STATISTICAL ANALYSIS PLAN

STUDY NUMBER: SLI-C40-001

Study Part A (Excisions)

Version: v. 1.0

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Safety and Efficacy of SLI-F06 in Wound Healing and Scar Appearance in Pre-Abdominoplasty Surgical Excisions and Post-Operative Scar Appearance in Subjects Undergoing Abdominoplasty

Study Sponsor
Scarless Laboratories Inc.
369 South Doheny Drive, Suite 1201
Beverly Hills, CA
USA 90211

Clinical Research Organization
ethica CRO Inc.
8555 Transcanada Hwy, Suite 201
Montreal, Canada H4S 1Z6
866-384-4221

SAP APPROVAL SIGNATURE PAGE

The following individuals approve this version of the SLI-C40-001 Part A Statistical Analysis Plan.

Accepted for the Sponsor – Scarless Laboratories Inc.

Printed Name	Title
Signature	Date

Accepted for the Clinical Research Organization - ethica CRO Inc.

Printed Name	Title
Signature	Date

TABLE OF CONTENTS

ABBREVIATIONS

AE	Adverse Event
BL	Baseline
BMI	Body Mass Index
CFR	U. S. Code of Federal Regulations
CTR	Common Treatment Response
CRO	Clinical Research Organization
DP	Drug Product
Excision site	A mapped area designated for a single excision.
eCRF	electronic Case Report Form
IRB	Institutional Review Board
ITT	Intent-to-Treat
MedDRA	Medical Dictionary for Regulatory Activities
PI	Principal Investigator
POC	Proof Of Concept
POSAS	Patient and Observer Scar Assessment Scale
PP	Per protocol
PT	Preferred Term
SAE	Serious Adverse Event
SAFT	Safety
SAP	Statistical Analysis Plan
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TRAE	Treatment Related Adverse Event
Tx	Treatment
UPT	Urine Pregnancy Test
USP	United States Pharmacopeia

1 INTRODUCTION

This statistical analysis plan (SAP) gives a comprehensive and detailed description of statistical techniques to be used for study SLI-C40-001. The purpose of this SAP is to ensure the credibility of the study findings by pre-specifying the statistical approaches for the analysis of study data prior to database lock. This SAP provides additional details concerning the statistical analyses outlined in the protocol. Whenever differences exist in descriptions or explanations provided in the protocol and SAP, the SAP prevails.

1.1 Background

SLI-F06 is a synthetic peptide that is being developed as a treatment to promote wound healing and improve scar appearance. The amino acid sequence of SLI-F06 is derived from an endogenous human protein that has been shown in animal models to promote accelerated wound healing, reduced scarring, and increased wound tensile strength. In these same animal models, the SLI-F06 has been demonstrated to retain similar pro-migration, pro-tensile strength, and anti-fibrotic properties as the endogenous protein.

SLI-F06 drug product (DP) is a sterile lyophilized powder consisting of SLI-F06 as the active ingredient and formulation buffer components. The DP will be reconstituted in clinic with USP Water for Injection and injected intradermally along both edges of a freshly made excision to achieve a primarily local effect.

The study population will consist of healthy patients planning to undergo elective abdominoplasty. During **Part A** of this study (i.e., Phase I Safety/Proof of Concept), each subject will receive 12, 14, or 18 small or large excisions at 8 weeks or 12 weeks pre-abdominoplasty. Wounds treated with SLI-F06 or vehicle will be followed until the time of abdominoplasty when the tissue is harvested. At the completion of study Part A, subjects will enter study **Part B** where they will undergo the abdominoplasty, have the abdominoplasty incision treated with SLI-F06, and be followed for an additional 12 months.

This SAP covers Study Part A only

1.2 Objectives

The primary objectives of this study are the following:

- Assess the safety and tolerability of SLI-F06 in the treatment of planned surgical excisions.

Secondary objectives include, but are not limited to, the following:

- Assess the effect of SLI-F06 on post-excisional scar appearance.
- Assess the effect of SLI-F06 on wound strength.
- Assess the effect of SLI-F06 on histological appearance of scars.
- Assess immunogenicity effects of SLI-F06.

1.3 Study Design

This is a multicenter, double-blind study comparing the safety of SLI-F06 to control formulation buffer (vehicle), as well as comparing the improvement in scar appearance and wound strength. Each subject will serve as his or her own control. The study is divided into 2 parts where Part A is a Phase I safety/proof of concept study of small scars pre-abdominoplasty, and Part B is a Phase IIa study of post-abdominoplasty scars.

In **Part A** of the study (i.e., Phase I safety/proof-of-concepts. Subjects will then be randomized by side of the pannus (right or left) for treatment with SLI-F06 or formulation buffer, wound tension (high or low), and by duration of follow-up post-excisions to 12 weeks (group 1) or 8 weeks (group 2) pre-abdominoplasty. Excision mapping and number of excisions will be determined by size of pannus as follows:

- Small pannus: 6 low tension and 6 high tension wounds will (12 wounds/subject).
- Medium pannus: 6 low tension and 8 high tension wounds will (14 wounds/subject).
- Large pannus: 8 low tension and 10 high tension wounds (18 wounds/subject).

Following completion of the follow-up period, the entire abdominoplasty site will be harvested and sent for analyses of histopathology and tensile strength.

In **Part B** of the study (i.e., Phase IIa), **ALL** subjects who complete Part A will be randomly assigned to receive injections of SLI-F06 along one half (left or right) of the abdominoplasty incision and control injections along the other half. The subject will undergo routine wound care and will attend study follow-up visits following abdominoplasty at Day 8 and at Months 1, 2, 3, 6, 9, and 12.

STUDY SUMMARY

	Part A (Phase I Safety/Proof of Concept)						Part B (Phase IIa)								
Visit Number	**1a**	**2a**	**3a**	**4a**	**5a**	**6a**	**1b**	**2b**	**SR**	**3b**	**4b**	**5b**	**6b**	**7b**	**8b**
Assessment and Procedures	**Screening Period**	**Excisions**	**Suture Removal**				**Abdomin-oplasty**		**Suture Removal**						
	D -30 to 0	**D1**	**D8 ± 1d**	**D29 ± 2d**	**D57 ± 3d**	**D85 ± 3d**	**D0**	**D8 ± 1d**	**PI Discretion**	**M1 ± 3d**	**M2 ± 7d**	**M3 ± 14d**	**M6 ± 14d**	**M9 ± 14d**	**M12 ± 14d**
Informed Consent	X														
Inc/Excl Criteria	X														
Medical/Surgical History	X														
Physical Exam	X														
Urine Pregnancy Test [1]	X	X [1]					X					X	X	X	X
Abdominoplasty Area Assessment & selection of Pannus Map size	X														
Immunogenicity sampling	X		X	X	X	X		X		X	X	X	X	X	X
Safety Laboratory Testing [2]	X [2]			X	Group 2	Group 1				X					X
Photography [3]		X [3]	X [3]	X	X	X				X	X	X	X	X	X
Randomization		X					X								
Excisions		X													
IP Injections		X					X								
Abdominoplasty/ Tissue Harvesting							X								
Suture removal			X						X						
POSAS grading			Post-removal of sutures	X	X	X				X	X	X	X	X	X
AE Assessment		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Group 1; 12 week assessment															
Exit from Part A / Start of Part B						**X**									
Group 2; 8 week assessment[4]															
Exit from Part A / Start of Part B					**X**										

1 UPT if female of childbearing potential and if last UPT performed >7 days of V2a.

2 Safety laboratory results to be reviewed by the PI prior to excisions in order to confirm absence of any health condition(s) that would make the subject inappropriate for study entry.

3 Day 1 photography occurs prior to excisions and following closure of all excisions, and Day 8 photography occurs pre- and post-removal of sutures.

4 Only **currently enrolled** participants who cannot be moved from group 2 to group 1 will remain in group 2

2 STUDY POPULATION

Healthy adult subjects presenting for abdominoplasty surgery will be enrolled and randomized. The full description of the inclusion and exclusion criteria is found in Section 5 of the study protocol.

3 TREATMENT ALLOCATION AND RANDOMIZATION

All excisions to be treated with SLI-F06 for a given subject will be on one side of the mapped area (i.e., left side or right side) and vehicle treated excisions will be on the other side of the mapped area.

4 STUDY EVALUATIONS

4.1 Primary Efficacy Variable

4.1.1 POSAS (PI Assessment) – Excisions

The Patient and Observer Scar Assessment Scale (POSAS) will be used to assess the various parameters of each excision site. At each observation time point, the **PI** will grade each scar using the "Observer Scale" of the POSAS.

4.2 Secondary Efficacy Variables

4.2.1 Histology

Histology of excision sites will be evaluated and reported separately from the analyses described in this SAP.

4.2.2 Tensile Strength

Ex vivo tensile strength of excision sites will be assessed and compared.

4.3 Exploratory Efficacy Variable

4.3.1 POSAS (Subject Assessment) – Excisions

Subjects will grade the abdominoplasty scar using the "Patient Scale" criteria of the POSAS.

4.4 Safety Variables

4.4.1 Adverse Events (AEs)

The Treating Investigator will assess AEs and record details of seriousness, severity, duration, and action taken with the study device, and relationship to the study device.

4.4.2 Clinical Safety Laboratory Tests

Standard clinical laboratory analyses (CBC/Diff, chemistry) will be conducted on blood samples collected at Screening V1a, V4a (D29), V5a (D57), V6a (D85). Clinically significant results, in the opinion of the PI, will be reported as AEs.

4.4.3 Immunogenicity Testing

Immunogenicity analyses will be conducted on blood samples collected from subjects at Screening V1a, V3a (D8), V4a (D29), V5a (D57) and V6a (D85).

4.4.4 Concomitant Medications and Procedures

Any medication or procedure (including OTC preparations) that the subject takes during the study protocol period will be considered concomitant medication and will recorded.

5 ANALYSIS POPULATIONS

5.1 Populations

5.1.1 Intent-to-Treat (ITT) Population

The ITT population will be the primary population for efficacy and safety analyses and will consist of all randomized subjects who received at least one injection of IP and provided at least one post-baseline evaluation, and will be analyzed in the treatment group they were allocated.

5.1.2 Per Protocol (PP) Population

A per-protocol (PP) population will neither be identified nor analyzed.

5.1.3 Safety (SAFT) Population

The SAFT population will be used for safety analysis and will consist of all randomized subjects who received one injection of IP, and will be analyzed as per the treatment actually received.

6 SAMPLE SIZE JUSTIFICATION

This is a Phase I safety/proof-of-concept study and a formal sample size justification is not required. It is the opinion of the Sponsor that a total of 25 subjects will be sufficient to achieve the objectives of the study.

7 STATISTICAL METHODS

7.1 Efficacy Analyses

Efficacy analyses will be conducted on an intent-to-treat (ITT) basis.

For categorical parameters, the number and percentage of subjects/observations in each category will be presented. The denominator will be based on the number of subjects/observations appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include n (number of subjects or observations), mean, standard deviation, median, and range.

Comparisons between treatment groups will be based on 95% confidence intervals.

7.2 Safety Analyses

Safety analysis will be conducted on the Safety Population (SAFT), by tabulations of AEs, safety laboratory parameters and immunogenicity outcomes.

7.3 Adverse Events (AEs)

Safety outcomes will be incidence rate of AEs, including SAEs, types of AEs and relationship to study treatment (i.e., Treatment-Emergent Adverse Events [TEAEs]; Treatment-Related-Adverse Events [TRAEs]). TEAEs will include all reported AE since the time of informed consent. TRAEs will include all reported AEs that were deemed by the Investigator to be related or not-related to study treatment.

Safety data will be tabulated with descriptive group statistics (mean, standard deviation, minimum, maximum). Severity and relationship to study treatment will be assessed.

AEs will be coded using MedDRA. These events, irrespective of relationship to study medication, will be summarized by treatment groups, MedDRA system organ class (SOC) and MedDRA preferred term (PT). The number of subjects reporting an AE, the number of AEs, and percentages of subjects in each category will be summarized. AEs by severity and relationship to study will be summarized in a similar way. Serious AEs will be summarized separately. Specifically, the following AE incidence tables will be provided:

- Treatment-Emergent AEs: Sorted By SOC and PT
- Treatment-Related AEs: Sorted By SOC and PT
- Treatment-Emergent SAEs: Sorted By SOC and PT
- Treatment-Related SAEs: Sorted By SOC and PT

AE incidence rates with exact 95% confidence intervals will be calculated for each safety variable; confidence intervals will be used to confirm whether distribution of subjects with events is homogeneous between the treatment groups.

7.4 Concomitant Medications and Procedures

Descriptive statistics (i.e., frequency and percent) will be calculated for each treatment group.

7.5 Safety Laboratory Tests

Determination of clinical significance for all out-of-range laboratory values will be made by each PI, and Adverse Event reports will be generated as necessary.

7.6 Immunogenicity

Changes from baseline in immunogenicity outcomes will be summarized with descriptive statistics and text, as appropriate.

7.7 General Statistical Considerations

7.7.1 Statistical Testing

For specific information regarding the statistical tests to be used in this study, please refer to Appendix A: Summary of Statistical Tests. Comparisons between treatment groups will be based on 95% confidence intervals.

7.7.2 Descriptive Statistics

Descriptive statistics (i.e., frequency and percent) will be calculated for each treatment group. Quantitative variables will be presented by way of number of observations, number of missing values, mean, standard deviation, extreme values (minimum and maximum), median, and 95% confidence internals. Categorical data will be presented by way of number of observations, number of missing values, and for each observed category, the number of occurrences and its corresponding percentage, and 95% confidence internals.

7.7.3 Missing Values

Missing data will not be imputed. Data will be analyzed as observed.

7.7.4 Discontinuation and Drop-Outs

Dropouts will not be replaced. All available data from dropouts will be included in the ITT analysis.

7.7.5 Multiple Comparisons

No methods will be used to accommodate multiplicity (unless otherwise specified).

7.7.6 Multicenter Data

The data will be pooled across centers for analysis. Additionally, data for each center will be provided in data listings.

7.7.7 Subject Disposition

A tabulation of subject disposition will be provided which will include the numbers of subjects

who enter, complete, and discontinue the study. The reasons for discontinuation will be included.

7.7.8 Outliers

No method to process outliers will be used. Data will be analyzed as reported in the database.

APPENDIX A: SUMMARY OF STATISTICAL TESTS

STUDY DISPOSITION

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Subject discontinuations	Listing: - Last Visit - Reason for discontinuing	Exit Form	IIT	--
Primary Reason for discontinuations	Categorical	Exit Form	IIT	--
Disposition at each Visit	Frequency of subjects attending visit	All Visits	IIT	--
Study dates	- FPFV - LPFV - LPLV - Enrolment duration - Study duration	All Visits	IIT	--

BASELINE CHARACTERISTICS

Demographics

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Age	Quantitative (years)	V1a (Scr)	IIT	95% CI
BMI	Quantitative	V1a (Scr)	IIT	95% CI
Gender	Categorical	V1a (Scr)	IIT	--
Race	Categorical	V1a (Scr)	IIT	--
Ethnicity	Categorical	V1a (Scr)	IIT	--
Keloid Hx	Categorical	V1a (Scr)	IIT	--
Smoking Hx	Categorical	V1a (Scr)	IIT	--
Pannus Size	Categorical	V1a (Scr)	IIT	--

Medical History

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Medical Hx	Categorical	V1a (Scr)	IIT	--

Concomitant Medications/Treatment

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Medication	Categorical	ConMed Form	IIT	--

EFFICACY ANALYSIS

PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS; Excisions)

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
POSAS (PI)	Quantitative	V3a (D8) V4a (D29) V5a (D57) V6a (D85)	IIT	95% CI
POSAS (Subject)	Quantitative	V3a (D8) V4a (D29) V5a (D57) V6a (D85)	IIT	95% CI

TENSILE STRENGTH

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
Tensile Strength	Quantitative	V5a (D57) V6a (D85)	IIT	95% CI

SAFETY ANALYSES

IMMUNOGENICITY

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
Immunogenicity	Categorical (positive / negative)	V1a (D0) V3a (D8) V4a (D29) V5a (D57) V6a (D85)	IIT	95% CI

ADVERSE EVENTS

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
Adverse Events (number of subjects with and number of events): - All Adverse Events - Treatment-Emergent Adverse Events - Treatment-Related Adverse Events - Serious Adverse Events	Categorical	AE Form	SAFT	95% CI

APPENDIX B: STATISTICAL TABLES

14.1 Subject Disposition

Table 14.1.1 Enrolment

Site	Screened	Screen Failures	Randomized	ITT	SAFT
01	xx	xx	xx	xx	xx
02	xx	xx	xx	xx	xx
03	xx	xx	xx	xx	xx
All sites	xx	xx	xx	xx	xx

Number of Participants

Table 14.1.2 Listing of Subject Discontinuations

Subject Number	Treatment Group	Gender*	Age	Last Visit	Primary Reason for Discontinuation
####	Active	M/F	xx	V#	xxxxxxxxxxxxxxxxxx
####	Active	M/F	xx	V#	xxxxxxxxxxxxxxxxxx
####	Control	M/F	xx	V#	xxxxxxxxxxxxxxxxxx
####	Active	M/F	xx	V#	xxxxxxxxxxxxxxxxxx

M=Male, F=Female

Table 14.1.3 Subject Disposition per Visit

Disposition of Subjects at each Study Visit	n = xx
N	xx
V1a (Scr)	xx (xx.x%)
V2a (BL/Excisions)	xx (xx.x%)
V3a (D8)	xx (xx.x%)
V4a (D29)	xx (xx.x%)
V5a (D57)	xx (xx.x%)
V6a (D85)	xx (xx.x%)

Number of participants (% in parenthesis)

Table 14.1.4 Study Dates – Part A

FPFV	LPFV	LPLV	Enrollment Duration	Study Duration
dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	xxx	xxx

FPFV= First Participant First Visit, LPFV= Last Participant First Visit, LPLV= Last Participant Last Visit. Enrollment duration=FPFV-LPFV+1, Study duration=FPFV-LPLV+1

14.2 Demographic, Baseline, and Con-Med Details

Table 14.2.1 Demographics

Demographics		**n = xx**
Age	N	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)
	Min, Max	xx, xx
	Missing values	xx
BMI	N	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)
	Min, Max	xx, xx
	Missing values	xx
Gender	N	xx
	Male	xx (xx.x%)
	Female	xx (xx.x%)
	Missing values	xx
Race	N	xx
	American Indian or Alaska Native	xx (xx.x%)
	Asian	xx (xx.x%)
	Black or African American	xx (xx.x%)
	Caucasian	xx (xx.x%)
	Hawaiian / Pacific Islander	xx (xx.x%)
	Other	xx (xx.x%)
	Missing values	xx
Ethnicity	N	xx
	Hispanic	xx (xx.x%)
	Non-Hispanic	xx (xx.x%)
	Missing values	xx
Keloid/Hyp Hx	N	xx
	Yes	xx (xx.x%)
	No	xx (xx.x%)
	Missing values	xx
Smoking Hx	N	xx
	Non-Smoker	xx (xx.x%)
	Smoker	xx (xx.x%)
	Ex-Smoker	xx (xx.x%)
	Missing values	xx
Pannus Size	N	xx
	Small	xx (xx.x%)
	Medium	xx (xx.x%)
	Large	xx (xx.x%)
	Missing values	xx

95% CI [xx.x, xx.x], Mean ± standard deviation. Number of Participants (% in parenthesis).

Table 14.2.2 Inclusion Criteria

Inclusion Criteria		n = xx
Inclusion 1	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 2	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 3	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 4	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 5	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 6	No	xx (xx.x%)
	Yes	xx (xx.x%)

Number of participants (% in parenthesis).

Table 14.2.3 Exclusion Criteria

Exclusion Criteria		n = xx
Exclusion 1	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 2	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 3	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 4	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 5	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 6	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 7	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 8	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 9	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 10	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 11	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 12	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 13	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 14	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 15	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 16	No	xx (xx.x%)
	Yes	xx (xx.x%)

Number of participants (% in parenthesis).

Table 14.2.4 Medical / Surgical History

Medical / Surgical History	**n = xx**
1. Blood and lymphatic system disorders	xx (xx.x%)
2. Cardiac/Vascular disorders	xx (xx.x%)
3. Eye/Ear and labyrinth disorders	xx (xx.x%)
4. Endocrine disorders	xx (xx.x%)
5. Gastrointestinal/Hepatobiliary disorders	xx (xx.x%)
6. General disorders and administration site conditions	xx (xx.x%)
7. Immune system disorders	xx (xx.x%)
8. Infections and infestations	xx (xx.x%)
9. Injury, poisoning and procedural complications	xx (xx.x%)
10. Metabolism and nutrition disorders	xx (xx.x%)
11. Musculoskeletal and connective tissue disorders	xx (xx.x%)
12. Neoplasms benign, malignant and unspecified	xx (xx.x%)
13. Nervous system disorders	xx (xx.x%)
14. Psychiatric disorders	xx (xx.x%)
15. Renal and urinary disorders	xx (xx.x%)
16. Reproductive system and breast disorders	xx (xx.x%)
17. Respiratory, thoracic and mediastinal disorders	xx (xx.x%)
18. Skin and subcutaneous tissue disorders	xx (xx.x%)
19. Surgical and medical procedures	xx (xx.x%)
20. Allergies	xx (xx.x%)
21. Other	xx (xx.x%)

Number of Participants (% in parenthesis).

Table 14.2.5 Concomitant Medications/Treatment

Concomitant Medication/Treatment	**n = xx**
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
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xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)

Number of Participants (% in parenthesis).

14.3 Efficacy Data

Table 14.3.1 POSAS (PI Assessment, Excisions)

POSAS (PI)			Active	Control
V3a (D8)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V4a (D29)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V5a (D57)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V6a (D85)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]

N = # of excisions, 95% CI [xx.x, xx.x], Mean ± standard deviation

Table 14.3.2 POSAS (Subject Assessment, Excisions)

POSAS (Subject)			Active	Control
V3a (D8)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V4a (D29)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V5a (D57)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V6a (D85)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]

N = # of excisions, 95% CI [xx.x, xx.x], Mean ± standard deviation

Table 14.3.4 Tensile Strength

Tensile Strength			Active	Control
V5a (D57)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
V6a (D85)	**Low Tension**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	High Tension	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	All Excisions	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x

95% CI [xx.x, xx.x]
Mean ± standard deviation

14.4 Safety Data

Table 14.4.1 Immunogenicity

Immunogenicity		n = xx
V1a (D0)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V3a (D8)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V4a (D29)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V5a (D57)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V6a (D85)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx

95% CI [xx.x, xx.x]

Table 14.4.2 AE Profile Overview – Part A

		Active (n = xx)	**Control (n = xx)**	**All (n = xx)**
Participants with any TEAE[a]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx
Participants with any TRAE[b]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx
Participants with any SAE[c]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx
Participants with any TRSAE[d]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx

95% CI [xx.x, xx.x]. [a]TEAE= Treatment-Emergent Adverse Events. [b]TRAE= Treatment-Related Adverse Events.
[c]SAE= Serious Adverse Events. [d]TRSAE= Treatment-Related Serious Adverse Events.

Table 14.4.3 Treatment-Emergent AEs Sorted by SOC – Part A

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TEAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

Table 14.4.4 Treatment-Related AEs Sorted by SOC – Part A

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TRAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

Table 14.4.5 Treatment-Emergent SAEs Sorted by SOC – Part A

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TESAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

Table 14.4.6 Treatment-Related SAEs Sorted by SOC – Part A

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TRSAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

STATISTICAL ANALYSIS PLAN

STUDY NUMBER: SLI-C40-001

Study Part B (Abdominoplasty)

Version: v. 1.0

Date: 09-Oct-2020

Safety and Efficacy of SLI-F06 in Wound Healing and Scar Appearance in Pre-Abdominoplasty Surgical Excisions and Post-Operative Scar Appearance in Subjects Undergoing Abdominoplasty

Study Sponsor
Scarless Laboratories Inc.
369 South Doheny Drive, Suite 1201
Beverly Hills, CA
USA 90211

Clinical Research Organization
ethica CRO Inc.
8555 Transcanada Hwy, Suite 201
Montreal, Canada H4S 1Z6
866-384-4221

SAP APPROVAL SIGNATURE PAGE

The following individuals approve this version of the SLI-C40-001 Part B Statistical Analysis Plan.

Accepted for the Sponsor – Scarless Laboratories Inc.

Printed Name	Title
Signature	Date

Accepted for the Clinical Research Organization - ethica CRO Inc.

Printed Name	Title
Signature	Date

TABLE OF CONTENTS

ABBREVIATIONS

AE	Adverse Event
BL	Baseline
BMI	Body Mass Index
CFR	U. S. Code of Federal Regulations
CTR	Common Treatment Response
CRO	Clinical Research Organization
DP	Drug Product
Excision site	A mapped area designated for a single excision.
eCRF	electronic Case Report Form
IRB	Institutional Review Board
ITT	Intent-to-Treat
MedDRA	Medical Dictionary for Regulatory Activities
PI	Principal Investigator
POC	Proof Of Concept
POSAS	Patient and Observer Scar Assessment Scale
PP	Per protocol
PT	Preferred Term
SAE	Serious Adverse Event
SAFT	Safety
SAP	Statistical Analysis Plan
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event
TRAE	Treatment Related Adverse Event
Tx	Treatment
UPT	Urine Pregnancy Test
USP	United States Pharmacopeia

1 INTRODUCTION

This statistical analysis plan (SAP) gives a comprehensive and detailed description of statistical techniques to be used for study SLI-C40-001. The purpose of this SAP is to ensure the credibility of the study findings by pre-specifying the statistical approaches for the analysis of study data prior to database lock. This SAP provides additional details concerning the statistical analyses outlined in the protocol. Whenever differences exist in descriptions or explanations provided in the protocol and SAP, the SAP prevails.

1.1 Background

SLI-F06 is a synthetic peptide that is being developed as a treatment to promote wound healing and improve scar appearance. The amino acid sequence of SLI-F06 is derived from an endogenous human protein that has been shown in animal models to promote accelerated wound healing, reduced scarring, and increased wound tensile strength. In these same animal models, the SLI-F06 has been demonstrated to retain similar pro-migration, pro-tensile strength, and anti-fibrotic properties as the endogenous protein.

SLI-F06 drug product (DP) is a sterile lyophilized powder consisting of SLI-F06 as the active ingredient and formulation buffer components. The DP will be reconstituted in clinic with USP Water for Injection and injected intradermally along both edges of a freshly made excision to achieve a primarily local effect.

The study population will consist of healthy patients planning to undergo elective abdominoplasty. During **Part A** of this study (i.e., Phase I Safety/Proof of Concept), each subject will receive 12, 14, or 18 small or large excisions at 8 weeks or 12 weeks pre-abdominoplasty. Wounds treated with SLI-F06 or vehicle will be followed until the time of abdominoplasty when the tissue is harvested. At the completion of study Part A, subjects will enter study **Part B** where they will undergo the abdominoplasty, have the abdominoplasty incision treated with SLI-F06, and be followed for an additional 12 months.

This SAP covers Study Part B only

1.2 Objectives

The primary objectives of this study are the following:

- Assess the safety and tolerability of SLI-F06 in the treatment of abdominoplasty incisions.

Secondary objectives include, but are not limited to, the following:

- Assess the effect of SLI-F06 on post-operative abdominoplasty scar appearance.
- Assess immunogenicity effects of SLI-F06.

1.3 Study Design

This is a multicenter, double-blind study comparing the safety of SLI-F06 to control formulation buffer (vehicle), as well as comparing the improvement in scar appearance and wound strength. Each subject will serve as his or her own control. The study is divided into 2 parts where Part A is a Phase I safety/proof of concept study of small scars pre-abdominoplasty, and Part B is a Phase IIa study of post-abdominoplasty scars.

In **Part A** of the study (i.e., Phase I safety/proof-of-concepts. Subjects will then be randomized by side of the pannus (right or left) for treatment with SLI-F06 or formulation buffer, wound tension (high or low), and by duration of follow-up post-excisions to 12 weeks (group 1) or 8 weeks (group 2) pre-abdominoplasty. Excision mapping and number of excisions will be determined by size of pannus as follows:

- Small pannus: 6 low tension and 6 high tension wounds will (12 wounds/subject).
- Medium pannus: 6 low tension and 8 high tension wounds will (14 wounds/subject).
- Large pannus: 8 low tension and 10 high tension wounds (18 wounds/subject).

Following completion of the follow-up period, the entire abdominoplasty site will be harvested and sent for analyses of histopathology and tensile strength.

In **Part B** of the study (i.e., Phase IIa), **ALL** subjects who complete Part A will be randomly assigned to receive injections of SLI-F06 along one half (left or right) of the abdominoplasty incision and control injections along the other half. The subject will undergo routine wound care and will attend study follow-up visits following abdominoplasty at Day 8 and at Months 1, 2, 3, 6, 9, and 12.

STUDY SUMMARY

	Part A (Phase I Safety/Proof of Concept)						Part B (Phase IIa)								
Visit Number	**1a**	**2a**	**3a**	**4a**	**5a**	**6a**	**1b**	**2b**	**SR**	**3b**	**4b**	**5b**	**6b**	**7b**	**8b**
Assessment and Procedures	**Screening Period**	**Excisions**	**Suture Removal**				**Abdomin-oplasty**		**Suture Removal**						
	D -30 to 0	**D1**	**D8 ± 1d**	**D29 ± 2d**	**D57 ± 3d**	**D85 ± 3d**	**D0**	**D8 ± 1d**	**PI Discretion**	**M1 ± 3d**	**M2 ± 7d**	**M3 ± 14d**	**M6 ± 14d**	**M9 ± 14d**	**M12 ± 14d**
Informed Consent	X														
Inc/Excl Criteria	X														
Medical/Surgical History	X														
Physical Exam	X														
Urine Pregnancy Test [1]	X	X [1]					X					X	X	X	X
Abdominoplasty Area Assessment & selection of Pannus Map size	X														
Immunogenicity sampling	X		X	X	X	X		X		X	X	X	X	X	X
Safety Laboratory Testing [2]	X [2]			X	Group 2	Group 1				X					X
Photography [3]		X [3]	X [3]	X	X	X				X	X	X	X	X	X
Randomization		X					X								
Excisions		X													
IP Injections		X					X								
Abdominoplasty/ Tissue Harvesting							X								
Suture removal			X						X						
POSAS grading			Post-removal of sutures	X	X	X				X	X	X	X	X	X
AE Assessment		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Group 1; 12 week assessment															
Exit from Part A / Start of Part B						**X**									
Group 2; 8 week assessment[4]															
Exit from Part A / Start of Part B					**X**										

1 UPT if female of childbearing potential and if last UPT performed >7 days of V2a.

2 Safety laboratory results to be reviewed by the PI prior to excisions in order to confirm absence of any health condition(s) that would make the subject inappropriate for study entry.

3 Day 1 photography occurs prior to excisions and following closure of all excisions, and Day 8 photography occurs pre- and post-removal of sutures.

4 Only **currently enrolled** participants who cannot be moved from group 2 to group 1 will remain in group 2

2 STUDY POPULATION

Healthy adult subjects presenting for abdominoplasty surgery will be enrolled and randomized. The full description of the inclusion and exclusion criteria is found in Section 5 of the study protocol.

3 TREATMENT ALLOCATION AND RANDOMIZATION

One side of the abdominoplasty incision will be treated with SLI-F06 (i.e., left side or right side) and the other side of the incision will be treated with vehicle.

4 STUDY EVALUATIONS

4.1 Primary Efficacy Variable

4.1.1 POSAS (PI Assessment) – Abdominoplasty Incisions

The Patient and Observer Scar Assessment Scale (POSAS) will be used to assess the various parameters of the abdominoplasty incision. At each observation time point, the **PI** will grade each scar using the "Observer Scale" of the POSAS.

4.2 Secondary Efficacy Variables

4.2.1 POSAS (Subject Assessment) – Abdominoplasty Incisions

Subjects will grade the abdominoplasty scar using the "Patient Scale" criteria of the POSAS.

4.3 Exploratory Efficacy Variable

4.3.1 POSAS (PI Assessment) – Abdominoplasty Incisions, 5cm Segments

The Patient and Observer Scar Assessment Scale (POSAS) will be used to assess the various parameters of the abdominoplasty incision at 5cm intervals. At each observation time point, the **PI** will grade each scar using the "Observer Scale" of the POSAS.

4.3.2 POSAS (Subject Assessment) – Abdominoplasty Incisions, 5cm Segments

The Patient and Observer Scar Assessment Scale (POSAS) will be used to assess the various parameters of the abdominoplasty incision at 5cm intervals. At each observation time point, the subject will grade each scar using the "Observer Scale" of the POSAS.

4.4 Safety Variables

4.4.1 Adverse Events (AEs)

The Treating Investigator will assess AEs and record details of seriousness, severity, duration, and action taken with the study device, and relationship to the study device.

4.4.2 Clinical Safety Laboratory Tests

Standard clinical laboratory analyses (CBC/Diff, chemistry) will be conducted on blood samples collected at V3b (M1) and V8b (M12). Clinically significant results, in the opinion of the PI, will be reported as AEs.

4.4.3 Immunogenicity Testing

Immunogenicity analyses will be conducted at V2b (Day 8), V3b (M1), V4b (M2), V5b (M3), V6b (M6), V7b (M9), and V8b (M12).

4.4.4 Concomitant Medications and Procedures

Any medication or procedure (including OTC preparations) that the subject takes during the study protocol period will be considered concomitant medication and will recorded.

5 ANALYSIS POPULATIONS

5.1 Populations

5.1.1 Intent-to-Treat (ITT) Population

The ITT population will be the primary population for efficacy and safety analyses and will consist of all randomized subjects who received at least one injection of IP and provided at least one post-baseline evaluation, and will be analyzed in the treatment group they were allocated.

5.1.2 Per Protocol (PP) Population

A per-protocol (PP) population will neither be identified nor analyzed.

5.1.3 Safety (SAFT) Population

The SAFT population will be used for safety analysis and will consist of all randomized subjects who received one injection of IP, and will be analyzed as per the treatment actually received.

6 SAMPLE SIZE JUSTIFICATION

This is a Phase IIa study and a formal sample size justification is not required. It is the opinion of the Sponsor that a total of 25 subjects will be sufficient to achieve the objectives of the study.

7 STATISTICAL METHODS

7.1 Efficacy Analyses

Efficacy analyses will be conducted on an intent-to-treat (ITT) basis.

For categorical parameters, the number and percentage of subjects/observations in each category will be presented. The denominator will be based on the number of subjects/observations appropriate for the purpose of analysis. For continuous parameters, descriptive statistics will include n (number of subjects or observations), mean, standard deviation, median, and range.

Comparisons between treatment groups will be based on 95% confidence intervals.

7.2 Safety Analyses

Safety analysis will be conducted on the Safety Population (SAFT), by tabulations of AEs, safety laboratory parameters and immunogenicity outcomes.

Subjects will be followed for AEs (local and systemic) throughout the study. Events specific to treatment sites will be recorded per side to allow comparison of study treatments.

7.3 Adverse Events (AEs)

Safety outcomes will be incidence rate of AEs, including SAEs, types of AEs and relationship to study treatment (i.e., Treatment-Emergent Adverse Events [TEAEs]; Treatment-Related-Adverse Events [TRAEs]). TEAEs will include all reported AE since the time of informed consent. TRAEs will include all reported AEs that were deemed by the Investigator to be related or not-related to study treatment.

Safety data will be tabulated with descriptive group statistics (mean, standard deviation, minimum, maximum). Severity and relationship to study treatment will be assessed.

AEs will be coded using MedDRA. These events, irrespective of relationship to study medication, will be summarized by treatment groups, MedDRA system organ class (SOC) and MedDRA preferred term (PT). The number of subjects reporting an AE, the number of AEs, and percentages of subjects in each category will be summarized. AEs by severity and relationship to study will be summarized in a similar way. Serious AEs will be summarized separately. Specifically, the

following AE incidence tables will be provided:

- Treatment-Emergent AEs: Sorted By SOC and PT
- Treatment-Related AEs: Sorted By SOC and PT
- Treatment-Emergent SAEs: Sorted By SOC and PT
- Treatment-Related SAEs: Sorted By SOC and PT

AE incidence rates with exact 95% confidence intervals will be calculated for each safety variable; confidence intervals will be used to confirm whether distribution of subjects with events is homogeneous between the treatment groups.

7.4 Concomitant Medications and Procedures

Descriptive statistics (i.e., frequency and percent) will be calculated for each treatment group.

7.5 Safety Laboratory Tests

Determination of clinical significance for all out-of-range laboratory values will be made by each PI, and Adverse Event reports will be generated as necessary.

7.6 Immunogenicity

Changes from baseline in immunogenicity outcomes will be summarized with descriptive statistics and text, as appropriate.

7.7 General Statistical Considerations

7.7.1 Statistical Testing

For specific information regarding the statistical tests to be used in this study, please refer to Appendix A: Summary of Statistical Tests. Comparisons between treatment groups will be based on 95% confidence intervals.

7.7.2 Descriptive Statistics

Descriptive statistics (i.e., frequency and percent) will be calculated for each treatment group. Quantitative variables will be presented by way of number of observations, number of missing values, mean, standard deviation, extreme values (minimum and maximum), median, and 95% confidence internals. Categorical data will be presented by way of number of observations, number of missing values, and for each observed category, the number of occurrences and its corresponding percentage, and 95% confidence internals.

7.7.3 Missing Values

Missing data will not be imputed. Data will be analyzed as observed.

7.7.4 Discontinuation and Drop-Outs

Dropouts will not be replaced. All available data from dropouts will be included in the ITT analysis.

7.7.5 Multiple Comparisons

No methods will be used to accommodate multiplicity (unless otherwise specified).

7.7.6 Multicenter Data

The data will be pooled across centers for analysis. Additionally, data for each center will be provided in data listings.

7.7.7 Subject Disposition

A tabulation of subject disposition will be provided which will include the numbers of subjects who enter, complete, and discontinue the study. The reasons for discontinuation will be included.

7.7.8 Outliers

No method to process outliers will be used. Data will be analyzed as reported in the database.

APPENDIX A: SUMMARY OF STATISTICAL TESTS

STUDY DISPOSITION

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Subject discontinuations	Listing: - Last Visit - Reason for discontinuing	Exit Form	IIT	--
Primary Reason for discontinuations	Categorical	Exit Form	IIT	--
Disposition at each Visit	Frequency of subjects attending visit	All Visits	IIT	--
Study dates	- FPFV - LPFV - LPLV - Enrolment duration - Study duration	All Visits	IIT	--

BASELINE CHARACTERISTICS

Demographics

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Age	Quantitative (years)	V1a (Scr)	IIT	95% CI
BMI	Quantitative	V1a (Scr)	IIT	95% CI
Gender	Categorical	V1a (Scr)	IIT	--
Race	Categorical	V1a (Scr)	IIT	--
Ethnicity	Categorical	V1a (Scr)	IIT	--
Keloid Hx	Categorical	V1a (Scr)	IIT	--
Smoking Hx	Categorical	V1a (Scr)	IIT	--
Pannus Size	Categorical	V1a (Scr)	IIT	--

Medical History

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Medical Hx	Categorical	V1a (Scr)	IIT	--

Concomitant Medications/Treatment

Variable	Type	Visits / CRF Section	Analyzed Populations	Statistical Tests
Medication	Categorical	ConMed Form	IIT	--

EFFICACY ANALYSIS

PATIENT AND OBSERVER SCAR ASSESSMENT SCALE (POSAS; Excisions)

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
POSAS (PI)	Quantitative	V3b (M1) V4b (M2) V5b (M3) V6b (M6) V7b (M9) V8b (M12)	IIT	95% CI
POSAS (Subject)	Quantitative	V3b (M1) V4b (M2) V5b (M3) V6b (M6) V7b (M9) V8b (M12)	IIT	95% CI
POSAS (PI; 5cm Segment)	Quantitative	V5b (M3) V6b (M6) V7b (M9) V8b (M12)	IIT	95% CI
POSAS (Subject; 5cm Segment)	Quantitative	V5b (M3) V6b (M6) V7b (M9) V8b (M12)	IIT	95% CI

SAFETY ANALYSES

IMMUNOGENICITY

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
Immunogenicity	Categorical (positive / negative)	V2b (D8) V3b (M1) V4b (M2) V5b (M3) V6b (M6) V7b (M9) V8b (M12)	IIT	95% CI

ADVERSE EVENTS

Variable	Type	Visits / CRF Section	Analyzed Population	Statistical Tests
Adverse Events (number of subjects with and number of events): - All Adverse Events - Treatment-Emergent Adverse Events - Treatment-Related Adverse Events - Serious Adverse Events	Categorical	AE Form	SAFT	95% CI

APPENDIX B: STATISTICAL TABLES

14.1 Subject Disposition

Table 14.1.1 Enrolment

Site	Screened	Screen Failures	Randomized	PP	ITT	SAFT
01	xx	xx	xx	xx	xx	xx
02	xx	xx	xx	xx	xx	xx
03	xx	xx	xx	xx	xx	xx
All sites	xx	xx	xx	xx	xx	xx

Number of Participants

Table 14.1.2 Listing of Subject Discontinuations

Subject Number	Treatment Group	Gender*	Age	Last Visit	Primary Reason for Discontinuation
####	Active	M/F	xx	V#	xxxxxxxxxxxxxxxxxx
####	Active	M/F	xx	V#	xxxxxxxxxxxxxxxxxx
####	Control	M/F	xx	V#	xxxxxxxxxxxxxxxxxx
####	Active	M/F	xx	V#	xxxxxxxxxxxxxxxxxx

M=Male, F=Female

Table 14.1.3 Subject Disposition per Visit

Disposition of Subjects at each Study Visit	n = xx
N	xx
V1b (Abdominoplasty)	xx (xx.x%)
V2b (D8)	xx (xx.x%)
V3b (M1)	xx (xx.x%)
V4b (M2)	xx (xx.x%)
V5b (M3)	xx (xx.x%)
V6b (M6)	xx (xx.x%)
V7b (M9)	xx (xx.x%)
V8b (M12)	xx (xx.x%)

Number of Participants (% in parenthesis)

Table 14.1.4 Study Dates – Part B

FPFV	LPFV	LPLV	Enrollment Duration	Study Duration
dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	xxx	xxx

FPFV= First Participant First Visit, LPFV= Last Participant First Visit, LPLV= Last Participant Last Visit. Enrollment duration=FPFV-LPFV+1, Study duration=FPFV-LPLV+1

14.2 Demographic, Baseline, and Con-Med Details

Table 14.2.1 Demographics

Demographics		**n = xx**
Age	N	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)
	Min, Max	xx, xx
	Missing values	xx
BMI	N	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)
	Min, Max	xx, xx
	Missing values	xx
Gender	N	xx
	Male	xx (xx.x%)
	Female	xx (xx.x%)
	Missing values	xx
Race	N	xx
	American Indian or Alaska Native	xx (xx.x%)
	Asian	xx (xx.x%)
	Black or African American	xx (xx.x%)
	Caucasian	xx (xx.x%)
	Hawaiian / Pacific Islander	xx (xx.x%)
	Other	xx (xx.x%)
	Missing values	xx
Ethnicity	N	xx
	Hispanic	xx (xx.x%)
	Non-Hispanic	xx (xx.x%)
	Missing values	xx
Keloid/Hyp Hx	N	xx
	Yes	xx (xx.x%)
	No	xx (xx.x%)
	Missing values	xx
Smoking Hx	N	xx
	Non-Smoker	xx (xx.x%)
	Smoker	xx (xx.x%)
	Ex-Smoker	xx (xx.x%)
	Missing values	xx
Pannus Size	N	xx
	Small	xx (xx.x%)
	Medium	xx (xx.x%)
	Large	xx (xx.x%)
	Missing values	xx

95% CI [xx.x, xx.x], Mean ± standard deviation. Number of Participants (% in parenthesis).

Table 14.2.2 Inclusion Criteria

Inclusion Criteria		n = xx
Inclusion 1	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 2	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 3	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 4	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 5	No	xx (xx.x%)
	Yes	xx (xx.x%)
Inclusion 6	No	xx (xx.x%)
	Yes	xx (xx.x%)

Number of Participants (% in parenthesis).

Table 14.2.3 Exclusion Criteria

Exclusion Criteria		n = xx
Exclusion 1	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 2	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 3	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 4	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 5	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 6	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 7	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 8	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 9	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 10	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 11	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 12	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 13	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 14	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 15	No	xx (xx.x%)
	Yes	xx (xx.x%)
Exclusion 16	No	xx (xx.x%)
	Yes	xx (xx.x%)

Number of Participants (% in parenthesis).

Table 14.2.4 Medical / Surgical History

Medical / Surgical History	**n = xx**
1. Blood and lymphatic system disorders	xx (xx.x%)
2. Cardiac/Vascular disorders	xx (xx.x%)
3. Eye/Ear and labyrinth disorders	xx (xx.x%)
4. Endocrine disorders	xx (xx.x%)
5. Gastrointestinal/Hepatobiliary disorders	xx (xx.x%)
6. General disorders and administration site conditions	xx (xx.x%)
7. Immune system disorders	xx (xx.x%)
8. Infections and infestations	xx (xx.x%)
9. Injury, poisoning and procedural complications	xx (xx.x%)
10. Metabolism and nutrition disorders	xx (xx.x%)
11. Musculoskeletal and connective tissue disorders	xx (xx.x%)
12. Neoplasms benign, malignant and unspecified	xx (xx.x%)
13. Nervous system disorders	xx (xx.x%)
14. Psychiatric disorders	xx (xx.x%)
15. Renal and urinary disorders	xx (xx.x%)
16. Reproductive system and breast disorders	xx (xx.x%)
17. Respiratory, thoracic and mediastinal disorders	xx (xx.x%)
18. Skin and subcutaneous tissue disorders	xx (xx.x%)
19. Surgical and medical procedures	xx (xx.x%)
20. Allergies	xx (xx.x%)
21. Other	xx (xx.x%)

Number of Participants (% in parenthesis).

Table 14.2.5 Concomitant Medications/Treatment

Concomitant Medication/Treatment	**n = xx**
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xx (xx.x%)

Number of Participants (% in parenthesis).

14.3 Efficacy Data

Table 14.3.1 POSAS (PI Assessment, Abdominoplasty, Full Scar)

POSAS (PI)		Active	Control
V3b (M1)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V4b (M2)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V5b (M3)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V6b (M6)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V7b (M9)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V8b (M12)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

95% CI [xx.x, xx.x]
Mean ± standard deviation

Table 14.3.2 POSAS (Subject Assessment, Abdominoplasty, Full Scar)

POSAS (Subject)		Active	Control
V3b (M1)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V4b (M2)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V5b (M3)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V6b (M6)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V7b (M9)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
V8b (M12)	N	xx	xx
	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
	Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)

95% CI [xx.x, xx.x]
Mean ± standard deviation

Table 14.3.3 POSAS (PI Assessment, Abdominoplasty, 5cm Segments)

POSAS (PI)			Active	Control
V5b (M3)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V6b (M6)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]

95% CI [xx.x, xx.x], Mean ± standard deviation

Table 14.3.3 POSAS (PI Assessment, Abdominoplasty, 5cm Segments) con't

POSAS (PI)			Active	Control
V7b (M9)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V8b (M12)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]

95% CI [xx.x, xx.x], Mean ± standard deviation

Table 14.3.4 POSAS (Subject Assessment, Abdominoplasty, 5cm Segments)

POSAS (Subject)			Active	Control
V5b (M3)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V6b (M6)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]

95% CI [xx.x, xx.x], Mean ± standard deviation

Table 14.3.3 POSAS (PI Assessment, Abdominoplasty, 5cm Segments) con't

POSAS (Subject)			Active	Control
V7b (M9)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
V8b (M12)	**Seg 1**	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 2	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 3	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 4	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 5	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Seg 6	N	xx	xx
		Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
	Q1/2/3/4/5/6	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]
		Median (P25, P75)	xx.x (xx.x, xx.x)	xx.x (xx.x, xx.x)
		Min, Max	xx.x, xx.x	xx.x, xx.x
	Opinion	Mean ± SD	xx.x ± xx.x [xx.x, xx.x]	xx.x ± xx.x [xx.x, xx.x]

95% CI [xx.x, xx.x], Mean ± standard deviation

14.4 Safety Data

Table 14.4.1 Immunogenicity

Immunogenicity		**n = xx**
V1a (D0)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V3a (D8)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V4a (D29)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V5a (D57)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx
V6a (D85)	N	xx
	Negative	xx (xx.x%) [xx.x, xx.x]
	Positive	xx (xx.x%) [xx.x, xx.x]
	Missing Data	xx

95% CI [xx.x, xx.x]

Table 14.4.2 AE Profile Overview – Part B

		Active (n = xx)	**Control (n = xx)**	**All (n = xx)**
Participants with any TEAE[a]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx
Participants with any TRAE[b]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx
Participants with any SAE[c]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx
Participants with any TRSAE[d]	Participants Events	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx	xx (xx.x%) [xx.x, xx.x] xxx

95% CI [xx.x, xx.x]. [a]TEAE= Treatment-Emergent Adverse Events. [b]TRAE= Treatment-Related Adverse Events.
[c]SAE= Serious Adverse Events. [d]TRSAE= Treatment-Related Serious Adverse Events.

Table 14.4.3 Treatment-Emergent AEs Sorted by SOC – Part B

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TEAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

Table 14.4.4 Treatment-Related AEs Sorted by SOC – Part B

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TEAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

Table 14.4.5 Treatment-Emergent SAEs Sorted by SOC – Part B

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TESAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].

Table 14.4.6 Treatment-Related SAEs Sorted by SOC – Part B

		Active (n = xx)		**Control (n = xx)**		**All (n = xx)**	
SOC	**PT**	Participants	**Events**	Participants	**Events**	Participants	**Events**
Any TRSAE		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
XXXXXXX		xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx
	XXXXXXX	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx	xx (xx.x%) [xx.x, xx.x]	xx

95% CI [xx.x, xx.x].