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Severe Solar Elastosis	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Facial Wounds or Acute Infections in the Lower Part of the Face or Neck	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Immunodeficiency	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Injury Requiring Implants or Metal Stents	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Cancer	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Cardiovascular Disease	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Allergies	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)

Psychiatric Disorders	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Congenital Anomaly	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)
Other [2]	
Current condition	XX.X (X/XX)
Past, resolved	XX.X (X/XX)
No prior history	XX.X (X/XX)

[1] Subjects may have multiple past conditions, but will only be accounted for once for each separate condition with "Current" superseding "Past, resolved".
[2] See supporting listing for details

Listing 4
Medical History

Subject ID	Aesthetic Procedures to the Lower Part of the Face and Neck	Injury to the Head	Severe Solar Elastosis	Facial Wounds or Acute Infections in the Lower Part of the Face or Neck	Immunodeficiency	Injury Requiring Implants or Metal Stents	Cancer	Cardiovascular Disease	Allergies	Psychiatric Disorders	Congenital Anomaly	Other (Specify)
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 5 **Screening Physical Exam** **ITT Population**	
	% (n/N)
Eyes	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)
Ears, Nose, Throat	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)
Head and Neck	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)
Heart	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)
Chest and Lungs	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)
Abdomen	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)
General Appearance	
Normal	XX.X (X/XX)
Abnormal	XX.X (X/XX)
Not Done	XX.X (X/XX)

Listing 5 **Screening Physical Exam**							
Subject ID	**Eyes**	**Ears, Nose, Throat**	**Head and Neck**	**Heart**	**Chest and Lungs**	**Abdomen**	**General Appearance**
XX-XXX	XX	XX	XX	XX	XX	XX	XX

Table 6
Treatment Details
ITT Population

	Right-lateral (N=XX)	Frontal (N=XX)	Left-Lateral (N=XX)	Total (N=XX)
Number of Incisions				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)
Number of RF Passes				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)
Maximum Temperature Reached				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)
Average Temperature Reached				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)
Surface Temperature				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)
Time per Unit Area				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)	XX.X (XX, XX)

Listing 6a
Treatment Details

	Right - Lateral						Frontal						Left-Lateral					
Subject ID	**# Incisions**	**# Passes**	**Avg. Temp**	**Max. Temp**	**Surface Temp.**	**Time**	**# Incisions**	**# Passes**	**Avg. Temp**	**Max. Temp**	**Surface Temp.**	**Time**	**# Incisions**	**# Passes**	**Avg. Temp**	**Max. Temp**	**Surface Temp.**	**Time**
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Listing 6b
Treatment Details

	Total					
Subject ID	**# Incisions**	**# Passes**	**Avg. Temp**	**Max. Temp**	**Surface Temp.**	**Time**
XX-XXX	XX	XX	XX	XX	XX	XX

Table 7.1 **Study Endpoints - Primary Endpoint** **ITT Population**				
	Population	**% (n/N)**	**One-sided p-value [1]**	**95% CI [2]**
Improvement ≥ 20 mm^2 at Day 90	**ITT (missing subjects as failures)**	XX.X (X/XX)	X.XXX	(X.X, X.X)
	Subjects with Day 90 missing data	XX		
	Subjects with Day 60 data carried forward	XX		
Improvement ≥ 20 mm^2 at Day 90	**ITT (excluding missing subjects)**	XX.X (X/XX)	X.XXX	(X.X, X.X)
	Subjects with Day 60 data carried forward	XX		

[1] Null hypothesis is that the true percentage of subjects with ≥ 20 mm^2 improvement is less than or equal to 45%.

P-value is calculated based on the one-sided exact binomial test.

[2] Two-sided 95% Clopper-Pearson confidence interval of the percent of subjects with improvement.

Listing 7.1 **Study Endpoints - Primary Endpoint**				
Subject ID	**Analysis Population**	**Day 60 Improvement**	**Day 90 Improvement**	**Endpoint**
XX-XXX	XX	XX or N/A	XX or Missing	XX

Table 7.1.1
Study Endpoints – Qualitative Assessment for the 2D Imaging
ITT Population [1]

	Percent Agreement	Kappa Statistic [2]
Overall		
	XX.X (X/XX)	X.XXX
Subgroups [3]		
Reader 1-2	XX.X (X/XX)	X.XXX
Reader 1-3	XX.X (X/XX)	X.XXX
Reader 1-4	XX.X (X/XX)	X.XXX
Reader 1-5	XX.X (X/XX)	X.XXX
Reader 2-3	XX.X (X/XX)	X.XXX
Reader 2-4	XX.X (X/XX)	X.XXX
Reader 2-5	XX.X (X/XX)	X.XXX
Reader 3-4	XX.X (X/XX)	X.XXX
Reader 3-5	XX.X (X/XX)	X.XXX
Reader 4-5	XX.X (X/XX)	X.XXX

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Readers compared using Cohen's unweighted Kappa statistic
[3] Readers 1 and 2 were unblinded to image visit date, Readers 3, 4, and 5 were blinded to image visit date.

Listing 7.1.1
Study Endpoints – Qualitative Assessment for the 2D Imaging

Subject ID	Analysis Population	Reader 1	Reader 2	Reader 3	Reader 4	Reader 5
XX-XXX	XX	XX	XX	XX	XX	XX

Table 7.1.2
Study Endpoints – Qualitative Assessment for the 2D Imaging at Day 60
ITT Population [1]

	Reader 1 [2]	Reader 2 [2]	Reader 3 [3]	Reader 4 [3]	Reader 5 [3]
Based on your perceived Baseline vs. Day 60, how would you rate observed submental area change at Day 60?					
Much Improved	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Minimally Improved	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
No change from Baseline	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Minimally Worse	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Much Worse	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Reader unblinded to image visit date.
[3] Reader blinded to image visit date.

Listing 7.1.2
Study Endpoints – Qualitative Assessment for the 2D Imaging

Subject ID	Analysis Population	Reader 1	Reader 2	Reader 3	Reader 4	Reader 5
XX-XXX	XX	XX	XX	XX	XX	XX

Table 7.2.1 **Secondary Endpoint – P-GAIS** **ITT Population with Available Data**						
	Day 60 [1]		**Day 90**		**Day 180**	
Assessment		**95% CI[2]**		**95% CI[2]**		**95% CI[2]**
Physician - Global Aesthetic Improvement Scale (P-GAIS)						
5 (Very Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
4 (Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
3 (Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
2 (No Change)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
1 (Worse)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.

[2] Two-sided 95% Clopper-Pearson confidence interval.

[3] p-value from Binomial Proportion Test for proportion of subjects who have at least "Improved" [score of 3 or greater]

Listing 7.2.1 **Secondary Endpoint – P-GAIS**				
Subject ID	**Analysis Population**	**Day 60 [1]**	**Day 90**	**Day 180**
XX-XXX	XX	XX	XX	XX

Table 7.2.2
Study Endpoints - S-GAIS
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
Assessment		**95% CI [2]**		**95% CI [2]**		**95% CI [2]**
Subject - Global Aesthetic Improvement Scale (S-GAIS)						
5 (Very Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
4 (Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
3 (Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
2 (No Change)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
1 (Worse)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.
[3] p-value from Binomial Proportion Test for proportion of subjects who have at least "Improved" [score of 3 or greater]

Listing 7.2.2
Secondary Endpoint – S-GAIS

Subject ID	Day 60 [1]	Day 90	Day 180
XX-XXX	XX	XX	XX

Table 7.2.3
Study Endpoints - P-GSQ
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
Assessment		**95% CI [2]**		**95% CI [2]**		**95% CI [2]**
Physician - Global Satisfaction Questionnaire (P-GSQ)						
When looking at the photo images and respective to your clinician assessment during this visit, do you see any change on the treated area with respect to "improvement" of the skin and overall area?						
Yes, *if "yes" please check all that apply:*	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less sagging on the jawline and cheeks	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Tighter/lift under the chin area	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother skin texture	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Jaw line more defined	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less wrinkles/lines	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Other	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	
Compared to "BEFORE" treatment how does the subject's skin ***feel*** today (check all that apply?						
Tighter	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Firmer	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change from prior to treatment	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
How satisfied are you with the results of the treatment?						
Very Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Neutral	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Very Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [4]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.
[3] p-value from Binomial Proportion Test for proportion of subjects who were marked "Improved"
[4] p-value from Binomial Proportion Test for proportion of subjects who were marked "Satisfied" or "Very Satisfied" and "Likely" or "Very Likely"

Listing 7.2.3
Study Endpoints - P-GSQ

		Day 60 [1]			Day 90			Day 180		
Subject ID	**Analysis Population**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 7.2.4
Study Endpoints - S-GSQ

ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
Assessment		**95% CI [2]**		**95% CI [2]**		**95% CI [2]**
Subject - Global Satisfaction Questionnaire (S-GSQ)						
Have you noticed any change with respect to "improvement" of the skin appearance of your neck?						
Yes, *if "yes" please check all that apply:*	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less sagging on the jawline and cheeks	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Tighter/lift under the chin area	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother skin texture	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Jaw line more defined	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less wrinkles/lines	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Other	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	
Compared to "BEFORE" treatment how does your skin ***feel*** today (check all that apply?						
Tighter	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Firmer	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Make-up application easier	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Shaving easier	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change from prior to treatment	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
How satisfied are you with the results of your treatment?						
Very Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Neutral	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Very Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [4]	X.XXX		X.XXX		X.XXX	
How likely are you to recommend this treatment to family and friends?						
Very Likely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Likely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Neutral	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Unlikely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Very Unlikely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [4]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.
[3] p-value from Binomial Proportion Test for proportion of subjects who were marked "Improved"
[4] p-value from Binomial Proportion Test for proportion of subjects who were marked "Satisfied" or "Very Satisfied" and "Likely" or "Very Likely"

Listing 7.2.4
Study Endpoints - S-GSQ

		Day 60 [1]				Day 90				Day 180			
Subject ID	Analysis Population	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Recommend?	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Recommend?	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Recommend?
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 7.2.5
Study Endpoints – Qualitative Assessment for the 2D Imaging at Day 90 and Day 180 compared to Baseline
ITT Population

	Day 90							
	Reader 1	**95% CI [1]**	**Reader 2**	**95% CI [1]**	**Reader 3**	**95% CI [1]**	**Total [3]**	**95% CI [1]**
Much Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Much Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Improvement								
Yes	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [2]	X.XXX		X.XXX		X.XXX		X.XXX	
	Day 180							
Much Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Much Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Improvement								
Yes	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [2]	X.XXX		X.XXX		X.XXX		X.XXX	

[1] Two-sided 95% Clopper-Pearson confidence interval.
[2] p-value from Binomial Proportion Test for proportion of subjects who were marked "Much Improved" or "Minimally Improved"
[3] Median of 3 Reader's scores

Listing 7.2.5
Study Endpoints – Qualitative Assessment for the 2D Imaging

		Day 90			**Day 180**		
Subject ID	**Analysis Population**	**Reader 1**	**Reader 2**	**Reader 3**	**Reader 1**	**Reader 2**	**Reader 3**
XX-XXX	XX	XX	XX	XX	XX	XX	XX

Table 7.3

Study Endpoints - Exploratory Endpoint Elasticity

ITT Population with Available Data

	Baseline N=		**Day 90 N=**		**Day 180 N=**	
Assessment	**Mean ± SD (N) Median (Min, Max)**	**95% CI [1]**	**Mean ± SD (N) Median (Min, Max)**	**95% CI [1]**	**Mean ± SD (N) Median (Min, Max)**	**95% CI [1]**
Elasticity						
R0	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R2	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R5	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R7	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R9	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
Change from Baseline Elasticity						
R0	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R2	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R5	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R7	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)
R9	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX, XX)	(X.X, X.X)

[1] Two-sided 95% confidence interval of the percentage or the mean.

Listing 7.3
Study Endpoints - Exploratory Endpoint Elasticity

Subject ID	**Analysis Population**	**Baseline**	**Day 90 (Change from Baseline)**	**Day 180 (Change from Baseline)**
XX-XXX	XX	XX	XX (XX)	XX (XX)

Figure 2. Bar chart for R0 and R9 output

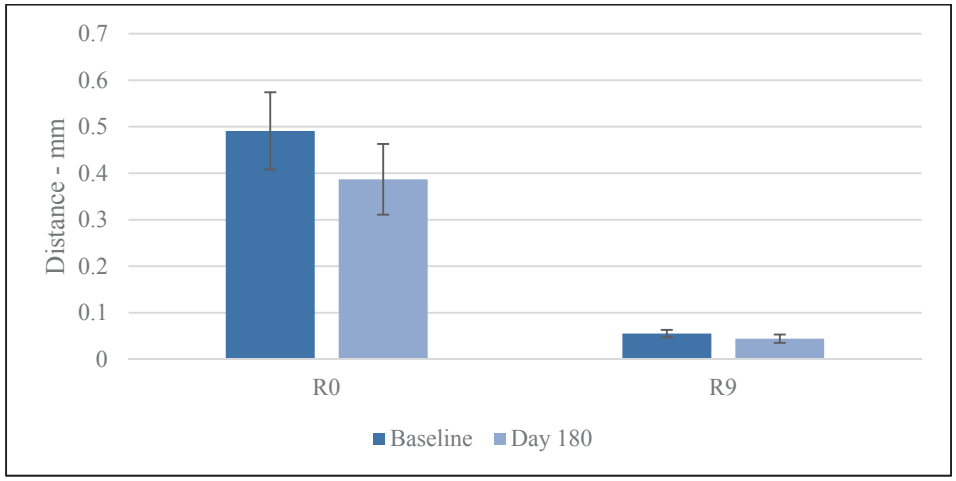

Figure 3. Bar chart for R2, R5, and R7 output

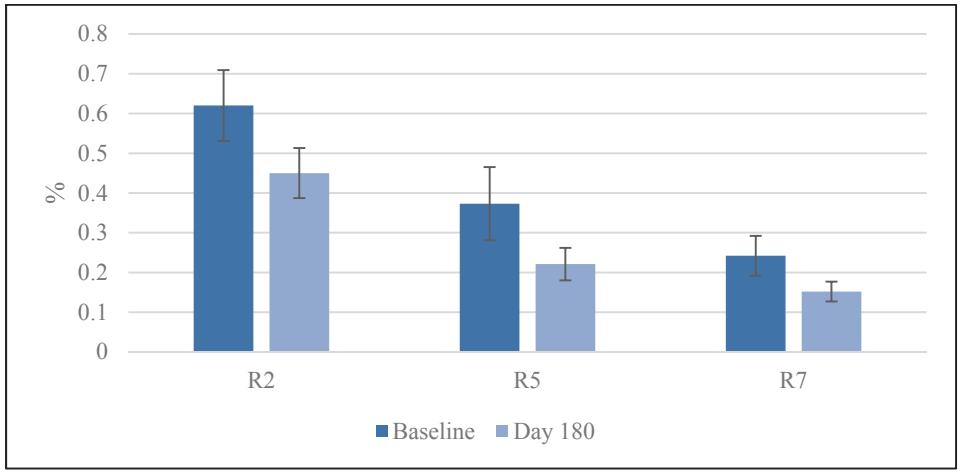

Table 8.1.1 **Study Endpoints by Sex - Primary Endpoint** **ITT Population**			
	Population	**Male** **% (n/N)** **95% CI [1]**	**Female** **% (n/N)** **95% CI [1]**
Improvement ≥ 20 mm^2 at Day 90	**ITT (missing subjects as failures)**	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX (X.X, X.X))
	Subjects with missing data	XX	XX
	Subjects with Day 60 data carried forward	XX	XX
Improvement ≥ 20 mm^2 at Day 90	**ITT (excluding missing subjects)**	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
	Subjects with Day 60 data carried forward	XX	XX

[1] Two-sided 95% Clopper-Pearson confidence interval.

Listing 8.1.1 **Study Endpoints by Sex - Primary Endpoint**					
Subject ID	**Sex**	**Analysis Population**	**Day 60 Improvement [1]**	**Day 90 Improvement**	**Endpoint**
XX-XXX	XX	XX	XX or N/A	XX or Missing	XX

Table 8.2.1.1
Study Endpoints by Sex - P-GAIS
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**
Assessment	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**
Physician - Global Aesthetic Improvement Scale (P-GAIS)						
5 (Very Much Improved)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
4 (Much Improved)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
3 (Improved)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
2 (No Change)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
1 (Worse)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.

Listing 8.2.1.1
Secondary Endpoint by Sex – P-GAIS

Subject ID	Sex	Analysis Population	Day 60 [1]	Day 90	Day 180
XX-XXX	XX	XX	XX	XX	XX

Table 8.2.1.2
Study Endpoints by Sex – S-GAIS
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**
Assessment	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**
Subject - Global Aesthetic Improvement Scale (S-GAIS)						
5 (Very Much Improved)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
4 (Much Improved)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
3 (Improved)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
2 (No Change)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
1 (Worse)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.

Listing 8.2.1.2
Secondary Endpoint by Sex – S-GAIS

Subject ID	Sex	Analysis Population	Day 60 [1]	Day 90	Day 180
XX-XXX	XX	XX	XX	XX	XX

Table 8.2.1.3
Study Endpoints by Sex – P-GSQ
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**
Assessment	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**
Physician - Global Satisfaction Questionnaire (P-GSQ)						
When looking at the photo images and respective to your clinician assessment during this visit, do you see any change on the treated area with respect to "improvement" of the skin and overall area?						
Yes, *if "yes" please check all that apply:*	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Less sagging on the jawline and cheeks	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Tighter/lift under the chin area	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Smoother skin texture	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Jaw line more defined	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Less wrinkles/lines	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Other	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
No	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Compared to "BEFORE" treatment how does the subject's skin ***feel*** today (check all that apply?						
Tighter	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Firmer	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Smoother	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
No change from prior to treatment	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
How satisfied are you with the results of the treatment?						
Very Satisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Satisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Neutral	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Dissatisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Very Dissatisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.

Listing 8.2.1.3 Study Endpoints - P-GSQ										
		Day 60 [1]			Day 90			Day 180		
Subject ID	Sex	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Improvement? (All reasons)	Skin Feel?	Satisfaction?
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 8.2.1.4
Study Endpoints by Sex – S-GSQ
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
	Male	Female	Male	Female	Male	Female
Assessment	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**	**% (n/N) 95% CI [2]**
Subject - Global Satisfaction Questionnaire (S-GSQ)						
Have you noticed any change with respect to "improvement" of the skin appearance of your neck?						
Yes, *if "yes" please check all that apply:*	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Less sagging on the jawline and cheeks	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Tighter/lift under the chin area	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Smoother skin texture	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Jaw line more defined	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Less wrinkles/lines	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Other	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
No	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Compared to "BEFORE" treatment how does your skin ***feel*** today (check all that apply?						
Tighter	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Firmer	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Smoother	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Make-up application easier	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Shaving easier	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
No change from prior to treatment	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
How satisfied are you with the results of your treatment?						
Very Satisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Satisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Neutral	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Dissatisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)

Table 8.2.1.4
Study Endpoints by Sex – S-GSQ
ITT Population with Available Data

	Day 60 [1]		Day 90		Day 180	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**
Very Dissatisfied	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
How likely are you to recommend this treatment to family and friends?						
Very Likely	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Likely	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Neutral	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Unlikely	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Very Unlikely	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.

Listing 8.2.1.4
Study Endpoints by Sex - S-GSQ

		Day 60 [1]				Day 90				Day 180			
Subject ID	**Sex**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Recommend?**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Recommend?**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Recommend?**
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 8.2.1.5

Study Endpoints by Sex – Qualitative Assessment for the 2D Imaging at Day 90 and Day 180 compared to Baseline

ITT Population with Available Data

	Reader 1		Reader 2		Reader 3		Total [3]	
	Male	Female	Male	Female	Male	Female	Male	Female
Assessment	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]	% (n/N) 95% CI [1]
	Day 90							
Much Improved	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Minimally Improved	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
No change	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Minimally Worse	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Much Worse	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
	Day 180							
Much Improved	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Minimally Improved	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
No change	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Minimally Worse	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)
Much Worse	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)	XX.X (X/XX) (X.X, X.X)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[1] Two-sided 95% Clopper-Pearson confidence interval.
[3] Median of 3 Readers Scores

Listing 8.2.1.5
Study Endpoints by Sex – Qualitative Assessment for the 2D Imaging

			Day 90			Day 180		
Subject ID	**Sex**	**Analysis Population**	**Reader 1**	**Reader 2**	**Reader 3**	**Reader 1**	**Reader 2**	**Reader 3**
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX

Table 8.3.1 **Study Endpoints by Sex - Exploratory Endpoint Elasticity** **ITT Population with Available Data**						
	Baseline		**Day 90**		**Day 180**	
	Male	**Female**	**Male**	**Female**	**Male**	**Female**
Assessment						
Elasticity – *by each parameter*						
Mean ± SD (N) Median (Min, Max)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)
95% CI [1]	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)
Change from Baseline Elasticity – *by each parameter*						
Mean ± SD (N) Median (Min, Max)	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)
95% CI [1]	*N/A*	*N/A*	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)	(XX.X, XX.X)

[1] Two-sided 95% confidence interval of the percentage or the mean.

Listing 8.3.1 **Study Endpoints by Sex - Exploratory Endpoint Elasticity**					
Subject ID	**Sex**	**Analysis Population**	**Baseline**	**Day 90** **(Change from Baseline)**	**Day 180** **(Change from Baseline)**
XX-XXX	XX	XX	XX	XX (XX)	XX (XX)

NOTE: Tables 8.1.1, 8.2.1.1, 8.2.1.2, 8.2.1.3, 8.2.1.4 and 8.3.1 will be repeated for the Age (dichotomous or categorical group comparison) as 8.1.2, 8.2.2.1, 8.2.2.2, 8.2.2.3, 8.2.2.4, and 8.3.2 to support the planned subgroup analyses

Table 9.1 **Study Endpoints - Primary Endpoint** **PP Population**				
	Population	**% (n/N)**	**One-sided p-value[1]**	**95% CI[2]**
Improvement ≥ 20 mm2 at Day 90	**PP**	XX.X (X/XX)	X.XXX	(X.X, X.X)

[1]Null hypothesis is that the true percentage of subjects with ≥ 20 mm2 improvement is less than or equal to 45%.

P-value is calculated based on the one-sided exact binomial test.

[2[Two-sided 95% Clopper-Pearson confidence interval.

Listing 9.1 **Study Endpoints - Primary Endpoint**			
Subject ID	**Analysis Population**	**Day 90 Improvement**	**Endpoint**
XX-XXX	XX	XX	XX

Table 9.1.1
Study Endpoints – Qualitative Assessment for the 2D Imaging
PP Population [1]

	Percent Agreement	Kappa Statistic [2]
Overall		
	XX.X (X/XX)	X.XXX
Subgroups [3]		
Reader 1-2	XX.X (X/XX)	X.XXX
Reader 1-3	XX.X (X/XX)	X.XXX
Reader 1-4	XX.X (X/XX)	X.XXX
Reader 1-5	XX.X (X/XX)	X.XXX
Reader 2-3	XX.X (X/XX)	X.XXX
Reader 2-4	XX.X (X/XX)	X.XXX
Reader 2-5	XX.X (X/XX)	X.XXX
Reader 3-4	XX.X (X/XX)	X.XXX
Reader 3-5	XX.X (X/XX)	X.XXX
Reader 4-5	XX.X (X/XX)	X.XXX

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Readers compared using Cohen's unweighted Kappa statistic
[3] Readers 1 and 2 were unblinded to image visit date, Readers 3, 4, and 5 were blinded to image visit date.

Listing 9.1.1
Study Endpoints – Qualitative Assessment for the 2D Imaging

Subject ID	Analysis Population	Reader 1	Reader 2	Reader 3	Reader 4	Reader 5
XX-XXX	XX	XX	XX	XX	XX	XX

Table 9.1.2
Study Endpoints – Qualitative Assessment for the 2D Imaging
PP Population [1]

	Reader 1 [2]	Reader 2 [2]	Reader 3 [3]	Reader 4 [3]	Reader 5 [3]
Based on your perceived Baseline vs. Day 60, how would you rate observed submental area change at Day 60?					
Much Improved	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Minimally Improved	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
No change from Baseline	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Minimally Worse	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)
Much Worse	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)	XX.X (X/XX)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.

[2] Reader unblinded to image visit date.

[3] Reader blinded to image visit date.

Listing 9.1.2
Study Endpoints – Qualitative Assessment for the 2D Imaging

Subject ID	Analysis Population	Reader 1	Reader 2	Reader 3	Reader 4	Reader 5
XX-XXX	XX	XX	XX	XX	XX	XX

Table 9.2.1
Secondary Endpoint – P-GAIS
PP Population with Available Data

	Day 60 [1]		**Day 90**		**Day 180**	
Assessment		**95% CI[2]**		**95% CI[2]**		**95% CI[2]**
Physician - Global Aesthetic Improvement Scale (P-GAIS)						
5 (Very Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
4 (Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
3 (Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
2 (No Change)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
1 (Worse)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.

[2] Two-sided 95% Clopper-Pearson confidence interval.

[3] p-value from Binomial Proportion Test for proportion of subjects who have at least "Improved" [score of 3 or greater]

Listing 9.2.1
Secondary Endpoint – P-GAIS

Subject ID	**Analysis Population**	**Day 60 [1]**	**Day 90**	**Day 180**
XX-XXX	XX	XX	XX	XX

Table 9.2.2 **Study Endpoints - S-GAIS** **PP Population with Available Data**						
	Day 60 [1]		**Day 90**		**Day 180**	
Assessment		**95% CI [2]**		**95% CI [2]**		**95% CI [2]**
Subject - Global Aesthetic Improvement Scale (S-GAIS)						
5 (Very Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
4 (Much Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
3 (Improved)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
2 (No Change)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
1 (Worse)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.

[2] Two-sided 95% Clopper-Pearson confidence interval.

[3] p-value from Binomial Proportion Test for proportion of subjects who have at least "Improved" [score of 3 or greater]

Listing 9.2.2 **Secondary Endpoint – S-GAIS**			
Subject ID	**Day 60 [1]**	**Day 90**	**Day 180**
XX-XXX	XX	XX	XX

Table 9.2.3
Study Endpoints - P-GSQ
PP Population with Available Data

	Day 60 [1]		Day 90		Day 180	
Assessment		**95% CI [2]**		**95% CI [2]**		**95% CI [2]**
Physician - Global Satisfaction Questionnaire (P-GSQ)						
When looking at the photo images and respective to your clinician assessment during this visit, do you see any change on the treated area with respect to "improvement" of the skin and overall area?						
Yes, *if "yes" please check all that apply:*	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less sagging on the jawline and cheeks	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Tighter/lift under the chin area	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother skin texture	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Jaw line more defined	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less wrinkles/lines	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Other	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	
Compared to "BEFORE" treatment how does the subject's skin ***feel*** today (check all that apply?						
Tighter	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Firmer	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change from prior to treatment	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
How satisfied are you with the results of the treatment?						
Very Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Neutral	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Very Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [4]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.
[3] p-value from Binomial Proportion Test for proportion of subjects who were marked "Improved"
[4] p-value from Binomial Proportion Test for proportion of subjects who were marked "Satisfied" or "Very Satisfied" and "Likely" or "Very Likely"

Listing 9.2.3
Study Endpoints - P-GSQ

		Day 60 [1]			Day 90			Day 180		
Subject ID	**Analysis Population**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**	**Improvement? (All reasons)**	**Skin Feel?**	**Satisfaction?**
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 9.2.4
Study Endpoints - S-GSQ
PP Population with Available Data

	Day 60 [1]		Day 90		Day 180	
Assessment		**95% CI [2]**		**95% CI [2]**		**95% CI [2]**
Subject - Global Satisfaction Questionnaire (S-GSQ)						
Have you noticed any change with respect to "improvement" of the skin appearance of your neck?						
Yes, *if "yes" please check all that apply:*	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less sagging on the jawline and cheeks	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Tighter/lift under the chin area	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother skin texture	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Jaw line more defined	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Less wrinkles/lines	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Other	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [3]	X.XXX		X.XXX		X.XXX	
Compared to "BEFORE" treatment how does your skin ***feel*** today (check all that apply?						
Tighter	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Firmer	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Smoother	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Make-up application easier	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Shaving easier	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change from prior to treatment	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
How satisfied are you with the results of your treatment?						
Very Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Satisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Neutral	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Very Dissatisfied	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [4]	X.XXX		X.XXX		X.XXX	
How likely are you to recommend this treatment to family and friends?						
Very Likely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Likely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Neutral	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Unlikely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Very Unlikely	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [4]	X.XXX		X.XXX		X.XXX	

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.
[2] Two-sided 95% Clopper-Pearson confidence interval.
[3] p-value from Binomial Proportion Test for proportion of subjects who were marked "Improved"
[4] p-value from Binomial Proportion Test for proportion of subjects who were marked "Satisfied" or "Very Satisfied" and "Likely" or "Very Likely"

Listing 9.2.4
Study Endpoints - S-GSQ

		Day 60 [1]				Day 90				Day 180			
Subject ID	Analysis Population	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Recommend?	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Recommend?	Improvement? (All reasons)	Skin Feel?	Satisfaction?	Recommend?
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX	XX

Table 9.2.5
Study Endpoints – Qualitative Assessment for the 2D Imaging at Day 90 and Day 180
PP Population

	Day 90							
	Reader 1	**95% CI [1]**	**Reader 2**	**95% CI [1]**	**Reader 3**	**95% CI [1]**	**Total [3]**	**95% CI [1]**
Much Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Much Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Improvement								
Yes	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [2]	X.XXX		X.XXX		X.XXX		X.XXX	
	Day 180							
Much Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Improved	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No change	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Minimally Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Much Worse	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
Improvement								
Yes	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
No	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)	XX.X (X/XX)	(X.X, X.X)
p-value [2]	X.XXX		X.XXX		X.XXX		X.XXX	

[1] Two-sided 95% Clopper-Pearson confidence interval.
[2] p-value from Binomial Proportion Test for proportion of subjects who were marked "Much Improved" or "Minimally Improved"
[3] Median of 3 Readers scores

Listing 9.2.5
Study Endpoints – Qualitative Assessment for the 2D Imaging

		Day 90			Day 180		
Subject ID	**Analysis Population**	**Reader 1**	**Reader 2**	**Reader 3**	**Reader 1**	**Reader 2**	**Reader 3**
XX-XXX	XX	XX	XX	XX	XX	XX	XX

Table 9.3 **Study Endpoints - Exploratory Endpoint Elasticity** **PP Population**						
	Baseline **N=**		**Day 90** **N=**		**Day 180** **N=**	
Assessment	**Mean ± SD (N)** **Median (Min, Max)**	**95% CI of the Mean**	**Mean ± SD (N)** **Median (Min, Max)**	**95% CI of the Mean**	**Mean ± SD (N)** **Median (Min, Max)**	**95% CI of the Mean**
Elasticity						
R0	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R2	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R5	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R7	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R9	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
Change from Baseline Elasticity						
R0	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R2	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R5	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R7	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)
R9	*N/A*	*N/A*	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)	XX.X ± XX.X (XX) XX.X (XX.X, XX.X)	(X.X, X.X)

[1] Two-sided 95% confidence interval of the percentage or the mean.

Listing 9.3 **Study Endpoints - Exploratory Endpoint Elasticity**				
Subject ID	**Analysis Population**	**Baseline**	**Day 90** **(Change from Baseline)**	**Day 180** **(Change from Baseline)**
XX-XXX	XX	XX	XX (XX)	XX (XX)

Figure 4. Bar chart for R0 and R9 output [PP Population]

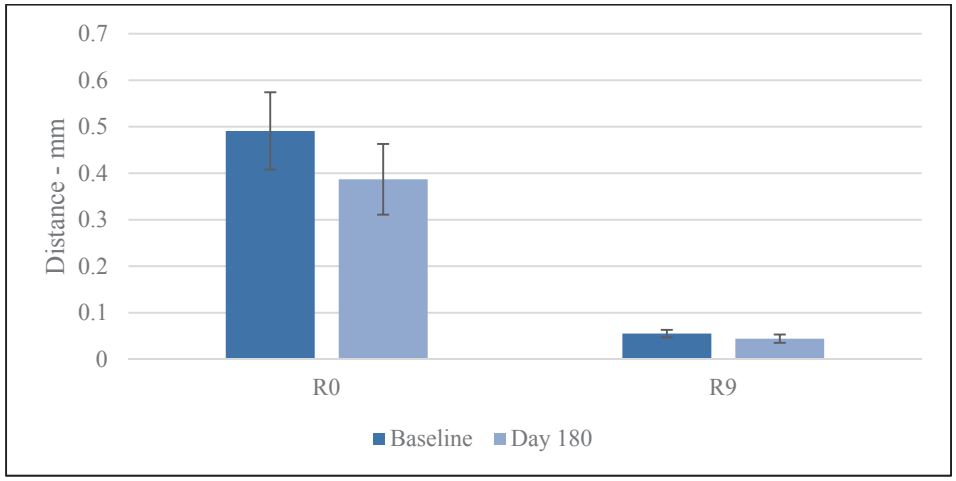

Figure 5. Bar chart for R2, R5, and R7 output [PP Population]

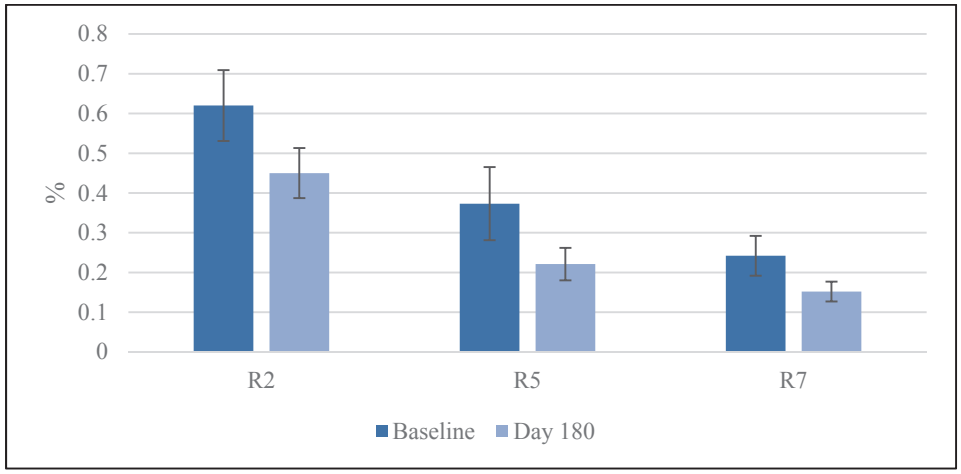

Table 10
Overall Treatment Emergent Adverse Events Summary [1] [2]
Safety Population

	After Treatment Prior to Day 30 N=XXX		After Day 30, up to Day 60 N=XXX		After Day 60, up to Day 90 N=XXX		After Day 90, up to day 180 N=XXX		Total N=XXX	
	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)
All Adverse Events	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
Device Related	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
Serious Adverse Events	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
Device Related	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)

[1] Events reported as adjudicated or by site if not adjudicated

[2] Denominators of time points are subjects past the visit window or with an event

Listing 10
Summary of Adverse Events

Subject ID	Adverse Event Number	SOC (Preferred Term)	Days Post Procedure	Any Adverse Event	Any Serious Adverse Event	Event Related to Study Treatment
XX-XXX	XX	XX	XX	XX	XX	XX

Table 11
Overall Treatment Emergent Adverse Events Summary by System Organ Class and Preferred Term [1] [2]
Safety Population

	After Treatment Prior to Day 30 N=XX		After Day 30, up to Day 60 N=XX		After Day 60, up to Day 90 N=XX		After Day 90, up to day 180 N=XX		Total N=XX	
	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)
All Adverse Events	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
SOC 1	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
PT 1.1	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
PT 1.2	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
SOC 2	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
PT 2.1	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
PT 2.2	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each System Organ Class	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each Preferred Term	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)

[1] Events reported as adjudicated or by site if not adjudicated

[2] Denominators of time points are subjects past the visit window or with an event

NOTE: This SOC and PT structure to be carried forward to tables

Listing 11
Summary of Adverse Events by SOC and PT

Subject ID	Adverse Event Number	SOC (Preferred Term)	Days Post Procedure	Any Adverse Event	Any Serious Adverse Event	Event Related to Study Treatment
XX-XXX	XX	XX	XX	XX	XX	XX

Table 12
Overall Treatment Emergent Serious Adverse Events Summary by System Organ Class and Preferred Term [1] [2]
Safety Population

	After Treatment Prior to Day 30 N=XX		After Day 30, up to Day 60 N=XX		After Day 60, up to Day 90 N=XX		After Day 90, up to day 180 N=XX		Total N=XX	
	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)
All Serious Adverse Events	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each System Organ Class	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each Preferred Term	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)

[1] Events reported as adjudicated or by site if not adjudicated

[2] Denominators of time points are subjects past the visit window or with an event

Listing 12
Summary of Serious Adverse Events by SOC and PT

Subject ID	Adverse Event Number	SOC (Preferred Term)	Days Post Procedure	Any Adverse Event	Any Serious Adverse Event	Event Related to Study Treatment
XX-XXX	XX	XX	XX	XX	XX	XX

Table 13
Device-Related Treatment Emergent Adverse Events Summary by System Organ Class and Preferred Term [1] [2]
Safety Population

	After Treatment Prior to Day 30 N=XX		After Day 30, up to Day 60 N=XX		After Day 60, up to Day 90 N=XX		After Day 90, up to day 180 N=XX		Total N=XX	
	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)
All Device-related AEs	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each System Organ Class	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each Preferred Term	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)

[1] Events reported as adjudicated or by site if not adjudicated

[2] Denominators of time points are subjects past the visit window or with an event

Listing 13
Summary of Adverse Events Related to Study Treatment

Subject ID	Adverse Event Number	SOC (Preferred Term)	Days Post Procedure	Any Adverse Event	Any Serious Adverse Event	Event Related to Study Treatment
XX-XXX	XX	XX	XX	XX	XX	XX

Table 14
Device-Related Treatment Emergent Serious Adverse Events Summary by System Organ Class and Preferred Term [1] [2]
Safety Population

	After Treatment Prior to Day 30 N=XX		After Day 30, up to Day 60 N=XX		After Day 60, up to Day 90 N=XX		After Day 90, up to day 180 N=XX		Total N=XX	
	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)
All Device-related, Serious AEs	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each System Organ Class	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each Preferred Term	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)

[1] Events reported as adjudicated or by site if not adjudicated

[2] Denominators of time points are subjects past the visit window or with an event

Listing 14
Summary of Serious Adverse Events Related to Study Treatment

Subject ID	Adverse Event Number	SOC (Preferred Term)	Days Post Procedure	Any Adverse Event	Any Serious Adverse Event	Event Related to Study Treatment
XX-XXX	XX	XX	XX	XX	XX	XX

Table 15
Treatment Emergent Adverse Events Leading to Withdrawal Summary by System Organ Class and Preferred Term[1] [2]
Safety Population

	After Treatment Prior to Day 30 N=XX		After Day 30, up to Day 60 N=XX		After Day 60, up to Day 90 N=XX		After Day 90, up to day 180 N=XX		Total N=XX	
	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)	# Events	Subjects w/Event % (n/N)
All Adverse Events	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each System Organ Class	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)
each Preferred Term	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)	XX	XX.X (X/XX)

[1] Events reported as adjudicated or by site if not adjudicated

[2] Denominators of time points are subjects past the visit window or with an event

Listing 15
Summary of Adverse Events Leading to Withdrawal

Subject ID	Adverse Event Number	SOC (Preferred Term)	Days Post Procedure	Any Adverse Event	Any Serious Adverse Event	Event Related to Study Treatment	Event Led to Subject Withdrawal	Comments
XX-XXX	XX	XX	XX	XX	XX	XX	XX	XX

Table 16 **Numerical Rating Scale (NRS)** **Safety Population**				
	Day 30	**Day 60 [1]**	**Day 90**	**Day 180**
	N=XX	**N=XX**	**N=XX**	**N=XX**
NRS				
Mean ± SD (N)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change in NRS from Day 30				
Mean ± SD (N)	*N/A*	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)	XX.X ± XX.X (XX)
Median (Min, Max)	*N/A*	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)	XX.X (XX.X, XX.X)
Change in NRS from Day 90				
Mean ± SD (N)	*N/A*	*N/A*	*N/A*	XX.X ± XX.X (XX)
Median (Min, Max)	*N/A*	*N/A*	*N/A*	XX.X (XX.X, XX.X)

[1] 30 subjects in sequential order of enrollment chosen for 60 day visit.

Listing 16 **Numerical Rating Scale (NRS)**				
Subject ID	**Day 30**	**Day 60**	**Day 90**	**Day 180**
XX-XXX	XX	XX	XX	XX

Table 17
Protocol Deviations
ITT Population

Category	Reason	Time Period	N=XX	
			# Deviations	Number of Subjects with Deviation % (n/N)
		Enrollment	XX	XX.X (X/XX)
		Baseline	XX	XX.X (X/XX)
		Treatment	XX	XX.X (X/XX)
		30 day follow-up	XX	XX.X (X/XX)
		90 day follow-up	XX	XX.X (X/XX)
		180 day follow-up	XX	XX.X (X/XX)
			XX	XX.X (X/XX)
			XX	XX.X (X/XX)
			XX	XX.X (X/XX)
			XX	XX.X (X/XX)

Listing 17
Protocol Deviations

Subject ID	Category	Reason	Time Period
XX-XXX	XX	XX	XX

Table 18 **Study Exit** **ITT Population**	
	N=XX
Study status, % (n/N)	
Complete	XX.X (X/XX)
Early exit	XX.X (X/XX)
Time to early exit (days)	
Mean ± SD (N)	XX.X ± XX.X (XX)
Median (Min, Max)	XX.X (XX.X, XX.X)
Reason for early exit, % (n/N)	
Subject withdrew consent [1]	XX.X (X/XX)
Study terminated prematurely by sponsor	XX.X (X/XX)
Subject non-compliance	XX.X (X/XX)
Adverse Event/Serious Adverse Event [2]	XX.X (X/XX)
Other [3]	XX.X (X/XX)

Note: Percentages are based on the number of subjects in the ITT Population.
[1] See supporting listing for reasons for consent withdrawal
[2] See supporting listing for adverse events/serious adverse events
[3] See supporting listing for other reason for early exit

Listing 18 **Study Exit**				
Subject ID	**Study Status**	**Time to Exit (Days)**	**Reason for Early Exit**	**Comments**
XX-XXX	XX	XX	XX	XX