STATISTICAL ANALYSIS PLAN

PHASE III

VERSION: 1.0

DATE OF PLAN:

27-May-2019

BASED ON:

Protocol Version 2.0 15-Jan-2018
Data Management Plan Final Version 1.0 02-Feb-2018

Study Drug:
Test Drug: Podofilox Topical Gel 0.5% (Hyloris Developments SA)
RLD: Condylox® Gel 0.5% (Allergan Pharmaceuticals)

Protocol Number:
016-POD-001

Study Title:

A Mulit-Center, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of Hyloris Development's Podofilox Topical Gel 0.5% compared to Allergan's Condylox® Gel 0.5%, and both active treatments to a vehicle control in male and female patients with external Anogenital Warts.

Sponsor:
Hyloris Developments SA
Bâtiment GIGA EE1
Avenue Hippocrate n° 5
4000 Liège (Sart-Tilman)
Belgium

STATISTICAL ANALYSIS PLAN REVIEW AND APPROVAL

This Statistical Analysis Plan has been prepared in accordance with team reviewers' specifications.

Prepared by:

Jose L. Nabut 30 May 2019

Statistician Name and Signature Date

Reviewed by Agron Collaku, Ph.D. Senior Manager Biostatistics, Clinical Affairs, Perrigo New York, Inc.

Name and Signature Date

Approved by:

Maurizio Passarini 28 May 2019

Sponsor Name and Signature Date

STATISTICAL ANALYSIS PLAN REVIEW AND APPROVAL

This Statistical Analysis Plan has been prepared in accordance with team reviewers' specifications.

Prepared by:

Statistician Name and Signature	Date

Reviewed by Agron Collaku, Ph.D. Senior Manager Biostatistics, Clinical Affairs, Perrigo New York, Inc.

Agron Collaku		05-28-2019
Name and Signature		Date

Approved by:

Sponsor Name and Signature	Date

PROTOCOL SYNOPSIS

Study Title	A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Study of Hyloris Developments's Podofilox Topical Gel 0.5% compared to Allergan's Condylox® Gel 0.5% in male and female patients with external anogenital warts.
Protocol Number	016-POD-001
Development Phase	3
Type of Study	Bioequivalence (BE) with Clinical Endpoints.
Study Medication:	1) Podofilox Topical Gel 0.5% (Test formulation), manufactured by Hyloris Developments. 2) Condylox® Gel 0.5% (Reference Product), manufactured by Allergan Pharmaceuticals. 3) Vehicle of test product, manufactured by Hyloris Developments SA.
Name of Active Ingredient	Podofilox
Route of administration	Topical application
Sponsor	Hyloris Developments SA Bâtiment GIGA EE1 Avenue Hippocrate n° 5 4000 Liège (Sart-Tilman) Belgium.
Study Objectives	PRIMARY • To compare the clinical efficacy among patients with anogenital warts when treated with Podofilox Topical Gel 0.5% or Condylox® Gel 0.5% or placebo. SECONDARY • To demonstrate safety of Podofilox Topical Gel 0.5% compared to Condylox® Gel 0.5% or placebo assessed by the frequency and severity of adverse events, and application site reaction scores

	(erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding).
Study Design	This is a multicenter, parallel group, randomized, double-blind, placebo-controlled, trial with clinical endpoint comparing Podofilox Topical Gel 0.5% to Condylox® Gel 0.5% and a matching placebo. The study will be conducted among adult male and female patients with external anogenital warts. All study related procedures will be conducted only after written informed consent is obtained at the Screening visit, which will occur up to 14 days prior to the Baseline (Days -14 to -1). During the Screening visit, the Investigator will record subject's demographics, medical history, review concomitant medication, identifying any prohibited therapies that subject is currently taking. The Investigator will assess vital signs and perform physical examination identifying any clinically significant abnormalities. Laboratory samples will be collected, including HIV, Hepatitis B&C and urine pregnancy tests (UPT) for women of childbearing potential. The Investigator will confirm the diagnosis of External Anogenital Warts (EAW) and the absence of contraindications specified in the exclusion criterion 4 during the visual examination. The biopsy of skin lesions will be performed per the discretion of the Investigator for microscopic verification of the diagnosis of EAWs if any doubts of the diagnosis. Once the results of Screening assessments are obtained, suggesting that the subject is eligible for entering the study, the Baseline visit (Day 0) will take place. During this visit, the Investigator will identify any AEs that occurred from the last visit, review concomitant and prohibited therapies, perform vital signs and physical examination. Those subjects who qualify for entering the study will be randomized to one of the following arms in a ratio of 3:3:1: • **Arm 1** (Test product): Subjects in this arm will receive test formulation of Podofilox Topical Gel 0.5% (Hyloris Developments SA). • **Arm 2** (Reference Listed Drug [RLD]): Subjects in this arm will receive RLD Condylox® Gel 0.5% (Allergan Pharmaceuticals).

	• **Arm 3** (Placebo): Subjects in this arm will receive a vehicle that matches the test product, except for the inclusion of the active ingredient (Hyloris Developments SA). Randomization and study medication number assignment will be performed using an Interactive Web Response System (IWRS). EAWs will be inspected and the count of EAWs will be captured in the source worksheet and electronic Case Report Form (eCRF). The Investigator will assess the baseline level of Local Application Site Reactions, recording the scores based on the Local Application Site Reactions Scale. During the inspection of EAWs, study physician (Principal Investigator (PI), or Sub-Investigator) will train the subject on proper application of the study drug using the properly labeled demonstration tube (contains vehicle of the study drug) and applicator. The subject will be trained to apply the study drug to the surface of the warts at a proper amount (not to exceed 0.5 g per day or 0.25 g per application), avoiding unaffected and wounded skin areas, and to let the gel dry completely before allowing the return of opposing skin surfaces to their normal positions. Mirrors are to be used in order to facilitate process of application. Subjects will be instructed to not use the study drug in the vagina or in the rectum, and remove medication from any areas that experience stinging or burning immediately upon application. Site staff will also visually show the subjects what the correct amount of drug to be used per application looks like. The subject will also be trained on Patient's Diary Card Completion and Contraception Methods. The subject will be given a study drug, mirror and a Patient's Diary Card to capture application details, and acknowledge any changes in skin reactions, other AEs and concomitant medications during the intervening time between the site visits. On the following day after the Baseline visit (Day 1) the subject will apply the study drug on EAWs following the recommendations given during training at the clinic site. The treatment phase will consist of four weekly treatment cycles at a maximum, during which the drug will be applied twice a day (in the morning and at the bedtime) for 3 consecutive days, then discontinuing for 4 consecutive days. Study drug will thus be applied only on Days 1, 2, 3, 8, 9, 10, 15, 16, 17, 22, 23 and 24.

	Study visits will occur on the seventh (7) day of each treatment cycle: on Day 7 (Week 1), Day 14 (Week 2), Day 21 (Week 3), and Day 28 (Week 4). Primary endpoint (total disappearance of all treated warts) will be evaluated during each of these visits. In case the primary endpoint is reached at any of the visits prior to the Day 28 visit, it will be considered as End of Study (EOS) visit – the Investigator will perform physical examination and repeat urine pregnancy test, and subject's participation will be considered complete. If total disappearance of warts is not achieved, a new treatment cycle will be initiated for a maximum of four cycles in total for the subject. During each study visit, the Investigator will collect vital signs, evaluate EAWs for absence or present, capturing the count of EAWs, record Local Application Site Reactions and adverse events (AEs), assess Patient's Diary Card completion and subject's compliance with the study drug application, review concomitant medication and confirm that there were no prohibited therapies applied from the last visit. In the event the primary endpoint (total disappearance of all warts within all treated areas) has been achieved prior to the Day 28 visit, this visit will be considered End of Study (EOS) visit. In case a subject discontinues prematurely, the Investigator will conduct an Early Termination (ET) visit, capturing the reason for discontinuation and performing assessments of EOS visit.
Number of Subjects and Sites	The planned overall sample size for this clinical trial is approximately 413 adult male and female subjects with external anogenital warts, who will be randomized at a 3:3:1 ratio (test:RLD:placebo) at about 16 clinical research centers in the United States, Russia and Ukraine. mITT and PP population size will be approximately 392 and 350 correspondingly.
Eligibility Criteria	Subjects who satisfy ALL of the following **inclusion** and have NONE of the following **exclusion** criteria may be enrolled in the study: INCLUSION CRITERIA 1. Willing and able to provide written informed consent prior to participating in this study. 2. Male or female subjects, aged 18-65 inclusive, with a clinical diagnosis of external anogenital warts (i.e., perianal warts and/or external genital warts), including two or more distinct external genital

	warts, and wart area that is equal or less than 10 cm^2. Histological confirmation should be obtained if there is any doubt of the diagnosis. 3. Females of childbearing potential may be enrolled if they practice a method of birth control with a reliability of at least 90% and agree to continue doing so throughout the treatment period. 4. In addition to birth control method with high reliability, sexually active study participants must use a barrier protection method of contraception such as male or female condom or abstinence throughout the treatment period in order to prevent cross- and reinfestation by Human Papilloma Virus (HPV). 5. Any female subject with childbearing potential has a negative urine pregnancy test on first day of dosing (study Day 1). 6. Negative HIV test within 4 weeks before the first day of dosing (study Day 1). EXCLUSION CRITERIA 1. Female subjects who are pregnant or lactating or planning to become pregnant during the study period. 2. Hypersensitivity or intolerance to Podofilox or any component of the formulation. 3. History of previous unsuccessful treatment with any formulation of Podofilox. 4. Wart area that is greater than 10 cm^2. 5. Patients with internal anogenital and mucous membrane warts, bowenoid papulosis, squamous cell carcinoma, active herpes lesion, or other skin abnormalities of treatment area, such as eczema, or skin that had not healed following surgery (cryosurgery, laser ablation or similar). 6. Primary or secondary immunodeficiency. 7. Known presence of diabetes type I or II. 8. Local irritation in any treatment area that would interfere with treatment. 9. Use within 4 weeks prior to baseline of any: 1) treatment for anogenital warts, 2) systemic corticosteroids, or 3) systemic immunosuppressive drug. 10. Any medical or surgical condition in the judgment of the Investigator that may interfere with the assessment of efficacy or safety, or pose a risk to the subject. 11. Patients known to abuse alcohol and/or drugs, or with a history of chronic alcohol or drug abuse that may result in protocol non-compliance.

	12. Received another investigational drug, device or biologic within 30 days prior to the start of Screening or has planned to participate in another clinical trial while enrolled in this study. 13. Subjects who in the opinion of the investigator, are unlikely to be able to follow the restrictions of the protocol and complete the study. 14. Employee (or employee's family member) of the research center or private practice, CRO or Sponsor, or subjects who have a conflict of interest. 15. Subjects living (e.g., siblings, spouses, relatives, roommates) in the same household cannot be enrolled in the study at the same time. 16. Previous enrollment in this study, current enrollment in this study at another participating site or current enrollment in another study (in parallel to this study) at another clinical research site.
Withdrawal and Early Discontinuation	Subjects whose condition worsens and require alternate or supplemental therapy for the treatment of external anogenital warts during the study should be discontinued, and the Early Termination visit must be performed.
Prohibited Concomitant Medication	Use of following therapies is prohibited during study participation: • Any other topical products applied to the treatment area(s). • Systemic corticosteroid or immunosuppressive drugs. • Antipruritics, including antihistamines, in the 24 hours prior to study visits.
Study Drug	Study drug includes Test, Reference and Placebo drug products. The Sponsor will supply study drug as matching 3.5 g of clear gel in aluminum tubes with an applicator tip, labeled for a blinded study. • Test Drug: Podofilox Topical Gel 0.5% (Hyloris Developments SA). • RLD: Condylox® Gel 0.5% (Allergan Pharmaceuticals). • Placebo: Vehicle of the test drug (Hyloris Developments SA). Storage temperature is 20-25°C (68-77°F).
Duration of Patient Study Participation	Up to 50 Days.
Study Endpoints	**PRIMARY**

	• The primary endpoint is the proportion of subjects in the per protocol (PP) population with "treatment success" defined as "total disappearance of all warts within all treated areas". **SECONDARY (Safety Endpoints)** • Local application site reactions scores (erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding) in each group during the study drug application period. • Other adverse events including serious adverse events throughout the study participation.
Statistical Analysis	**EFFICACY ANALYSIS** The difference in the proportion of subjects in the test and reference treatment groups who achieve "treatment success" defined as "total disappearance of all warts within all treated areas" at four days (± 5 days) after the last day of the last cycle of treatment will be evaluated using a two-sided, continuity-corrected 90% confidence interval. The therapeutic equivalence of the test and reference products will be established if the confidence bounds of the 90% confidence interval are contained within the limits of -0.20 to +0.20. The results in the per-protocol (PP) population will be considered definitive for therapeutic equivalence with those in the modified Intent-To-Treat (mITT) population considered supportive. Superiority will be assessed through continuity-corrected Z-tests comparing each active treatment to placebo. If both the test and RLD success proportions are statistically significantly greater than the placebo proportion ($p<0.05$, two-sided) then they will be considered to be superior to the placebo. The results in the mITT population will be considered definitive for superiority with those in the PP population considered supportive. Subjects discontinuing due to "treatment failure", defined as worsening of condition and requiring alternate or supplemental therapy for the treatment of external anogenital warts during the study, will be included in the PP population analysis as treatment failures, and provided with effective treatment. Subjects discontinued prematurely from the study for any other reason (i.e., noncompliance, or withdrawal of consent, etc.) will be excluded from the PP population, but included in the mITT population, using Last Observation Carried Forward (LOCF). **SAFETY ANALYSIS**

	Safety data analysis will include local application site reaction scores (erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding), reported adverse events, vital signs and concomitant medication assessments summarized by treatment group and time point of collection, when appropriate. Descriptive statistics (arithmetic mean, standard deviation (SD), coefficient of variation (CV), median, minimum, and maximum) will be calculated for quantitative safety data as well as for the difference from baseline, when appropriate. Adverse events will be coded using the most recent version of the Medical Dictionary of Regulatory Activities (MedDRA®) noted in the Statistical Analysis Plan. A subject AE listing by MedDRA® system organ class and by preferred term within system organ class, including verbatim term, dose level, severity, and relationship to treatment, will be provided. This listing will include all AEs and serious adverse events (SAEs). Adverse events will also be presented in summary tables. Concomitant medications will be listed by treatment and coded using the most recent version of the World Health Organization (WHO) Drug Dictionary.

1 TABLE OF CONTENTS

2 LIST OF ABBREVIATIONS

AE	Adverse Event
BE	Bioequivalence
CRF	Case Report Form
CRO	Contract Research Organization
CV	Coefficient of Variation
DD	Drug Dictionary
EAW	External Anogenital Warts
eCRF	Electronic Case Report Form
EOS	End of Study
ET	Early Termination
g	Gram
GCP	Good Clinical Practice
H	Hours
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
ICH	International Conference on Harmonization
IWRS	Interactive Web Response System
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary of Regulatory Activities
mITT	Modified Intent-To-Treat
PD	Protocol Deviation
PI	Principal Investigator
PP	Per-Protocol
PV	Protocol Violation
PVPD	Protocol Violation and Protocol Deviation
RLD	Referenced Listed Drug
SAE	Serious Adverse Event
SD	Standard Deviation

TEAE	Treatment Emergent Adverse Event
UPT	Urine Pregnancy Test
WHO	World Health Organization

3 INTRODUCTION

This document describes the statistical methods and data presentations to be used in the summary and analysis of data from Protocol 016-POD-001 version 2.0 dated 15Jan2018. Background information is provided for the overall study design and objectives. The reader is referred to the study protocol and electronic case report forms (eCRFs) for details of study conduct and data collection.

3.1 Study Overview

Clinical study of protocol 016-POD-001 is a multicenter, parallel group, randomized, double-blind, placebo-controlled, trial with clinical endpoint comparing Podofilox Topical Gel 0.5% to Condylox® Gel 0.5% and a matching placebo. The study will be conducted in adult male and female patients with external anogenital warts. The study also assesses comparative safety of Podofilox Topical Gel 0.5% and Condylox® Gel 0.5%.

Safety data analysis will include local application site reaction scores (erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding), reported adverse events, vital signs and concomitant medication assessments summarized by treatment group and time point of collection, when appropriate.

The primary objective is to compare the clinical efficacy among patients with anogenital warts when treated with Podofilox Topical Gel 0.5% versus Condylox® Gel 0.5% and placebo. The secondary objective is to demonstrate safety of Podofilox Topical Gel 0.5% compared to Condylox® Gel 0.5% and placebo assessed by the frequency and severity of adverse events, and application site reaction scores (erythema, dryness, burning/stinging, erosion, edema, pain, itching, and bleeding).

The planned overall sample size for this clinical trial is approximately 413 adult male and female patients with external anogenital warts, who will be randomized at a 3:3:1 ratio (test: RLD: placebo) at about 16 clinical research centers in the United States, Russia and Ukraine. The mITT and PP population sizes will be approximately 392 and 350, correspondingly. A subject is considered enrolled after he/she has provided a signed informed consent and begins the screening process. A subject is considered randomized upon receiving his/her randomized treatment assignment.

The entire study will consist of a maximum of 6 visits:

1. Visit l (Day -14 up to -1): Screening Evaluations at the Study Site performed.
2. Visit 2 (Day 0): Study Drug Dispensation.
3. Visit 3-5 (Day 7 ±1 [Week 1], Day 14 ±1 [Week 2], and Day 21 ±1 [Week 3]: Follow-up of the Study Drugs.
4. Visit 6 (Day 28 ± 5 [Week 4]): End of Study Visit / Early Termination Visit at the Study Site including Safety and Efficacy Evaluation.

3.2 Schedule of Events

Table 2.2.1 Study visits and assessments.

Study Visit	**Screening Visit 1**	**Baseline Visit 2**	**Treatment Period**			
			Visit 3	**Visit 4**	**Visit 5**	**EOS/ET Visit 6**
Visit Day	**Day -14 to -1**	**Day 0**	**Day 7 (±1)**	**Day 14 (±1)**	**Day 21 (±1)**	**Day 28 (±5)**
Informed Consent	X					
Subject Demographics	X					
Medical History	X					
Concomitant and Prohibited Therapies Review	X	X	X	X	X	X
Vital Signs	X	X	X	X	X	X
Physical Examination	X	X				X
Visual Inspection of EAWs[1]	X	X	X	X	X	X
Serology test for HIV[2]	X					
Test for Hepatitis B, C	X					
Test for Syphilis[3]	X					
Urine Pregnancy Test	X	X				X
Eligibility Criteria Check	X	X				
Randomization		X				
Training on Study Drug Application		X				
Training on Subject Diary Card Completion and Contraception Methods		X				
Study Drug Dispensation		X	X	X	X	
Assessment of Local Application Site Reactions		X	X	X	X	X
Adverse Events Assessment	X	X	X	X	X	X
Study Drug Return and Accountability			X	X	X	X
Subject Diary Card Return and Review			X	X	X	X

Subject Diary Card Dispensation		X	X	X	X	
Histological Confirmation of Diagnosis[4]	X					

1 If total disappearance of all warts is achieved within all treated areas at visits 2, 3, 4, or 5, respective visit will be considered an End of Study (EOS) visit. In the case where reduction of warts is absent or incomplete, a new treatment cycle will be initiated for a maximum of four cycles in total for the subject.
2 Test may not be repeated if the subject has negative HIV test results within 4 weeks before baseline. Copy of the test result needs to be filed with the study records.
3 If required by applicable local regulations.
4 Histological confirmation will be obtained if there is any doubt of the diagnosis.

4 STUDY OBJECTIVE AND ENDPOINTS

4.1 Study Objectives

The primary objective of this study is:

- To compare the clinical efficacy of anogenital warts treatment of patients treated with Podofilox Topical Gel 0.5% and patients treated with Condylox® Gel 0.5% to patients treated with placebo (superiority comparisons), and to compare efficacy of Podofilox Topical Gel 0.5% with that of Condylox® Gel 0.5% (bioequivalence comparison).

The secondary objective of this study is:

- To demonstrate safety of Podofilox Topical Gel 0.5% compared to Condylox® Gel 0.5% or placebo assessed by the frequency and severity of adverse events and application site reaction scores (erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding).

4.2 Study Endpoints

4.2.1 Primary Endpoint

The primary endpoint is the proportion of subjects who achieve complete cure within the follow up period. The proportion of subjects with complete cure for Podofilox Topical Gel 0.5% will be compared with that of Condylox® Gel 0.5% using an equivalence analysis. For superiority analysis, each active treatment will be compared with Placebo.

4.2.2 Secondary (Safety) Endpoints

Adverse events will be summarized by frequency, by severity and will be tabulated by body system/organ class.

Local application site reactions scores (erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding) in each group during the study drug application period will be summarized by type of reaction and by intensity score.

5 STUDY DESIGN

5.1 Summary of Study Design

This is a multicenter, parallel group, randomized, double-blind, placebo-controlled trial with clinical endpoint comparing Podofilox Topical Gel 0.5% to Condylox® Gel 0.5% and a matching placebo. The study will be conducted among adult male and female patients with external anogenital warts.

On the following day after the Baseline visit (Day 1) the subject will apply the study drug on EAWs following the recommendations given during training at the clinic site. The treatment phase will consist of four weekly treatment cycles at a maximum, during which the drug will be applied twice a day (in the morning and at the bedtime) for 3 consecutive days, then discontinuing for 4 consecutive days. Study drug will thus be applied only on Days 1, 2, 3, 8, 9, 10, 15, 16, 17, 22, 23 and 24.

Study visits will occur on the seventh (7) day of each treatment cycle: on Day 7 (Week 1), Day 14 (Week 2), Day 21 (Week 3), and Day 28 (Week 4). Primary endpoint (total disappearance of all treated warts) will be evaluated during each of these visits. In case the primary endpoint is reached at any of the visits prior to the Day 28 visit, it will be considered the End of Study (EOS) visit – the Investigator will perform physical examination and repeat urine pregnancy test, and subject's participation will be considered complete. If total disappearance of warts is not achieved, a new treatment cycle will be initiated for a maximum of four cycles in total for the subject.

During each study visit, the Investigator will collect vital signs, evaluate EAWs for absence or presence, capturing the count of EAWs, record Local Application Site Reactions and adverse events (AEs), assess Patient's Diary Card completion and subject's compliance with the study drug application, review concomitant medication and confirm that there were no prohibited therapies applied since the last visit.

In the event the primary endpoint (total disappearance of all warts within all treated areas) has been achieved prior to the Day 28 visit, this visit will be considered End of Study (EOS) visit. In case a subject discontinues prematurely, the Investigator will conduct an Early Termination (ET) visit, capturing the reason for discontinuation and performing assessments of EOS visit.

5.2 Definition of Study Drugs

- Arm 1 (Test product): Subjects in this arm will receive test formulation of Podofilox Topical Gel 0.5% (Hyloris Developments SA).
- Arm 2 (Reference Listed Drug [RLD]): Subjects in this arm will receive RLD Condylox® Gel 0.5% (Allergan Pharmaceuticals).
- Arm 3 (Placebo): Subjects in this arm will receive a vehicle that matches the test product, except for the inclusion of the active ingredient (Hyloris Developments SA).

5.3 Sample Size Considerations

Approximately 413 subjects (177 in each active arm and 59 in placebo group) will be enrolled to obtain at least 392 mITT subjects (168 in each active treatment arm and 56 in placebo group) and to complete 350 PP subjects (150 in each active arm and 50 in placebo group). This sample size was calculated assuming that both active treatments would have equivalent success rates of 40% and placebo would have a success rate of 15%. This sample size will provide an overall probability of at least 0.9 of having the 90% Wald confidence interval, with Yates' continuity correction, of the difference between the test and reference success rates contained within the interval -0.20 to +0.20 in the PP population, in addition to establishing that the success rates for both active treatments are statistically greater than that of the placebo arm (two-sided continuity-corrected Z-tests, $\alpha = 0.05$) in the mITT population.

mITT (T:R:Placebo)	Prob. of Superiority*	PP (T:R:Placebo)	Prob. of BE**	Prob. of study success
168:168:56 (392)	0.98	150:150:50 (350)	0.92	0.90

*) Superiority analysis based on two-sided, $\alpha = 0.05$, continuity-corrected Z-tests.
**) Bioequivalence (BE) analysis based on 90% confidence interval (CI) of the difference between Test and reference for proportions of subjects with treatment success, calculated by the Wald's method with Yates' continuity correction.

6 PLANNED ANALYSIS

The analysis planned in the SAP will be performed after the database lock. The Efficacy Analyses will be conducted as follow:

- Superiority to placebo: "treatment success" rate occurring at four days (± 5 days) after the last day of the last cycle of treatment using the mITT study population (PP population considered as supportive) and LOCF.
- BE: "treatment success" rate between the test product and RLD treatment groups occurring at four days (± 5 days) after the last day of the last cycle of treatment must be within [-0.20, +0.20] for the dichotomous primary endpoint, using the PP study population (mITT population considered as supportive).

Due to GCP non-compliance of site 201, Sponsor decided to generate two sets of Efficacy Analysis:

- a Definitive Efficacy Analysis Set excluding site 201 and
- a Supplemental Efficacy Analysis Set including site 201.

Please see corresponding Note to File (NTF) dated 27 Feb 2019 in study documentation detailing the specifics of the GCP non-compliance of site 201.

7 GENERAL CONSIDERATION FOR DATA ANALYSIS AND HANDLING

7.1 General Summary Table and Individual Subject Data Listing

Summary tables and listings (e.g., post text tables and individual subject data listings are prepared according to ICH Guideline E3) include a "footer" providing explanatory notes that indicate as a minimum:

1. SAS program name.

2. Programmer initials.

3. Date of data extraction.

4. Date of output generation.

Post text tables also include reference(s) to the subject data listing(s) that supports the summary data. The data extraction date links the output to the archived database that is locked to ensure the replication of the results.

Post text tables will be organized with respect to treatment group and a column will be included to summarize all treated subjects. The order of drug presentation will be investigational drug

first followed by the reference drug, then the placebo, then the vehicle control. A total column will appear as the last column. The summary tables clearly indicate the number of subjects to which the data apply and unknown or not performed are distinguished from missing data.

Summary tables for medications and medical conditions are coded according the WHO Drug Dictionary. Adverse event preferred terms and body/organ systems are coded using the MedDRA dictionary. The MedDRA dictionary can be used, as well, in the coding of signs and symptoms, medical history, physical examination abnormalities, and clinical diagnoses.

Supportive individual subject data listings, as a minimum, are sorted and presented by treatment group and subject ID. Listings also include visit number, visit date, and days relative to the initiation of double-blind treatment.

7.2 General Summary Table and Individual Subject Data Listing Considerations

The default convention is to number tables and listings using a decimal system to reflect main levels of unique tables and listings and sub-levels of replicate tables and listings with two digits per level (e.g., Table XX.YY.ZZ. …).

1. The first level number should be consistent with the corresponding CSR appendix in which the tables or listings will appear. For example, the post text tables usually occupy Appendix 14 and the individual subject data listings are put in Appendix 16. All post text tables should have a main number level 14 and listings 16. The subject accounting and disposition table is usually first in the first section of the report and should be numbered Table 14.1. The supportive subject data listing would be Listing 16.1. A subset by sex 2. Subject accounting and final disposition should appear as the second level number (Table 14.1 series). Baseline and demographic profile occupy the next sub-level (Table 14.1.2 series). Efficacy should come next (Table 14.3 series) followed by safety (Table 14.4 series). Reasons for subjects' being excluded from efficacy and protocol violation summary tables should appear as the last level (Table 14.5 series). Similar conventions should be applied to the subject data listings.

3. The title should be complete, accurate, and concise. The last line of the title should provide the analysis group being summarized (e.g., Intent-to-Treat Subjects or Per-Protocol Efficacy Subjects). If possible, the units of measurement for data contained in the table can appear in parentheses to conserve space in the body of the table. For example, the summary of vital signs title could read "Summary of Sitting and Standing Blood Pressure (mmHg) and Heart Rate (bpm)." Whether in the title or body of a table or listing, units must always be specified for all appropriate data.

4. If possible, variables being summarized and statistics reported should appear in the left most column of a table. The next columns for treatment groups should report the data from left to right for the investigational drug, comparative agents, placebo, and all treated subjects, respectively.

In general, the listings should be sorted and presented by treatment assignment, investigational site, and subject number. Treatment assignment and site can appear in the banner of the listing.

From left to right, the subject number, visit number, visit date, and relative day should appear.

All tables and listings must have explanatory notes that give, as a minimum, data extraction date, output generation date, complete program name and path where it is stored, CRF pages from which the data were obtained, and supportive listings or tables supported, as appropriate. The definition of all derived variables and decodes for coded data must appear in the notes. Due to space limitations, tables and listings may require a page of notes as a one-time preface to the output.

7.3 Data Management

Biorasi will create SDTM data sets and ADaM analysis data sets using (SAS®) software. Data analyses and summary tables wil be generated using SAS version 9.4 or above.

7.4 Data Presentation Conventions

Continuous variables (e.g. age) are summarized using descriptive statistics (number of subjects with available data, mean, standard deviation (SD), coefficient of variation (CV), median, minimum and maximum). Categorical variables (e.g. race) are summarized using counts and percentages. Percentages are calculated using the total subjects per treatment group.

The following conventions are applied to all data presentations and summaries.

For continuous variables, all mean, median, and coefficient of variation values are formatted to one more decimal place than the measured value. Standard deviation values are formatted to two more decimal places than the measured value. Minimum and maximum values are presented with the same number of decimal places as the measured value.

For categorical variables, the number and percentage of responses are presented in the form XX (XX.X %) where the percentage is in the parentheses.

Date variables are formatted as DDMMMYYYY for presentation. Time is formatted in military time as HH:MM for presentation.

Wherever possible, data will be decimal aligned.

P-values, if applicable, will be presented to 4 decimal places. If the p-value is less than 0.0001 then it will be presented as <0.0001.

Unless otherwise stated, any statistical tests performed will be 2-sided at the 5% significance level.

The table and listing shells and table of contents as part of this SAP provide the expected layout and titles of the tables, listings and figures. Any changes to format, layout, titles, numbering, or any other minor deviation will not necessitate a revision to the SAP nor will it be considered a deviation from planned analyses. Only true differences in the analysis methods or data handling will necessitate such documentation. The appropriate listings supporting the tables will be included and are not specified in the individual sections throughout the document.

7.5 Analysis Populations

7.5.1 Definitive and Supplemetal

Due to GCP non-compliance at site 201, it was decided to exclude data from that site from the Definitive Efficacy Analysis. A Supplemental Efficay Analysis will be presented including the data from site 201.

The mITT and PP populations defined below will not inlcude site 201. However, there will be a supplemental mITT population (mITTs) and a supplemental PP population (PPs), both of which will include site 201.

7.5.2 Screen Failures

Investigators must account for all subjects who sign informed consent and will maintain an Enrollment Log capturing subjects screened and indicating who was enrolled or excluded and the reason why. If the subject is found not to be eligible prior to enrollment, the reason(s) for ineligibility must be documented by the Investigator.

These subjects will neither contribute to data presentations nor be included in formal statistical analyses. The number of screen failures will be included in the data disposition table. Subject Numbers assigned to subjects who fail Screening will not be re-used.

7.5.3 Protocol Deviations

A deviation is defined as an "unintentional and/or accidental change to, or non-adherence to, the IRB/EC approved trial protocol (Biorasi SOP CL-035)." Protocol deviations will be documented for randomized subjects as well as screen failures in this trial.

- Minor Protocol Deviation - defined as any change, divergence, or departure from the IRB/IEC Approved Trial Protocol, criteria or procedures that does not affect the Subject's safety, rights, or welfare and/or the integrity of the Trial and its resultant data.
- Major Protocol Deviation - defined as any change, divergence, or departure from the IRB/IEC Approved Trial Protocol, criteria or procedures that may affect the Subject's safety, rights, or welfare and/or integrity of the Trial and its resultant data.

Prior to database lock, there will be a joint classification meeting held between the Sponsor, Data Management, Biostatistics, and Clinical in order to classify protocol deviations and patient classification. This information will be added to the PVPD log and utilized for setting the population flags for analysis.

Any subject adjudication to the PP population and mITT population should be supported by Data Management according to protocol and take into consideration the PVPD log provided by Principal Investigators. Subjects who experience a Major Deviation will be excluded from the PP population.

7.5.4 Safety Population

The safety population includes all randomized subjects who received and used study product.

7.5.5 Modified Intent-to-Treat (mITT) Population

The modified intent-to-treat population (mITT) includes all subjects who are randomized, applied at least one dose of assigned product, and returned for at least one post-baseline evaluation visit. Subjects discontinued prematurely from the study for any reason other than Treatment Failure, (i.e., noncompliance, withdrawal of consent, etc.) will be included in the mITT population, using Last Observation Carried Forward (LOCF).

7.5.6 Per-Protocol (PP) Population

All randomized subjects who met all inclusion/exclusion criteria, had no protocol violations that would affect the treatment evaluation , were compliant with applying study product, and returned to the study site for the primary endpoint evaluation at 4 days (± 5 days) after the last day of the last cycle of treatment. Compliant subjects are defined as those who used

at least 75% and no more than 125% of study drug doses until treatment success or four cycles of treatment.

Subjects discontinuing due to “treatment failure” will be included in the PP population analysis as Treatment Failures and will have alternative treatment recommended by the Investigator.

The results in the PP population will be considered definitive for therapeutic equivalence and those in the mITT population considered supportive. The results in the mITT population will be considered definitive for superiority analysis of each active treatment to placebo and those in the PP population will be considered supportive. Safety analyses will be performed using the Safety population.

7.6 Baseline Definition

The Baseline visit (Day 0) will take place once the results of Screening assessments are obtained, suggesting that the subject is eligible for entering the study. During this visit, those subjects who qualify for entering the study will be randomized to one of the study arms in a ratio of 3:3:1.

Derived and Transformed Data.

7.6.1 Baseline Age

Subject’s age in years will be calculated based on the date of the Baseline Visit date using the following formula:

Age (years) = FLOOR((INTCK('month', Date of Birth, Date of Baseline Visit) - (DAY(Date of Baseline Visit) < MIN(DAY(Date of Birth), DAY (INTNX ('month', Date of Baseline Visit, 1) -))) /12)17 where:

•FLOOR( ) is a SAS function that returns the largest integer that is less than or equal to the argument.

•INTCK() is a SAS function that returns the number of interval boundaries of a given kind that lie between two dates, times, or datetime values.

•DAY() is a SAS function that returns the day of the month from a SAS date value.

•INTNX() is a SAS function that increments a date, time, or datetime value by a given time interval, and returns a date, time, or datetime value.

7.6.2 Study Day

•Day 1 is defined as the day after the baseline when the subject will receive the first dose.

•For a visit date on or after the date of the first dose: Study Day = (date of interest – date of first dose) + 1

•For a visit date before the date of the first dose: Study Day = (date of interest – date of first dose)

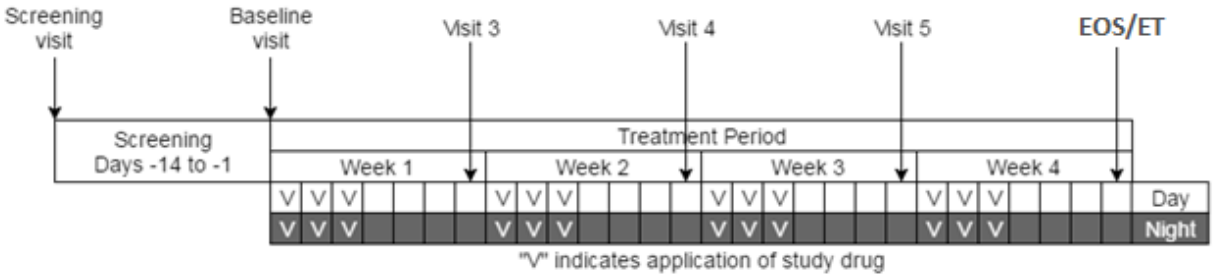
7.6.3 Visit Windows

Visit windows for study 016-POD-001 are as follows:

Study Phase	Visit	Visit Name	Day
Screening	Visit 1	Screening	-14 to -1 days
Baseline	Visit 2	Baseline	Day 0
Follow-up	Visit 3	1st Follow-up Visit (FU 1)	Day 7 (±1)
	Visit 4	2nd Follow-up Visit (FU 2)	Day 14 (±1)
	Visit 5	3rd Follow-up Visit (FU 2)	Day 21 (±1)
	Visit 6	End of Study	Day 28 (±5)
End of Study[1]	EOS	End of Study	Day1 – Day 28 (+5)
	ET	Early Termination Visit	From Screening to Day 28
	US	Unscheduled Visit	From Screening to Day 28 (+5)

1. If total disappearance of all warts is achieved within all treated areas at visits 2, 3, 4, or 5, respective visit will be considered an End of Study (EOS) visit.

The flowchart for the study is as follows:



7.6.4 Multiple Assessments

No multiple assessments for same visit are scheduled.

7.6.5 Handling of Missing Data

No data will be imputed for the Safety population. Missing Data for Efficacy analyses will not be imputed for the PP population. However, if data is missing due to other than early termination because of treatment failure, it will be imputed as LOCF for the mITT population.

7.6.6 Missing Start and Stop Dates for Prior and Concomitant Medication

Start date:

1. If start date is completely missing, start date will not be imputed.
2. If (year is present and month and day are missing) or (year and day are present and month is missing), set month and day to January 1.
3. If year and month are present and day is missing, set day to the 1st day of month.

Stop date:

1. If end date is completely missing, end date will not be imputed.
2. If (year is present and month and day are missing) or (year and day are present and month is missing), set month and day to December 31st.
3. If year and month are present and day is missing, set day to the last day of month.

7.6.7 Missing Start and Stop Dates for Adverse Events

Start date:

1. If start date is completely missing, start date is set to date of first dose.

2. If (year is present and month and day are missing) or (year and day are present and month is missing):
   a. If year = year of first dose, then set month and day to month and day of first dose.
   b. If year < year of first dose, then set month and day to December 31st.
   c. If year > year of first dose, then set month and day to January 1st.
3. If month and year are present and day is missing:
   a. If year = year of first dose and
      i. If month = month of first dose, then set day to day of first dose date.
      ii. If month < month of first dose, then set day to last day of month.
      iii. If month > month of first dose, then set day to 1st day of month.
   b. If year < year of first dose, then set day to last day of month.
   c. If year > year of first dose, then set day to 1st day of month.

Stop date:

If the outcome of the AE was ongoing or unknown, then the rules outlined below will not be applied.

1. If stop date is completely missing, stop date is set to date of study discontinuation.
2. If (year is present and month and day are missing) or (year and day are present and month is missing):
   a. If year = year of study discontinuation, then set month and day to month and day of study discontinuation.
   b. If year < year of study discontinuation, then set month and day to December 31st.
   c. If year > year of study discontinuation, then set month and day to December 31st.
3. If month and year are present and day is missing:
   a. If year = year of study discontinuation and
      i. If month = month of study discontinuation, then set day to day of study discontinuation date.
      ii. If month < month of study discontinuation, then set day to last day of month.
      iii. If month > month of study discontinuation, then set day to last day of month.
   b. If year < year of study discontinuation, then set day to last day of month.
   c. If year > year of study discontinuation, then set day to last day of month.

8 STUDY POPULATION

8.1 Subject Disposition

The subject disposition summary will include the number screened, the number of screen failures, the number enrolled, the number in each patient population for analysis, the number who completed the study, the number who discontinued the study and reason for discontinuation from the study. Disposition data will be summarized by treatment and overall.

A by-subject data listing of study completion information including the reason for study discontinuation will be presented. A by-subject listing of inclusion/exclusion criteria not met will also be presented.

8.2 Protocol Deviations

A summary of all protocol deviations by type will be generated. Protocol deviation data will be summarized by treatment and overall. A by-subject data listing of protocol deviations will also be presented.

Any subject adjudication to the PP population and mITT population should be supported by Data Management according to protocol and take into consideration the PVPD log provided by Principal Investigators.

8.3 Demographic and Baseline Characteristics

Descriptive statistics will be generated by treatment group for selected continuous variables. The number and percentage of subjects in each class of categorical demographic and baseline variables (e.g., gender, ethnicity, and race) will be tabulated by treatment group. Individual subject demographic and baseline characteristic data will be listed.

8.4 Medical History

A by subject data listing of medical history will be presented.

9 EFFICACY ANALYSES

9.1 Primary Efficacy Endpoint

The primary endpoint is the proportion of subjects with "treatment success" defined as "total disappearance of all warts within all treated areas." The primary endpoint will be evaluated at 4 days (± 5 days) after the last day of the last cycle of treatment. The results of analysis for bioequivalence in the PP population will be considered definitive and those in the mITT population as supportive.

Due to GCP non-compliance at site 201, it was decided to exclude data from that site from the Definitive Efficacy Analysis. A Supplemental Primary Efficay Analysis will be presented including the data from site 201.

9.1.1 Bioequivalence Analysis

The efficacy bioequivalence of the test and reference treatments will be based on the proportions of subjects with clinical success. The hypothesis tested for clinical equivalence between test and reference will be:

Bioequivalence between the test and the reference product will be established if the 90% confidence interval for the difference in success proportions is contained within the equivalence limits [-0.20, +0.20].

In this case, the compound hypothesis to be tested is:
$H_0: P_T - P_R < -0.2 \ or \ P_T - P_R > 0.2$ (meaning test product is not bioequivalent to the reference);

versus

$H_a: -0.2 \leq P_T - P_R \leq 0.2$ (supporting bioequivalence);

where P_T = success proportion of test treatment, P_R = success proportion of reference treatment.

Let

1. n_T = sample size of test treatment group
2. cn_T = number of subjects with success in test treatment group
3. n_R = sample size of reference treatment group
4. cn_R = number of subjects with success in reference treatment group

$\hat{P}_T = {}^{cn_T}/_{n_T}$, $\hat{P}_R = {}^{cn_R}/_{n_R}$,

and $se = \left(\hat{P}_R(1-\widehat{P_R})/n_R + \hat{P}_T(1-\widehat{P_T})/n_T\right)^{1/2}$

The 90% confidence interval will be estimated using Wald's method with Yates' continuity correction, as:

$$L = (\hat{p}_T - \hat{p}_R) - 1.645\ se - (1/n_T + 1/n_R)/2$$

$$U = (\hat{p}_T - \hat{p}_R) + 1.645\ se + (1/n_T + 1/n_R)/2$$

H_0 will be rejected if L ≥ -0.20 and U ≤ 0.20 resulting in accepting H_A and concluding bioequivalence of the two products.

Tthe following SAS code will be used to test bioequivalence:

```
proc freq data = dataset;
tables treat*outcome/ riskdiff (Equiv correct);
run;
```

9.1.2 Superiority Analysis

Superiority will be assessed through continuity-corrected Z-tests comparing each active treatment to placebo. If both the test and RLD success proportions are statistically significantly greater than the placebo proportion ($p<0.05$) then they will be considered superior to the placebo. The results in the mITT population will be considered definitive and those in the PP population will be considered supportive.

For each treatment (Test and RLD) the Hypothesis to be tested is:

$H_0: p_t - p_p \leq 0$

$H_a: p_t - p_p > 0$

Where p_t = Proportion of cure for Treatment, and p_p is proportion of cure for Placebo.

The rest of the formulation is the similar to the one for Equivalence assessment, using 95% Confidence Interval. For testing the superiority, the following SAS code will be used:

```
proc freq data = dataset;
```

```
tables treat*outcome/ riskdiff (Equal correct);
run;
```

10 SAFETY ANALYSES

10.1 Safety Endpoints

The reporting of safety data is descriptive, and it will include all subjects who receive at least one dose of investigational product. The variables for safety endpoints are AEs, Local Application Site Reactions and vital signs measurements. Safety data will be summarized by treatment group and time point of collection, when appropriate.

Concomitant medications will be coded using the World Health Organization Drug Dictionary (WHO-DD). These data will be summarized by treatment group. Previous and concomitant medications will be presented in a data listing.

10.1.1 Adverse Events

Adverse events will be coded using the most recent version of the Medical Dictionary for Regulatory Activities (MedDRA) and will be summarized based on frequency and severity of AEs for all treated subjects. Data will be summarized using preferred term and system organ classifications. Summary will show number and percentage of subjects who experience each AE.

If a subject experiences multiple events that map to a single preferred term, the greatest severity and strongest Investigator assessment of relation to study drug will be assigned to the preferred term for the appropriate summaries. Should an event have a missing severity or relationship, it will be classified as having the highest severity and/or strongest relationship to study drug.

Summaries of treatment-emergent AEs will include any AEs reported beginning with the first dose of study drug on Day 1. The occurrence of treatment-emergent adverse events will be summarized by treatment group using preferred terms, system organ classifications, and severity. Separate summaries of treatment-emergent serious adverse events, treatment-emergent adverse events related to study drug, and events leading to the discontinuation of study drug will be generated. All adverse events reported will be listed for individual subjects showing both verbatim and preferred terms.

10.1.2 Local Application Site Reactions

Local Application Site Reactions will be recorded at each study visit and will be summarized by the type of reaction (erythema, dryness, burning/stinging, erosion, edema, pain, itching and bleeding) and intensity score: 0=absent, 1=mild (slight, barely perceptible), 2=moderate (distinct presence), 3=severe (marked, intense The number and percentage of subjects affected will also be presented.

10.1.3 Vital Signs

Vital Signs will be examined at several visits as per schedule on Section 3.2 above and will be summarized by visit and by treatment group.

11 REFERNCES

1 Protocol Number 016-POD-001. Version 1.0 “A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of Hyloris Development’s Podofilox Topical Gel 0.5% compared to Allergan’s Condylox® Gel 0.5%, and Both Active Treatments to a Vehicle Control in male and female patients with external anogenital warts”.

2 Wang, Wei. (1988, October 28). Calculating Age in One Line of Code. Paper presented at annual meeting of Northeast SAS Users Group, New York, New York. Paper retrieved from http://www.lexjansen.com/nesug/nesug01/cc/cc4022.pdf.

3 Kim, Yeonhee and Won, Seunghyun. (2013, May 15). Adjusted Proportion Difference and Confidence Interval in Stratified Randomized Trials. Paper presented at annual meeting of Pharma SAS Users Group, Chicago, Illinois. Paper retrieved from http://www.pharmasug.org/proceedings/2013/SP/PharmaSUG-2013-SP04.pdf.

4 Oracle. (2016, February 22). Oracle Health Sciences Empirica Study - Data sheet | Oracle [PDF]. Redwood City, CA: Oracle. http://www.oracle.com/us/industries/lifesciences/empirica-study-on-demand-ds-396095.pdf.

5 Oracle. (2016, March 22). Clinical Significance Criteria. Retrieved January 26, 2018, form https://docs.oracle.com/health-sciences/empirica-study-80/WEWUG/Clinical_Significance_Criteria.htm.

12 APPENDIX

12.1 APPENDIX A. Tables and Listings

12.1.1 List of Tables

Display Number	Title	Population	Unique/Repeat
Study Population			
Table 14.1.1.1.1	Subject Disposition	All Subjects	Unique
Table 14.1.1.1.2.1	Subject Enrollment and Disposition	All Subjects	Unique
Table 14.1.1.1.2.2	Subject Enrollment and Disposition, Supplemental (including site 201)	All Subjects	Repeat
Table 14.1.1.1.3	Subject Disposition by Site and Treatment	All Subjects	Unique
Table 14.1.1.2	Randomized Subjects Not Included in Safety, PP, and mITT Populations by Treatment	All Subjects	Unique
Table 14.1.2.1	Summary of Protocol Deviations by Classification and Category	Safety Population	Unique
Table 14.1.2.2	Summary of Protocol Deviations by Classification and Category Supplemental (including site 201)	Safety Population	Repeat
Table 14.1.3.1.1	Summary of Demographic	mITT	Unique
Table 14.1.3.1.2	Summary of Demographic	PP	Repeat
Table 14.1.3.1.3	Summary of Demographic	Safety	Repeat
Efficacy Tables			
Table 14.2.1.1.1	Summary of Treatment Success by Visit	PP	Unique
Table 14.2.1.1.2	Summary of Treatment Success by Visit, Supplemental (including site 201)	PPs	Repeat
Table 14.2.1.2.1	Summary of Treatment Success by Visit	mITT	Repeat
Table 14.2.1.2.2	Summary of Treatment Success by Visit, Supplemental (including site 201)	mITTs	Repeat
Table 14.2.2.1.1	Treatment Success, Bioequivalence Test between Test Product and Reference	PP/mITT	Unique

Display Number	Title	Population	Unique/Repeat
Table 14.2.2.1.2	Treatment Success, Bioequivalence Test between Test Product and Reference, Supplemental (including site 201)	PPs/mITTs	Repeat
Table 14.2.3.1.1	Treatment Success, Superiority Test from Placebo	mITT/PP	Unique
Table 14.2.3.1.2	Treatment Success, Superiority Test from Placebo, Supplemental (including site 201)	mITTs/PPs	Repeat
Table 14.2.4.1.1	Number of Genital Warts by Visit	PP	Unique
Table 14.2.4.1.2	Number of Genital Warts by Visit, Supplemental (including site 201)	PPs	Repeat
Table 14.2.4.2.1	Number of Genital Warts by Visit	mITT	Repeat
Table 14.2.4.2.2	Number of Genital Warts by Visit, Supplemental (including site 201)	mITTs	Repeat
Table 14.2.5.1.1	Number of Perianal Warts by Visit	PP	Unique
Table 14.2.5.1.2	Number of Perianal Warts by Visit, Supplemental (including site 201)	PPs	Repeat
Table 14.2.5.2.1	Number of Perianal Warts by Visit	mITT	Repeat
Table 14.2.5.2.2	Number of Perianal Warts by Visit, Supplemental (including site 201)	mITTs	Repeat
Table 14.2.6.1.1	Number of Genital and Perianal Warts by Visit	PP	Unique
Table 14.2.6.1.2	Number of Genital and Perianal Warts by Visit, Supplemental (including site 201)	PPs	Repeat
Table 14.2.6.2.1	Number of Genital and Perianal Warts by Visit	mITT	Repeat
Table 14.2.6.2.2	Number of Genital and Perianal Warts by Visit, Supplemental (including site 201)	mITTs	Repeat
Table 14.2.7.1.1	Warts Area (cm^2) by Visit	PP	Unique
Table 14.2.7.1.2	Warts Area (cm^2) by Visit, Supplemental (including site 201)	PPs	Repeat
Table 14.2.7.2.1	Warts Area (cm^2) by Visit	mITT	Repeat
Table 14.2.7.2.2	Warts Area (cm^2) by Visit, Supplemental (including site 201)	mITTs	Repeat
Safety			
Table 14.3.1.1	Summary of Vital Sign	Safety	Unique

Display Number	Title	Population	Unique/Repeat
Table 14.3.1.2	Vital Signs Changes from Baseline	Safety	Unique
Table 14.3.2	Summary of Physical Examination	Safety	Unique
Table 14.3.3	Summary of Study Drug Exposure, Dose in grams by Week	Safety	Unique
Table 14.3.4.1	Summary of Study Drug Exposure, Number of Applications by Week	Safety	Unique
Table 14.3.4.2	Summary of Study Drug Exposure, Duration of Exposure in Hours by Week	Safety	Unique
Table 14.3.5	Summary of Treatment Compliance (%) by Week	Safety	Unique
Table 14.3.6	Summary of Concomitant Medications by Preferred Term	Safety	Repeat
Table 14.3.7	Summary of Site Reaction by Intensity and Visit	Safety	Unique
Table 14.3.8	Overall Summary of Adverse Events	Safety	Unique
Table 14.3.8.1.1	Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term	Safety	Unique
Table 14.3.8.1.2	Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Severity	Safety	Unique
Table 14.3.8.1.3	Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Causality	Safety	Repeat
Table 14.3.8.2	Summary of Treatment Emergent Serious Adverse Events (TESAEs) by System Organ Class and Preferred Term	Safety	Unique

Table 14.1.1.1.1
Subject Disposition, All Subjects

Population	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
All Subjects	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Safety Population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
mITT Population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PP Population	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.1.1.1 Snapshot Data: DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.1.1.1.2.1
Subject Enrollment and Disposition, All Subjects

Disposition	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
Screened				xx (xx.x)
Randomized	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treated	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Study	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Day 0 (Baseline)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Day 7 (Visit 3)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Day 14 (Visit 4)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Day 21 (Visit 5)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed Day 28 (Visit 6)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Screen Failure				xx (xx.x)
Withdrawal of consent by subject	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal of subject by Investigator's Decision	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Pregnancy	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Occurrence of an Adverse Event (AE) or Serious Adverse Event (SAE)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Significant non-compliance with study procedures	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treatment failure	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Disposition	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
Subject's medication code unblinded	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subject no longer meets the entry criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost of follow-up	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator discretion	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.1.1.1 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat as Supplemental Analysis including site 201

Table 14.1.1.1.3
Subject Disposition by Site and Treatment, All Subjects

Site	Disposition	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
101	Screened				xx (xx.x)
	Screen failure				xx (xx.x)
	Randomized	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Treated	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Completed	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Discontinued	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Repeat for each site					

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset>
Program Name: <Pgm name>
Listing: 16.1.1.1
Date: YYYY-MM-DD Time: HH:MM:SS
Snapshot Data DD-MMM-YYYY
Programmer: <Programmer Initials>

Table 14.1.1.2
Randomized Subjects Not Included in Safety, PP, and mITT Populations by Treatment, All Subjects

	Statistic	Test Product	Reference	Placebo	All Subjects
Randomized	N	xx	xx	xx	xx
Total Safety Population	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total exclusion from Safety population	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for exclusion from Safety	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No record of first dose	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total mITT Population	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total exclusion from mITT population	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for exclusion from mITT	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No record of first dose	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
No post-treatment data	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[add additional items]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total PP Population	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Total exclusion from PP population	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for exclusion from PP	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Enrolled in error	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Non-compliant (dosing)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Outside visit window	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Randomized in error	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Restricted medication	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[add additional items]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.1.1.2 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.1.2.2
Summary of Protocol Deviations by Classification and Category,
Safety Population

Classification/Category	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
Number of patients with:				
At least one Major Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At least one Minor Deviation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Major Deviations	xx	xx	xx	xx
Subject Dosing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Inclusion/Exclusion criteria	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[add additional items]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Minor Deviations	xx	xx	xx	xx
Out of window	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[add additional items]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

n: Number of deviations, except for the two first lines where it is specified as number of patients.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.1.2 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.1.3.1.1
Summary of Demographics, mITT Population

Variable	Statistic	Test Product N =	Reference N=	Placebo N=	All Subjects N =
Age	N	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Sex	n				
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity	n (%)				
Hispanic or Latino		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race	n (%)				
American Indian or Alaskan Native		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black or African American		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other		xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.1.3.1 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat for PP and Safety populations

Table 14.2.1.1.1
Summary of Treatment Success by Visit, PP Population

Visit	Test Product N = n (%)	Reference N = n (%)	Placebo N = n (%)	All Subjects N = n (%)
Visit 3 (Day 7)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Visit 4 (Day 14)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Visit 5 (Day 21)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
Visit 6 (Day 28)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
EOS	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)

Treatment success: total disappearance of all warts within all treated areas.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat for mITT population, and as Supplemental Analysis including site 201 for PPs and mITTs

Table 14.2.2.1.1
Bioequivalence Test for Proportion of Treatment Success between Test and Reference Products

Population		Test Product n (%)	Reference n (%)	Difference (SE)	90% CI
PP	EOS	xx (xx.xx)	xx (xx.xx)	x.xx (x.xxx)	(x.xx, x.xx)
mITT		xx (xx.xx)	xx (xx.xx)	x.xx (x.xxx)	(x.xx, x.xx)

n: Number of subjects who experienced treatment success
SE: Standard Error
CI: Confidence Interval
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat as Supplemental Analysis including site 201 for PPs/mITTs

Table 14.2.3.1.1
Treatment Success, Superiority Test from Placebo

	Test Productn (%)	Reference n (%)	Placebo n (%)	Test vs. Placebo Diff (95% CI) p	Reference vs. Placebo- Diff (95% CI)
mITT	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	x.xx (x.xx, x.xx) x.xxxx	x.xx (x.xx, x.xx)
PP	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)	x.xx (x.xx, x.xx) x.xxxx	x.xx (x.xx, x.xx)

n: Number of subjects who experienced treatment success
SE: Standard Error
CI: Confidence Interval
p: Probability of lower bound of CI with Walt-Yate's continuity correction
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD THH:MM:SS Programmer: <Programmer Initials>

Repeat as Supplemental Analysis including site 201 for PPs/mITTs

Table 14.2.4.1.1
Number of Genital Warts by Visit, PP Population

Visit	Statistic N =	Test Product N =	Reference N =	Placebo N =	All Subjects N =
Baseline (Day 0)	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 (Day 7)	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 change from baseline	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for Visits 4, 5, 6 and EOS					

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat for mITT population, and as Supplemental Analysis including site 201 for PPs and mITTs

Table 14.2.5.1.1
Number of Perianal Warts by Visit, PP Population

Visit	Statistic	Test Product N=	Reference N=	Placebo N=	All Subjects N=
Baseline (Day 0)	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 (Day 7)	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 change from baseline	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

Repeat for Visits 4, 5, 6 and EOS.

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat for mITT population, and as Supplemental Analysis including site 201 for PPs and mITTs

Table 14.2.6.1.1
Number of Genital and Perianal Warts by Visit, PP Population

Visit	Statistic	Test Product N=	Reference N=	Placebo N=	All Subjects N=
Baseline (Day 0)	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 (Day 7)	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 change from baseline	n	n (%)	n (%)	n (%)	n (%)
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for Visits 4, 5, 6 and EOS.					

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat for mITT population, and as Supplemental Analysis including site 201 for PPs and mITTs

Table 14.2.7.1.1
Warts Area (cm^2) by Visit, PP population

Visit	Statistic	Test Product	Reference	Placebo	All Subjects
Baseline (Day 0)	n	n			
	Mean (SD)	xx.x (xx.xx)			
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 (Day 7)	n				
	Mean (SD)	xx.x (xx.xx)			
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Visit 3 change from baseline	n				
	Mean (SD)	xx.x (xx.xx)			
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for Visits 4, 5, 6 and EOS.					

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Repeat for mITT population, and as Supplemental Analysis including site 201 for PPs and mITTs

Table 14.3.1.1
Summary of Vital Signs, Safety Population

Visit	Vital Sign	Statistic	Test Product	Reference	Placebo	All Subjects
Baseline (Day 0)	Temperature (°C)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Heart Rate (beats per minute)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Systolic BP (mmHg)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Diastolic BP (mmHg)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for visits 3, 4, 5 and 6.						

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.1 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.1.2
Vital Signs Changes from Baseline, Safety Population

Visit	Vital Sign	Statistic	Test Product	Reference	Placebo	All Subjects
Visit 3 (Day 7)	Temperature (°C)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Heart Rate (beats per minute)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Systolic BP (mmHg)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Diastolic BP (mmHg)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for Visits 4, 5 and 6.						

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.1 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.2
Summary of Physical Examination, Safety Population

Visit	Physical Examination	Statistic	Test Product	Reference	Placebo	All Subjects
Baseline (Day 0)	Height (cm)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	Weight (kg)	n	xx	xx	xx	xx
		Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
		CV	xx.x	xx.x	xx.x	xx.x
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
	General Appearance					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Heart Cardiovascular					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Lungs					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Gastrointestinal					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Visit	Physical Examination	Statistic	Test Product	Reference	Placebo	All Subjects
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Ear/Nose/Throat					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Extremities					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Skin					
	Normal	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal NCS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Abnormal CS	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not done	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Other					
Repeat for EOS, ET visit and the change from Baseline.						

NCS: Non-Clinically Significant
CS: Clinically Significant
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.2 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.3
Summary of Study Drug Exposure, Dose in grams by Week, Safety Population

Week	Statistic	Test Product	Reference	Placebo	All Subjects
Week 1	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for all Weeks					
Weekly Average	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

n: Number of Subjects
Mean, SD, Median, Min, and Max in Grams.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.3 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.4.1
Summary of Study Drug Exposure, Number of Applications by Week, Safety Population

Week	Statistic	Test Product	Reference	Placebo	All Subjects
Week 1	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for all Weeks					
Weekly Average	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Q1, Q3	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

n: Number of Subjects
Mean, SD, Median, Min, and Max of number of applications during a week.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.4 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.4.2
Summary of Study Drug Exposure, Duration of Exposure in Hours by Week, Safety Population

Week	Statistic	Test Product	Reference	Placebo	All Subjects
Week 1	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for all Weeks					
Weekly Average	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

n: Number of Subjects
Mean, SD, Median, Min, and Max of hours from first application of the week to last application of the week.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.4 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.5
Summary of Treatment Compliance (%) by Week, Safety Population

Week	Statistic	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
Week 1	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Repeat for all Weeks					
Weekly Average	n	xx	xx	xx	xx
	Mean (SD)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)	xx.x (xx.xxx)
	CV	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x

n: Number of Subjects
Mean, SD, Median, Min, and Max of percentage of treatment compliance by week.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.5 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.6
Summary of Concomitant Medications by Preferred Term, Safety Population

WHO-DD ATC Class Level 1 WHO-DD ATC Class Level 2 WHO-DD Preferred Term	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
Number of subjects with at least one concomitant medication	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD ATC Class Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD ATC Class Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.				
WHO-DD ATC Class Level 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD ATC Class Level 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD Preferred Term 1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
WHO-DD Preferred Term 2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.				

Concomitant medications are coded using the World Health Organization Drug Dictionary (WHO-DD).
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.6 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.7
Summary of Site Reaction by Intensity and Visit, Safety Population

Site Reaction	Visit	Score	Test Product n (%)	Reference n (%)	Placebo n (%)	All Subjects n (%)
Erythema	Baseline (Day 0)	Absent	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Present	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Visit 3(Day7)	Absent	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Present	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Visit 3 Change from Baseline	Absent	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Present	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
		Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Repeat for Site reactions: dryness, burning/stinging, erosion, edema, pain, itching, and bleeding.
Then Repeat for visit 4, 5, 6 and EOS.

n: number of patients affected.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.7 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.8
Overall Summary of Adverse Events, Safety Population

	Test Product (N=xxx) n (%)	Reference (N=xxx) n (%)	Placebo (N=xxx) n (%)	All Subjects (N=xxx) n (%)
Total number of AEs	xx	xx	xx	xx
Total number of SAEs	xx	xx	xx	xx
Total Number of TEAEs	xx	xx	xx	xx
Total Number of TESAEs	xx	xx	xx	xx
Number of Subjects with:				
At Least One TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One Related TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One Severe TEAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One TEAE Leading to Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One TEAE Leading to Death	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One TESAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One Related TESAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One Severe TESAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
At Least One TESAE Leading to Discontinuation	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

(S)AE: (Serious) Adverse Event reported from signature of the Informed Consent Form to 30 days following the last study drug application.
TE(S)AE: Treatment Emerging (Serious) Adverse Event reported during the treatment period (from the day of the first application of the study drug and up to the last visit).
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listings: 16.3.8.1 – 16.3.8.2 – 16.3.8.3 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.8.1.1
Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term, Safety Population

	Test Product (N=xxx) n (%)	Reference (N=xxx) n (%)	Placebo (N=xxx) n (%)	All Subjects (N=xxx) n (%)
Total Number of AEs	xx	xx	xx	xx
Number of Subjects with at Least One AE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of subjects with at least One AE:				
System Organ Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.				
System Organ Class #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.				

AE: Adverse Event reported from signature of the informed Consent Form to 30 days following the last study drug application.
N (%): Number of subjects and % of subjects, except for first line where it is specified as Number of AEs.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing:16.3.8.1 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.8.1.2
Summary of Tretment Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Severity, Safety Population

	Severity	Test Product (N=xxx) n (%)	Reference (N=xxx) n (%)	Placebo (N=xxx) n (%)	All Subjects (N=xxx) n (%)
Number of Subjects with at Least One TEAE	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects with at Least One TEAE:					
System Organ Class #1	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	Mild	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.					

TEAE: Treatment Emergent Adverse Event reported during the treatment period (from the day of the first application of the study drug and up to the last visit).
n (%): Number of subjects and % of subjects, except for first line where it is specified as Number of TEAEs.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.8.1 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Table 14.3.8.1.3

Summary of Treatment Emergent Adverse Events (TEAEs) by System Organ Class, Preferred Term, and Causality, Safety Population

	Causality	Test Product (N=xxx) n (%)	Reference (N=xxx) n (%)	Placebo (N=xxx) n (%)	All Subjects (N=xxx) n (%)
Number of Subjects with at Least One TEAE	Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Probably Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Possibly Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Probably not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of Subjects with at Least One TEAE: System Organ Class #1	Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Probably Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Possibly Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Probably not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Probably Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Possibly Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Probably not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Not Related	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

TEAE: Treatment Emergent Adverse Event reported during the treatment period (from the day of the first application of the study drug and up to the last visit)
n (%): Number of subjects and % of subjects, except for first line where it is specified as Number of TEAEs.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset>		Listings:16.3.8.1 - 16.3.8.3			Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name>		Date: YYYY-MM-DD Time: HH:MM:SS			Programmer: <Programmer Initials>
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.					

Table 14.3.8.2
Summary of Treatment Emergent Serious Adverse Events (TESAEs) by System Organ Class and Preferred Term, Safety Population

	Test Product (N=xxx) n (%)	Reference (N=xxx) n (%)	Placebo (N=xxx) n (%)	All Subjects (N=xxx) n (%)
Total Number of TESAEs	xx	xx	xx	xx
Number of Subjects with at Least One TESAE	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Number of subjects with at least One TESAE:				
System Organ Class #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.				
System Organ Class #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term #3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.				

TE(S)AE: Treatment Emergent (Serious) Adverse Event reported during the treatment period (from the day of the first application of the study drug and up to the last visit).N (%): Number of subjects and % of subjects, except for first line where it is specified as Number of TESAEs.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Listing: 16.3.8.2 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

12.1.2 List of Listings

Display Number	Title	Population
Study Population		
Listing 16.1.1.1	Subject Enrollment and Disposition	All Subjects
Listing 16.1.1.2	Randomized Patients Not Included in the Safety, PP and mITT Populations	Randomized Subjects
Listing 16.1.2	Protocol Deviations	All Subjects
Listing 16.1.3.1	Subject Demographics and Characteristics	All Subjects
Listing 16.1.3.2	Medical History	All Subjects
Listing 16.1.3.3	Laboratory Results.	All Subjects
Listing 16.1.3.4	Prior Medications	Safety
Efficacy		
Listing 16.2	Number of Warts and Area	All Subjects
Safety		
Listing 16.3.1	Vital Signs	All Subjects
Listing 16.3.2	Physical Examinations	All Subjects
Listing 16.3.3	Study Drug Dispensation and Return	Safety
Listing 16.3.4	Drug Administrations	Safety
Listing 16.3.5	Diary Card Dispensation and Return, and Treatment Compliance	Safety
Listing 16.3.6	Concomitant Medications	Safety
Listing 16.3.7	Site Reaction	Safety
Listing 16.3.8.1	Adverse Events by System Organ Class, Preferred Term, Frequency and Severity	All Subjects
Listing 16.3.8.2	Adverse Events by System Organ Class, Preferred Term, Seriousness, Treatment Unblinding and	All Subjects

	Discontinuation of the subject from the Study	
Listing 16.3.8.3	Adverse Events by System Organ Class, Preferred Term, Causality, Action Taken with the Study Drug, Outcome	All Subjects

Listing 16.1.1.1
Subject Enrollment and Disposition by Study Site, All Sujects

Site	Patient ID	Treatment Group	Population	Visit	Date	Disposition	Primary Reason for Screen Failure/Discontinuation
100	100001	Test Product, Reference, Placebo	Safety, PP, mITT	Screening, Baseline, Visit 3 (Day 7), Visit 4 (Day14), Visit 5 (Day 21), Visit 6 (Day 28) ET, EOS, US	DDMMMYYYY	Screened, Screen failure, Randomized, FU 1, FU 2, FU 3, Discontinuated, Completed	xxxxxxxxxxxxxxxxxxx

FU: Follow-up visit
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 6, 19-22, 23, 35-38, 39, 44, 56, 68, 79, 104, 105, 110 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.1.1.2
Randomized Patients Not Included in the Safety, PP and mITT Populations, Randomized Subjects

Site	Patient ID	Treatment Group	Not Included Population	Reason for Exclusion
100	100001	Test Product, Reference, Placebo	PP, mITT, Safety	xxxxxxxxxx

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Derived from multiple sources Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.1.2
Protocol Deviations, All Subjects

Site	Patient ID	Treatment Group	Population	Date	Classification	Category	Verbatim Text
100	100001	Test Product, Reference, Placebo	Safety, PP, mITT	DDMMMYYYY	Major, Minor	Subject Dosing, Inclusion/Exclusion criteria, ect…	

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> Derived from multiple sources Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.1.3.1
Subject Demographics and Characteristics, All Subjects

Patient ID	Treatment Group	Population	Date of Informed Consent	Date of Birth	Age (Years)	Sex	Ethnicity	Race
100001	Test Product, Reference, Placebo	Safety, PP, mITT	DDMMMYYYY	DDMMMYYYY	xxx	Male, Female	Hispanic or Latino, Not Hispanic or Latino	American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, Other (xxx)

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF page 7 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.1.3.2

Medical History, All Subjects

Patient ID	Treatment Group	Population	MH Seq	System Organ Class / Preferred Term / MH / Procedure Term Verbatim	Start Date	End date	Ongoing
100001	Test Product, Reference, Placebo	Safety, PP, mITT	xxx	xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxx	DDMMYYYY	DDMMYYYY	Yes/ No

MH: Medical History
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 8, 9 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.1.3.3
Laboratory Results, All Subjects

Patient ID	Treatment Group	Population	Visit	Lab Seq	Lab Test	Sample collected	Result	Reason fot Test Not Done
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Screening, Baseline, ET, EOS, US	xxx	HIV, Hepatitis B, Hepatitis C, Syphilis, Pregnancy	Yes, No	Positive, Negative	xxxxxx

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 16, 17, 30, 87, 112, 113 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.1.3.4
Prior Medications, All Subjects

Patient ID	Treatment Group	Population	PM Seq	WHO-DD ATC Class Level1/ WHO-DD ATC Class Level 2/ WHO-DD Preferred Term/ PM Verbatim	Indication/ Type	Treatment was Given	Dose/ Unit/ Form/ Frequency/ Route/	Start Date/ End Date
100001	Test Product, Reference, Placebo	Safety, PP, mITT	xxx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	xxxxxx/ Medication/Non-drug Treatment (xxxxx), Surgical/ Diagnostic Procedure (xxxxxxx)	AE, MH, Study Indication, Prophylactically, Other (xxxxxx)	xxx.xx/ xxxxxx/ xxxxxx/ xxxxxxxx/ xxxxxxxx	DDMMYYYY/ DDMMYYYY, Ongoing

Prior medication: any medications taken within the 30 days prior to the start of the study and with stop dates occurring before the date of first administration of the study drug.
PM: Prior Medication
AE: Adverse Event
MH: Medical History
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 97, 98, 99, 101 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.2
Number of Warts and Area, Safety Population

Patient ID	Treatment Group	Population	Visit	Date	Number of Genital Warts	Number of Perianal Warts	Area of Warts (cm^2)	Reason for Assessment Not Done
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Screening, Baseline, Visit 3 (Day 7), Visit 4 (Day 14), Visit 5 (Day 21), Visit 6 (Day 28), ET, EOS, US	DDMMYYYY	xxx	xxx	xxx	xxxxxxxxxxx

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 18, 31, 48, 60, 72, 86, 128 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.1
Vital Signs, Safety Population

Patient ID	Treatment Group	Population	Visit	Date	Test [1]	Result/ Not Done	5 min Rest	Clinical Significance	Reason for Test Not Done	Reason for Not Rest 5 min
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Screening, Baseline, Visit 3 (Day 7), Visit 4 (Day 14), Visit 5 (Day 21), Visit 6 (Day 28), EOS, ET, US	DDMMMYYYY	1, 2, 3, 4	xx.xx, xxx, ND	Yes, No	CS, NCS	xxxxx	xxxxx

[1] 1 = Temperature (°C). 2 = Pulse rate (beats per minute). 3 = Systolic Blood Pressure (mmHg). 4 = Diastolic Blood Pressure (mmHg).
ND: Not Done
CS: Clinically Significant
NCS: Not Clinically Significant
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 10, 11, 24, 25, 46, 47, 58, 59, 70, 71, 80, 81, 118, 119 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.2
Physical Examinations, All Subjects

Patient ID	Treatment Group	Population	Visit	Height (cm)	Weight (kg)	Body System	Result	Clinical significance	Finding (if Abnormal)/ Reason (if not done)
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Screening, Baseline, EOS, ET, US	xxx.xx	xxx.xx	General Appearance, Heart/Cardivascular, Lungs, Gastrointestina, Ear/Nose:/Throat, Extremities, Skin, [Other]	Normal, Abbnormal, Not Done	CS, NCS	xxxxxx

CS: Clinically Significant
NCS: Not Clinically Significant
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset>
Program Name: <Pgm name>

CRF pages 12-15, 26-29, 82-85, 114-117
Date: YYYY-MM-DD Time: HH:MM:SS

Snapshot Data DD-MMM-YYYY
Programmer: <Programmer Initials>

Listing 16.3.3
Study Drug Dispensation and Return, Safety Population

Patient ID	Treatment Group	Population	Visit	Dispensation Date/ Time	Drug Dispensed Weight (gram)	Return Date	Drug Returned Weight (gram)	Reason for no Return
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Baseline, Visit 3 (day 7), Visit 4 (Day 14), Visit 5 (day 21), Visit 6 (Day 28), EOS, ET, US	DDMMMYYYY/ HH24:MI	x.xx	DDMMMYYYY	x.xx	xxxxx

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 41, 52, 53, 61, 62, 73, 74, 88, 120, 121, 126 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.4
Study Drug Administrations, Safety Population

Patient ID	Treatment Group	Population	Day	Date of Application	Time of AM Application	Time of PM Application
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Day 1, Day 2, Day 3, Day 8, Day 9, Day 10, Day 15, Day 16, Day 17, Day 22, Day 23, Day 24	DDMMMYYYY	HH24:MI	HH24:MI

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF page 102 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.5

Diary Card Dispensation and Return, and Treatment Compliance, Safety Population

Patient ID	Treatment Group	Population	Visit	Diary Card Dispensed	Diary Card Return	Reason for Diary Card not Dispensed/Returned	Treatment Compliance (%)
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Visit 3 (Day 7), Visit 4 (Day 14), Visit 5 (Day 21), Visit 6 (Day 28), EOS, ET, US	Yes, No	Yes, No	xxxxxxx	xxx

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 42, 45, 54, 57, 66, 69, 78, 92, 125, 129 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.6
Concomitant Medications, Safety Population

Patient ID	Treatment Group	Population	CM Seq	WHO-DD ATC Class Level1/ WHO-DD ATC Class Level 2/ WHO-DD Preferred Term/ CM Verbatim	Indication/ Type	Treatment was Given	Dose/ Unit/ Form/ Frequency/ Route/	Start Date/ End Date
100001	Test Product, Reference, Placebo	Safety, PP, mITT	xxx	xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxx/ Medication/Non-drug Treatment (xxxxx), Surgical/ Diagnostic Procedure (xxxxxxx)	AE, MH, Study Indication, Prophilactically, Other (xxxxxx)	xxx.xx/ xxxxxx/ xxxxxx/ xxxxxxxx/ xxxxxxxx	DDMMYYYY/ DDMMYYYY, Ongoing

Concomittant medication: any medications taken within 30 days prior to the start of the Study Treatment and through the final study visit.
CM: Concomittent Medication
AE: Adverse Event
MH: Medical History
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 97, 98, 99, 101 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.7
Site Reaction, Safety Population

Patient ID	Treatment Group	Population	Visit	Assessment	Assessement Date	Site Reaction	Severity	Reason for no Assement
100001	Test Product, Reference, Placebo	Safety, PP, mITT	Baseline/ Visit 3 (Day 7), Visit 4 (Day 14), Visit 5 (Day 21), ET, EOS, US	Yes, No	DDMMYYYY	Erythema, Dryness, Burning/Stinging, Erosion, Edema, Pain, Itching, Bleeding	Absent, Mild, Moderate, Severe	xxxxxxx

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 32-34, 49-51, 63-65, 75-77, 89-91, 122-124 Snapshot Data DD-MMM-YYYY

Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.8.1
Adverse Events by System Organ Class, Preferred Term, Frequency and Severity, Safety Population

Patient ID	Treatment Group	Population	AE Seq	System Organ Class/ Preferred Term/ AE Verbatim	Start Date/Time	Stop Date/Time	Frequency	Severity
100001	Test Product, Reference, Placebo	Safety, PP, mITT	xx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxx	DDMMYYYY/ HH24:MI	DDMMYYYY/ HH24:MI, Ongoing	Single occurrence, Intermittent, Continuous	Mild, Moderate, Severe

Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 93, 94 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.8.2

Adverse Events by System Organ Class, Preferred Term, Seriousness, Treatment Unblinding and Discontinuation of the Subject from the Study, Safety Population

Patient ID	Treatment Group	Population	AE Seq	System Organ Class/ Preferred Term/ AE Verbatim	Seriousness	SAE Criteria [1]	Treatment Unblinding/ Date and Time	AE causes Subject Discontinuation from the Study
100001	Test Product, Reference, Placebo	Safety, PP, mITT	xx	xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxx	Yes, No	1, 2, 3, 4, 5, 6, 7	Yes, No/ DDMMYYYY/ HH24:MI	Yes, No

[1] 1 = Death. 2 = Life-Threatening. 3 = Hospitalization. 4 = Prolongation of Hospitalization. 5 = Congenital anomaly / Birth defec. 6 = Persistent or significant disability / Incapacity. 7 = Other Important Medical Event
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 94, 95, 96 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>

Listing 16.3.8.3
Adverse Events by System Organ Class, Preferred Term, Causality, Action Taken with the Study Drug, Outcome, Safety Population

Patient ID	Treatment Group	Population	AE Seq	System Organ Class / Preferred Term / AE Verbatim	Causality [1]	Action Taken with the study Drug [2]	Other Action Taken [3]	Outcome [4]	Death Date
100001	Test Product, Reference, Placebo	Safety, PP, mITT	xx	xxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxxx/ xxxxxxxxxxxxxx	1, 2, 3, 4, 5, 6	1, 2, 3, 4	1, 2, 3, 4	1, 2, 3, 4, 5	DDMMYYYY

[1] 1 = Related. 2 = Probably Related. 3 = Possibly Related. 4 = Probably Not Related, 5 = Not Related. 6 = Aleternative Ethiology.
[2] 1 = None. 2 = Drug interrupted. 3 = Drug Withdrawn. 4 = Not Applicable.
[3] 1 = None. 2 = Medication Administered. 3 = Non-Drug Treatment. 4 = Other.
[4] 1 = Reolved. 2 = Resolved with Sequelae. 3 = Improving. 4 = Still present and unchanging. 5 = Death.
Test Product: Podofilox Topical Gel 0.5%
Reference: Condylox® Gel 0.5%
Placebo: vehicle that matches the test product

Source: <Dataset> CRF pages 93, 95, 96 Snapshot Data DD-MMM-YYYY
Program Name: <Pgm name> Date: YYYY-MM-DD Time: HH:MM:SS Programmer: <Programmer Initials>