STATISTICAL ANALYSIS PLAN

Protocol Code: ReGl/19/PAS-Acn/001
EudraCT number: NA

"OPEN LABEL, UNCONTROLLED CLINICAL INVESTIGATION ON THE SAFETY AND CLINICAL PERFORMANCE OF PAPIX ACNE SCAR IN THE PREVENTION AND IMPROVEMENT OF SCARS AND LESIONS ASSOCIATED WITH ACNE"

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APPROVAL

Protocol code: ReGl/19/PAS-Acn/001

Title: OPEN LABEL, UNCONTROLLED CLINICAL INVESTIGATION ON THE SAFETY AND CLINICAL PERFORMANCE OF PAPIX ACNE SCAR IN THE PREVENTION AND IMPROVEMENT OF SCARS AND LESIONS ASSOCIATED WITH ACNE

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LIST OF ABBREVIATIONS

ADE	Adverse Device Effect
AE	Adverse Event
CIP	Clinical Investigation Plan
CRF	Case Report Form
CRO	Contract Research Organization
CTCAE	Common Terminology Criteria for Adverse Events
DLQI	Dermatology Life Quality Index questionnaire
FAS	Full Analysis Set
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonization
IFU	Instructions For Use
IGA	Investigator Global Assessment
IEC	Indipendent Ethics Committee
MedDRA	Medical Dictionary for Regulatory Activities
PPAS	Per-Protocol Analysis Set
PT	Preferred Term
ml	Milliliters
SADE	Serious Adverse Device Effect
SAF	Safety Analysis Set
SAE	Serious Adverse Event
SGA	Scar Global Assessment
SOC	System Organ Class
SOP	Standard Operating Procedure
USADE	Unanticipated Serious Adverse Device Effect

1. VERSION HISTORY

1.1 Version history of the SAP

Version Number	Summary/Reason for changes	Date issued
1.0	First version	30/07/2021
2.0	SAP amendment to correct the efficacy endpoints	09/11/2021

1.2 Version history of the Protocol

Version Number	Date	Description
1.0	02/12/2019	First version submitted
2.0	02/07/2020	The protocol was amended in order to correct the number of tubes of the investigational product dispensed to the study subject.

1.3 Version history of the CRF

Version Number	Date	Description
1.0	13/02/2020	First version in production

2. INTRODUCTION

The clinical investigation ReGl/19/PAS-Acn/001 was conducted to evaluate the clinical performance and safety of PAPIX ACNE SCAR in the treatment of acne scars and lesions.

Acne vulgaris is a common and widespread dermatological disorder that predominantly affects teenagers but can also affect preadolescents and post-teen individuals. In general, the prevalence of scars increases with acne severity, in the presence of large lesions and severe inflammation, but also subjects with mild acne are at risk of scarring. There are no general guidelines available to optimize acne scar treatment. However, there is a variety of therapies that may reduce the prominence of acne scars.

PAPIX ACNE SCAR, the medical device tested in the present post market clinical follow-up investigation, is a silicone gel indicated for acne lesions and scars; this acts by creating a sheer physical barrier that separates the skin from surrounding environment, useful for generating favorable conditions for the maintenance and/or recovery of the physiological cutaneous layer in case of acne lesion. Thus, PAPIX ACNE SCAR improves skin by keeping it hydrated and works to prevent and reduce acne scars, also thanks to the presence of humectant/moisturizing ingredients.

The present study was conducted in Italy with the purpose of confirming and supporting the CE mark of PAPIX ACNE SCAR in the post-market phase. In this post-market clinical follow-up investigation PAPIX ACNE SCAR

was used according to its Instructions for Use (IFU), in males and females ≥ 12 years of age, affected by mild to moderate acne.

3. STUDY OBJECTIVES

3.1 Primary Objectives

The primary objective of this clinical investigation was to evaluate and confirm the performance of PAPIX ACNE SCAR in the prevention and improvement of acne scars in subject suffering for mild to moderate acne, after 4 weeks of treatment.

3.2 Secondary Objectives

The secondary objectives of this clinical investigation were:

1. To evaluate the performance of PAPIX ACNE SCAR in the prevention and improvement of acne scars after 2 and 8 weeks of treatment.
2. To evaluate the performance of PAPIX ACNE SCAR in the prevention of acne lesions after 2, 4 and 8 weeks of treatment.
3. To evaluate the improvement in acne severity after 2, 4 and 8 weeks of treatment, through the Investigator Global Assessment, ranging from 0 (clear; clear skin with no lesions) to 4 (severe; many inflammatory and non- inflammatory lesions).
4. To evaluate the improvement of the skin roughness on a 4-point scale from 0 (none; very smooth) to 3 (severe; very rough) after 2, 4 and 8 weeks of treatment.
5. To evaluate the improvement of the skin texture on a 6-point scale from 0 (worse) to 5 (complete improvement), after 2, 4 and 8 weeks of treatment.
6. To evaluate the subject's and Investigator's global evaluation of satisfaction with regards to the performance of PAPIX ACNE SCAR, through a specific questionnaire.
7. To evaluate the subject's overall acceptability of PAPIX ACNE SCAR, through a specific questionnaire.
8. To evaluate the subject's adherence to treatment by the product accountability and information asked to the subject.

4. STUDY METHODS

4.1 Study Design

This was a multicenter, open label, uncontrolled, post-market clinical follow-up investigation.
All the subjects were allocated to the following treatment group:
- PAPIX ACNE SCAR, topically applied twice a day for 8 weeks.

The subject started treatment on the first day of study and continued for 8 weeks after the first administration.

4.2 Treatment Administration

Subjects were instructed to use PAPIX ACNE SCAR applied twice a day, in the morning and in the evening before bedtime, and massaged gently into the skin until absorbed. The treatment duration was of 8 weeks.

4.3 Randomization and Blinding

Not applicable: open-label clinical investigation.

5. STUDY ENDPOINTS

5.1 Primary Endpoints

Proportion of subjects with improved acne scars and marks at week 4 of treatment (Visit 3) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1).

5.2 Secondary Endpoints

Secondary endpoints were:

1. Proportion of subjects with improved acne scars and marks at week 2 and 8 of treatment (Visits 2 and 4) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1).
2. Proportion of subjects at week 2, 4 and 8 of treatment, without any new facial acne lesions with respect to baseline (Visit 1).
3. Change from baseline (Visit 1) to each following time point in the acne severity, according to the Investigator Global Assessment.
4. Change from baseline (Visit 1) to each following time point in the skin roughness, on a 4-point scale from 0 (none; very smooth) to 3 (severe; very rough).
5. Change from baseline (Visit 1) to each following time point in the skin texture on a 6-point scale from 0 (worse) to 5 (complete improvement).
6. The subject's adherence to treatment by the product accountability.
7. The subject's and Investigator's global evaluation of satisfaction with regards to the performance of PAPIX ACNE SCAR, through a specific questionnaire.
8. To evaluate the subject's overall acceptability of the treatment, through a specific questionnaire.

5.3 Safety Endpoints

To evaluate the local and general tolerability of PAPIX ACNE SCAR. Adverse events and adverse reactions were recorded and evaluated.

6. PLANNED ANALYSIS

6.1 Interim Analysis

No interim analysis is planned.

6.2 Final Analysis

Final analysis will be performed according to the protocol and to this Statistical Analysis Plan, after data cleaning operations and DB Lock will be performed. The statistical analysis will be performed using SAS 9.4 for Windows (SAS Institute Inc., Cary, NC, USA).

7. SAMPLE SIZE AND STATISTICAL POWER CONSIDERATION

An exact binomial test with a nominal 5% two-sided significance level has 80% power to detect the difference between the Null hypothesis proportion, π_0 of 0.5 (i.e., 50% of subjects with treatment success) and the Alternative

proportion, π_1, of 0.75 (i.e., 75% of subjects with treatment success) when the sample size is 30 subjects. Assuming a possible 25% dropout rate, 40 subjects were enrolled, according to the CIP provisions.

8. ANALYSIS POPULATIONS

8.1 Full Analysis Set (FAS)

The FAS population includes all subjects of the safety population who have performed the baseline assessments and had at least one post-baseline assessment of any performance endpoint (primary or secondary).

8.2 Per-Protocol (PP) Population

The PP population includes all subjects of the FAS who also met all inclusion/exclusion criteria and who did not have any major protocol deviation (i.e. wrong inclusion, use of forbidden concomitant medications, etc.).

8.3 Safety Population

The Safety Population includes all the subjects enrolled who signed informed consent and received at least one administration of the investigational device.

9. GENERAL ISSUES FOR STATISTICAL ANALYSIS

9.1 Definitions, Derived Variables and Datasets

Variable	Type	Description
lesion_num	Continous	Number of lesions
scar_num	Continous	Number of scars
srorres_iga	Discrete	Investigator's Global Assessment: 0 = Clear skin 1 = Almost clear skin 2 = Mild severity 3 = Moderate severity 4 = Severe
srorres_sga	Discrete	Scar Global Assessment: 0 = Clear skin 1 = Almost clear skin 2 = Mild severity 3 = Moderate severity 4 = Severe
srorres_rough	Discrete	Skin roughness assessment: 0 = None, very smooth 1 = Mild, slightly rough 2 = Moderate, rough 3 = Severe, very rough
srorres_texture	Discrete	Skin texture assessment: 0 = worse 1 = slightly worse 2 = no change 3 = slightly improved 4 = improved

		5 = complete improvement
qsorres_perf_subj	Discrete	Subject's global evaluation of performance: 1 = Very much improved 2 = Improved 3 = Minimally improved 4 = No change 5 = Minimally worse 6 = Worse 7 = Very much worse
qsorres_perf_inv	Discrete	Investigator's global evaluation of performance: 1 = Very much improved 2 = Improved 3 = Minimally improved 4 = No change 5 = Minimally worse 6 = Worse 7 = Very much worse
qsorres_satisf	Discrete	Subject's overall acceptability: 1 = Very much satisfied 2 = Satisfied 3 = Neither satisfied nor dissatisfied 4 = Dissatisfied 5 = Very much dissatisfied
ecoccur	Discrete	Compliance
ecdur	Continous	Treatment skipped times
aeterm	Discrete	Adverse event description

9.1.1 Baseline Values

Data and Measures collected at Visit 1, before any study treatment administration, are considered as baseline values.

9.1.2 Duration of Exposure

The planned treatment duration was of 8 weeks.

9.1.3 Treatment Compliance

The Investigator was responsible for ensuring the accountability of the study product.

The Investigator should maintain records that adequately documented:

- that the subjects were provided with the quantities specified by the clinical investigation plan/amendment(s)
- that all study products provided by the Sponsor were fully reconciled.

The investigator visually checked the used/unused tubes of study product returned by the subjects at study visit. In order to quantify the compliance to the treatment the Investigator also asked to the subject if the product was used according to the instructions and how many times the treatment was skipped (if any). The subject will be considered compliant to the treatment if the number of skipped applications is not exceeding 20% of the expected applications.

In the Listing 16.2.5, both accountability of returned product and adherence to treatment reported by the subject will be described.

9.1.4 Methods for Withdrawals and Missing Data

Missing data will not be replaced in any statistical analysis.

9.2 Multicenter Studies Considerations

Although two centers were planned for this investigational study, multicenter considerations will not be performed because the site 02 did not enroll any subjects.

9.3 Multiple Comparisons and Multiplicity

This was a single-arm clinical investigation and no adjustment for multiplicity will be used.

9.4 Data Safety Monitoring Board (DSMB)

No DSMB was established for this study.

10. STUDY SUBJECTS

10.1 Disposition of Subjects

Subjects' disposition by study visit will be described and summarized in the Table 14.1.1. Reasons for withdrawal will be described.

10.2 Protocol Deviations

Protocol deviations will be reviewed and discussed with the sponsor before the database lock during Data Review Meeting.

Protocol deviations will be described in the Table 14.1.2 and in the Listing 16.2.2.

11. EFFICACY ANALYSIS

11.1 Analysis datasets

The analysis of safety endpoints will be performed in the Safety population (SAF). Analysis of performance endpoints will be performed on the FAS population. The analysis of primary endpoint will be repeated in the Per-Protocol population.

11.2 Demographics and Baseline Characteristics

Demographic (gender, age, ethnic origin) and baseline characteristics will be summarized in the Tables 14.1.3 and 14.1.4 and in the Listing 16.2.4.

The descriptive statistics will include number of observations, mean, standard deviation, median, minimum and maximum for continuous variables and number of observations and their percentages for categorical parameters.

11.3 Measurements of Treatment Compliance

Treatment compliance will be assessed through the counting of the number of applications performed. The following formula will be used:

$$\frac{Number\ of\ applications\ performed}{Number\ of\ applications\ planned} * 100$$

The number of planned applications will be estimated on the basis of the treatment duration x 2 times.

Treatment compliance will be estimated separately for the two study periods: Visit 1 – Visit 3 and Visit 3 – Visit 4 and it will be described in the Listing 16.2.5.

11.4 Efficacy Analysis

11.4.1 Primary Efficacy Endpoints

The primary endpoint will be the proportion of subjects with acne scars and marks improved with respect to baseline and, at the same time, without any new facial acne scars after 4 weeks of treatment (treatment success). The improvement of acne scars and marks will be assessed as the change of at least one grade in the qualitative Scar Global Assessment (SGA) by Goodman and Baron between baseline and Week 4. The number of new acne scars will be assessed by count and comparison with baseline.

The primary endpoint will be described using number (N) and the proportion of subjects (%) in the Tables 14.2.1.1 and 14.2.1.2. The proportion of treatment successes will be compared to a referent proportion (50%, Null hypothesis proportion) using the exact binomial test.

11.4.2 Secondary Efficacy Endpoints

The proportion of subjects with acne scars and marks improved with respect to baseline and, at the same time, without any new facial acne scars after 2 and 8 weeks of treatment (treatment success) will be described using number (N) and percentage (%). The improvement of acne scars and marks will be assessed as the change of at least one grade in the qualitative Scar Global Assessment (SGA) by Goodman and Baron between baseline and Week 2 and 8. The number of new acne scars will be assessed by count after 2 and 8 weeks and comparison with baseline. The proportion of treatment successes will be compared to a referent proportion (50%, Null hypothesis proportion) using the exact binomial test.

The proportion of subjects at week 2, 4 and 8 of treatment, without any new facial acne lesions with respect to baseline (Visit 1) will be described using number (N) and percentage (%); the proportion of treatment successes will be compared to a referent proportion (50%, Null hypothesis proportion) using the exact binomial test.

Acne severity after 2, 4 and 8 weeks of treatment will be assessed through the IGA. Changes from baseline will be compared using Wilcoxon signed rank-sum test.

The improvement of skin roughness will be assessed on a 4-point scale from 0 (none; very smooth) to 3 (severe; very rough). Changes from baseline will be compared using Wilcoxon signed rank-sum test.

Skin texture change will be assessed on a 6-point scale from 0 (worse) to 5 (complete improvement), after 2, 4 and 8 weeks of treatment and it will be summarized through the number (N) and the proportion of subjects (%) for each item.

The number of applications will be self-reported by the subject to assess adherence to treatment.

Subject's and Investigator's global evaluation on performance of the study product obtained at the end of the study (Visit 4) by means of a 7-items scale will be summarized through number (N) and proportion of subjects (%) for each item.

Subject's evaluation of overall acceptability with treatment, obtained by means of a 5-item scale will be summarized through number (N) and the proportion of subjects (%) for each item.

The secondary endpoints will be described from Table 14.2.2.1 to Table 14.2.2.8.

11.5 Summary of Efficacy Analyses

Endpoint	Analysis	Populations
Proportion of subjects with improved acne scars and marks at week 4 of treatment (Visit 3) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1).	Exact binomial test	*FAS* *PP*
Proportion of subjects with improved acne scars and marks at week 2 and 8 of treatment (Visits 2 and 4) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1).	Exact binomial test	*FAS*
Proportion of subjects at week 2, 4 and 8 of treatment, without any new facial acne lesions with respect to baseline (Visit 1).	Exact binomial test	*FAS*
Change from baseline (Visit 1) to each time point (Visit 2, 3 and 4) in the acne severity, according to the Investigator Global Assessment.	Wilcoxon signed rank-sum test	*FAS*
Change from baseline (Visit 1) to each time point (Visit 2, 3 and 4) in the skin roughness, on a 4-point scale from 0 (none; very smooth) to 3 (severe; very rough).	Wilcoxon signed rank-sum test	*FAS*
Change from baseline (Visit 1) to each time point (Visit 2, 3 and 4) in the skin texture on a 6-point scale from 0 (worse) to 5 (complete improvement).	Number (N) and the proportion of subjects (%) for each item	*FAS*
Subject's and Investigator's global evaluation on performance of the study product at the end of the study (Visit 4) by means of a 7-items scale.	Number (N) and the proportion of subjects (%) for each item	*FAS*
Subject's overall acceptability of the treatment at the end of the study (Visit 4) by means of a 5-item scale.	Number (N) and the proportion of subjects (%) for each item	*FAS*

Subject's adherence to treatment by the product accountability.	Mean percentage within each treatment group	*FAS*

12. SAFETY EVALUATION

12.1 Extent of Exposure

The extent of exposure is of 8 weeks (56 days ±3).

12.2 Adverse Events

All enrolled subjects receiving at least one treatment application will be included in the safety analysis. The safety analysis will include Deaths, Serious Adverse Events and other significant Adverse Events.

Adverse events (AEs) and Adverse Device Events (ADEs) will be coded using the last updated version of the Medical Dictionary for Regulatory Activities (MedDRA) to give a preferred term (PT) and a system/organ class term (SOC) for each event. The number of subjects who experienced at least one AE or ADE, study product-related AE or ADE, serious AE or ADE, severe AE or ADE and the number of subjects withdrawn due to AE will be summarized in the Table 14.3.1.

For each SOC and preferred term, summaries will be made with respect to the proportion of subjects having at least one occurrence of that event during the study and the total number of events. The incidence of AEs and ADEs will be presented overall, by SOC and preferred term, and additional grouping by severity and relationship to the study treatment in the Table 14.3.2.

12.3 Other safety endpoints

Local tolerability at the site of administration (e.g. skin increased itching or redness or irritation) will be reported and summarized in the Table 14.3.3 and in the Listing 16.2.8.

13. DEVIATIONS FROM THE PROTOCOL SPECIFIED ANALYSIS

No deviation from the analyses specified in the study protocol have been included in this Statistical Analysis Plan (SAP).

14. LIST AND SAMPLES OF TABLES, FIGURES AND GRAPHS

The following lists of tables might not be exhaustive. Additional tables can be produced if necessary.

14.1 Demographic data

Table 14.1.1 Subjects' disposition

Table 14.1.2 Protocol deviations

Table 14.1.3 Demographic characteristics

Table 14.1.4 Disease details at baseline

Table 14.1.5 Medical history

Table 14.1.6 Surgical history

Table 14.1.7 Physical examination

14.2 Efficacy data

14.2.1 Primary endpoints

Table 14.2.1.1 Proportion of subjects with improved acne scars and marks at week 4 of treatment (Visit 3) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1) (FAS Population)

Table 14.2.1.2 Proportion of subjects with improved acne scars and marks at week 4 of treatment (Visit 3) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1) (PP Population)

14.2.2 Secondary endpoints

Table 14.2.2.1 Proportion of subjects with improved acne scars and marks at week 2 and 8 of treatment (Visits 2 and 4) and, at the same time, without any new facial acne scars with respect to baseline (Visit 1) (FAS Population)

Table 14.2.2.2 Proportion of subjects at week 2, 4 and 8 of treatment, without any new facial acne lesions with respect to baseline (Visit 1) (FAS Population)

Table 14.2.2.3 Change from baseline (Visit 1) to each time point (Visit 2, 3 and 4) in the acne severity, according to the Investigator Global Assessment (FAS Population)

Table 14.2.2.4 Change from baseline (Visit 1) to each time point (Visit 2, 3 and 4) in the skin roughness on a 4-point scale (FAS Population)

Table 14.2.2.5 Change from baseline (Visit 1) to each time point (Visit 2, 3 and 4) in the skin texture on a 6-point scale (FAS Population)

Table 14.2.2.6 Subject's and Investigator's global evaluation on performance of the study product at the end of the study (Visit 4) by means of a 7-items scale (FAS Population)

Table 14.2.2.7 Subject's overall acceptability of the treatment at the end of the study (Visit 4) by means of a 5-item scale (FAS Population)

Table 14.2.2.8 Subject's adherence to treatment by the product accountability (FAS Population)

14.3 Safety data

Table 14.3.1 Analysis of adverse events observed (Safety population)

Table 14.3.2 Display of adverse events observed (Safety population)

Table 14.3.3 Subject's local tolerability of study product at the site of administration (Safety population)

14.4 Sample tables

Tables reporting statistical analysis will be issued as PDF files. Mock samples are reported in the following sections.

14.4.1 Sample summary table

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Table xx.x.x
(………………… Population)

Characteristic	Statistic	PAPIX ACNE SCAR
VAR 1	Class A	xx (xx.x%)
	Class B	xx (xx.x%)
VAR 2	N	xx
	Mean (SD)	xx.xx (xx.xx)
	Median	xx.xx
	Min - Max	xx.xx / xx.xx
VAR 3	Class A	xx (xx.x%)
	Class B	xx (xx.x%)
	Class C	xx (xx.x%)
	Class D	xx (xx.x%)
VAR 4	N	xx
	Mean (SD)	xxx.xx (x.xx)
	Median	xxx.xx
	Min - Max	xxx.xx / xxx.x
VAR 5	N	xx
	Mean (SD)	xx.xx (xx.xx)
	Median	xx.xx
	Min - Max	xx.xx / xxx.xx
VAR 6	N	xx
	Mean (SD)	xx.xx (x.xx)
	Median	xx.xx
	Min - Max	xx.xx / xx.xx

Note: ……………………………………………………

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14.4.2 Sample table for efficacy analysis – continuous variables

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Table xx.x.x.x
Summary and Analysis of _____
(_____ Population)

Endpoint	Statistic	PAPIX ACNE SCAR
Visit 1 (Baseline)	N	xxx
	Mean (SD)	-x.xx (x.xx)
	Median	-x.xx
	Min - Max	-x.xx / x.xx
Visit 2	N	xxx
	Mean (SD)	-x.xx (x.xx)
	Median	-x.xx
	Min - Max	-x.xx / x.xx
	p-value	x.xxx
Visit 3	N	xxx
	Mean (SD)	-x.xx (x.xx)
	Median	-x.xx
	Min - Max	-x.xx / x.xx
	p-value	x.xxx
Visit 4 (End of study)	N	xxx
	Mean (SD)	-x.xx (x.xx)
	Median	-x.xx
	Min - Max	-x.xx / x.xx
	p-value	x.xxx

Statistical significance: * p<0.05; ** p<0.01; *** p<0.001.

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14.4.3 Sample table for efficacy analysis – discrete variables

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Table xx.x.x.x
Summary and Analysis of _____
(_____ Population)

Characteristic	Statistic	PAPIX ACNE SCAR
Visit 1 (Baseline)	Class A	xx (xx.x%)
	Class B	xx (xx.x%)
Visit 2	Class A	xx (xx.x%)
	Class B	xx (xx.x%)
	p-value	x.xxx
Visit 3	Class A	xx (xx.x%)
	Class B	xx (xx.x%)
	p-value	x.xxx
Visit 4 (End of study)	Class A	xx (xx.x%)
	Class B	xx (xx.x%)
	p-value	x.xxx

Statistical significance: * p<0.05; ** p<0.01; *** p<0.001.

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14.4.4 Sample table for adverse events analysis

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Table xx.x.x.x
Adverse Events
(Safety Population)

AE details	Statistic	PAPIX ACNE SCAR
Have any AE occurred?	NO	x (xx.x%)
	YES	x (xx.x%)
Total number of adverse events*	N	(N=xxx)
Relatedness with study treatment	Certain	x (xx.x%)
	Probable	x (xx.x%)
	Possible	x (xx.x%)
	Doubtful	x (xx.x%)
	None	x (xx.x%)
	Unknown	
Severity	Mild	x (xx.x%)
	Moderate	x (xx.x%)
	Severe	x (xx.x%)
Seriousness	YES	x (xx.x%)
	NO	x (xx.x%)

* More than one adverse event per patient.

Statistical significance: * p<0.05; ** p<0.01; *** p<0.001.
Note: p-values from a chi-square test for discrete variables and T-test for continuous variables.

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14.4.5 Sample table for adverse events display

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Table xx.x.x.x
Summary of Number (%) of Adverse Events and Patients with Adverse Events by System Organ Class and Preferred Term
(Safety Population)

	PAPIX ACNE SCAR		
System Organ Class (SOC) . Preferred Term (PT)	Event	Patients	(%)
OVERALL	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx
SOC 1	x	x	x.xx
. PT 1	x	x	x.xx
. PT 2	x	x	x.xx
. PT 3	x	x	x.xx

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15. REFERENCES

None.

16. APPENDICES

16.1 Study information

The following appendices will be attached to the CIR.:

Appendix 16.1.1 Protocol and Protocol Amendments

Appendix 16.1.2 Sample Case Report Form

Appendix 16.1.3 List of IECs or IRBs - Representative Written Information for Subject and Sample Consent Forms

Appendix 16.1.4 List and Description of Investigators and Other Important Study Participants in the Study Including Curricula Vitae

Appendix 16.1.5 Signature Pages

Appendix 16.1.6 Listing of Subjects Receiving Test Drug/Investigational product from Specific Batches, Where More Than One Batch Was Used

Appendix 16.1.7 Randomization Scheme and Codes

Appendix 16.1.8 Audit Certificates

Appendix 16.1.9 Documentation of Statistical Methods

Appendix 16.1.10 Documentation of Inter-laboratory Standardization Methods and Quality Assurance Procedures, If Used

Appendix 16.1.11 Publications Based on the Study

Appendix 16.1.12 Important Publications Referenced in the Report

16.2 List and samples of Subject Data Listings

The following list of listings might not be exhaustive. Additional listings can be produced if necessary.

The following data listings will be attached to the CIR:

Listing 16.2.1 Discontinued Subjects

Listing 16.2.2 Protocol Deviations

Listing 16.2.3 Subjects Excluded from the Efficacy Analysis

Listing 16.2.4 Demographic Data and Other Baseline Characteristics

Listing 16.2.5 Compliance

Listing 16.2.6 Individual Efficacy Response Data

Listing 16.2.7 Adverse Event Listings

Listing 16.2.8 Concomitant Medications

16.2.1 Sample listing

Listings will be issued as PDF files. Mock listings are reported in the following section.

Sponsor: Relife S.r.l.
Protocol: ReGl/19/PAS-Acn/001

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Listing xx.x.x.x

SUBJECT	VISIT	VAR 1	VAR 2	VAR 3	VAR 4	VAR 5	VAR 6	VAR 7	VAR 8	VAR 9	VAR 10	VAR 11	VAR 12	VAR 13
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	x	x	x	x.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	xx.x	xx	xx	xx	xx.x	-x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	x.x	xx	xx	xx	xx.x	x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xxx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	xx.x	xx	xx	xx	xx.x	x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	x	x	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	x	x	x	x.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	x.x	xx	xx	xx	xx.x	-x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x					
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-x.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xxx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	xx	xx	xx.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-xx.x	xx	x	x	x.x	-xx.x
XXxxxx-xxx	x	xx	xx	xx.x	xx	xx	xx	xx.x	-x.x	xx	x	x	x.x	-xx.x

Program: Lxxxxxxxx.sas　　CONFIDENTIAL　　Date: xxXXXxxxx