

STATISTICAL ANALYSIS PLAN

Date: 06-May-2021

A randomized, controlled, single-blinded, within-subject (split-face), multicenter, prospective clinical study to evaluate the effectiveness and safety of using the dermal filler RHA® injected with a cannula or with a needle for the treatment of moderate to severe nasolabial folds

Study Sponsor

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Confidentiality Statement

The information contained in this document is provided in confidence. It is understood that this information will not be disclosed to others without prior agreement with the Sponsor.

SAP APPROVAL SIGNATURE PAGE

The following individuals approve this version of the [REDACTED] Statistical Analysis Plan.

Sponsor – TEOXANE SA:


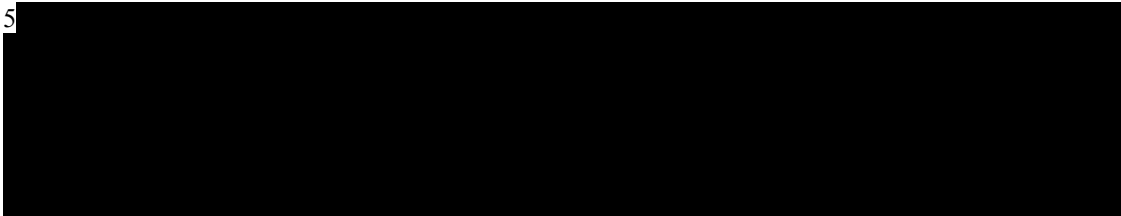

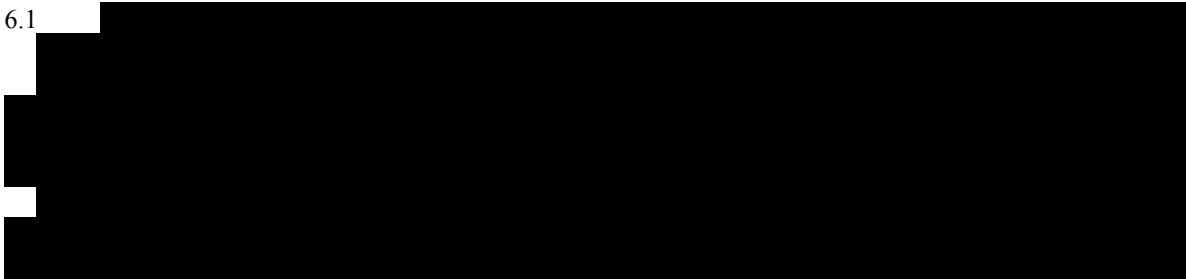

[REDACTED], Clinical Program Manager DATE

Clinical Research Organization - [REDACTED]

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1. INTRODUCTION

This statistical analysis plan (SAP) gives a comprehensive and detailed description of statistical techniques to be used for [REDACTED]. 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.

The structure and content of this SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA) and International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance on Statistical Principles in Clinical Trials. All work planned and reported for this SAP will follow internationally accepted guidelines, published by the American Statistical Association and the Royal Statistical Society, for statistical practice.

The planned analyses identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post-hoc analyses not identified in this SAP may be performed to further examine study data. Any post hoc or unplanned analysis performed will be clearly identified as such in the final CSR.

1.1 Background

Hyaluronic acid (HA) is a long-chain, repeated dimer, N-acetyl glucosamine and D-glucuronic acid polymer and is a major component of the extracellular matrix. Due to its natural viscoelastic and hydrogel properties, HA is widely used as matrix in tissue regeneration and particularly in dermal defect reconstruction.

RHA® [REDACTED] dermal filler is a device containing colorless, biodegradable, sterile, biocompatible, crosslinked HA of non-animal origin (i.e., bacterial fermentation using *Streptococcus zooepidemicus*). Crosslinking is performed using 1,4-butanediol diglycidyl ether (BDDE) to form a gel. RHA® [REDACTED] contains 0.3% w/w of lidocaine hydrochloride, a drug substance widely used for its anesthetic properties (i.e., it blocks the origin and transmission of nervous influx at the point of injection by stabilizing the neuronal membrane). [REDACTED]

1.2 Rationale for Study

1.3 Hypothesis

RHA® [REDACTED] injected in NLFs with a small cannula is non-inferior to RHA® [REDACTED] injected in the NLFs with a needle for the correction of moderate to severe NLFs as determined by the NLF-WSRS (validated NLF Wrinkle Severity Rating Scale) at [REDACTED] from last treatment.

A change from Baseline in the NLF-WSRS of ≥ 1 -grade will be considered clinically meaningful, and the non-inferiority margin for change in NLF-WSRS between needle and cannula will be 0.5 grade. The formal hypothesis set to be tested is as follows:

$$H_0: \mu_{\Delta(\text{needle} - \text{cannula})} \geq 0.5$$

$$H_a: \mu_{\Delta(\text{needle} - \text{cannula})} < 0.5$$

where $\mu_{\Delta(\text{needle} - \text{cannula})}$ represents the mean difference in change from Baseline between needle and cannula.

1.4 Study Objectives

The study is designed to achieve the following objectives:

1. Demonstrate the non-inferiority of RHA[®] injected in the NLFs with a cannula versus the control (RHA[®] injected in NLF with a needle) from last treatment for the correction of moderate to severe NLFs. Assessment of non-inferiority will be based on the change from Baseline in NLF-WSRS as rated by the Blinded Live Evaluator (BLE) at each investigative site.
2. Evaluate the safety of RHA[®] injected in NLF with a cannula versus the control up to from last treatment.

2. OVERVIEW OF STUDY DESIGN

2.1 Study Design

This is a randomized, controlled, single-blinded, within-subject (split-face), multicenter, prospective study to investigate whether RHA[®] injected in NLFs with a small cannula is non-inferior to RHA[®] injected in NLFs with a needle for the correction of moderate to severe NLFs as determined by the Blinded Live Evaluator (BLE) using the NLF-WSRS (validated NLF Wrinkle Severity Rating Scale) following last

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2.2 Study Design Rationale

2.2.1 Study Population

[REDACTED]

2.2.2 Primary Endpoint

The primary effectiveness endpoint will be aesthetic improvement from pre-injection as assessed by the NLF-WSRS (BLE) at [REDACTED] following last treatment (initial or touch-up). The primary hypothesis is that RHA[®] [REDACTED] used in conjunction with cannula is non-inferior to RHA[®] [REDACTED] with needle. An NLF-WSRS change from Baseline of ≥ 1 -grade will be considered clinically significant. [REDACTED]

[REDACTED]

[illegible]

[REDACTED]

[REDACTED]

3. TREATMENT ALLOCATION, RANDOMIZATION AND BLINDING

[REDACTED]

[REDACTED]

[REDACTED]

4. DEVICE ADMINISTRATION

[REDACTED]

[REDACTED]

[REDACTED]

4.1 Injection of Study Devices

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5.1 Effectiveness Variables

Case No.	Case Name	Case Description
1	Case 1	Case 1 Description
2	Case 2	Case 2 Description
3	Case 3	Case 3 Description
4	Case 4	Case 4 Description
5	Case 5	Case 5 Description
6	Case 6	Case 6 Description
7	Case 7	Case 7 Description
8	Case 8	Case 8 Description
9	Case 9	Case 9 Description
10	Case 10	Case 10 Description
11	Case 11	Case 11 Description
12	Case 12	Case 12 Description
13	Case 13	Case 13 Description
14	Case 14	Case 14 Description
15	Case 15	Case 15 Description
16	Case 16	Case 16 Description
17	Case 17	Case 17 Description
18	Case 18	Case 18 Description
19	Case 19	Case 19 Description
20	Case 20	Case 20 Description
21	Case 21	Case 21 Description
22	Case 22	Case 22 Description
23	Case 23	Case 23 Description
24	Case 24	Case 24 Description
25	Case 25	Case 25 Description
26	Case 26	Case 26 Description
27	Case 27	Case 27 Description
28	Case 28	Case 28 Description
29	Case 29	Case 29 Description
30	Case 30	Case 30 Description
31	Case 31	Case 31 Description
32	Case 32	Case 32 Description
33	Case 33	Case 33 Description
34	Case 34	Case 34 Description
35	Case 35	Case 35 Description
36	Case 36	Case 36 Description
37	Case 37	Case 37 Description
38	Case 38	Case 38 Description
39	Case 39	Case 39 Description
40	Case 40	Case 40 Description
41	Case 41	Case 41 Description
42	Case 42	Case 42 Description
43	Case 43	Case 43 Description
44	Case 44	Case 44 Description
45	Case 45	Case 45 Description
46	Case 46	Case 46 Description
47	Case 47	Case 47 Description
48	Case 48	Case 48 Description
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94	Case 94	Case 94 Description
95	Case 95	Case 95 Description
96	Case 96	Case 96 Description
97	Case 97	Case 97 Description
98	Case 98	Case 98 Description
99	Case 99	Case 99 Description
100	Case 100	Case 100 Description

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

5.2 Safety

5.2.1 Adverse Events

The Treating Investigator will assess AEs

5.2.2 Patient Common Treatment Response Diary

The study coordinator will provide subjects with instructions for daily recording of his/her observations of the CTRs of the study treatments into an electronic diary for the first 4 weeks after each treatment. The diary will be activated after treatment and will be discussed during the 3-day post-injection telephone follow-up.

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[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

6. STATISTICAL METHODS

6.1 Analysis Populations

[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

6.2 Primary Effectiveness Endpoint

The primary endpoint of NLF-WSRS change from Baseline [REDACTED] as rated by the BLE will be analyzed in a non-inferiority statistical model using the PP population with a 0.5 margin for the difference between cannula and needle. A sensitivity analysis will be done using the ITT population. Expressing the difference between treatment groups as the mean of change from Baseline in RHA® injected with needle minus change from Baseline in RHA® injected with cannula, the one-sided 97.5% confidence limit must be < 0.5 to conclude non-inferiority. A paired t-test will be used to calculate the confidence interval to account for dependence. The formal hypothesis set to be tested is:

$$H_0: \mu_{\Delta(\text{needle} - \text{cannula})} \geq 0.5$$

$$H_a: \mu_{\Delta(\text{needle} - \text{cannula})} < 0.5$$

where $\mu_{\Delta(\text{needle} - \text{cannula})}$ represents the mean difference in change from Baseline between needle and cannula.

6.3 Secondary Effectiveness Endpoints

All statistical inference tests will be performed at the same significance level (α) of 0.05. For categorical and continuous variables, the two groups will be compared using two-sided parametric or non-parametric tests for paired data, as appropriate. For continuous variables, the Shapiro-Wilk test will be used to assess normality. If data are normally distributed, testing will be conducted using the Student t-test, while testing will be conducted with the Wilcoxon signed-rank test if not normally distributed.

[REDACTED]

6.4 Safety Endpoints

The SAFT Population will be used to summarize the safety of the study devices and will consist of all treated subjects. The primary safety analysis is the calculation of the incidence of CTRs and adverse events in the study period. Point estimates for all CTRs, AEs and SAEs will be presented and two-sided exact 95% confidence intervals will be calculated for the overall incidence of AEs and SAEs. Tables will be generated which summarize AEs by investigator assessments of both relationship to treatment and severity.

[REDACTED]

6.4.1 Safety (SAFT) Population

6.5 Sample Size Considerations

6.6 General Considerations

Data will be listed by treatment group and subject number. Safety and efficacy data will be summarized by treatment group. Descriptive statistics will consist of mean, standard deviation, median, minimum/maximum for **continuous variables** (quantitative), and frequency and percent for **discrete variables** (qualitative), and 95% CIs will be provided for select data. Missing values will be presented for all variables.

All programs for data output and analyses will be written in SAS version 9.4 or higher (SAS Institute, Inc., Cary, NC).

Missing Values

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Wilcoxon signed-rank test
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	Wilcoxon signed-rank test
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Category	Sub-category	Value
Category 1	Sub-category 1.1	10
	Sub-category 1.2	20
	Sub-category 1.3	30
	Sub-category 1.4	40
Category 2	Sub-category 2.1	50
	Sub-category 2.2	60
	Sub-category 2.3	70
	Sub-category 2.4	80
Category 3	Sub-category 3.1	90
	Sub-category 3.2	100
	Sub-category 3.3	110
	Sub-category 3.4	120

[illegible]

[illegible]

[illegible][illegible]

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[REDACTED]		[REDACTED]	[REDACTED]
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Category	Item	Value	Unit	Notes
Agriculture	Wheat	1200	kg	
	Corn	800	kg	
	Barley	500	kg	
	Oats	300	kg	
	Hay	1500	kg	
	Straw	2000	kg	
	Grain	1000	kg	
	Seeds	200	kg	
	Fertilizer	100	kg	
	Pesticides	50	kg	
Livestock	Cattle	100	kg	
	Pigs	50	kg	
	Sheep	200	kg	
	Goats	150	kg	
	Hens	300	kg	
	Ducks	100	kg	
	Chickens	200	kg	
	Geese	50	kg	
	Quacks	20	kg	
	Donkeys	10	kg	
Fishing	Salmon	500	kg	
	Trout	300	kg	
	Perch	200	kg	
	Carp	100	kg	
	Shrimp	100	kg	
	Crab	50	kg	
	Scallop	30	kg	
	Clam	20	kg	
	Octopus	10	kg	
	Squid	5	kg	
Hunting	Deer	100	kg	
	Antelope	50	kg	
	Goat	200	kg	
	Sheep	150	kg	
	Wild Boar	100	kg	
	Wild Duck	50	kg	
	Wild Goose	30	kg	
	Wild Chicken	20	kg	
	Wild Rabbit	10	kg	
	Wild Squirrel	5	kg	

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