CLINICAL RESEARCH IN INFECTIOUS DISEASES

STATISTICAL ANALYSIS PLAN

for

DMID Protocol: 12-0021

Study Title:

A Phase II, Double-Blind, Randomized, Placebo-Controlled, Multicenter Trial to Assess the Safety and Efficacy of 5% Monolaurin Vaginal Gel Administered Intravaginally for the Treatment of Bacterial Vaginosis

Version 1.0

DATE: 02 NOVEMBER 2017

Study Title

Protocol Number Code:	DMID Protocol: 12-0021
Development Phase:	Phase II
Products:	5% Monolaurin Vaginal Gel
Form/Route:	Intravaginally
Indication Studied:	Bacterial Vaginosis
Sponsor:	Division of Microbiology and Infectious Diseases National Institute of Allergy and Infectious Diseases National Institutes of Health
Clinical Trial Initiation Date:	
Clinical Trial Completion Date:	
Date of the Analysis Plan:	02 November 2017
Version Number:	1.0

This study is performed in compliance with Good Clinical Practice.

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LIST OF ABBREVIATIONS

AE	Adverse Event
AGUS	Atypical glandular cells of uncertain significance
ALT	Alanine Aminotransferase
ASCUS	Atypical squamous cells of undetermined significance HPV negative
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Classification
BV	Bacterial Vaginosis
CDC	Centers for Disease Control and Prevention
CI	Confidence Interval
CIN	Cervical intraepithelial neoplasia
CRF	Case Report Form
CSR	Clinical Study Report
DMID	Division of Microbiology and Infectious Diseases
DSMB	Data and Safety Monitoring Board
EDC	Electronic Data Capture
ER	Emergency Room
F	Fahrenheit
FDA	Food and Drug Administration
GML	Glycerol monolaurate
HEENT	Head, Ears, Eyes, Nose, and Throat
HIV	Human Immunodeficiency Virus
HSIL	High grade Squamous Intraepithelial Lesion
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
ITT	Intention to Treat
kg	kilogram
KOH	Potassium Hydroxide
L	Liter
LLN	Lower Limit of Normal
LOCF	Last observation carried forward
MedDRA	Medical Dictionary for Regulatory Activities

LIST OF ABBREVIATIONS *(continued)*

mg	Milligram
mITT	Modified Intention to Treat
mL	Milliliter
N	Number (typically refers to subjects)
NAAT	Nucleic Acid Amplification Test
NF	National Formulary
NIH	National Institutes of Health
pH	Potential of Hydrogen
PI	Principal Investigator
PP	Per Protocol
PT	Preferred Term
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDCC	Statistical and Data Coordinating Center
SGOT	Serum glutamic oxaloacetic transaminase
SGPT	Serum glutamate pyruvate transaminase
SMC	Safety Monitoring Committee
SOC	System Organ Class
SOP	Standard Operating Procedures
TOC	Test of Cure
U	Units
ug	microgram
ULN	Upper Limit of Normal
WBC	White Blood Cell
WHO	World Health Organization

1. PREFACE

The Statistical Analysis Plan (SAP) for "A Phase II, Double-Blind, Randomized, Placebo-Controlled, Multicenter Trial to Assess the Safety and Efficacy of 5% Monolaurin Vaginal Gel Administered Intravaginally for the Treatment of Bacterial Vaginosis" (Division of Microbiology and Infectious Diseases (DMID) Protocol 12-0021) describes and expands upon the statistical information presented in the protocol.

This document describes all planned analyses and provides reasons and justifications for these analyses. It also includes sample tables, listings, and figures planned for the final analyses. Regarding the final analyses and Clinical Study Report (CSR), this SAP follows the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines, as indicated in Topic E3 (Structure and Content of Clinical Study Reports), and more generally is consistent with Topic E8 (General Considerations for Clinical Trials) and Topic E9 (Statistical Principles for Clinical Trials). The structure and content of the SAP provides sufficient detail to meet the requirements identified by the Food and Drug Administration (FDA) and ICH, while all work planned and reported for this SAP will follow internationally accepted guidelines published by the American Statistical Association and the Royal Statistical Society for statistical practice.

This document contains four sections: (1) a review of the study design, (2) general statistical considerations, (3) comprehensive statistical analysis methods for efficacy and safety outcomes, and (4) a list of proposed tables and figures. Any deviation from this SAP will be described and justified in the CSR. The reader of this SAP is encouraged to also review the study protocol for details on conduct of the study and the operational aspects of clinical assessments.

2. INTRODUCTION

Bacterial Vaginosis (BV) is a disorder of the chemical and biological balance of the normal vaginal flora [1]. In women of childbearing age, BV is the most common cause of vaginitis accounting for 22-50% of women who have symptoms of vaginitis [2]. In a cohort of young healthy women, nearly 30% had been treated for BV [3]. The diagnosis of BV has been based clinically on Amsel and Nugent scoring criteria using direct Gram stain of vaginal secretions. The Centers for Disease Control and Prevention (CDC) recommends metronidazole 500 mg orally twice daily for 7 days, intravaginal metronidazole gel 0.75% once daily for 5 days or clindamycin cream 2% intravaginally once daily for 7 days as first line therapy for BV [1]. However, up to 30% of women will have recurrent BV within 3 months of therapy [4]. Given BV's high recurrence rates and the risks for antimicrobial resistance, additional treatment options are desirable.

Monolaurin, also commonly referred to as glycerol monolaurate (GML), is a monoglyceride surfactant. It is an ester formed from glycerol and lauric acid. This formulation promotes rapid drug distribution, as well as adequate coverage, throughout the vaginal cavity. The acidic pH keeps monolaurin in its non-ionized form in the vagina. Monolaurin, which is practically insoluble in water, is highly soluble in this formulation. Laboratory studies have shown that Monolaurin has antibacterial, antifungal and antiviral properties. Monolaurin's mechanism of

action of blocking signals at the pathogen's plasma membrane provides an advantage over other antibiotics with regard to the development of resistance [5, 6]. Information on dosage forms can be found in Section 6 of the protocol.

New therapies for BV are needed and 5% Monolaurin Vaginal Gel has the potential to eradicate flora associated with BV while maintaining some of the normal flora that is considered protective for vaginal health, and with the added potential of preventing the emergence of vaginal candidiasis. This phase II study is designed to evaluate the safety of 5% Monolaurin Vaginal Gel compared to placebo gel and provide an early assessment of efficacy in treatment of women with BV. The July 2016 FDA draft guidance was used in the development of the study design.

2.1. Purpose of the Analyses

The analyses contained in this Statistical Analysis Plan will assess the safety and efficacy of 5% Monolaurin Vaginal Gel in comparison with Vehicle Placebo Gel and will be included in the clinical study report.

The protocol for DMID 12-0021 calls for a planned interim analysis to reassess the adequacy of the sample size based on subjects meeting eligibility for the Modified Intent-to-Treat (mITT) population. After eighty subjects have been enrolled and have available baseline test results for Nugent score, Human Immunodeficiency Virus (HIV), chlamydia and gonorrhea, the fraction of subjects enrolled to date who are eligible for the mITT cohort will be estimated. The tables and figures for the interim analysis are contained in the Data Safety Monitoring Board (DSMB) Interim Analysis Safety Summary Report Table and Figure Shells. The goal of the interim analysis is to review aggregate enrollment data in order to recommend whether an extension to the trial is necessary, while it is still possible to do so without halting enrollment and losing momentum in subject accrual.

3. STUDY OBJECTIVES AND ENDPOINTS

3.1. Study Objectives

Primary Objectives

- To assess the safety and tolerability of 5% Monolaurin Vaginal Gel compared to Vehicle Placebo Gel (excipients only).
- To assess the efficacy by clinical cure rate of 5% Monolaurin Vaginal Gel compared to Vehicle Placebo Gel at Visit 2.

Secondary Objectives

- To evaluate the therapeutic cure rate of 5% Monolaurin Vaginal Gel compared to Vehicle Placebo Gel at Visits 2 and 3.
- To evaluate the clinical cure rate of 5% Monolaurin Vaginal Gel compared to Vehicle Placebo Gel at Visit 3.
- To evaluate the changes in Nugent's criteria of vaginal bacterial flora at Visits 2 and 3.

Exploratory Objectives

- To evaluate the clinical and therapeutic cure rates of 5% Monolaurin Vaginal Gel compared to Vehicle Placebo Gel for each subgroup (first episode BV and recurrent BV) at Visits 2 and 3.
- To evaluate quantitative changes in selected bacterial species at Visits 2 and 3.
- To evaluate the quantitative changes of *Candida spp*. (in subjects with *Candida spp.* identified at screening) at Visits 2 and 3.

3.2. Endpoints

3.2.1. Primary Efficacy Outcomes

The primary efficacy outcome is assessed overall and in both treatment arms and is as follows:

1. Proportion of subjects with clinical cure in each study arm at Visit 2 (Day 8-15).

See Section 3.3 for definition of clinical cure.

3.2.2. Secondary Efficacy Outcomes

1. Proportion of subjects with therapeutic cure in each study arm at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31).
2. Proportion of subjects with Nugent score of 3 or less (negative for BV) and 4-6 (intermediate) in each study arm at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31).
3. Proportion of subjects with clinical cure in each study arm at Visit 3 (Day 22-31).

See section 3.3 for definition of therapeutic cure.

3.2.3. Exploratory Efficacy Outcomes

1. Proportion of subjects with clinical cure in each study arm by subgroup (first time or recurrent infection) by Visit 2 (Day 8-15) and by Visit 3 (Day 22-31).
2. Proportion of subjects with therapeutic cure in each study arm by subgroup (first time or recurrent infection) by Visit 2 (Day 8-15) and by Visit 3 (Day 22-31).
3. Mean count of *Lactobacillus spp.*, *Gardnerella spp.*, and *Mobiluncus spp.*, respectively, in each study arm at baseline, Visit 2 (Day 8-15) and at Visit 3 (Day 22-31).
4. Mean fungal colony count in vaginal secretions in each study arm at baseline, at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31).

See Section 3.3 for cure definitions.

3.2.4. Primary Safety Outcomes

1. Number of subjects reporting solicited urogenital adverse events (AEs) following the first dose of the study product through Visit 2 (Day 8-15).
2. Number of subjects reporting serious adverse events (SAEs) considered product-related following the first dose of the study product through Visit 3 (Day 22-31).

3.2.5. Secondary Safety Outcomes

1. Number of subjects experiencing non-laboratory, non-solicited AEs following the first dose of the study product through Visit 3 (Day 22-31).
2. Number of subjects experiencing laboratory AEs following the first dose of the study product through Visit 2 (Day 8-15).

3.3. Study Definitions and Derived Variables

3.3.1. Amsel Criteria

During gynecologic examination, any three of the following will be used for the clinical diagnosis of BV by Amsel Criteria:

a. Off-white (milky or gray), thin, homogenous discharge with minimal or absent pruritus or inflammation of the vulva or vagina.

b. ≥20% "Clue" cells of total epithelial cells on microscopic examination of saline wet mount.

c. Vaginal secretion pH >4.5.

d. Positive "whiff test."

3.3.2. Bacteriological Cure

A vaginal swab for bacteriological assessment of BV by Nugent criteria will be performed. The Nugent score utilizes a 10-point scale for evaluation of vaginal flora. The Nugent score can range from 0 to 10. A score of 7 to 10 is consistent with BV while 4-6 is considered intermediate and 0-3 is negative for BV. Bacteriological cure of BV is defined as a normal Nugent score of 0-3. Laboratory examination of vaginal smears and the determination of the Nugent score is as follows:

N Score = The sum of the scores for each bacterial morphotype listed below. (Note: Number of Organisms seen/high power field as determined by averaging a representative field by two independent evaluators)

Lactobacilli	SCORE	*Gardnerella, Bacteroides*	SCORE	Curved gram-negative bacilli	SCORE	Sum= *N SCORE
≥30	0	0	0	0	0	0
<30-5	1	<1	1	<1	1	3
<5-1	2	1 to <5	2	1 to <5	1	5
<1	3	5 to <30	3	5 to <30	2	8
0	4	≥30	4	≥30	2	10

3.3.3. Clinical Cure

A clinical cure is defined by normal Amsel criteria. Normal Amsel criteria are defined as: normal physiological vaginal discharge, whiff test negative for any amine "fishy" odor, saline wet mount

less than 20% for clue cells, and vaginal pH is <=4.5. All four criteria must be normal and none of the clinical failure criteria listed below can be met to be considered a clinical cure.

A clinical failure is defined by at least one of the following:

a. one or more abnormal Amsel criteria,

b. early discontinuation of study therapy due to lack of treatment effect,

c. use of any vaginosis therapy or systemic antimicrobial therapy other than study product during the study, or

d. in the investigator's opinion, requires additional treatment for vaginosis.

Subjects who do not have enough information to determine a clinical cure or clinical failure status will not be evaluable for clinical cure.

3.3.4. Therapeutic cure

Therapeutic cure is defined as both a clinical cure and a bacteriological cure.

Subjects who were clinical failures, or have a Nugent score >3 are therapeutic failures.

All other subjects will be considered not evaluable for therapeutic cure. See the table below for therapeutic cure outcome determinations.

If the clinical cure outcome is…	and the Nugent (bacteriological) score result is…	then the overall therapeutic cure outcome is…
Cure	0-3	Cure
Cure	>3	Failure
Cure	Not Evaluable	Not Evaluable
Failure	0-3	Failure
Failure	>3	Failure
Failure	Not Evaluable	Failure
Not Evaluable	0-3	Not Evaluable
Not Evaluable	>3	Failure
Not Evaluable	Not Evaluable	Not Evaluable

All cure related outcomes are assessed at follow-up Visits 2 and 3.

3.3.5. Recurrent BV

Recurrent BV infection is defined as 2 or more episodes of BV in the previous 12 months, including the subject's current episode, as reported by the subject in the sexual history interview.

3.3.6. First Time BV

First time BV infection is defined as one episode of BV in the previous 12 months including the subject's current episode, as reported by the subject in the sexual history interview.

3.3.7. Baseline Value

The baseline value is defined as the last value obtained prior to the first dose of study product.

3.3.8. Test of Cure Visit

The Test of Cure (TOC) visit is Visit 2, Day 8-15. For the ITT, mITT, and Evaluable analysis populations, if a subject is evaluable for clinical cure, even if they return outside of the 8 to 15-day window, their results will be included in the Test of Cure Visit 2 efficacy analyses. Subjects who return outside of the 8 to 15-day window will be excluded from the Per-Protocol analysis population. Similarly, if a subject does not have an assessment at Visit 2, but returns for an unscheduled Visit 2, the data collected at the unscheduled visit will be used for Visit 2 assessments. This applies for all tables that present data by study visit. See Section 6.3 for more details.

3.3.9. Treatment Compliance

Compliance is assessed by the study coordinator's count of used/unused applicators in each returned subject kit. If a kit is not returned, compliance will be assessed by the subject's self-report on the memory aid. If an incomplete kit is returned, the subject's self-report will be used in conjunction with the count of used/unused applicators to determine subject compliance. In addition to the count of used/unused applicators, the timing of dosing will be considered. Subjects are instructed to administer study product twice daily (morning and evening) with at least 8 hours between doses. If the subject received her first dose after 3 pm, she will be instructed to administer the next dose the following morning. A subject is compliant if she uses at least 5 of 6 doses and they were administered within 72 hours from the first dose, at least 8 hours apart, and if no more than 2 doses in a 24 hour period are taken.

4. INVESTIGATIONAL PLAN

4.1. Overall Study Design and Plan

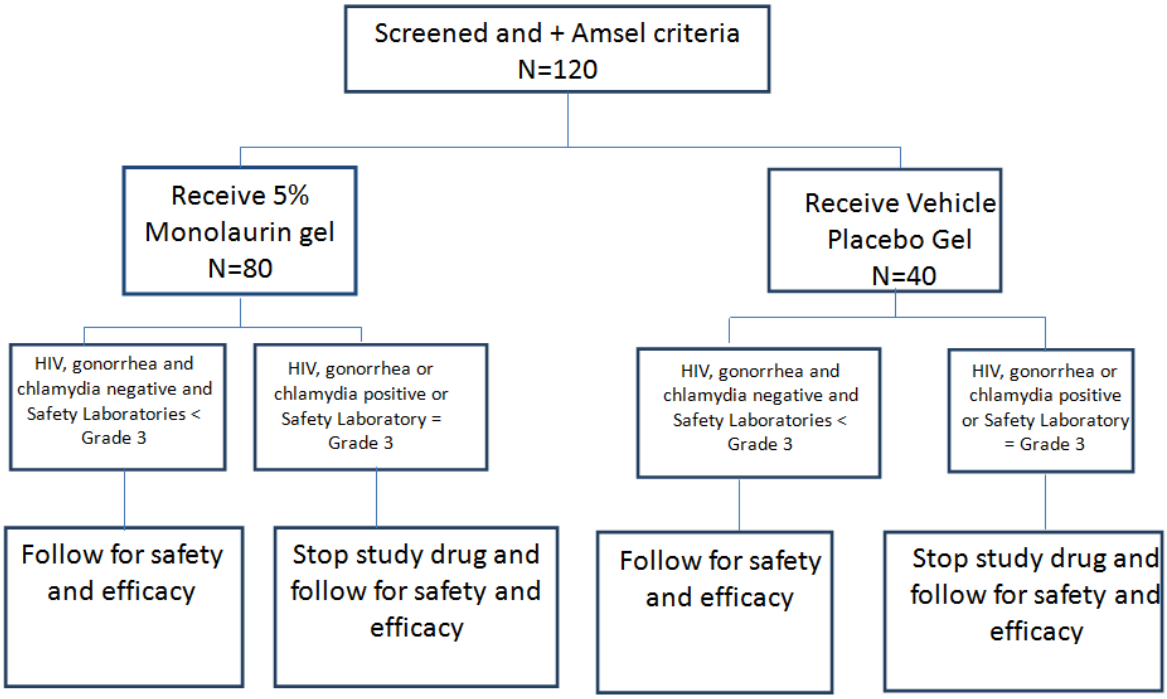
This is a Phase 2, double-blind, randomized, placebo-controlled, multi-center trial comparing 5% Monolaurin Vaginal Gel to Vehicle Placebo Gel as outpatient therapy. A total of 120 eligible subjects with BV will be enrolled. Treatment assignments will be randomly allocated in a 2:1 ratio of test article to placebo, with the randomization stratified by clinical site. Each subject will receive intravaginal gel twice daily for three successive days for a total of 6 doses. There will be 3 clinic visits over 31 days.

The primary study objectives are to compare 5% Monolaurin Vaginal Gel with vehicle placebo gel (excipients only) with respect to safety and tolerability, and efficacy by clinical, bacteriological, and therapeutic cure. Treatment response is evaluated at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31).

The DSMB met after 30 subjects received at least one dose of study drug and completed Visit 2. The DSMB may also review study progress and subject safety data at other specified times during the course of the study and hold a study closeout meeting, as defined in the DSMB Charter.

Additionally, a single, fully blinded interim analysis occurred to reassess the adequacy of the sample size based on subjects meeting eligibility for the mITT population. After eighty subjects had been enrolled and had available baseline test results for Nugent score, HIV, chlamydia and gonorrhea, the fraction of subjects enrolled to date who were eligible for the mITT cohort was estimated. See Section 6.6 for more details.

The figure below presents the schematic of the study design.



Baseline clinical information is collected on all subjects at the screening/enrollment visit (Day 1). This information consists of demographics, medical and sexual history, including number of episodes of BV in the past year, concomitant medications review, and a physical exam including a gynecological exam.

Vaginal swabs are taken to perform a KOH test, vaginal pH, and to review a wet prep. Vaginal swabs for Gram stain of vaginal smear, and assessment for *Candida spp*., selected bacterial species, *Trichomonas vaginalis, Chlamydia trachomatis,* and *Neisseria gonorrhoeae* are collected.

Blood samples are collected for safety assessments (HIV, White Blood Cell [WBC] count, hemoglobin, platelets, neutrophil count, creatinine, aspartate aminotransferase [AST], alanine aminotransferase [ALT], total bilirubin, random glucose).

All subjects are provided with a 5-day memory aid to aid in their recall of local solicited events. **Table 1** below presents the schedule of events at each visit.

Table 1: Schedule of Events

	Visit 1	Visit 2	Visit 3	Early Termination	Unscheduled
	Day 1	8 (Window Days 8-15)	28 (Window Days 22-31)		
Informed Consent	X				
Inclusion/Exclusion	X				
Demographics	X				
Medical History[1]	X				
Concomitant Medication	X	X	X	X	X
Intercurrent Medical History[2]		X	X	X	X
Physical Exam	X				
Targeted Physical Exam		{X}	{X}	{X}	
Urine Pregnancy Test	X				
Gynecological Exam[3]	X	X	X	X	X[†]
Vaginal Swabs for Nugent Score, bacterial/fungal cultures, trichomonas testing and appropriate samples for gonorrhea, chlamydia testing[4]	X	X	X	X	X[†]
Vaginal Swab for Future Use (if subject consents to future use sample collection)	X	X	X	X	
Randomization	X				
Study Drug Administration[5]	X				
Distribute Memory Aid and Study Drug Kit	X				
Counsel on intravaginal products, objects, sexual intercourse, and pregnancy avoidance	X	X			
Safety Labs[6]	X	X	X[^]	X	
Telephone Contact to Stop Study Treatment	[X]				
Review Vaginal Symptomology	X	X	X	X	X
Review for insertion of intravaginal products, objects, and sexual intercourse		X	X	X	
Review Memory Aid and Collect Study Drug Kit		X	X[+]	X	
Assessment of Clinical Cure		X	X	X	
Assessment of Therapeutic Cure		X	X	X	
AE/SAE	X	X	X	X[*]	X

1 Include menstrual, contraceptive, sexual history and history of previous episodes of vaginitis.

2 Include use of intravaginal products or objects, sexual intercourse, treatment for vaginitis (other than the study product).

3 Evaluate cervix, vagina, and vulva. Perform Vaginal pH, Saline Wet Mount, KOH Wet Mount, "Whiff Test".

4 Collect vaginal swabs for study specific tests (gram stain, cultures for bacterial flora and yeast) and trichomonas OSOM testing (if saline wet mount is negative, Visit 1 only) and institution specific samples for culture or molecular testing for *Chlamydia, Neisseria gonorrheae.* (*Visit 1 only). Samples for gonorrhea and chlamydia testing will be consistent with standard of care at the institution).*

5 Provide instructions on proper use of study drug applicator and observe first dose. Remaining 5 doses will be administered by the subject at home on Day 2 and Day 3.

6 Safety Laboratories Include: White blood cell count, hemoglobin, platelet count, absolute neutrophil count, creatinine, ALT, AST, total bilirubin, random glucose, HIV test *(Visit 1 only)*.

{ } Targeted physical examination if indicated based on review of symptoms.

[ ] Subjects will be called regarding grade 3 laboratory abnormalities within 24 hours of receipt of results and told to discontinue study product. Subjects with positive HIV, chlamydia or gonorrhea tests will be contacted as soon as possible after results are available and referred to their primary care provider for appropriate treatment.

+ Memory Aid will be reviewed *only* if solicited events continued at Visit 2. Study Drug Kit returned *only* if not returned at Visit 2.
* If subject declines to return for an in-person visit, the study personnel will ask to contact the subject by telephone to assess for AE/SAEs on Day 22-31.

† Evaluate cervix, vagina, and vulva. Collect appropriate clinical samples for genital infectious pathogens.

Assess for vaginal discharge (quantity, color, odor, and consistency) and record presence or absence of objective signs of inflammation of cervix, vagina, and vulva (edema, erythema, excoriation).
^ Laboratory abnormalities that occurred between Visit 1 and Visit 2 or worsened at Visit 2 should be repeated until resolved or has stabilized. Further testing beyond Visit 3 is at the discretion of the PI or study investigator.

4.2. Discussion of Study Design, Including the Choice of Control Groups

Subjects are randomized at a ratio of 2:1 to receive 5% Monolaurin Vaginal Gel or Vehicle Placebo Gel, which has the same formulation except not containing 5% GML, administered vaginally morning and night for 6 consecutive doses (3 days). The July 2016 FDA draft guidance was used in the development of the study design.

4.3. Selection of Study Population

Subjects may have asymptomatic BV, but must meet any three of the four Amsel criteria for BV as defined in Section 3.3.

Subjects must meet all of the following inclusion criteria to participate in this study:

1. Non-pregnant, non-breastfeeding females between the ages of 18 and 50 years, inclusive.
2. Women of childbearing potential* must agree to practice reliable contraception** for the 28-day period before enrollment through 30 days following treatment.

   *(not surgically sterile via tubal ligation, bilateral oophorectomy or hysterectomy, or who have not been postmenopausal for ≥1 year)
   **Acceptable birth control methods for the purposes of this study may include, but are not limited to, abstinence from intercourse with a male partner, monogamous relationship with vasectomized partner, barrier methods to include condoms and diaphragms, intrauterine devices, and licensed hormonal methods. NuvaRing® contraceptive use will be prohibited from this study since the device can alter vaginal secretions.
3. Presenting with signs of BV (as per Amsel Criteria). Subjects must meet any three of the four criteria for enrollment*

   *Presence of discharge, greater than or equal to 20% clue cells on wet prep, positive "whiff test" on KOH prep, vaginal pH of greater than 4.5.
4. Not currently menstruating or expected to in the next 4 days.
5. Able to understand and comply with planned study procedures.
6. Willing to abstain from sexual intercourse, insertion of tampons, douches, or other intravaginal medications or objects between Visit 1 and Visit 2 and 48 hours prior to Visit 3.

7. Provide written informed consent before initiation of any study procedures and be available for all study visits.
8. No known history of HIV.

Subjects are not able to participate if they meet any of the following exclusion criteria:

1. Signs or symptoms of vaginal/cervical/pelvic infection on screening or clinical diagnosis of vaginal/cervical/pelvic infection in the past 14 days.

   *(including but not limited to yeast vulvovaginitis, chlamydia, gonorrhea, trichomonas, genital ulcer disease, pelvic inflammatory disease). Self-treatment for presumed yeast vaginitis is not an exclusion if treatment was discontinued 7 days or greater prior to enrollment.

2. Treatment for BV within the past 14 days.
3. Cervical or vaginal high grade squamous intraepithelial dysplasia (HSIL), atypical glandular cells of uncertain significance (AGUS) or cervical intraepithelial neoplasia grade 2 (CIN2) or higher*

   *Atypical squamous cells of undetermined significance (ASCUS), low grade squamous intraepithelial lesion (LSIL) or cervical intraepithelial neoplasia grade 1 (CIN1) are acceptable. Individuals with a history of atypical glandular cells of uncertain significance (AGUS), HSIL or CIN2 and who have received subsequent evaluation and/or treatment with follow up normal PAP smear are eligible. Patient report will be accepted.

4. History of undiagnosed vaginal bleeding.
5. Use of a systemic, vaginal, or perineal antibiotic within 7 days prior to enrollment in this study.
6. Use of an immunosuppressive or immunomodulatory drug* for two or more consecutive weeks within 6 months prior to enrollment

   *such as >0.5 mg/kg/day or ≥20 mg total dose/day of prednisone orally or >800 μg of inhaled beclomethasone (nasal and non-genital topical steroids are allowed).

7. History of allergic reactions attributed to compounds of similar chemical or biologic composition to Monolaurin Vaginal Gel.
8. Uncontrolled concurrent illness*. Subjects with a history of organ or marrow transplant are excluded.

   *Including, but not limited to, ongoing or active infection, active liver, kidney or autoimmune diseases (a history of thyroid disease will be permitted as long as the thyroid disease is now stable), symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements.

9. Acute illness within 3 days before receipt of study product (per investigator's discretion).
10. Pregnant women and women who are planning to become pregnant within 30 days after the final study dose, or women who are breastfeeding.
11. Immunosuppression as a result of an underlying illness or treatment or use of anticancer chemotherapy or radiation therapy (cytotoxic) within the preceding 36 months.

12. Active neoplastic disease* or a history of any hematologic malignancy. Active neoplastic disease is defined as neoplastic disease or treatment for neoplastic disease within the past 5 years.

    *(excluding non-melanoma skin cancer)

13. Received an experimental agent* within 30 days before receipt of study product or expect to receive an experimental agent during the 1-month study period.

    *(vaccine, drug, biologic, device, blood product, or medication)

14. Any condition that would place the subject at an unacceptable risk of injury, render her unable to meet the requirements of the protocol, or that may interfere with successful completion of the study.
15. A history of alcohol or drug abuse* during the previous 1 year that in the opinion of the site investigator would interfere with study procedures

    *For example, daily excessive alcohol use or frequent binge drinking as determined by the investigator, or daily marijuana use.

Any enrolled subject may withdraw or be withdrawn from the study for the following reasons:

- The subject withdraws consent.
- The study is terminated.
- For any reason that, in the opinion of the investigator, precludes the subject's participation in the study.
- The subject no longer meets inclusion/exclusion criteria.
- The subject develops an SAE that warrants withdrawal.
- Other safety-related reasons at the discretion of the Principal Investigator (PI), DMID Medical Monitor, DSMB, or the subject.

Any subject who has received at least one dose of study drug is continued in efficacy and safety follow-up, if the subject agrees.

Subjects who test positive for chlamydia, gonorrhea, HIV, or are incidentally found to have a PAP result consistent with AGUS or HSIL, or have a Grade 3 laboratory abnormality are discontinued from receiving study product if the result is available within the 3 days of study drug administration. They are continued in follow up for safety and efficacy if they have received one dose of study drug. (PAP smears are not part of the study protocol, but may have been done outside of the study protocol by the subject's provider. Patient report of PAP smear abnormalities may be accepted as a criterion for discontinuation of study product).

If a subject develops a grade 3 laboratory abnormality while still receiving study product, they are contacted and asked to discontinue study product and are continued in safety and efficacy follow up. If any subject experiences a severe AE related to the study product, further doses are discontinued. Additionally, subjects who experience a new or worsening solicited reactogenicity symptom that is grade 2 or higher are asked to contact the study site to confirm the severity. A determination is made whether to continue or discontinue the study product by a licensed study clinician. A subject who withdraws voluntarily from or has been discontinued from receiving

further treatment is encouraged to permit continued follow-up of AEs and to follow scheduled visits. If the subject agrees, study procedures (e.g., blood sampling for safety and vaginal sampling) are continued.

4.4. Treatments

4.4.1. Treatments Administered

5% Monolaurin Vaginal Gel

Monolaurin Vaginal Gel is a clear and colorless non-sterile glycol-based gel for vaginal administration. Monolaurin Vaginal Gel is comprised of 5% monolaurin and the following excipients: [redacted]

Active test article is comprised of 5% monolaurin prepared as pre-filled vaginal gel applicators of identical likeness to placebo. The components of the applicator are biocompatible and latex-free.

Vehicle Placebo Gel

The Vehicle Placebo Gel is a clear to opaque, colorless to light gray, non-sterile glycol-based gel for vaginal administration and contains the following: [redacted]. The Vehicle Placebo Gel contains the same excipients as the active product.

The Vehicle Placebo Gel is comprised of the identical vehicle contained in the active test article prepared as pre-filled vaginal gel applicators of identical likeness to active test article. The components of the applicator are biocompatible and latex-free.

The first dose of Monolaurin Vaginal Gel or Vehicle Placebo Gel is administered by the subject while the subject is still in clinic. The remaining 5 doses are administered twice daily (morning and evening), with at least 8 hours between doses by the subject at home. If the subject receives her first dose after 3 p.m., she is instructed to administer the next dose the following morning.

4.4.2. Method of Assigning Subjects to Treatment Groups (Randomization)

Enrollment of subjects is done online using the enrollment module of AdvantageEDC^{SM}. Subjects are randomly assigned to active drug or placebo in a 2:1 ratio. The study uses a stratified, permuted blocked randomization scheme. Permuted block randomization is used to avoid the potential for serious imbalance in the number of subjects assigned to each group during the study, an imbalance that can occur in the simple randomization procedures. Stratification is by clinical site.

The randomization is prepared by statisticians at the Statistical and Data Coordinating Center (SDCC) and included in the enrollment module for the trial. AdvantageEDC assigns each subject to a treatment group after the demographic and eligibility data have been entered into the system.

The vaginal gel applicators are packaged as a kit sufficient for twice daily administration for 3 consecutive days (six applicators). Random kit numbers are provided to Fisher, the investigational product distributor, in order to ensure the associated sets of applicators are filled with the same contents (placebo or active) without unblinding the sites to what treatment is in

each kit once the shipments arrive. Each vaginal gel dispensing kit is individually labeled with the kit number. Once a subject is assigned a randomization number, a kit corresponding to the assigned treatment is distributed to the subject.

4.4.3. Blinding

A designated individual at each site is provided with a treatment key, which links the treatment code to the actual treatment assignment, which is kept in a secure place.

The applicators of vaginal gels are selected by the unmasked Site Research Pharmacist or designated unmasked study personnel and are distributed to masked study personnel with no labels that identify the product or applicators to the site as Monolaurin Vaginal Gel or Vehicle Placebo Gel.

The volunteers, the study personnel who perform study assessments after administration, data entry personnel at the sites, and laboratory personnel are masked to treatment assignment. The DSMB may receive data in aggregate and presented by treatment group. The DSMB may be unmasked to individual study treatment assignments, as needed, to adequately assess safety issues.

For the interim analysis, the blind was maintained when reporting results prepared for the DSMB meeting.

4.5. Efficacy and Safety Variables

Subject assessment of solicited urogenital adverse events constitutes a primary safety endpoint. Solicited event assessments were captured on a memory aid starting on Day 1, the first day of therapy and continuing for 5 days. The subject was to record the presence and intensity of vulvovaginal solicited events on the memory aid. Any symptom that was present at the time that the subject was screened should have been considered as baseline and not reported as a solicited urogenital AE. However, if the symptom deteriorated at any time during the study, it was to be recorded as an AE. If a symptom was reported that was not present at baseline, it too was to be recorded as an AE. Any symptoms still present on Day 5 were continued to be followed by subject memory aid notations until symptom resolution. Solicited events include vaginal odor, vaginal pain, vaginal tenderness, vulvar/vaginal itching, vaginal dryness, vaginal discharge, and vulvar inflammation. Severity of solicited events symptoms are graded according to the table in Appendix C in the protocol. Symptoms not specifically mentioned will be graded using the following scale:

- Grade 1: Mild (does not interfere with activity)
- Grade 2: Moderate (interferes with activity)
- Grade 3: Severe (prevents daily activity)

Clinical laboratory evaluations constitute a secondary safety endpoint. Hematology includes: WBC count, hemoglobin, platelets, and neutrophil count. Clinical chemistry includes: creatinine, AST (SGOT), ALT (SGPT), total bilirubin, and glucose (random). Grade 3 abnormal laboratory values were to be repeated within 10 days. Laboratory abnormalities that were stable at Visit 2 were not repeated at Visit 3. Laboratory abnormalities that occurred between Visit 1 and Visit 2 or worsened at Visit 2 were repeated at Visit 3. A laboratory abnormality is considered an

adverse event if there was a worsening of the laboratory value at Visit 2 from the baseline value and it increased in laboratory toxicity grading from the baseline toxicity grading. For laboratory abnormalities repeated at Visit 3, if there was a worsening of the laboratory value at Visit 3 from the Visit 2 value and it increased in laboratory toxicity grading, it was considered an additional adverse event.

Multiple observations within a specific visit period are accepted. In the case of multiple observations within a specific window, the assessment value that is closest to the scheduled visit window will be used in the analyses for the post-baseline records. For screening and baseline visits, the last assessment value prior to first dose will be used as the baseline measurement. All the recorded data will be listed. If observations have the same distance to the scheduled assessment, the latest one will be used.

Culture counts for following bacterial and yeast species will be collected: Lactobacillus, Gardnerella, Mobiluncus, and Candida. Nugent score and Budding yeast will be reported from the Gram Stain. Budding yeast will be categorized as Few, Moderate, Many, or No organisms seen.

See Section 3.3 for efficacy variable definitions.

5. SAMPLE SIZE CONSIDERATIONS

The statistical informational goal for the study is 90 subjects eligible for the primary efficacy analysis of clinical cure in the modified Intent-to-Treat (mITT) efficacy population. This is an ad-hoc sample size determined by logistical and feasibility considerations, as there is insufficient pilot data upon which to base more formal sample size calculations.

Subjects who did not meet all inclusion/exclusion criteria, who have a Nugent score <4 at Visit 1 or are positive for other concomitant vulvovaginal infections at baseline which may interfere with the efficacy assessment will be excluded from the mITT population.

Based on observed rates of these outcomes at the participating clinics, it is anticipated that a total of 120 subjects will be enrolled to reach this target. However, enrollment will be continued past 120 subjects to a maximum of 150, if necessary, to reach the informational goal of 90 eligible subjects.

The table below shows the statistical power conferred by this sample size for a two-sided significance level 5% Fisher's exact test comparing binomial proportions, under different assumed proportions.

Power to compare binomial proportions using a two-sided significance level 0.05 Fisher's Exact Test with a sample size of N = 90 (60 subjects in the 5% Monolaurin Vaginal Gel arm, 30 subjects in the Vehicle Placebo Gel arm) is shown below. Conditions in which Power is ≥.80 are highlighted.

Vehicle Placebo Gel (N=30)	5% Monolaurin Vaginal Gel (N=60)										
	.05	**.10**	**.20**	**.30**	**.40**	**.50**	**.60**	**.70**	**.80**	**.90**	**.95**
.05	.02	.04	.38	.82	.97	>.99	>.99	>.99	>.99	>.99	>.99
.10	.13	.03	.15	.52	.85	.98	>.99	>.99	>.99	>.99	>.99
.20	.53	.22	.03	.12	.42	.78	.96	>.99	>.99	>.99	>.99
.30	.86	.61	.15	.03	.12	.41	.76	.95	>.99	>.99	>.99
.40	.98	.89	.47	.13	.04	.13	.41	.76	.96	>.99	>.99
.50	>.99	.98	.79	.42	.13	.04	.13	.42	.79	.98	>.99
.60	>.99	>.99	.96	.76	.41	.13	.04	.13	.47	.89	.98
.70	>.99	>.99	>.99	.95	.76	.41	.12	.03	.15	.61	.86
.80	>.99	>.99	>.99	>.99	.96	.78	.42	.12	.03	.22	.53
.90	>.99	>.99	>.99	>.99	>.99	.98	.85	.52	.15	.03	.13
.95	>.99	>.99	>.99	>.99	>.99	>.99	.97	.82	.38	.04	.02

With respect to the safety objectives, for a sample size of 60 subjects in the treatment arm with no observed SAEs related to study product, the 95% confidence interval (CI) for the estimated proportion is (.00,.06) (Clopper-Pearson interval).

In actuality, the safety analysis cohort will be larger than the mITT cohort, and the CI will be more precise than this.

6. GENERAL STATISTICAL CONSIDERATIONS

6.1. General Principles

Tabulations will be used extensively to summarize the data. All continuous variables will be summarized using the following descriptive statistics: n (sample size), mean, standard deviation, median, maximum and minimum. The frequency and percentages (based on the sample size) of observed levels will be reported for all categorical measures. Wilson confidence intervals for binomial proportions and differences in binomial proportions will be computed for efficacy variables. Clopper-Pearson confidence intervals for binomial proportions and differences in binomial proportions will be computed for safety variables. In general, all data will be listed by treatment group and/or subject, and when appropriate by visit number within subject.

All summary tables will be structured with a column/sub-table for each treatment group (5% Monolaurin Vaginal Gel, Placebo Gel, and All Subjects). The total population size relevant to that table/column if applicable, including any missing observations will be displayed in the tables.

Note that in the data listings, Subject ID is the unique subject identifier, not the Study ID used on study and dates will not be included, only Study Day. Study Day 1 will be the day of the first dose of treatment.

6.1.1. Pseudo Code

The following SAS® peudo code will be used to calculate the following:

Fisher's Exact test:

```
proc freq;
  Table treatment*analysis_variable / exact;
   ods output FishersExact=outputdsn1;
run;
```

95% Wilson CI for proportions/percents:

```
Proc freq;
  Table treatment*analysisvariable / binomial(wilson);
   ods output binomialcls=outputdsn2;
Run;
```

95% Wilson CI for difference in proportions (produces Newcombe CI):

```
Proc freq;
  Table treatment*analysisvariable /  riskdiff(cl=Wilson);
  Exact Riskdiff;
   ods output pdiffcls=outputdsn3;
Run;
```

95% Clopper-Pearson CI for proportions/percents:

```
Proc freq;
  Table treatment*analysisvariable / binomial(clopperpearson);
   ods output binomialcls=outputdsn2;
Run;
```

95% Exact CI for difference in proportions:

```
Proc freq;
  Table treatment*analysisvariable /  riskdiff(cl=Exact);
  Exact Riskdiff;
   ods output pdiffcls=outputdsn3;
Run;
```

6.2. Timing of Analyses

The fully blinded interim analysis will be performed when 80 subjects have been enrolled and have available baseline test results for Nugent score, HIV, Chlamydia, and gonorrhea.

The final analysis will be performed after database lock when all subjects have been followed through Visit 3, the final study visit, at Day 28 (Window: Days 22-30).

6.3. Analysis Populations

A tabular listing of all subjects, visits, and observations excluded from the efficacy analysis will be provided in the CSR **(Listing 4).** Five analysis populations will be used in the analyses, the Intent-to-Treat (ITT), Safety, mITT, Evaluable, and Per Protocol (PP). A listing of subjects whose assigned treatment group does not match their randomized treatment group will be provided in **Listing 20.**

6.3.1. Intent-to-Treat Analysis (ITT) Population

The ITT population includes all randomized subjects, regardless of whether or not they received study treatment. In the unlikely event of an error in randomization or study product administration (i.e., incorrect product), subjects will be grouped by their intended randomized assignment.

6.3.2. Safety Analysis Population

The safety population includes all randomized subjects who received at least one dose of study treatment. In the unlikely event of an error in randomization or study product administration (i.e., incorrect product), subjects will be grouped by the product they actually received.

6.3.3. Modified Intention-to-Treat (mITT) Population

The mITT population includes all randomized subjects who met all inclusion/exclusion criteria, excluding those who have a Nugent score <4 at Visit 1 or a positive Visit 1 HIV, Chlamydia, or Neisseria gonorrhoeae test. A review of medical history and concomitant medications will be performed to identify any other infections that may interfere with the efficacy assessment. Subjects with these identified infections will be excluded from the mITT population. In the unlikely event of an error in randomization or study product administration (i.e., incorrect product), subjects will be grouped by their intended randomized assignment. The mITT population will be used as the primary analysis population for the primary efficacy endpoint test of 5% Monolaurin Vaginal Gel to Vehicle Placebo Gel.

6.3.4. Evaluable Population

The Evaluable population includes all subjects in the mITT population who received study treatment and returned for at least one post-baseline visit that includes an assessment of efficacy.

In the unlikely event of an error in randomization or study product administration (i.e., incorrect product), subjects will be grouped by the product they actually received.

6.3.5. Per Protocol Population

The Per Protocol (PP) population for all endpoints measured at Visit 2 includes all randomized subjects who met all inclusion/exclusion criteria, did not have sexual intercourse including receptive oral sex or insertion of substances or objects intravaginally between Visit 1 and Visit 2, complied with the assigned study treatment, returned to the study site for the Test of Cure visit within the specified window (Visit 2 Study Day 8 relative to the first day of treatment [Window: Days 8-15]), or discontinued study product early due to lack of treatment effect or received vaginosis or systemic antimicrobial therapy other than study drug before Visit 2. Subjects with

Visit 1 test results including a grade 3 laboratory abnormality, a positive Visit 1 HIV, Chlamydia, or *Neisseria gonorrhoeae* test, are found to have a PAP result consistent with HSIL, AGUS, or CIN2 or greater, or a Visit 1 Nugent score < 4 will be excluded from the PP population. A review of medical history and concomitant medications will be performed to identify any other infections that may interfere with the efficacy assessment. Subjects with these identified infections will be excluded from the PP population.

The PP population for all endpoints measured at Visit 3 includes all randomized subjects who met all inclusion/exclusion criteria, did not have sexual intercourse including receptive oral sex or insertion of substances or objects intravaginally between Visit 1 and Visit 2 or 48 hours before Visit 3, complied with the assigned study treatment, returned to the study site for Visit 2 and Visit 3 within the specified windows (Visit 2 Study Day 8 relative to the first day of treatment [Window: Days 8-15]), Visit 3 Study Day 28 relative to the first day of treatment [Window: Days 22-31]), or discontinued study product early due to lack of treatment effect or received vaginosis or systemic antimicrobial therapy other than study drug between Visits 1 and 3. Subjects with Visit 1 test results including a grade 3 laboratory abnormality, a positive Visit 1 HIV, Chlamydia, or Neisseria gonorrhoeae test, are found to have a PAP result consistent with HSIL, AGUS, or CIN2 or greater, or a Visit 1 Nugent score < 4 will be excluded from the PP population. A review of medical history and concomitant medications will be performed to identify any other infections that may interfere with the efficacy assessment. Subjects with these identified infections will be excluded from the PP population.

See Section 9.2 for measurements of compliance.

In the unlikely event of an error in randomization or study product administration (i.e., incorrect product), subjects will be grouped by the product they actually received.

6.4. Covariates and Subgroups

Clinical and therapeutic cure will be analyzed by subgroup. Subgroups will be defined by first time or recurrent BV infection as defined in Section 3.3. Additionally, subjects with *Candida spp.* identified at screening will be analyzed to evaluate quantitative changes of *Candida spp*. See Section 8.3 for more details on the exploratory efficacy analyses.

6.5. Missing Data

Subjects who are non-evaluable for clinical cure at the TOC visit will be excluded from the PP population. Non-evaluable therapeutic cures will be handled similarly for the PP population. For the mITT, ITT, and Evaluable analysis populations, the cure status of subjects whose status cannot be determined at the TOC visit for any reason will be considered 'not cured' or failure for all cure-related endpoints. The cure status of subjects whose status cannot be determined at Visit 3 for any reason will be imputed using Last Observation Carried Forward (LOCF). Note this differs from what is stated in Section 11.3 of the protocol. See Section 12 for more details.

A sensitivity analysis will be performed to assess the impact of missing results on the primary efficacy outcome. The primary analysis will be repeated in which subjects in the 5% Monolaurin Vaginal Gel arm who are not evaluable for clinical cure will have their cure status imputed as a clinical failure and subjects in the placebo arm who are not evaluable for clinical cure will have their cure status imputed as a clinical cure. See **Table 56**.

6.6. Interim Analyses and Data Monitoring

The study is monitored to determine if any of the safety halting rules are met.

Enrollment will be halted for DSMB review/recommendation if any of the following are reported:

1. One or more subjects experiences a treatment-related SAE.
2. One or more subjects experiences vulvar and/or vaginal ulceration, abscess, or necrosis associated with study product administration.
3. Two or more subjects experience a treatment-related severe (Grade 3) unsolicited adverse event.
4. Three or more subjects who received at least one treatment dose experience the same severe (Grade 3) solicited AE as evaluated by a licensed clinician.
5. Three or more subjects who received at least one treatment dose experience a severe (Grade 3) study-related laboratory abnormality in the same laboratory parameter.
6. An overall pattern of symptomatic, clinical, or laboratory events that the DMID, Medical Monitor, or DSMB consider associated with study product and that may collectively represent a serious potential concern for safety.

If any of the halting rules are met, the study will not continue with the remaining enrollments or study treatments without a review by and recommendation from the DSMB to proceed. A summary of halting rules is provided in **Table 85.**

The DSMB met after 30 subjects received at least one dose of study drug and completed Visit 2. The DSMB will also review study progress and subject safety data at least annually during the course of the study and will hold a study closeout meeting 6 to 8 months after database lock, as defined in the DSMB Charter. The DSMB may also meet for an ad hoc review in response to a safety issue.

Additionally, a single, fully blinded interim analysis took place to reassess the adequacy of the sample size based on subjects meeting eligibility for the mITT population. After eighty subjects were enrolled and had available baseline test results for Nugent score, HIV, chlamydia and gonorrhea, the fraction of subjects enrolled to date who were eligible for the mITT cohort was estimated. Based on this calculation, the enrollment target was not increased from 120 subjects. The study sponsor and investigators had access to the data shared in fully blinded reports issued to the DSMB. The tables and figures for the interim analysis are contained in the DSMB Interim Analysis Safety Summary Report.

6.7. Multicenter Studies

Safety and efficacy data will be pooled across all clinical sites. Center effects are not anticipated because treatment is self-administered, the sites are using standardized procedures for assessment of unsolicited adverse events, and the study relies on a central laboratory for Gram stain Nugent scoring. See Sections 8.3 and 9.3 for more details.

6.8. Multiple Comparisons/Multiplicity

No adjustments for multiplicity are planned.

7. STUDY SUBJECTS

7.1. Subject Disposition

The disposition of subjects in the study will be tabulated by randomized treatment group and all subjects. **Table 2** shows the number of subjects who are screen failures and the number of subjects that met each inclusion/exclusion criterion. **Table 3** summarizes the ITT and mITT population eligibilities by randomized treatment group and reasons excluded and **Table 4** summarizes the safety, Evaluable and PP analysis population eligibilities by actual treatment group and reasons excluded. Subjects will be included in the count for a particular reason for Exclusion if they met that criterion. As subjects may meet more than one criterion for exclusion, the "Excluded from…" counts may be less than the sum of the individual reason counts. A listing of the subjects excluded from each of the analysis populations and the reasons for exclusion will be provided (**Listing 4**). The number of enrolled subjects in the study completing study milestones will be tabulated separately by randomized treatment group. **Table 5** shows the total number of subjects enrolled, randomized, treated, complying with treatment, completing Visits 2, and 3, and completing Visits 2 and 3 and in the PP population by randomized treatment group. A listing of subjects who completed the study, terminated early from study, or discontinued treatment and the reason for early termination or treatment discontinuation is included in **Listing 1**.

Figure 1 is a flowchart showing the disposition of study subjects in the primary efficacy analysis, adapted from the CONSORT statement. It shows the number of subjects eligible, enrolled and randomized, lost to follow-up, and analyzed for the primary efficacy analysis, overall and by treatment group.

7.2. Protocol Deviations

A summary of subject-specific protocol deviations will be presented by the deviation category, the type of deviation, and randomized treatment group for all enrolled subjects (**Table 6**). All subject-specific protocol deviations and non-subject-specific protocol deviations will be included in Appendix III as data listings (**Listings 2** and **3**, respectively).

8. EFFICACY EVALUATION

All efficacy variables will be listed by subject and summarized by analysis population and treatment group. Continuous efficacy variables will use some or all of the following: N, Mean, Standard Deviation, Median, Minimum and Maximum, whereas Number and Percent will summarize categorical efficacy variables. Confidence intervals for binomial proportions and difference in binomial proportions will be computed using the Wilson confidence limits.

8.1. Primary Efficacy Analysis

The primary efficacy endpoint is the proportion of subjects with clinical cure in each study arm at Visit 2 (Day 8-15), TOC.

A test of hypothesis comparing the proportion of subjects who achieve clinical cure at the Test of Cure Visit, Visit 2 (Day 8-15), will be conducted in the mITT population using the randomized treatment, and repeated as a secondary analysis using the actual treatment received in the PP population and the Evaluable analysis population, and using the randomized treatment in the Intent-to-Treat population. The null hypothesis for each comparison is that there is no difference in proportions of clinical cure between treatment groups, with a two-sided alternative that considers the possibility of a difference in either direction. Fisher's exact test at the 5% two-sided level of significance will be used without adjustment for multiplicity. The number of subjects, the proportion of subjects who achieved clinical cure (clinical cure rate), and the 95% Wilson confidence interval for the proportion of subjects achieving clinical cure will be presented for each analysis population and treatment group. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Wilson confidence intervals will be presented. See **Table 29**. See Section 6.1 for pseudocode to fit the above analyses.

A subject listing of individual Amsel criteria will be provided in **Listing 22**. A summary of Amsel criteria is provided for subjects by visit and site in **Table 33**. The number of Amsel criteria present (0,1,2,3,4), pH (> 4.5, ≤4.5), Clue cells (≥20%, < 20%), Amine ("whiff") test on KOH wet mount (Positive, Negative), and discharge (yes/no) will be summarized. A summary of Amsel criteria is provided for subjects by visit and treatment group for each analysis population in **Tables 34-37**. Individual efficacy response data is presented in **Listing 10**. Reasons for clinical failure are provided in **Listing 24**.

8.2. Secondary Efficacy Analyses

Secondary efficacy analyses will be performed in the mITT, ITT, Evaluable and PP populations. The mITT and ITT populations will be summarized by randomized treatment and the Evaluable and PP populations will be summarized by actual treatment received.

Table 30 presents the proportion of subjects with clinical cure in each treatment group at Visit 3 (Day 22-31). The number of subjects, the proportion of subjects who achieved clinical cure (clinical cure rate), and the 95% Wilson confidence interval for the proportion of subjects achieving clinical cure will be presented for each analysis population and treatment group. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Wilson confidence intervals will be presented.

Tables 31 and 32 present the proportion of subjects with therapeutic cure in each treatment group at Test of Cure Visit, Visit 2 (Day 8-15) and at Visit 3 (Day 22-31), respectively. The number of subjects, the proportion of subjects who achieved therapeutic cure (therapeutic cure rate), and the 95% Wilson confidence interval for the proportion of subjects achieving therapeutic cure will be presented for each analysis population, treatment group, and study visit. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Wilson confidence intervals will be presented.

Tables 38-41 presents the number and proportion of subjects with Nugent scores falling in negative BV (3 or less), intermediate (4-6), and BV (7-10) range by analysis population, study visit, and site. The 95% Wilson confidence intervals for the proportion of subjects falling in each category will also be presented. **Tables 42-43** presents the proportion of subjects with Nugent score of 3 or less (negative for BV), 4-6 (intermediate), and 7-10 (positive for BV) in each treatment group at Visit 1, at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31). The number and proportion of subjects with Nugent scores falling in negative, intermediate, and BV range is presented by analysis population, study visit, and treatment group. The 95% Wilson confidence intervals will also be presented. Mean Nugent scores will also be presented by analysis population, study visit, and treatment group in **Table 44.** A subject listing of Nugent scores and bacterial morphotypes will be presented in **Listing 23**. Raw Nugent scores are displayed graphically by visit, treatment group, and analysis population in **Figures 2-5**. Categorical and Continuous Nugent Score characteristics are presented by study visit, clinical cure status, and treatment group for subjects in the ITT population in **Tables 45 and 46**. See Section 6.1 for pseudocode to use in calculating the 95% CIs.

8.3. Exploratory Efficacy Analyses

Exploratory efficacy analyses will be performed in the mITT, ITT, Evaluable and PP populations. The mITT and ITT populations will be summarized by randomized treatment and the Evaluable and PP populations will be summarized by actual treatment received.

The first exploratory efficacy endpoint is the proportion of subjects with clinical cure in each treatment group by subgroup (first time or recurrent infection) at the Test of Cure Visit, Visit 2 (Day 8-15) and at Visit 3 (Day 22-31). The number of subjects, the proportion of subjects who achieved clinical cure (clinical cure rate), and the 95% Wilson confidence interval for the proportion of subjects achieving clinical cure will be presented for each analysis population, treatment group, and infection type (first time or recurrent). In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Wilson confidence intervals will be presented. See **Tables 47-50**. A listing of subjects BV infection status (first time or recurrent) will be provided in **Listing 25.** See Section 6.1 for pseudocode to use in calculating the 95% CIs.

The second exploratory efficacy endpoint is the proportion of subjects with therapeutic cure in each study arm by subgroup (first time or recurrent infection) at the Test of Cure Visit, Visit 2 (Day 8-15) and at Visit 3 (Day 22-31). The number of subjects, the proportion of subjects who achieved therapeutic cure (therapeutic cure rate), and the 95% Wilson confidence interval for the proportion of subjects achieving therapeutic cure will be presented for each analysis population, treatment group, and infection type (first time or recurrent). In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Wilson confidence intervals will be presented. See **Tables 51-54**.

The third exploratory efficacy endpoint is the mean count of *Lactobacillus spp.*, *Gardnerella spp.*, and *Mobiluncus spp.*, respectively, in each treatment group at Visit 1, at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31). Mean count and standard deviation of each specimen type will be presented by study visit, analysis population, and treatment group. Additionally, mean change from baseline and corresponding standard deviation will be presented for Visit 2 and Visit 3. See **Tables 57-60**.

The fourth exploratory efficacy endpoint is the mean fungal colony count of *Candida spp*. in vaginal secretions in each study arm at baseline, at Visit 2 (Day 8-15) and at Visit 3 (Day 22-31). Mean count and standard deviation will be presented by study visit, analysis population, and treatment group for subjects with *Candida spp*. identified by either positive culture counts or presence of budding yeast organisms at screening. Additionally, mean change from baseline and corresponding standard deviation will be presented for Visit 2 and Visit 3. See **Table 61**.

9. SAFETY EVALUATION

9.1. Demographic and Other Baseline Characteristics

Ethnicity and race will be summarized by site in **Table 7** and by randomized treatment group in **Table 9**. Ethnicity is categorized as Hispanic or Latino, or Not Hispanic or Latino. Race is categorized as American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, Black or African American, White, Multi-Racial or Unknown In accordance with NIH reporting policy. Subjects may self-designate as belonging to more than one race (Multi-Racial) or may refuse to identify a race (Unknown), the latter reflected in the Case Report Form (CRF) as "No" to each racial option. Age and episodes of BV (including current episode) in the previous 12 months (from the sexual history questionnaire) will be summarized by site in **Table 8** and by randomized treatment in **Table 10**.

Baseline sexual history will be presented by site in **Table 11** and by randomized treatment group in **Table 12** for all enrolled subjects**.**

Baseline clinical assessment of BV will be presented by sign/symptom, maximum severity, and site for subjects in the Safety population in **Table 13.** Baseline clinical assessment of BV will be presented by sign/symptom, maximum severity, and actual treatment group for subjects in the Safety population in **Table 14**.

Individual subject listings will be presented for all demographics (**Listing 5**); sexual history (**Listings 7-8**).

9.1.1. Concurrent Illnesses and Medical Conditions

All current illnesses and past pre-existing medical conditions will be MedDRA® coded using MedDRA® dictionary version 20.1 or higher. Summaries of subjects' pre-existing medical conditions will be presented by randomized treatment group overall and by each site (**Tables 15-18).**

Individual subject listings will be presented for all medical conditions (**Listing 6).**

9.2. Measurements of Treatment Compliance

All subjects are to receive a total of six doses of study product (twice daily for three consecutive days). The first dose is administered in clinic and the remaining 5 doses will be administered by the subject at home. Subjects record the timing of all remaining doses on a memory aid, which is reviewed with clinic staff at Visit 2. Compliance is assessed by the study coordinator's count of used/unused applicators in each returned subject kit. If a kit is not returned, compliance will be

assessed by the subject's self-report on the memory aid. If an incomplete kit is returned, the subject's self-report will be used in conjunction with the count of used/unused applicators to determine subject compliance. In addition to the count of used/unused applicators, the timing of dosing will be considered. Subjects are instructed to administer study product twice daily (morning and evening) with at least 8 hours between doses. If the subject received her first dose after 3 pm, she will be instructed to administer the next dose the following morning. A subject is compliant if she uses at least 5 of 6 doses and they were administered within 72 hours from the first dose, at least 8 hours apart, and if no more than 2 doses in a 24 hour period are taken.

If a subject is found to have a positive test for HIV, chlamydia or gonorrhea or a Grade 3 laboratory abnormality from Visit 1, she will be notified of the results, withdrawn from receiving further study product, but will be followed for safety and efficacy. All subjects who were randomized will be followed for safety and efficacy. If any subject experiences a severe AE related to the study product, further doses will be discontinued.

The dates of first treatment are presented for subjects in the Safety population by site in **Table 19** and actual treatment group in **Table 20**. The number of subjects not compliant with study treatment will be presented by treatment group as part of the subject disposition table (**Table 5**). The number of doses administered as scheduled and out of window is summarized for subjects in the Safety population by site in **Table 21** and by actual treatment in **Table 23**.

Administration schedule is categorized as either "as scheduled" or "out of window." As scheduled is defined as twice daily (morning and evening) with at least 8 hours between doses as reported on the memory aid. **Tables 22 and 24** show the number and percentage of subjects who received the dose as scheduled, received the dose out of window, or missed the dose, for each of the 6 doses, by site and actual treatment group, respectively for subjects in the Safety population.

Table 25 displays product administration position by site and number of doses administered and **Table 27** displays product administration position by actual treatment group and number of doses administered for the subjects in the Safety population. Product administration position is categorized as either "Recumbent" or "Not Recumbent." A subject contributes to the "Recumbent" rows if they administer each of the specified number of doses in the recumbent position. If a subject was not recumbent for at least one of the specified number of doses or is missing product administration position, they will appear in the "Not Recumbent" rows. **Tables 26 and 28** show the number and percentage of subjects who received the dose and remained in the recumbent position, received the dose and did not remain in the recumbent position, or did not enter the position they were in for the dose, for each of the 6 doses, by site and actual treatment group, respectively for subjects in the Safety population.

Individual subject listings of treatment compliance assessment will be presented (**Listing 9**).

9.3. Adverse Events

When calculating the incidence of adverse events (i.e., on a per subject basis), each subject will only be counted once and any repetitions of adverse events within a subject will be ignored; the denominator will be the total safety population size and population within actual treatment group. All adverse events reported will be included in the summaries and analyses. All analyses in Section 9.3 will be performed in the safety analysis population using the actual treatment received.

9.3.1. Solicited Events and Symptoms

Solicited urogenital symptoms were collected before study product administration, and then daily for 5 days and graded on a scale of 0 (absent), 1 (mild), 2 (moderate) and 3 (severe). Urogenital symptoms include: vaginal odor, vaginal pain, vaginal tenderness, vulvar/vaginal itching, vaginal dryness, vaginal discharge, and vulvar inflammation. Any symptom that is present at the time that the subject is screened should be considered as baseline and not reported as a solicited urogenital AE. However, if it deteriorates at any time during the study, it will be recorded as a solicited urogenital AE. If a symptom is reported that was not present at baseline, it too will be recorded as a solicited urogenital AE. Treatment emergent solicited urogenital adverse events will be identified by comparing the severity of the baseline solicited urogenital symptoms with the severity of the post-baseline solicited urogenital symptoms. If the severity increases post-baseline or the symptoms appears post-baseline when it was 'None' at baseline, then the symptom will be considered to be treatment-emergent.

The first primary safety endpoint is the number of subjects reporting treatment-emergent solicited urogenital AEs following the first dose of the study product through Visit 2 (Day 8-15).

The number and percent of subjects reporting at least one treatment-emergent solicited urogenital adverse event will be summarized for each solicited adverse event and any solicited adverse event along with the 95% Clopper-Pearson CI and presented in **Table 62**. **Table 63** will present the proportion of subjects experiencing any solicited urogenital event and each specific urogential solicited event, along with the 95% Clopper-Pearson CI of the proportion, the difference in the proportions of subjects experiencing a solicited event between 5% Monolaurin Vaginal Gel and Placebo Gel, the 95% Exact CI of the difference and the p-value for a Fisher's exact test. A Fisher's exact test will be performed to test for the difference in the proportion of subjects reporting a treatment emergent solicited urogenital adverse event. The null hypothesis is that there is no difference in proportions of subjects reporting solicited urogenital AEs between treatment groups, with a two-sided alternative which considers the possibility of a difference in either direction. Section 6.1 provides pseudo SAS code to use for the analyses.

For each treatment-emergent solicited urogenital adverse event and any solicited adverse events, the maximum severity over 5 days after the first dose will be summarized for the Safety population. The number and percentage of subjects reporting each treatment-emergent solicited adverse event will be summarized by the maximum severity and actual treatment group along with the 95% Clopper-Pearson CIs. For each event the denominator is the number of subjects with non-missing data for the specific solicited urogenital adverse event. See **Table 64** and **Figure 6**.

Table 64 and **Figure 7** will summarize any reported solicited symptom (treatment-emergent and non treatment-emergent) and each solicited symptom by maximum severity over 5 days after the first dose along with the 95% Clopper-Pearson CI for the Safety population. The number and percentage of subjects reporting each symptom will be summarized by the maximum severity and actual treatment group. For each event, the denominator is the number of subjects with non-missing data for the specific symptom. Maximum severity of solicited symptoms is displayed by study day and treatment group in **Figure 8.**

The number of subjects reporting a solicited symptom will be summarized for each day for all subjects and separately for each treatment group **(Tables 66-68**) and graphically in a bar chart (**Figure 7**).

Solicited symptoms by subject will be presented in **Listing 12.**

9.3.2. Unsolicited Adverse Events

The first secondary safety endpoint is the number of subjects experiencing non-laboratory, non-solicited AEs following the first dose of the study product through Visit 3 (Day 22-31). Laboratory events are defined as WBC count, hemoglobin, platelets, neutrophil count, creatinine, AST (SGOT), ALT (SGPT), and total bilirubin, and glucose (random). Events involving laboratory parameters that are not collected as part of the protocol will be counted as non-laboratory, non-solicited adverse events. The number of subjects, the proportion of subjects who experienced non-laboratory, non-solicited AEs following the first dose of the study product through Visit 3 (Day 22-31), and the 95% Clopper-Pearson CIs for the proportion of subjects who experienced non-laboratory, non-solicited AEs through Visit 3 will be presented for the safety population and actual treatment group. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Exact CIs will be presented in **Table 69**.

The proportion of subjects reporting at least one non-laboratory, non-solicited adverse event will be summarized by MedDRA® system organ class and preferred term for all subjects and each actual treatment group. Denominators for percentages are the number of subjects who received the study product being summarized. A 95% Clopper-Pearson CI will be presented for each MedDRA® system organ class and preferred term (**Table 70**). Adverse events by subject will be presented in **Listing 13**.

The following summaries for non-solicited, non-laboratory adverse events will be presented by MedDRA® system organ class, preferred term, and treatment group:

- Subject level summary of severity and relationship to study product (**Tables 71-73**);
- Subject level summary of severity by related AEs **(Tables 74-76)**;
- Subject incidence of adverse events over time (**Tables 77-79**). AEs will be categorized as occurring from Visit 1 through the TOC, Visit 2, from the TOC, Visit 2 through Visit 3, and anytime during the study;
- Total frequency of adverse events over time (**Tables 80-82)**. AEs will be categorized as occurring from Visit 1 through the TOC, Visit 2, from the TOC, Visit 2 through Visit 3, and anytime during the study.
- Subject listing of non-serious adverse events of moderate or greater severity (**Table 88)**;
- Bar chart of total frequency of adverse events by severity and MedDRA® system organ class (**Figure 9**);
- Bar chart of subject incidence of adverse events by severity and MedDRA® system organ class (**Figure 10**);

- Bar chart of total frequency of adverse events by severity and treatment group (**Figure 11**);
- Bar chart of subject incidence of adverse events by severity and treatment group (**Figure 12**):
- Bar chart of total frequency of adverse events by relationship to study product and MedDRA® system organ class (**Figure 13**);
- Bar chart of subject incidence of adverse events by relationship to study product and MedDRA® system organ class (**Figure 14**):
- Bar chart of total frequency of adverse events by relationship to study product (**Figure 15**).
- Bar chart of subject incidence of adverse events by relationship to study product (**Figure 16**).
- The number of adverse events occurring in 5% of subjects in any treatment group will be presented by MedDRA® system organ class, preferred term, and treatment group in **Table 83.**
- The number of subjects reporting adverse events occurring in 5% of subjects in any treatment group presented by MedDRA® system organ class, preferred term and treatment group in **Table 84.**

9.4. Deaths, Serious Adverse Events and other Significant Adverse Events

The second primary safety outcome is the number of subjects reporting serious adverse events (SAEs) considered product related following the first dose of the study product through Visit 3 (Day 22-31). The number of subjects, the proportion of subjects who experienced product-related SAEs, and the 95% Clopper-Pearson confidence interval for the proportion of subjects who experienced product-related SAEs will be presented for each analysis population, treatment group, and study visit. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Exact confidence intervals will be presented. The proportion of subjects in each treatment group who experience product-related SAEs following the first dose of the study product through Visit 3 (Day 22-31) will be tested using a Fisher's exact test at the 5% two-sided level of significance level without adjustment for multiplicity in the safety analysis population (**Table 86**). See Section 6.1 for pseudocode for calculating p-values and CIs.

A listing of deaths and serious adverse events will be presented, including Subject ID, treatment group, Adverse Event Description, Study Day the Event became Serious, Reason Reported as an SAE, Relationship to Treatment, Alternate Etiology if not Related, Outcome, and Duration of Event in days (**Table 87**).

9.5. Pregnancies

For any subjects in the Safety population who became pregnant during the study, every attempt will be made to follow these subjects to completion of pregnancy to document the outcome,

including information regarding any complications with pregnancy and/or delivery. A listing of the total pregnancies, number of live births, and number of spontaneous abortions, elective abortions or still births will be presented (**Listings 26-29**).

9.6. Clinical Laboratory Evaluations

Safety clinical laboratory data includes: WBC count, hemoglobin, platelets, neutrophil count, creatinine, AST (SGOT), ALT (SGPT), total bilirubin, and glucose (random). These hematology and chemistry parameters will be collected at Visit 1 and Visit 2. Laboratory abnormalities that were stable at Visit 2 will not be repeated at Visit 3. Laboratory abnormalities that occurred between Visit 1 and Visit 2 or worsened at Visit 2 will be repeated at Visit 3. A laboratory abnormality is considered an adverse event if there is a worsening of the laboratory value at Visit 2 from the baseline value and it increases in laboratory toxicity grading from the baseline toxicity grading. For laboratory abnormalities repeated at Visit 3, if there is a worsening of the laboratory value at Visit 3 from the Visit 2 value and it increases in laboratory toxicity grading, it is considered an additional adverse event. Toxicity grading can be found in Appendix B of the protocol. All analyses in Section 9.6 will be performed in the safety analysis population.

The second secondary safety endpoint is number of subjects experiencing laboratory AEs following the first dose of the study product through Visit 2 (Day 8-15). The number of subjects reporting at least one laboratory measurement at the visit, the proportion of subjects who experienced laboratory AEs, and the 95% Clopper-Pearson confidence interval for the proportion of subjects who experienced laboratory AEs will be presented by treatment group. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Exact confidence intervals will be presented in **Table 89.**

The proportion of subjects with laboratory results meeting toxicity grading criteria will be presented for each parameter in **Tables 90 and 92** by severity, study day and treatment group. The proportion of subjects with laboratory results related to study product meeting toxicity grading criteria will be presented for each parameter in **Tables 91 and 93** by severity, study day and treatment group. Descriptive statistics including mean, standard deviation, median, mean change from baseline and associated standard deviation by study day, for each laboratory parameter, will be summarized in **Table 94** by treatment group. Laboratory values will be presented by parameter, severity and visit in **Figures 17-19.** Mean changes in laboratory values will be presented in **Figures 20-28**.

The denominator for proportions is the number of subjects with each specific laboratory value at the visit.

Laboratory abnormalities are those that meet toxicity grading. When the site-specific laboratory normal range is available, if there is a discrepancy between the laboratory value in Appendix B of the protocol and the site-specific laboratory normal range, the value in Appendix B of the protocol will take precedence in determining Grade 1 adverse events. Otherwise, all laboratory tests will be graded per the toxicity table in Appendix B of the protocol. Unscheduled or repeated follow-up laboratory tests for medical or safety reasons will be listed, but excluded from tabular and graphical summaries.

A listing of laboratory tests with toxicity Grade >=1 will also be provided. If a subject meets this criterion, the listing will provide data from all visits for the particular lab test that meet the criteria

so that the time course for the particular lab parameter can be observed. See **Tables 95-96.** A listing of all clinical laboratory values will be generated in **Listings 14 and 15.**

9.7. Physical Evaluations

A physical exam including a gynecological exam will be performed at Visit 1. A gynecological exam and a targeted physical exam based on symptoms will be performed at Visit 2 and Visit 3. The change in physical examination data from Day 1 will be summarized for each visit by treatment group for subjects in the Safety population. The following body systems will be assessed: Abdomen, Cardiovascular/Heart Extremities, General Appearance, Head, Eyes, Ears, Nose, and Throat (HEENT), Lymph nodes, Musculoskeletal, Neck, Neurological, Pulmonary/Chest, and Skin (**Listing 16**). Findings from the pelvic exam which includes signs of inflammation in the cervix, vagina, and vulva, as well as vaginal discharge, will be presented in **Listing 17**. Other gynecological test results including saline wet mount, Trichomonas, and KOH wet mount will be presented in **Listing 18.** Clinical assessment of BV symptoms will be presented in **Listing 11**.

9.8. Concomitant Medications

Summaries of medications that were started prior to dosing and continuing at the time of dosing as well as medications that were starting during dosing or during follow up will be presented by WHO Drug Anatomical codes (ATC) level 1 and level 2 and actual treatment group for subjects in the Safety population (**Tables 97-100**).

Individual subject listings will be presented for all concomitant medications (**Listing 19**).

10. OTHER ANALYSES

During the course of the study, the product administration form was updated to capture whether or not the subject remained in a recumbent position for 5 minutes after administration of study treatment. The primary efficacy analysis will be repeated as an exploratory, supplementary analysis of the primary outcome in **Table 55.** This analysis will be performed in the PP population, with the additional stipulation that the subject remain in the recumbent position for 5 of 6 doses to be considered compliant with study product. The number of subjects, the proportion of subjects who achieved clinical cure, and the 95% Wilson confidence interval for the proportion of subjects achieving clinical cure will be presented for each analysis population and treatment group. In addition, the difference in proportions between the 5% Monolaurin Vaginal Gel arm and the Placebo gel arm and 95% Wilson confidence intervals will be presented. A listing of subjects' product administration position for each dose is provided in **Listing 21.**

11. REPORTING CONVENTIONS

P-values $\geq$0.001 and $\leq$0.999 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001"; p-values greater than 0.999 will be reported as "> 0.999". The mean, median, standard deviation, and any other statistics other than quantiles, will be reported to one decimal place greater than the original data. Quantiles other than the median will use the same number of decimal places as the original data. Proportions will be presented as two decimal

places; values <0.01 will be presented as "<0.01". Percentages will be reported to the nearest whole number; values < 1% will be presented as "<1". Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

12. SUMMARY OF CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

Protocol version 5.0 (August 31, 2016) changed the criterion requiring all four Amsel criteria for inclusion to any 3 of 4 Amsel criteria; changed the allowable interval between a previous vaginal/cervical/pelvic infection or episode of BV from 60 days prior to enrollment to 14 days and removed the prohibition of systemic, vaginal or perineal immunosuppressant or anti-inflammatory medications within 14 days of treatment; and changed the procedure for review of the Gram stain when two independent reviewers have different Nugent scores. Protocol version 6.0 (November 29, 2016) included the addition of a clinical site, Duke University, and clarification of temperature range for specimen storage. Protocol version 7.0 (May 11, 2017) removed the criterion requiring subjects over age 21 to report a normal PAP smear within the past 3 years, revised the exclusion for HPV and cervical or vaginal dysplasia to exclude only HSIL, AGUS, or CIN2 or higher, changed exclusions for previous self-treatment for yeast vaginitis and systemic, vaginal, or perineal antibiotics from 14 days to 7 days, and removed exclusion for 6 or more episodes of vaginitis within the past year, clarified that subjects found to have HSIL or AGUS at visit 1 will have study treatment discontinued and subjects found to have HSIL, AGUS, or CIN2 or higher at visit 1 will be excluded from the PP analysis population, and corrected protocol deviation plan such that sexual intercourse 48 hours prior to Visit 3 will not exclude subjects from the Per-Protocol data analysis population definition. Protocol version 8.0 (May 23, 2017) removed exclusion for diabetes.

Protocol Section 11.3 states Last Observation Carried Forward (LOCF) will be used as a sensitivity analysis. Section 6.5 of this analysis plan clarifies that LOCF will be used to impute the cure status of subjects whose status cannot be determined at Visit 3 for any reason. Subjects whose status cannot be determined at the TOC visit, will be considered 'not cured' for all cure-related endpoints.

13. TECHNICAL DETAILS

SAS version 9.4 or above will be used to generate all tables, figures and listings.

14. REFERENCES

1. Workowski KA, Berman S. Sexually transmitted diseases treatment guidelines, 2010. MMWR Recommendations and reports: Morbidity and mortality weekly report Recommendations andreports / Centers for Disease Control **2010**; 59:1-110
2. ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists, Number 72, May 2006: Vaginitis. Obstetrics and gynecology **2006**; 107:1195-206.

3. McCormack WM, Jr., Zinner SH, McCormack WM. The incidence of genitourinary infections in a cohort of healthy women. Sexually transmitted diseases **1994**; 21:63-4.
4. Wilson J. Managing recurrent bacterial vaginosis. Sex Transm Infect **2004**; 80:8-11.
5. Pechous R, Ledala N, Wilkinson BJ, Jayaswal RK. Regulation of the expression of cell wall stress stimulon member gene msrA1 in methicillin-susceptible or -resistant Staphylococcus aureus. Antimicrobial agents and chemotherapy **2004**; 48:3057-63.
6. Schlievert PM, Peterson ML. Glycerol monolaurate antibacterial activity in broth and biofilm cultures. PloS one **2012**; 7:e40350.

15. LISTING OF TABLES, FIGURES, AND LISTINGS

Table, figure, and listing shells are presented in Appendices I, II, and III.

16. APPENDICES

Appendix I: Table Mock-Ups

This document includes examples mock-ups of tables to present efficacy and safety data.

Sites that are activated after the SAP has been drafted will not appear in the table, figure, or listing shells, but will appear in the final CSR.

Instructional text is included in brackets [Instruction or Implementation Note:].

LIST OF TABLES

Section 14.1 Demographic Data

Table 2: Ineligibility Summary of Screen Failures

Inclusion/Exclusion Category	Inclusion/Exclusion Criterion	Number of Subjects*
Inclusion and Exclusion	Any criterion	x
Inclusion	Any inclusion criterion	x
	[inclusion criterion 1]	x
	[inclusion criterion 2]	x
	[inclusion criterion 3]	x
Exclusion	Any exclusion criterion	x
	[exclusion criterion 1]	x
	[exclusion criterion 2]	x
	[exclusion criterion 3]	x
Declined Enrollment	Any Reason	x
	Time commitment	x
	Concern of potential risks	x
	Number of procedures	x
	Unable to contact subject	x
	Other	x

Note: *More than one criterion may be marked per subject.

Table 3: Intent-to-Treat and Modified Intent-to-Treat Analysis Populations by Treatment Group

			5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
Analysis Population	**Eligibility Category**	**Reason Subjects Excluded**	**n**	**%**	**n**	**%**	**n**	**%**
Intent-to-Treat (ITT) Analysis Population	Eligible for ITT		x	x	x	x	x	x
Modified Intent-to-Treat (mITT) Analysis	Eligible for mITT		x	x	x	x	x	x
	Excluded from mITT	Any Reason	x	x	x	x	x	x
		Did not meet inclusion/exclusion criteria	x	x	x	x	x	x
		Nugent score < 4 from Visit 1	x	x	x	x	x	x
		Positive HIV, Chlamydia or Neisseria gonorrhoeae test	x	x	x	x	x	x
		Positive for other concomitant vulvovaginal infections	x	x	x	x	x	x

Note: N=number of enrolled subjects

Treatment group is the treatment group to which a subject was randomized.

Table 4: Safety, Evaluable, and Per-Protocol Analysis Populations by Treatment Group

			5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
Analysis Population	**Eligibility Category**	**Reason Subjects Excluded**	**n**	**%**	**n**	**%**	**n**	**%**
Safety Analysis Population	Eligible for Safety		x	x	x	x	x	x
	Excluded from Safety	Any Reason	x	x	x	x	x	x
		Did not Receive Study product	x	x	x	x	x	x
Evaluable Analysis Population	Eligible for Evaluable		x	x	x	x	x	x
	Excluded from Evaluable	Any Reason	x	x	x	x	x	x
		Did not meet inclusion/exclusion criteria	x	x	x	x	x	x
		Nugent score < 4 from Visit 1	x	x	x	x	x	x
		Positive Chlamydia or Neisseria gonorrhoeae test	x	x	x	x	x	x
		Positive for other concomitant vulvovaginal infections	x	x	x	x	x	x
		Did not receive study product	x	x	x	x	x	x
		Did not return for at least one post-baseline visit	x	x	x	x	x	x
Per-Protocol (PP) Analysis Population	Eligible for PP		x	x	x	x	x	x
	Excluded from PP	Any Reason	x	x	x	x	x	x
		Did not meet inclusion/exclusion criteria	x	x	x	x	x	x
		Had significant protocol deviations	x	x	x	x	x	x
		Received less than 5 doses of study product	x	x	x	x	x	x
		Did Not Return for Test of Cure visit	x	x	x	x	x	x
		Out of window Test of Cure visit	x	x	x	x	x	x
		Discontinued early due to lack of treatment effect	x	x	x	x	x	x
		Received systemic antimicrobial therapy other than study drug	x	x	x	x	x	x
		Grade 3 Lab Abnormality from Visit 1	x	x	x	x	x	x
		Positive HIV, Chlamydia or Neisseria gonorrhoeae test	x	x	x	x	x	x
		Positive for other concomitant vulvovaginal infections	x	x	x	x	x	x
		PAP result consistent with HSIL, AGUS, or CIN2 or greater	x	x	x	x	x	x
		Nugent score < 4 from Visit 1	x	x	x	x	x	x

Note: N=number of enrolled subjects; Treatment group is the actual treatment a subject received

Table 5: Subject Disposition by Treatment Group - All Enrolled Subjects

Subject Disposition	5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
	N	%	n	%	n	%
Screened	--	--	--	--	x	--
Enrolled/Randomized	x	100	x	100	x	100
Received Treatment	x	x	x	x	x	x
Complied with Treatment[a, b]	x	x	x	x	x	x
Completed Test of Cure Visit, Visit 2 (Study Day 8-15)	x	x	x	x	x	x
Completed Test of Cure Visit Per Protocol[c]	x	x	x	x	x	x
Completed Visit 3 (Study Day 22-31)	x	x	x	x	x	x
Completed Visit 3 Per Protocol[c]	x	x	x	x	x	x

Notes: N=Number of enrolled subjects

[a]Refer to Listing 1 (16.2.1) for reasons subjects discontinued or terminated early.

[b] Refer to Listing 9 (16.2.5) for treatment compliance.

[c]Refer to Listing 4 (16.2.3) for reasons subjects are excluded from the per protocol population.

Table 6: Distribution of Protocol Deviations by Category, Type, and Treatment Group - All Enrolled Subjects

Category	Deviation Type	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		# of Subj.	%	# of Dev.	# of Subj.	%	# of Dev.	# of Subj.	%	# of Dev.
Eligibility/enrollment	Any type	x	x	x	x	x	x	x	x	x
	Did not meet inclusion criterion	x	x	x	x	x	x	x	x	x
	Met exclusion criterion	x	x	x	x	x	x	x	x	x
	ICF not signed prior to study procedures	x	x	x	x	x	x	x	x	x
	Other	x	x	x	x	x	x	x	x	x
Treatment administration schedule	Any type	x	x	x	x	x	x	x	x	x
	Out of window visit	x	x	x	x	x	x	x	x	x
	Missed visit/visit not conducted	x	x	x	x	x	x	x	x	x
	Missed treatment administration	x	x	x	x	x	x	x	x	x
	Delayed treatment administration	x	x	x	x	x	x	x	x	x
	Other	x	x	x	x	x	x	x	x	x
Follow-up visit schedule	Any type	x	x	x	x	x	x	x	x	x
	Out of window visit	x	x	x	x	x	x	x	x	x
	Missed visit/visit not conducted	x	x	x	x	x	x	x	x	x
	Other	x	x	x	x	x	x	x	x	x
Protocol procedure/assessment	Any type	x	x	x	x	x	x	x	x	x
	Incorrect version of ICF signed	x	x	x	x	x	x	x	x	x
	Blood not collected	x	x	x	x	x	x	x	x	x
	Urine not collected	x	x	x	x	x	x	x	x	x
	Other specimen not collected	x	x	x	x	x	x	x	x	x
	Specimen result not obtained	x	x	x	x	x	x	x	x	x
	Required procedure not conducted	x	x	x	x	x	x	x	x	x

Table 6: Distribution of Protocol Deviations by Category, Type and Treatment Group – All Enrolled Subjects *(continued)*

Category	Deviation Type	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		# of Subj.	%	# of Dev.	# of Subj.	%	# of Dev.	# of Subj.	%	# of Dev.
	Required procedure done incorrectly	x	x	x	x	x	x	x	x	x
	Study product temperature excursion	x	x	x	x	x	x	x	x	x
	Specimen temperature excursion	x	x	x	x	x	x	x	x	x
	Other	x	x	x	x	x	x	x	x	x
Treatment administration	Any type	x	x	x	x	x	x	x	x	x
	Required procedure done incorrectly	x	x	x	x	x	x	x	x	x
	Study product temperature excursion	x	x	x	x	x	x	x	x	x
	Other	x	x	x	x	x	x	x	x	x
Blinding policy/procedure	Any type	x	x	x	x	x	x	x	x	x
	Treatment unblinded	x	x	x	x	x	x	x	x	x
	Other	x	x	x	x	x	x	x	x	x

Notes: N=Number of enrolled subjects. Treatment group is the treatment the subject was randomized to.

Table 7: Summary of Categorical Demographic and Baseline Characteristics by Site - ITT Population

Variable	Characteristic	Cincinnati Children's Hospital (N=X)		University of Iowa (N=X)		Duke University (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%
Ethnicity	Not Hispanic or Latino	x	x	x	x	x	x	x	x
	Hispanic or Latino	x	x	x	x	x	x	x	x
	Not Reported/Unknown	x	x	x	x	x	x	x	x
Race	American Indian or Alaska Native	x	x	x	x	x	x	x	x
	Asian	x	x	x	x	x	x	x	x
	Native Hawaiian or Other Pacific Islander	x	x	x	x	x	x	x	x
	Black or African American	x	x	x	x	x	x	x	x
	White	x	x	x	x	x	x	x	x
	Multi-Racial	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x

Note: N=number of enrolled subjects

Table 8: Summary of Continuous Demographic and Baseline Characteristic by Site - ITT Population

Variable	Statistic	Cincinnati Children's Hospital (N=X)	University of Iowa (N=X)	Duke University (N=X)	All Subjects (N=X)
Age	Mean	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x
	Minimum	x	x	x	x
	Maximum	x	x	x	x
Episodes of BV (Including Current Episode) in the previous 12 months	Mean	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x
	Minimum	x	x	x	x
	Maximum	x	x	x	x

Notes: N=number of enrolled subjects

Protocol version 7.0 (May 11, 2017) removed exclusion for 6 or more episodes of vaginitis within the past year.

Table 9: Summary of Categorical Demographic and Baseline Characteristics by Treatment Group - ITT Population

Variable	Characteristic	5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%
Ethnicity	Not Hispanic or Latino	x	x	x	x	x	x
	Hispanic or Latino	x	x	x	x	x	x
	Not Reported/Unknown	x	x	x	x	x	x
Race	American Indian or Alaska Native	x	x	x	x	x	x
	Asian	x	x	x	x	x	x
	Native Hawaiian or Other Pacific Islander	x	x	x	x	x	x
	Black or African American	x	x	x	x	x	x
	White	x	x	x	x	x	x
	Multi-Racial	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x

Note: N=number of enrolled subjects

Table 10: Summary of Continuous Baseline Characteristics by Treatment Group - ITT Population

Variable	Statistic	5% Monolaurin Vaginal Gel (N=X)	Placebo Gel (N=X)	All Subjects (N=X)
Age (Years)	Mean	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x
	Median	x	x	x
	Minimum	x	x	x
	Maximum	x	x	x
Episodes of BV (Including Current Episode) in the previous 12 months	Mean	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x
	Median	x.x	x.x	x.x
	Minimum	x	x	x
	Maximum	x	x	x

Notes: N=number of enrolled subjects

Protocol version 7.0 (May 11, 2017) removed exclusion for 6 or more episodes of vaginitis within the past year.

Table 11: Baseline Sexual History by Site - ITT Population

Sexual History Category	Value	Cincinnati Children's Hospital (N=X)		University of Iowa (N=X)		Duke University (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%	n	%
Subject has received treatment for previous episodes of BV in the previous 12 months	Yes	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x
Subject is sexually active	Yes	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x
Subject's sexual orientation*	Heterosexual	x	x	x	x	x	x	x	x
	Gay/Homosexual	x	x	x	x	x	x	x	x
	Bisexual	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x
Subject has had sex with men or women in the past 12 months*	Men	x	x	x	x	x	x	x	x
	Women	x	x	x	x	x	x	x	x
	Both	x	x	x	x	x	x	x	x
	Neither	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x
Subject has had vaginal intercourse in the past 12 months*	Yes	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x
Subject has had receptive oral intercourse in the past 12 months*	Yes	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x
Subject has had receptive anal intercourse in the past 12 months*	Yes	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x	x	x

Notes: N=number of enrolled subjects. *Denominator for percentages is the number of subjects who were sexually active in the respective site.

Table 12: Baseline Sexual History by Treatment Group - ITT Population

Sexual History Category	Value	5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%
Subject has received treatment for previous episodes of BV in the previous 12 months?	Yes	x	x	x	x	x	x
	No	x	x	x	x	x	x
Subject is sexually active	Yes	x	x	x	x	x	x
	No	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x
Subject's sexual orientation*	Heterosexual	x	x	x	x	x	x
	Gay/Homosexual	x	x	x	x	x	x
	Bisexual	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x
Subject has had sex with men or women in the past 12 months*	Men	x	x	x	x	x	x
	Women	x	x	x	x	x	x
	Both	x	x	x	x	x	x
	Neither	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x
Subject has had vaginal intercourse in the past 12 months*	Yes	x	x	x	x	x	x
	No	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x
Subject has had receptive oral intercourse in the past 12 months*	Yes	x	x	x	x	x	x
	No	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x
Subject has had receptive anal intercourse in the past 12 months*	Yes	x	x	x	x	x	x
	No	x	x	x	x	x	x
	Unknown	x	x	x	x	x	x

Notes: N=number of enrolled subjects. *Denominator for percentages is the number of subjects who were sexually active in the respective treatment group.

Table 13: Summary of Baseline Clinical Assessment of BV by Site - Safety Population

	Cincinnati Children's Hospital (N=X)								University of Iowa (N=X)								Duke University (N=X)								All Subjects (N=X)							
	None		Mild		Moderate		Severe		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
Sign/Symptom	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Sign/Symptom[1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Odor	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Pain	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Tenderness	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vulvar/Vaginal Itching	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Dryness	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Discharge	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vulvar Inflammation	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Notes: Denominator for percentages is the number of subjects in the Safety Population (N) for each Site.
Assessment is performed by the clinician.
[1]The maximum severity of any sign or symptom is summarized. A subject is only counted once at the maximum severity.

Table 14: Summary of Baseline Clinical Assessment of BV by Treatment Group - Safety Population

	5% Monolaurin Vaginal Gel (N=X)								Placebo Gel (N=X)								All Subjects (N=X)							
	None		Mild		Moderate		Severe		None		Mild		Moderate		Severe		None		Mild		Moderate		Severe	
Sign/Symptom	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Sign/Symptom[1]	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Odor	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Pain	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Tenderness	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vulvar/Vaginal Itching	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Dryness	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Discharge	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vulvar Inflammation	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Notes: Denominator for percentages is the number of subjects in the Safety Population (N) for each treatment group.
Assessment is performed by the clinician.
[1]The maximum severity of any sign or symptom is summarized. A subject is only counted once at the maximum severity.

Table 15: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA System Organ Class and Treatment Group - ITT Population - All Sites

MedDRA System Organ Class	5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
	n	%	n	%	n	%
Any SOC	x	x	x	x	x	x
[SOC 1]	x	x	x	x	x	x
[SOC 2]	x	x	x	x	x	x

Notes: N=number of enrolled subjects.
n = Number of subjects reporting medical history within the specified SOC.
A subject is only counted once per SOC.

Tables with Similar Format:

Table 16: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA System Organ Class and Treatment Group -ITT Population- Cincinnati Children's Hospital

Table 17: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA System Organ Class and Treatment Group -ITT Population- University of Iowa

Table 18: Summary of Subjects with Pre-Existing Medical Conditions by MedDRA System Organ Class and Treatment Group -ITT Population- Duke University

Table 19: Dates of First Treatment by Site - Safety Population

[Note: Dates will be categorized by breaking the calendar year into quarters.]

Dates of Dosing	Cincinnati Children's Hospital (N = X)		University of Iowa (N = X)		Duke University (N = X)		All Subjects (N = X)	
	n	%	n	%	n	%	n	%
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x	x	x

Note: N=Number of subjects in the safety population

Table 20: Dates of First Treatment by Treatment Group - Safety Population

[Note: Dates will be categorized by breaking the calendar year into quarters.]

Dates of Dosing	5% Monolaurin Vaginal Gel (N = X)		Placebo Gel (N = X)		All Subjects (N = X)	
	n	%	n	%	n	%
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x
DDMMMYYYY-DDMMMYYYY	x	x	x	x	x	x

Note: N=Number of subjects in the safety population

Table 21: Dose Administration Schedule by Site and Number of Doses Administered - Safety Population

Cincinnati Children's Hospital (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
University of Iowa (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Duke University (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Site who received the specified number of doses.

Table 22: Dose Administration Schedule by Site and Dose Number - Safety Population

Site	**Dose Administration Schedule**	**Dose 1 n (%)**	**Dose 2 n (%)**	**Dose 3 n (%)**	**Dose 4 n (%)**	**Dose 5 n (%)**	**Dose 6 n (%)**
Cincinnati Children's Hospital (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
University of Iowa (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Duke University (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Site

Table 23: Dose Administration Schedule by Treatment Group and Number of Doses Administered - Safety Population

5% Monolaurin Vaginal Gel (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Placebo Gel (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)							
	Number of Doses Administered n (%)						
Dose Administration Schedule	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Treatment Group who received the specified number of doses.

Table 24: Dose Administration Schedule by Treatment Group and Dose Number - Safety Population

Site	**Dose Administration Schedule**	**Dose 1 n (%)**	**Dose 2 n (%)**	**Dose 3 n (%)**	**Dose 4 n (%)**	**Dose 5 n (%)**	**Dose 6 n (%)**
5% Monolaurin Vaginal Gel (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Placebo Gel (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)	As scheduled	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Out of Window	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missed	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Treatment Group

Table 25: Product Administration Position by Site and Number of Doses Administered - Safety Population

Cincinnati Children's Hospital (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
University of Iowa (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Duke University (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Site who received the specified number of doses.

Table 26: Product Administration Position by Site and Dose Number - Safety Population

Site	Product Administration Position	Dose 1 n (%)	Dose 2 n (%)	Dose 3 n (%)	Dose 4 n (%)	Dose 5 n (%)	Dose 6 n (%)
Cincinnati Children's Hospital (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
University of Iowa (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Duke University (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Site

Table 27: Product Administration Position and Number of Doses Administered - Safety Population

5% Monolaurin Vaginal Gel (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Placebo Gel (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)							
	Number of Doses Administered n (%)						
Product Administration Position	**0 (N=X)**	**1 (N=X)**	**2 (N=X)**	**3 (N=X)**	**4 (N=X)**	**5 (N=X)**	**6 (N=X)**
Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Treatment Group who received the specified number of doses.

Table 28: Product Administration Position by Treatment Group and Dose Number - Safety Population

Site	Product Administration Position	Dose 1 n (%)	Dose 2 n (%)	Dose 3 n (%)	Dose 4 n (%)	Dose 5 n (%)	Dose 6 n (%)
5% Monolaurin Vaginal Gel (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
Placebo Gel (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
All Subjects (N=X)	Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Not Recumbent	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)
	Missing	x (x)	x (x)	x (x)	x (x)	x (x)	x (x)

Note: Denominator for percentages is the number of subjects in the Safety Population for each Treatment Group

Section 14.2 Efficacy Data

Table 29: Clinical Cure Results at the Test of Cure Visit, Visit 2 by Analysis Population and Treatment Group

Analysis Population	Treatment Group	Number of Subjects with Clinical Cure n	Number of Subjects N	Proportion of Subjects with Clinical Cure	Proportion of Subjects with Clinical Cure 95% CI	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI	P-Value*
ITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--	--
mITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--	--
Evaluable	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--	--
PP	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--	--

Notes: The denominator for proportions is based on the number of subjects enrolled in the respective treatment group and analysis population.

*P-value from the Fisher's exact two-sided test at the .05 level of significance.

Table 30: Clinical Cure Results at Visit 3 by Analysis Population and Treatment Group

Analysis Population	Treatment Group	Number of Subjects with Clinical Cure n	Number of Subjects N	Proportion of Subjects with Clinical Cure	Proportion of Subjects with Clinical Cure 95% CI	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
ITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
mITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
Evaluable	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
PP	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Note: The denominator for proportions is based on the number of subjects enrolled in the respective treatment group and analysis population.

Table 31: Therapeutic Cure Results at the Test of Cure Visit, Visit 2 by Analysis Population and Treatment Group

Analysis Population	Treatment Group	Number of Subjects with Therapeutic Cure n	Number of Subjects N	Proportion of Subjects with Therapeutic Cure	Proportion of Subjects with Clinical Cure 95% CI	Difference in Proportion of Subjects with Therapeutic Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Therapeutic Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
ITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
mITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
Evaluable	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
PP	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Note: The denominator for proportions is based on the number of subjects enrolled in the respective treatment group and analysis population.

Table with similar format:

Table 32: Therapeutic Cure Results at Visit 3 by Analysis Population and Treatment Group

Table 33: Summary of Amsel Criteria by Site and Study Visit - All Enrolled Subjects

		Cincinnati Children's Hospital (N=X)						University of Iowa (N=X)						Duke University (N=X)						All Subjects (N=X)					
Amsel Criteria		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**	
		n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Number of Amsel Criteria Present	0/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	1/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	2/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	3/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	4/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Secretion pH	>4.5	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	≤4.5	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Clue Cells	≥20%	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	<20%	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Amine ("whiff") test on KOH wet mount	Positive	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Negative	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Off-white (milky or gray), thin, homogenous discharge	Yes	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: Denominator for percentages is the number of subjects enrolled (N) in the study for each Site.

Table 34: Summary of Amsel Criteria by Treatment Group and Study Visit - ITT Population

		5% Monolaurin Vaginal Gel (N=X)						Placebo Gel (N=X)						All Subjects (N=X)					
Amsel Criteria		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**		**Visit 1 (N=X)**		**Visit 2 (N=X)**		**Visit 3 (N=X)**	
		n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Number of Amsel Criteria Present	0/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	1/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	2/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	3/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	4/4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Secretion pH	>4.5	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	≤4.5	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Clue Cells	≥20%	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	<20%	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Amine ("whiff") test on KOH wet mount	Positive	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Negative	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Off-white (milky or gray), thin, homogenous discharge	Yes	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	No	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: Denominator for percentages is the number of subjects enrolled (N) in the study for each treatment group.

Tables with similar format:

Table 35: Summary of Amsel Criteria by Treatment Group and Study Visit - mITT Population

Table 36: Summary of Amsel Criteria by Treatment Group and Study Visit - Evaluable Population

Table 37: Summary of Amsel Criteria by Treatment Group and Study Visit - PP Population

Table 38: Nugent Scores by Category, Study Visit, Analysis Population, and Site – All Subjects

Analysis Population	Nugent Score Category	All Subjects (N = X)								
		Visit 1 (N = X)			Visit 2 (N = X)			Visit 3 (N = X)		
		Number of Subjects n	Proportion of Subjects	Proportion of Subjects 95% CI	Number of Subjects n	Proportion of Subjects	Proportion of Subjects 95% CI	Number of Subjects n	Proportion of Subjects	Proportion of Subjects 95% CI
ITT	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
mITT	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
Evaluable	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
PP	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx

Note: Denominator for percentages is the number of subjects enrolled (N) in the study for each Site.

Tables with Similar Format:

Table 39: Nugent Scores by Category, Study Visit, Analysis Population, and Site—Cincinnati Children's Hospital

Table 40: Nugent Scores by Category, Study Visit, Analysis Population, and Site—University of Iowa

Table 41: Nugent Scores by Category, Study Visit, Analysis Population, and Site—Duke University

Table 42: Nugent Scores by Category, Study Visit, Analysis Population, and Treatment Group - 5% Monolaurin Vaginal Gel

Analysis Population	Nugent Score Category	5% Monolaurin Vaginal Gel (N = X)								
		Visit 1 (N = X)			Visit 2 (N = X)			Visit 3 (N = X)		
		Number of Subjects n	Proportion of Subjects	Proportion of Subjects 95% CI	Number of Subjects n	Proportion of Subjects	Proportion of Subjects 95% CI	Number of Subjects n	Proportion of Subjects	Proportion of Subjects 95% CI
ITT	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
mITT	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
Evaluable	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
PP	0-3 (Normal)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	4-6 (Intermediate)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx
	7-10 (BV)	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx	x	0.xx	0.xx, 0.xx

Note: Denominator for percentages is the number of subjects enrolled (N) in the study for each treatment group.

Tables with Similar Format:

Table 43: Nugent Scores by Category, Study Visit, Analysis Population, and Treatment Group - Placebo Gel

Table 44: Continuous Nugent Score Characteristics by Study Visit, Analysis Population, and Treatment Group

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N = X)		
Analysis Population	**Statistic**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**
ITT	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
mITT	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
Evaluable	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
PP	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx

Table 45: Nugent Scores by Category, Study Visit, Clinical Cure Status, and Treatment Group -ITT Population

		5% Monolaurin Vaginal Gel (N=X)						Placebo Gel (N=X)						All Subjects (N = xxx)					
Visit	Nugent Score Category	Clinical Cure (N = X)		Clinical Failure (N = X)		Not Evaluable (N = X)		Clinical Cure (N = X)		Clinical Failure (N = X)		Not Evaluable (N = X)		Clinical Cure (N = X)		Clinical Failure (N = X)		Not Evaluable (N = X)	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit 2 Test of Cure	0-3 (Normal)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	4-6 (Intermediate)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	7-10 (BV)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Visit 3	0-3 (Normal)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	4-6 (Intermediate)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	7-10 (BV)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Note: Denominator for percentages is the number of subjects in the ITT population for each treatment group.

Table 46: Continuous Nugent Score Characteristics by Study Visit, Clinical Cure Status, and Treatment Group- ITT Population

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N = X)		
Study Visit	**Statistic**	**Clinical Cure (N = X)**	**Clinical Failure (N = X)**	**Not Evaluable (N = X)**	**Clinical Cure (N = X)**	**Clinical Failure (N = X)**	**Not Evaluable (N = X)**	**Clinical Cure (N = X)**	**Clinical Failure (N = X)**	**Not Evaluable (N = X)**
Visit 2 Test of Cure	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
Visit 3	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx

Table 47: Clinical Cure Results at the Test of Cure Visit, Visit 2 by Analysis Population and Treatment Group - First Time BV

Analysis Population	Treatment Group	Number of Subjects with Clinical Cure n	Number of Subjects N	Proportion of Subjects with Clinical Cure	Proportion of Subjects with Clinical Cure 95% CI	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
ITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
mITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
Evaluable	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
PP	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Note: The denominator for proportions is based on the number of subjects with first time BV enrolled in the respective treatment group and analysis population.

Tables with similar format:

Table 48: Clinical Cure Results at the Test of Cure Visit, Visit 2 by Analysis Population and Treatment Group - Recurrent BV

Table 49: Clinical Cure Results at Visit 3 by Analysis Population and Treatment Group - First Time BV

Table 50: Clinical Cure Results at Visit 3 by Analysis Population and Treatment Group - Recurrent BV

Table 51: Therapeutic Cure Results at the Test of Cure Visit, Visit 2 by Analysis Population and Treatment Group - First Time BV

Analysis Population	Treatment Group	Number of Subjects with Therapeutic Cure n	Number of Subjects N	Proportion of Subjects with Therapeutic Cure	Proportion of Subjects with Therapeutic Cure 95% CI	Difference in Proportion of Subjects with Therapeutic Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Therapeutic Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
ITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
mITT	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
Evaluable	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--
PP	5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
	Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
	All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Note: The denominator for proportions is based on the number of subjects with first time BV enrolled in the respective treatment group and analysis population.

Tables with similar format:

Table 52: Therapeutic Cure Results at the Test of Cure Visit, Visit 2 by Analysis Population and Treatment Group - Recurrent BV

Table 53: Therapeutic Cure Results at Visit 3 by Analysis Population and Treatment Group - First Time BV

Table 54: Therapeutic Cure Results at Visit 3 by Analysis Population and Treatment Group - Recurrent BV

Table 55: Clinical Cure Results at the Test of Cure Visit, Visit 2 by Treatment Group- Recumbent Subjects - PP Population

Treatment Group	Number of Subjects with Clinical Cure n	Number of Subjects N	Proportion of Subjects with Clinical Cure	Proportion of Subjects with Clinical Cure 95% CI	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Notes: The denominator for proportions is based on the number of subjects enrolled in the PP population* in the respective treatment group.
In this analysis, the PP population, has the additional stipulation that the subject remain in the recumbent position for 5 of 6 doses to be considered compliant with study product

Table 56: Clinical Cure Results at the Test of Cure Visit, Visit 2 by Treatment Group Using Imputation - mITT Population

Treatment Group	Number of Subjects with Clinical Cure n	Number of Subjects N	Proportion of Subjects with Clinical Cure	Proportion of Subjects with Clinical Cure 95% CI	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Clinical Cure between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Notes: The denominator for proportions is based on the number of subjects enrolled in the mITT population* in the respective treatment group.
*In this analysis, subjects in the 5% Monolaurin Vaginal Gel arm who are not evaluable for clinical cure will have their cure status imputed as a clinical failure and subjects in the placebo arm who are not evaluable for clinical cure will have their cure status imputed as a clinical cure.

Table 57: Mean count of *Lactobacillus spp.*, *Gardnerella spp.*, and *Mobiluncus spp.* by Study Visit, and Treatment Group - ITT Population

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N = X)		
Species	**Statistic**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**
Lactobacillus spp.	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
Gardnerella spp	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
Mobiluncus spp	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx

Tables with similar format:

Table 58: Mean count of *Lactobacillus spp.*, *Gardnerella spp.*, and *Mobiluncus spp.* by Study Visit, and Treatment Group - mITT Population

Table 59: Mean count of *Lactobacillus spp.*, *Gardnerella spp.*, and *Mobiluncus spp.* by Study Visit, and Treatment Group - Evaluable Population

Table 60: Mean count of *Lactobacillus spp.*, *Gardnerella spp.*, and *Mobiluncus spp.* by Study Visit, and Treatment Group - PP Population

Table 61: Mean fungal colony count of *Candida Spp*. by Study Visit, Analysis Population, and Treatment Group in Subjects with Candida spp. Identified at Screening

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N = X)		
Analysis Population	**Statistic**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**	**Visit 1 (N = X)**	**Visit 2 (N = X)**	**Visit 3 (N = X)**
ITT	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
mITT	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
Evaluable	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
PP	Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Standard Deviation of Mean	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx	x.xx
	Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx
	Standard Deviation of Mean Change from Visit 1	--	x.xx	x.xx	--	x.xx	x.xx	--	x.xx	x.xx

Section 14.3 Safety Data

Table 62: Number and Percentage of Subjects Experiencing Treatment Emergent Solicited Urogenital Adverse Events with 95% Confidence Intervals by Symptom and Treatment Group - Safety Population

	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
Solicited Urogenital Adverse Event	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**
Any Solicited Adverse Event	x	x	x, x	x	x	x, x	x	x	x, x
Vaginal Odor	x	x	x, x	x	x	x, x	x	x	x, x
Vaginal Pain	x	x	x, x	x	x	x, x	x	x	x, x
Vaginal Tenderness	x	x	x, x	x	x	x, x	x	x	x, x
Vulvar/Vaginal Itching	x	x	x, x	x	x	x, x	x	x	x, x
Vaginal Dryness	x	x	x, x	x	x	x, x	x	x	x, x
Vaginal Discharge	x	x	x, x	x	x	x, x	x	x	x, x
Vulvar Inflammation	x	x	x, x	x	x	x, x	x	x	x, x

Notes: N = number of subjects in the Safety Analysis Population who received the specified treatment.
This table presents number and percentage of subjects.
A subject is only counted once per solicited adverse event.

Table 63: Comparison of the Proportion of Subjects Experiencing Treatment Emergent Solicited Urogenital Adverse Events through the Test of Cure Visit, Visit 2 by Treatment Group - Safety Population

Solicited Urogenital Adverse Event	Treatment Group	Proportion of Subjects Experiencing Solicited Event	Proportion of Subjects Experiencing Solicited Event 95% CI	Difference in Proportion of Subjects Experiencing Solicited Event between 5% Monolaurin Vaginal Gel and Placebo Gel %	Difference in Proportion of Subjects Experiencing Solicited Event between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI	P-Value
Any Solicited Adverse event	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	
Vaginal Odor	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	
Vaginal Pain	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	
Vaginal Tenderness	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	
Vulvar/Vaginal Itching	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	

Table 63 Comparison of the Proportion of Subjects Experiencing Treatment Emergent Solicited Urogenital Adverse Events through the Test of Cure Visit, Visit 2 by Treatment Group- Safety Population *(continued)*

Solicited Urogenital Adverse Event	Treatment Group	Proportion of Subjects Experiencing Solicited Event	Proportion of Subjects Experiencing Solicited Event 95% CI	Difference in Proportion of Subjects Experiencing Solicited Event between 5% Monolaurin Vaginal Gel and Placebo Gel %	Difference in Proportion of Subjects Experiencing Solicited Event between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI	P-Value
Vaginal Dryness	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	
Vaginal Discharge	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	
Vulvar Inflammation	5% Monolaurin Vaginal Gel	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
	Placebo Gel	0.xx	0.xx, 0.xx	--	--	
	All Subjects	0.xx	0.xx, 0.xx	--	--	

Table 64: Number and Percentage of Subjects Experiencing Treatment Emergent Solicited Urogenital Adverse Events by Symptom, Maximum Severity, and Treatment Group - Safety Population

Solicited Urogenital Adverse Event	Severity	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI
Any Solicited Urogenital Adverse Event	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Odor	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Pain	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Tenderness	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x

Table 64 Number and Percentage of Subjects Experiencing Treatment Emergent Solicited Urogenital Adverse Events by Symptom, Maximum Severity, and Treatment Group- Safety Population *(continued)*

Solicited Urogenital Adverse Event	Severity	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI
Vulvar/Vaginal Itching	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Dryness	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Discharge	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vulvar Inflammation	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x

Notes: Denominator for percentages is the number of subjects in the Safety Population (N) with treatment emergent solicited urogenital adverse event data available for the specific solicited urogenital adverse event for each treatment group.
[1]Each subject's maximum severity is reported for each treatment emergent solicited urogenital adverse event across all doses. Table includes solicited urogenital adverse events reported from the first dose of study product through Visit 2.

Table 65: Number and Percentage of Subjects Experiencing Solicited Symptoms by Symptom, Maximum Severity, and Treatment Group - Safety Population

Solicited Symptom	Severity	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI
Any Solicited Symptom	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Odor	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Pain	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Tenderness	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x

Table 65 Number and Percentage of Subjects Experiencing Solicited Symptoms by Symptom, Maximum Severity, and Treatment Group-Safety Population *(continued)*

Solicited Symptom	Severity	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI
Vulvar/Vaginal Itching	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Dryness	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vaginal Discharge	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x
Vulvar Inflammation	None	x	x	x,x	x	x	x,x	x	x	x,x
	Mild	x	x	x,x	x	x	x,x	x	x	x,x
	Moderate	x	x	x,x	x	x	x,x	x	x	x,x
	Severe	x	x	x,x	x	x	x,x	x	x	x,x
	Not Reported	x	x	x,x	x	x	x,x	x	x	x,x
	Total	x	x	x,x	x	x	x,x	x	x	x,x

Notes: Denominator for percentages is the number of subjects in the Safety Population (N) with solicited symptom data available for the specific symptom for each treatment group.
[1]Each subject's maximum severity is reported for each solicited symptom across all doses. Table includes solicited symptoms reported from the first dose of study product through Visit 2.

Table 66: Number and Percentage of Subjects Experiencing Solicited Symptoms by Symptom, Severity, Study Day, and Treatment Group - All Treatment Groups - Safety Population

		Pre-Dose (N=X)		Day 1 (N=X)		Day 2 (N=X)		Day 3 (N=X)		Day 4 (N=X)		Day 5 (N=X)	
Solicited Symptom	**Severity[1]**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Any Solicited Symptom	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Odor	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Pain	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Tenderness	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x

Table 66 Number and Percentage of Subjects Experiencing Solicited Symptoms by Symptom, Severity, Study Day, and Treatment Group- All Treatment Groups - Safety Population *(continued)*

		Pre-Dose (N=X)		Day 1 (N=X)		Day 2 (N=X)		Day 3 (N=X)		Day 4 (N=X)		Day 5 (N=X)	
Solicited Symptom	**Severity[1]**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Vulvar/Vaginal Itching	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Dryness	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x
Vaginal Discharge	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x
Vulvar Inflammation	None	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x
	Not Reported	x	x	x	x	x	x	x	x	x	x	x	x
	Total	x	x	x	x	x	x	x	x	x	x	x	x

Notes: Denominator for percentages is the number of subjects in the Safety Population (N) with solicited event data available reporting a solicited adverse event at the day being summarized for each treatment group.
[1]The maximum severity of any solicited adverse event is summarized. A subject is only counted once at the maximum severity.

Tables with similar format:

Table 67: Number and Percentage of Subjects Experiencing Solicited Symptoms by Symptom, Severity, Study Day, and Treatment Group-5% Monolaurin Vaginal Gel - Safety Population

Table 68: Number and Percentage of Subjects Experiencing Solicited Symptoms by Symptom, Severity, Study Day, and Treatment Group-Placebo Gel - Safety Population

Table 69: Proportion of Subjects Reporting Non-Solicited Non-Laboratory Adverse Events Following the First Dose of Study Product through Visit 3 by Treatment Group - Safety Population

Treatment Group	Number of Subjects with AEs n	Number of Subjects N	Proportion of Subjects with AEs	Proportion of Subjects with AEs 95% CI	Difference in Proportion of Subjects with AEs between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with AEs between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Table 70: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Events with 95% Confidence Intervals by MedDRA System Organ Class, and Preferred Term, and Treatment Group - Safety Population

MedDRA System Organ Class	MedDRA Preferred Term	5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
		n	%	95% CI	n	%	95% CI	n	%	95% CI
Any SOC	Any PT	x	x	x, x	x	x	x, x	x	x	x, x
[SOC 1]	Any PT	x	x	x, x	x	x	x, x	x	x	x, x
	[PT 1]	x	x	x, x	x	x	x, x	x	x	x, x
	[PT 2]	x	x	x, x	x	x	x, x	x	x	x, x
[SOC 2]	Any PT	x	x	x, x	x	x	x, x	x	x	x, x
	[PT 1]	x	x	x, x	x	x	x, x	x	x	x, x
	[PT 2]	x	x	x, x	x	x	x, x	x	x	x, x

Notes: N = number of subjects in the Safety Analysis Population who received the specified treatment.
This table presents number and percentage of subjects.
A subject is only counted once per PT/timepoint.

Table 71: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group - Safety Population

All Subjects (N=X)													
				Severity [1]						Relationship to Treatment [2]			
		Any Incidence		Mild		Moderate		Severe		Not Related		Related	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%	n	%	n	%
Any SOC	Any PT	x	x	x	x	x	x	x	x	x	x	x	x
[SOC 1]	Any PT	x	x	x	x	x	x	x	x	x	x	x	x
	[PT 1]	x	x	x	x	x	x	x	x	x	x	x	x
	[PT 2]	x	x	x	x	x	x	x	x	x	x	x	x
[SOC 2]	Any PT	x	x	x	x	x	x	x	x	x	x	x	x
	[PT 1]	x	x	x	x	x	x	x	x	x	x	x	x
	[PT 2]	x	x	x	x	x	x	x	x	x	x	x	x

Notes: N = Number of subjects in the Safety Analysis Population.
[1] For severity, a subject is counted once per preferred term and is summarized according to their highest severity.
[2] For relationship, a subject is only counted once per preferred term and is summarized according to their closest relationship.

Tables with Similar Format:

Table 72: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group - 5% Monolaurin Vaginal Gel - Safety Population

Table 73: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, Relationship, and Treatment Group-Placebo Gel - Safety Population

Table 74: Number and Percentage of Subjects Experiencing Related Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, and Treatment Group - Safety Population - All Subjects

All Subjects (N=X)									
		Any Incidence		Severity [1]					
				Mild		Moderate		Severe	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%	n	%
Any SOC	Any PT	x	x	x	x	x	x	x	x
[SOC 1]	Any PT	x	x	x	x	x	x	x	x
	[PT 1]	x	x	x	x	x	x	x	x
	[PT 2]	x	x	x	x	x	x	x	x
[SOC 2]	Any PT	x	x	x	x	x	x	x	x
	[PT 1]	x	x	x	x	x	x	x	x
	[PT 2]	x	x	x	x	x	x	x	x

Notes: N = Number of subjects in the Safety Analysis Population This table presents number and percentage of subjects.
[1] For severity, a subject is counted once per preferred term and is summarized according to their highest severity.

Tables with Similar Format:

Table 75: Number and Percentage of Subjects Experiencing Related Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, and Treatment Group-5% Monolaurin Vaginal Gel - Safety Population

Table 76: Number and Percentage of Subjects Experiencing Related Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Maximum Severity, and Treatment Group-Placebo Gel - Safety Population

Table 77: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Study Day, and Treatment Group - Safety Population - All Subjects

All Subjects (N=X)							
		Visit 1 (Day 1) – TOC Visit 2 (Day 8-15)		TOC Visit 2 (Day 8-15) – Visit 3 (Day 22-31)		Any Study Day	
MedDRA System Organ Class	MedDRA Preferred Term	n	%	n	%	n	%
Any SOC	Any PT	x	x	x	x	x	x
[SOC 1]	Any PT	x	x	x	x	x	x
	[PT 1]	x	x	x	x	x	x
	[PT 2]	x	x	x	x	x	x
[SOC 2]	Any PT	x	x	x	x	x	x
	[PT 1]	x	x	x	x	x	x
	[PT 2]	x	x	x	x	x	x

Notes: N = Number of subjects in the Safety Analysis Population
This table presents number and percentage of subjects.
For each time period, a subject is only counted once per PT.

Tables with Similar Format:

Table 78: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Study Day, and Treatment Group-5% Monolaurin Vaginal Gel - Safety Population

Table 79: Number and Percentage of Subjects Experiencing Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Study Day, and Treatment Group-Placebo Gel - Safety Population

Table 80: Number of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Study Day, and Treatment Group - Safety Population - All Subjects

All Subjects (N=X)				
		Visit 1 (Day 1) – TOC Visit 2 (Day 8-15)	TOC Visit 2 (Day 8-15) – Visit 3 (Day 22-31)	Any Study Day
MedDRA System Organ Class	MedDRA Preferred Term	# of Events	# of Events	# of Events
Any SOC	Any PT	x	x	x
[SOC 1]	Any PT	x	x	x
	[PT 1]	x	x	x
	[PT 2]	x	x	x
[SOC 2]	Any PT	x	x	x
	[PT 1]	x	x	x
	[PT 2]	x	x	x

Notes: N = Number of subjects in the Safety Analysis Population.
This table presents number of events; a subject may be counted multiple times.

Tables with Similar Format:

Table 81: Number of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Study Day, and Treatment Group-5% Monolaurin Vaginal Gel - Safety Population

Table 82: Number of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Preferred Term, Study Day, and Treatment Group-Placebo Gel - Safety Population

Table 83: Number of Non-Solicited Non-Laboratory Adverse Events Occurring in 5% of Subjects in Any Treatment Group by MedDRA System Organ Class and Preferred Term, and Treatment Group - Safety Population

Preferred Term	MedDRA System Organ Class	MedDRA Version	5% Monolaurin Vaginal Gel	Placebo Gel	All Treatment Groups
xxxxxx	xxxxxxxxxx	xx.x	xx	xx	xx

Table 84: Subjects Reporting Non-Solicited Non-Laboratory Adverse Events occurring in 5% of Subjects in Any Treatment Group by MedDRA System Organ Class and Preferred Term, and Treatment Group - Safety Population

Preferred Term	MedDRA System Organ Class	MedDRA Version	5% Monolaurin Vaginal Gel	Placebo Gel	All Treatment Groups
xxxxxx	xxxxxxxxxx	xx.x	xx	xx	xx

Table 85: Summary of Halting Rules - Safety Population

Halting Rules	Number of Subjects
One or more subjects experiences a treatment-related SAE	x
One or more subjects experiences vulvar and/or vaginal ulceration, abscess, or necrosis associated with study product administration	x
Two or more subjects experience a treatment-related severe (Grade 3) unsolicited adverse event	x
Three or more subjects who received at least one treatment dose experience the same severe (Grade 3) solicited AE as evaluated by a licensed clinician	x
Three or more subjects who received at least one treatment dose experience a severe (Grade 3) study related laboratory abnormality in the same laboratory parameter	x
An overall pattern of symptomatic, clinical, or laboratory events that the DMID Medical Monitor or DSMB consider associated with study drug and that may appear minor in terms of individual events, but that may collectively represent a serious potential concern for safety	x

Table 86: Number and Percentage of Subjects Experiencing Serious Adverse Events Related to Study Product with 95% Confidence Intervals by Treatment Group - Safety Population

Treatment Group	Number of Subjects with Related SAEs n	Number of Subjects N	Proportion of Subjects with Related SAEs	Related SAE 95% CI	Difference in Proportion of Subjects with Related SAEs between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Related SAEs between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI	P-Value
5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx	0.xxx
Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--	
All Subjects	x	x	0.xx	0.xx, 0.xx	--	--	

Table 87: Listing of Serious Adverse Events - Safety Population

Adverse Event	Study Day the Event Became Serious	Reason Reported as an SAE	Severity	Relationship to Study Treatment	In Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Treatment Group: , AE Number:										
xxxxxxx	**xx**	**xxxxxx**	**xxxxxx**	**xxxxxx**	**xxxxx**	**xxxxxx**	**Y/N**	**xxxxx**	**xxxxx**	**xxxxx**
Comments: xxxxxxxxxxxx										
Subject ID: , Treatment Group: , AE Number:										
xxxxxxx	**xx**	**xxxxxx**	**xxxxxx**	**xxxxxx**	**xxxxx**	**xxxxxx**	**Y/N**	**xxxxx**	**xxxxx**	**xxxxx**
Comments: xxxxxxxxxxxx										

Table 88: Listing of Non-Serious, Non-Solicited, Non-Laboratory, Moderate or Severe Adverse Events - Safety Population

Adverse Event	Study Day	Severity	Relationship to Study Treatment	In Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Treatment Group: , AE Number:									
xxxxxxx	xx	xxxxxx	xxxxxx	xxxxx	xxxxxx	Y/N	xxxxx	xxxxx	xxxxx
Comments:xxxxxxxxxxx									
Subject ID: , Treatment Group: , AE Number:									
xxxxxxx	xx	xxxxxx	xxxxxx	xxxxx	xxxxxx	Y/N	xxxxx	xxxxx	xxxxx
Comments:xxxxxxxxxxx									

Section 14.3.3 Narratives of Deaths, Other Serious and Significant Adverse Events

(not included in SAP, placeholder for the CSR)

Table 89: Proportion of Subjects Reporting Laboratory Adverse Events Following the First Dose of Study Product through the Test of Cure Visit, Visit 2 by Treatment Group - Safety Population

Treatment Group	Number of Subjects with Laboratory AEs n	Number of Subjects N	Proportion of Subjects with Laboratory AEs	Proportion of Subjects with Laboratory AEs 95% CI	Difference in Proportion of Subjects with Laboratory AEs between 5% Monolaurin Vaginal Gel and Placebo Gel	Difference in Proportion of Subjects with Laboratory AEs between 5% Monolaurin Vaginal Gel and Placebo Gel 95% CI
5% Monolaurin Vaginal Gel	x	x	0.xx	0.xx, 0.xx	0.xx	0.xx, 0.xx
Placebo Gel	x	x	0.xx	0.xx, 0.xx	--	--
All Subjects	x	x	0.xx	0.xx, 0.xx	--	--

Table 90: Laboratory Results by Parameter, Maximum Severity, Study Visit, and Treatment Group - Hematology - Safety Population

		5% Monolaurin Vaginal Gel (N=X)						Placebo Gel (N=X)						All Subjects (N=X)					
		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)	
Laboratory Parameter	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Hemoglobin	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Neutrophils	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Platelets	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
White Blood Cell Count, Decreased	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Table 90 Laboratory Results by Parameter, Maximum Severity, Study Visit, and Treatment Group- Hematology - Safety Population
(continued)

		5% Monolaurin Vaginal Gel (N=X)						Placebo Gel (N=X)						All Subjects (N=X)					
		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)	
Laboratory Parameter	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
White Blood Cell Count, Increased	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Max of Hematology Parameters	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Notes: N=number of subjects in the Safety Population reporting at least one laboratory measurement at the visit. Denominator for percentages is the number of subjects with the specific laboratory value at the visit.
*Laboratory abnormalities that were stable at Visit 2 will not be repeated at Visit 3. Laboratory abnormalities that occurred between Visit 1 and Visit 2 or worsened at Visit 2 will be repeated at Visit 3.
A laboratory abnormality is considered an adverse event if there is a worsening of the laboratory value from the baseline value and it meets the laboratory toxicity grading.

Tables with Similar Format:

Table 91: Laboratory Results Related to Study Product by Parameter, Maximum Severity, Study Visit, and Treatment Group - Hematology - Safety Population

Table 92: Laboratory Results by Parameter, Maximum Severity, Study Visit, and Treatment Group – Biochemistry - Safety Population

		5% Monolaurin Vaginal Gel (N=X)						Placebo Gel (N=X)						All Therapies (N=X)					
		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)	
Laboratory Parameter	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Alanine Aminotransferase	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Aspartate Aminotransferase	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Bilirubin	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Creatinine	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Table 92 Laboratory Results by Parameter, Maximum Severity, Study Visit, and Treatment Group- Biochemistry - Safety Population
(continued)

		5% Monolaurin Vaginal Gel (N=X)						Placebo Gel (N=X)						All Therapies (N=X)					
		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)		Visit 1 Day 1 (N=X)		Visit 2 Day 8 (N=X)		Visit 3* Day 28 (N=X)	
Laboratory Parameter	**Severity**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Glucose, Hypoglycemia	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Glucose, Hyperglycemia	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Max of Biochemistry Parameters	None	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Any	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Mild	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Moderate	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	Severe	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

Notes: N=number of subjects reporting at least one laboratory measurement at the visit.
Denominator for percentages is the number of subjects with the specific laboratory value at the visit.
*Laboratory abnormalities that were stable at Visit 2 will not be repeated at Visit 3. Laboratory abnormalities that occurred between Visit 1 and Visit 2 or worsened at Visit 2 will be repeated at Visit 3.
A laboratory abnormality is considered an adverse event if there is a worsening of the laboratory value from the baseline value and it meets the laboratory toxicity grading.

Tables with Similar Format:

Table 93: Laboratory Results Related to Study Product by Parameter, Maximum Severity, Study Visit, and Treatment Group - Biochemistry - Safety Population

Table 94: Laboratory Summary Statistics by Parameter, Study Visit, and Treatment Group - Safety Population

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
Laboratory Parameter (unit)	**Statistic**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**
Hemoglobin (g/dL)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Neutrophils (10^9/L)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Platelets (10^9/L)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
White Blood Cells (10^9/L)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x

Table 94 Laboratory Summary Statistics by Parameter, Study Visit, and Treatment Group - Safety Population *(continued)*

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
Laboratory Parameter (unit)	**Statistic**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Alanine Aminotransferase (U/L)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Aspartate Aminotransferase (U/L)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Bilirubin (mg/dL)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Creatinine (mg/dL)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x

Table 94 Laboratory Summary Statistics by Parameter, Study Visit, and Treatment Group - Safety Population *(continued)*

		5% Monolaurin Vaginal Gel (N=X)			Placebo Gel (N=X)			All Subjects (N=X)		
Laboratory Parameter (unit)	**Statistic**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**	**Visit 1 Day 1 (N=X)**	**Visit 2 Day 8 (N=X)**	**Visit 3[1] Day 28 (N=X)**
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
Glucose (mg/dL)	n	x	x	x	x	x	x	x	x	x
	Mean	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Standard Deviation	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Median	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x	x.x
	Mean Change from Visit 1	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x
	Standard Deviation	-	x.x	x.x	-	x.x	x.x	-	x.x	x.x

Notes: N = number of subjects in the Safety Population completing each visit;
n = number of subjects with a laboratory test at the visit specified.
[1]Laboratory abnormalities that were stable at Visit 2 will not be repeated at Visit 3. Laboratory abnormalities that occurred between Visit 1 and Visit 2 or worsened at Visit 2 will be repeated at Visit 3. A laboratory abnormality is considered an adverse event if there is a worsening of the laboratory value from the baseline value and it meets the laboratory toxicity grading.

Table 95: Listing of Abnormal Laboratory Results - Hematology - Safety Population

Subject ID	Treatment Group	Age (years)	Planned Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternate Etiology	Action Taken with Study Treatment	Subject Discontinued Due to Result?
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	xx	xxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	Y/N

Table 96: Listing of Abnormal Laboratory Results - Biochemistry - Safety Population

Subject ID	Treatment Group	Age (years)	Planned Time Point	Actual Study Day	Laboratory Parameter (Units)	Result (Severity)	Relationship to Treatment	If Not Related, Alternate Etiology	Action Taken with Study Treatment	Subject Discontinued Due to Result?
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	xx	xxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	Y/N

Table 97: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group - Safety Population - All Subjects

All Subjects (N=X)							
WHO Drug Code Level 1, Anatomic Group	WHO Drug Code Level 2, Therapeutic Subgroup	5% Monolaurin Vaginal Gel (N=X)		Placebo Gel (N=X)		All Subjects (N=X)	
		n	%	n	%	n	%
Any Level 1 Codes	Any Level 2 Codes	x	x	x	x	x	x
[ATC Level 1 - 1]	Any	x	x	x	x	x	x
	[ATC 2 - 1]	x	x	x	x	x	x
	[ATC 2 - 2]	x	x	x	x	x	x
	[ATC 2 - 3]	x	x	x	x	x	x
[ATC Level 1 – 2]	Any	x	x	x	x	x	x
	[ATC 2 - 1]	x	x	x	x	x	x
	[ATC 2 - 2]	x	x	x	x	x	x
	[ATC 2 - 3]	x	x	x	x	x	x

Notes: N= Number of subjects in the Safety population

n=Number of subjects reporting taking at least one medication in the specific WHO Drug Class.

Tables with Similar Format:

Table 98: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group-Safety Population-Cincinnati Children's Hospital

Table 99: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group-Safety Population-University of Iowa

Table 100: Number and Percentage of Subjects with Prior and Concurrent Medications by WHO Drug Classification and Treatment Group-Safety Population-Duke University

Appendix II: Figure Mock-Ups

Figure 1: CONSORT Flow Diagram - All Subjects

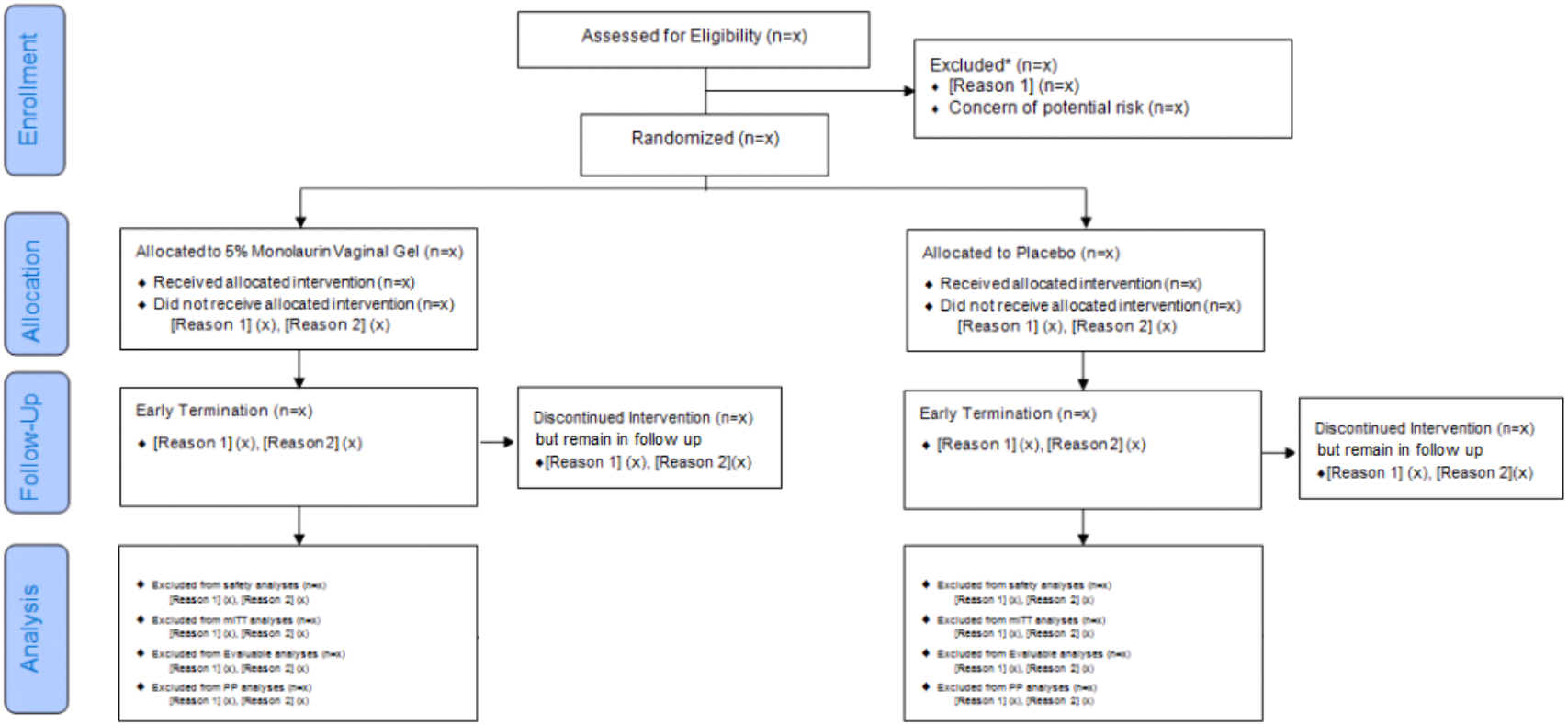
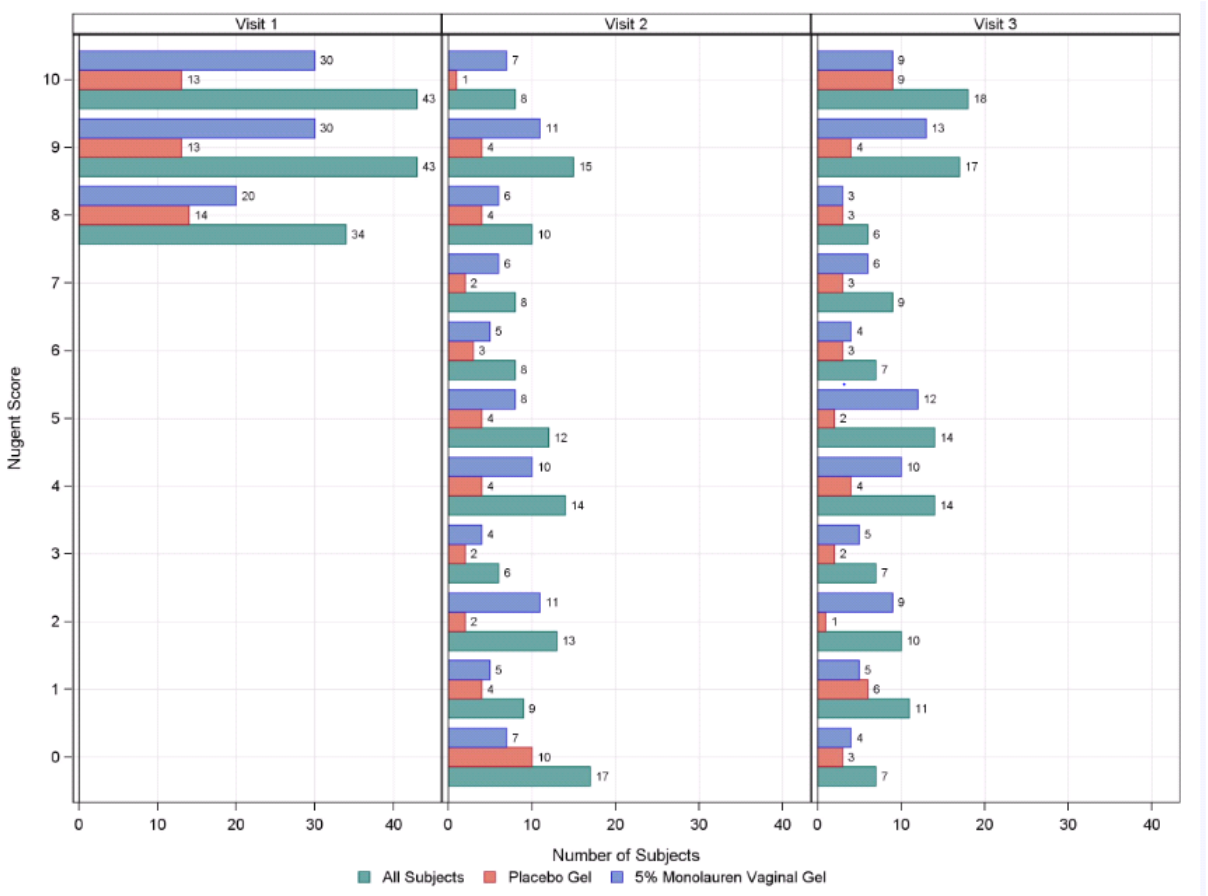


Figure 2: Nugent Scores by Visit and Treatment Group - ITT Population



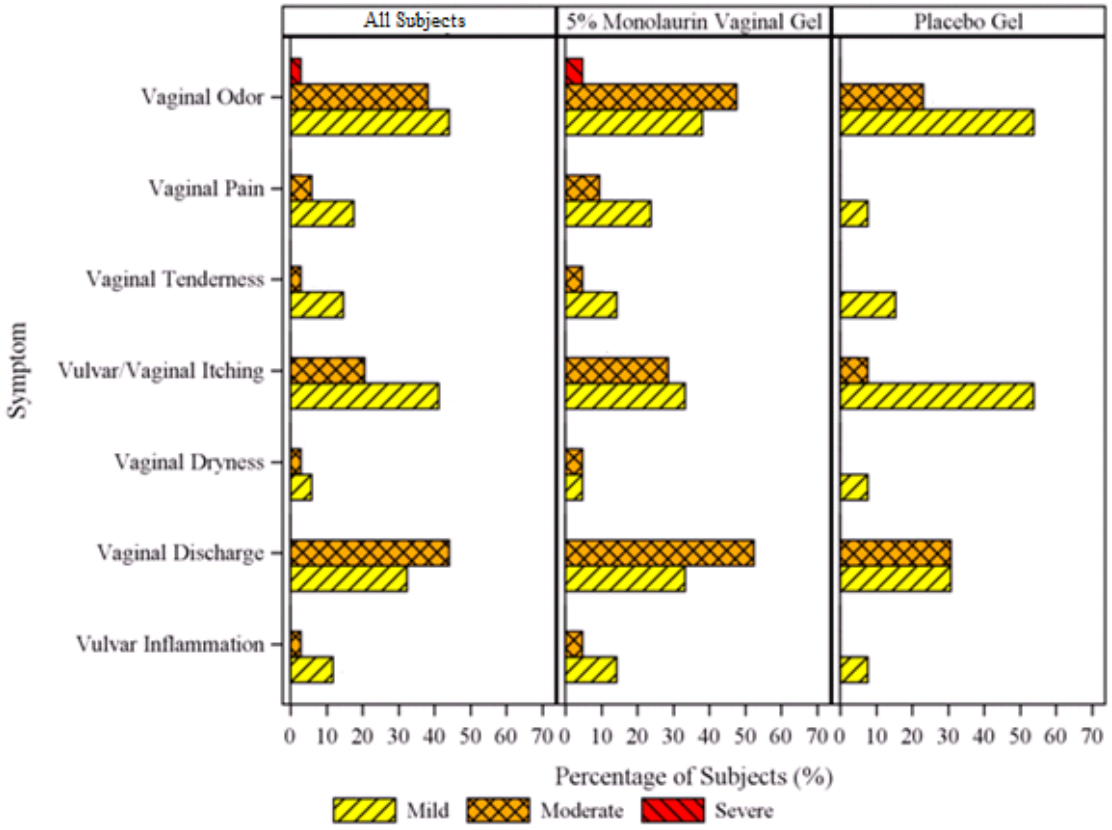
Figures with similar Format:

Figure 3: Nugent Scores by Visit and Treatment Group - mITT Population

Figure 4: Nugent Scores by Visit and Treatment Group - Evaluable Population

Figure 5: Nugent Scores by Visit and Treatment Group - PP Population

Figure 6: Maximum Severity of Treatment Emergent Solicited Urogenital Adverse Events by Symptom and Treatment Group - Safety Population



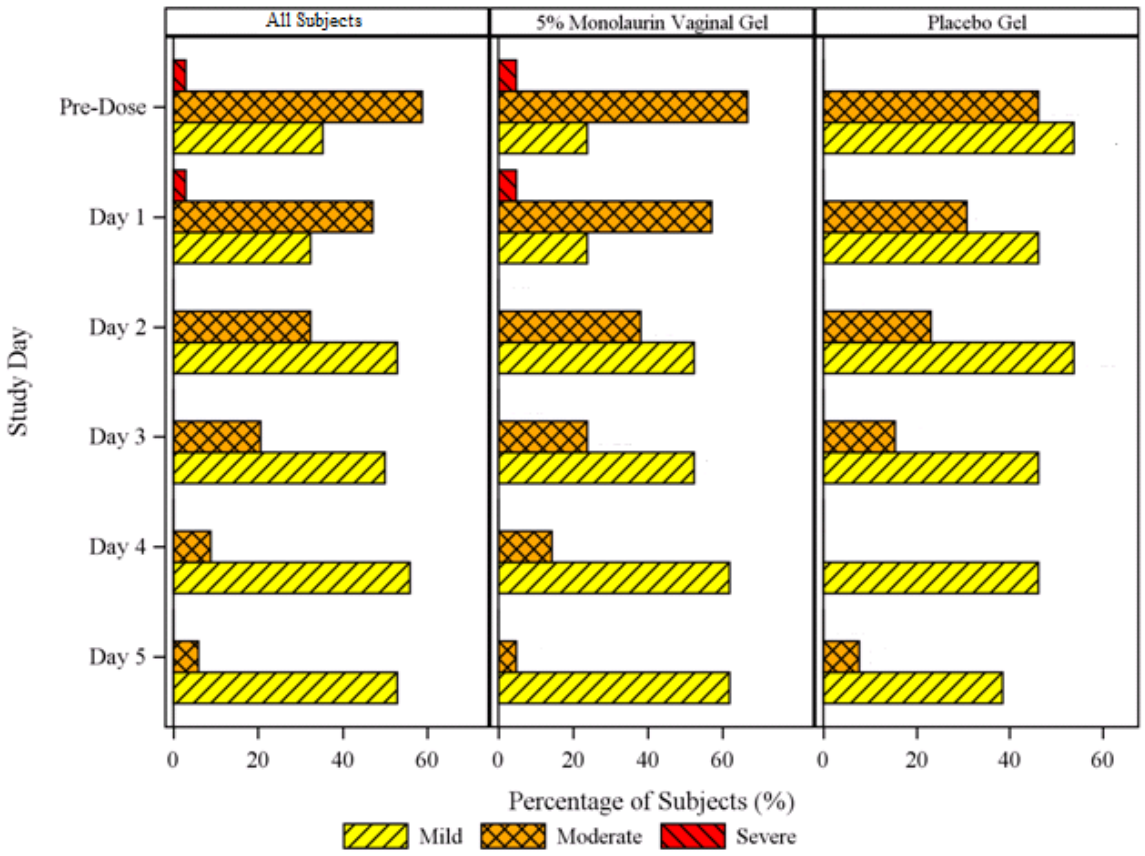
Figures with similar format:

Figure 7: Maximum Severity of Solicited Symptoms by Symptom and Treatment Group - Safety Population

Implementation Note:

Figures will be paneled in the following order: 5% Monolaurin Vaginal Gel, Placebo Gel, All Subjects

Figure 8: Maximum Severity of Solicited Symptoms by Study Day and Treatment Group - Safety Population



Implementation Note:

Figures will be paneled in the following order: 5% Monolaurin Vaginal Gel, Placebo Gel, All Subjects

Figure 9: Frequency of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Severity - Safety Population

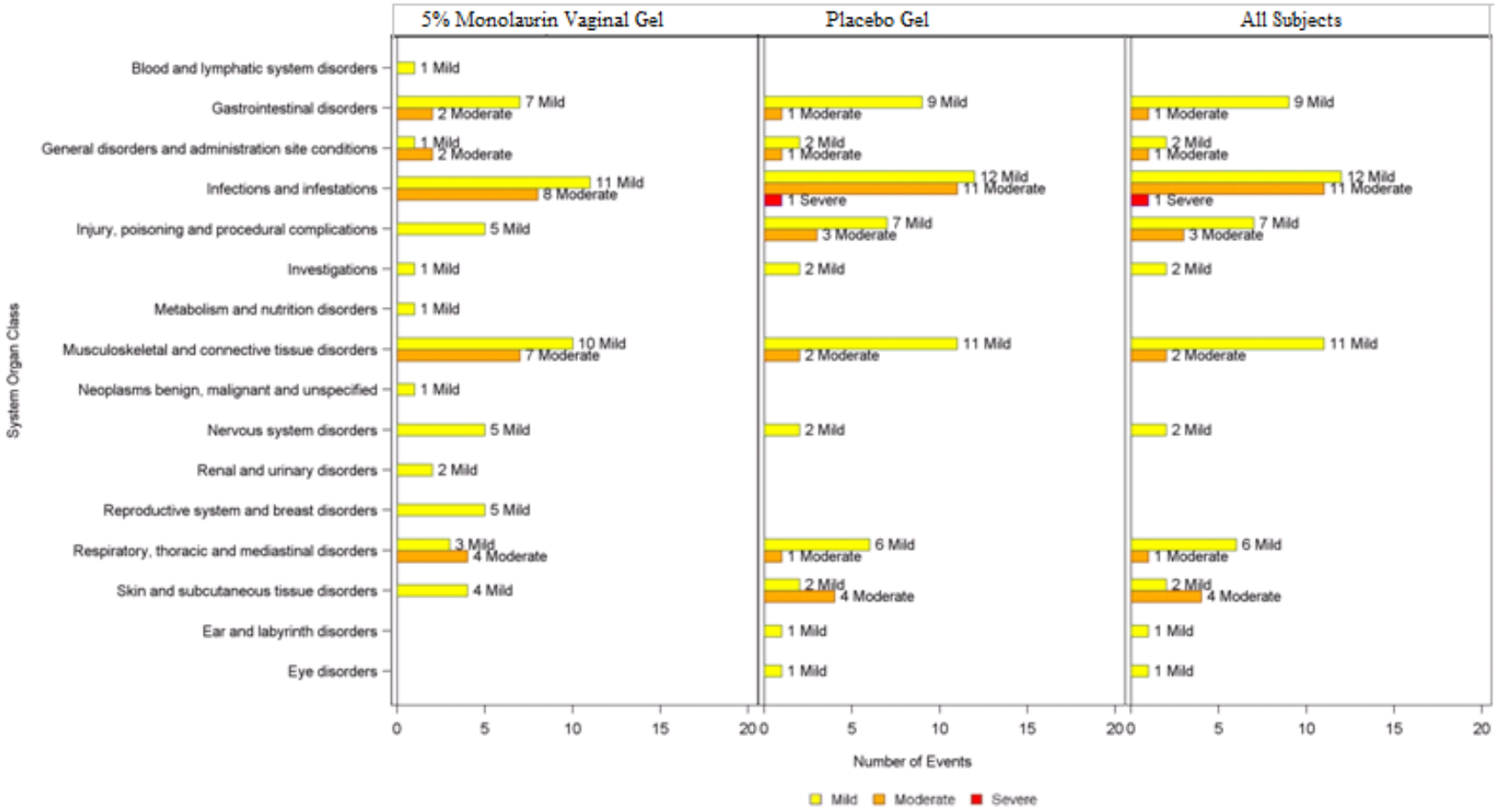


Figure 10: Incidence of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Severity - Safety Population

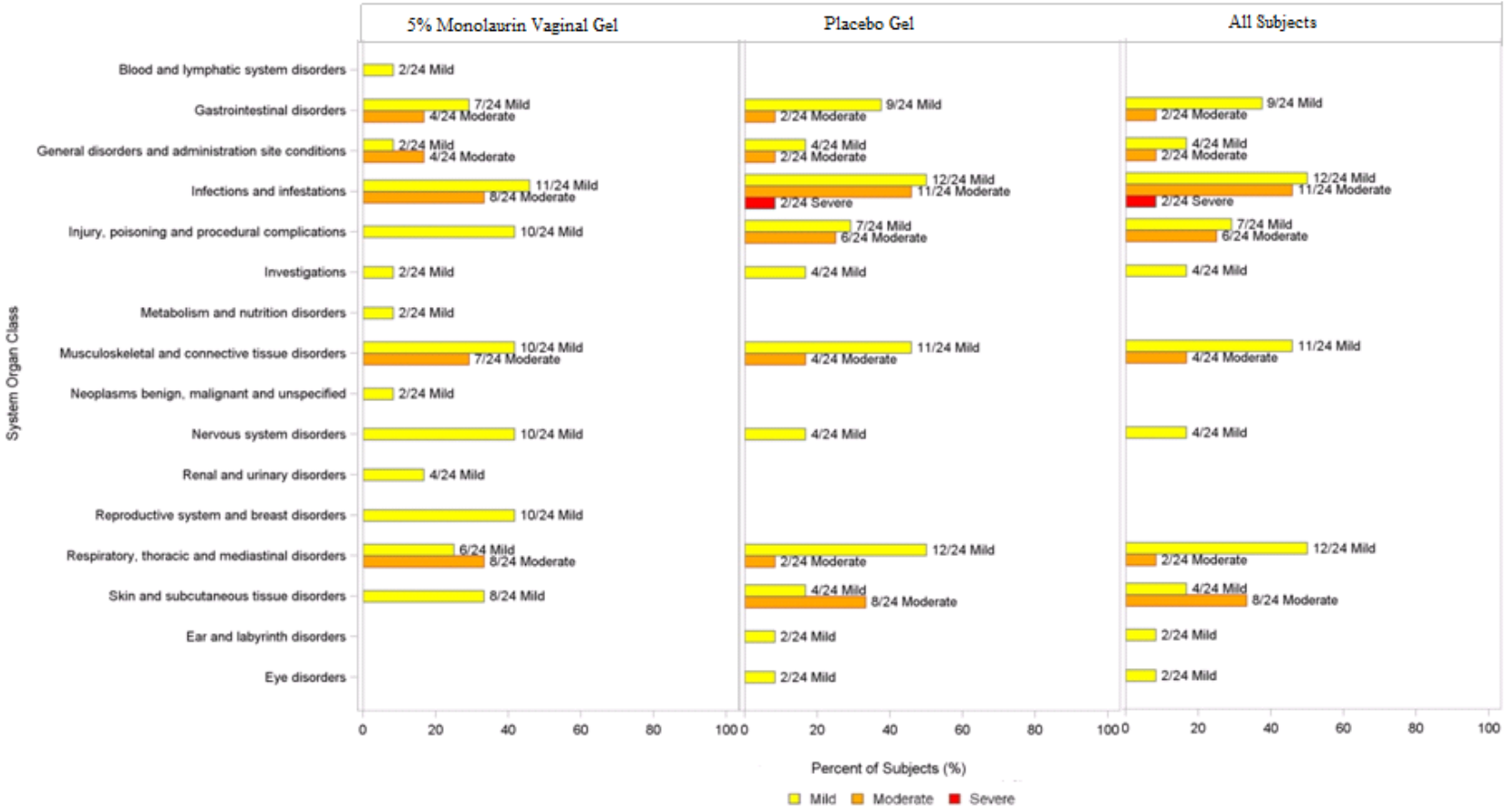
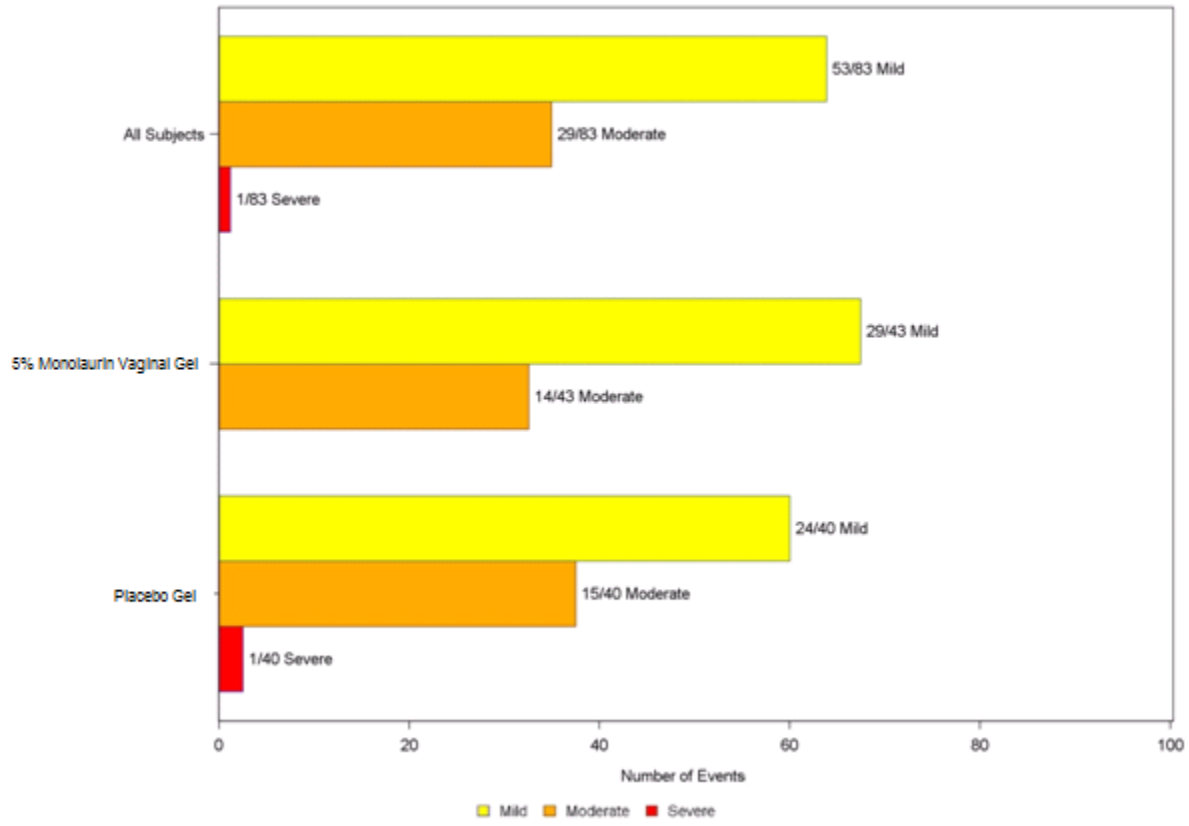


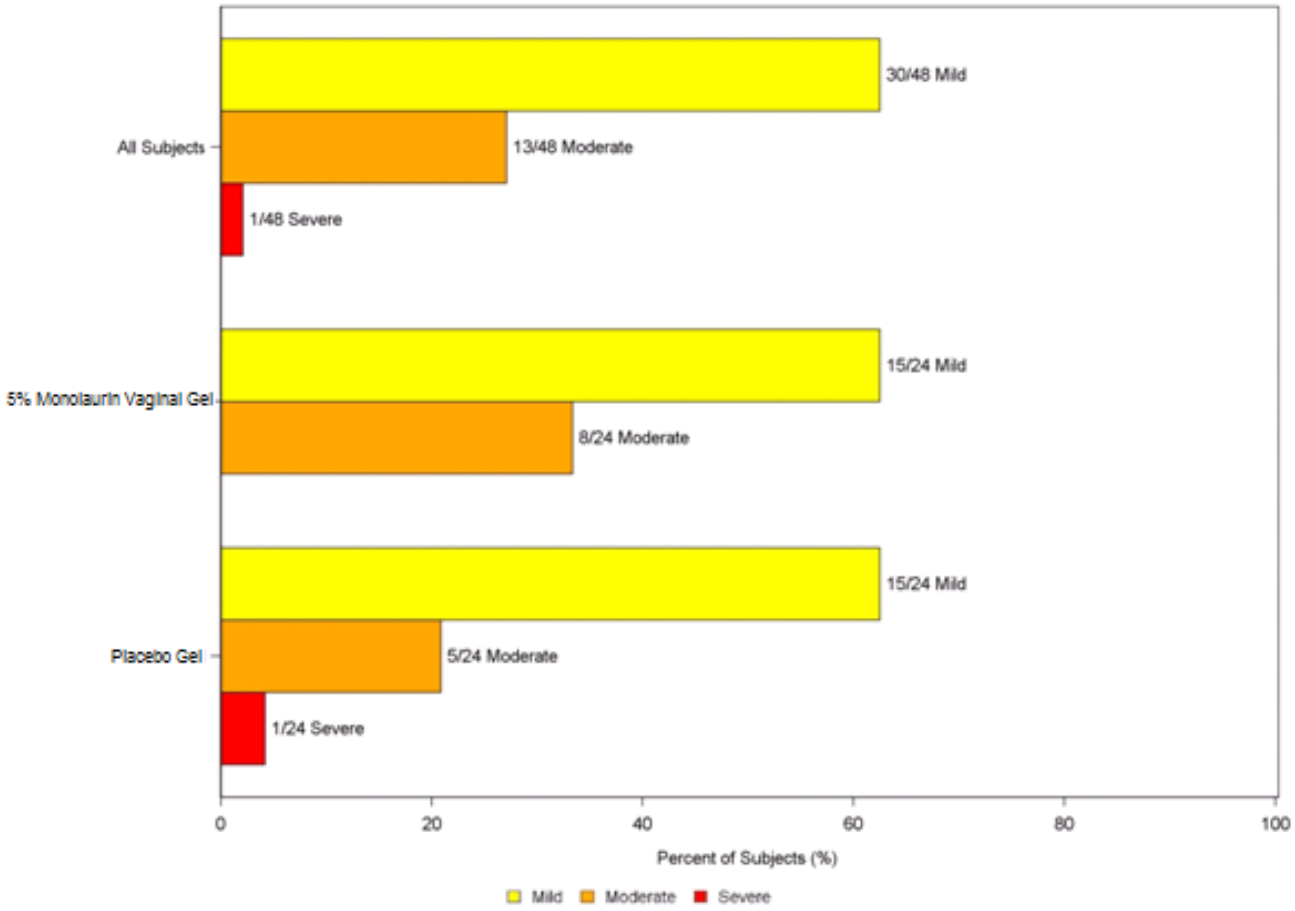
Figure 11: Frequency of Non-Solicited Non-Laboratory Adverse Events by Severity - Safety Population



Implementation Note:

Figures will be presented in the following order: 5% Monolaurin Vaginal Gel, Placebo Gel, All Subjects

Figure 12: Incidence of Non-Solicited Non-Laboratory Adverse Events by Severity - Safety Population



Implementation Note: Figures will be presented in the following order: 5% Monolaurin Vaginal Gel, Placebo Gel, All Subjects

Figure 13: Frequency of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Relationship to Treatment - Safety Population

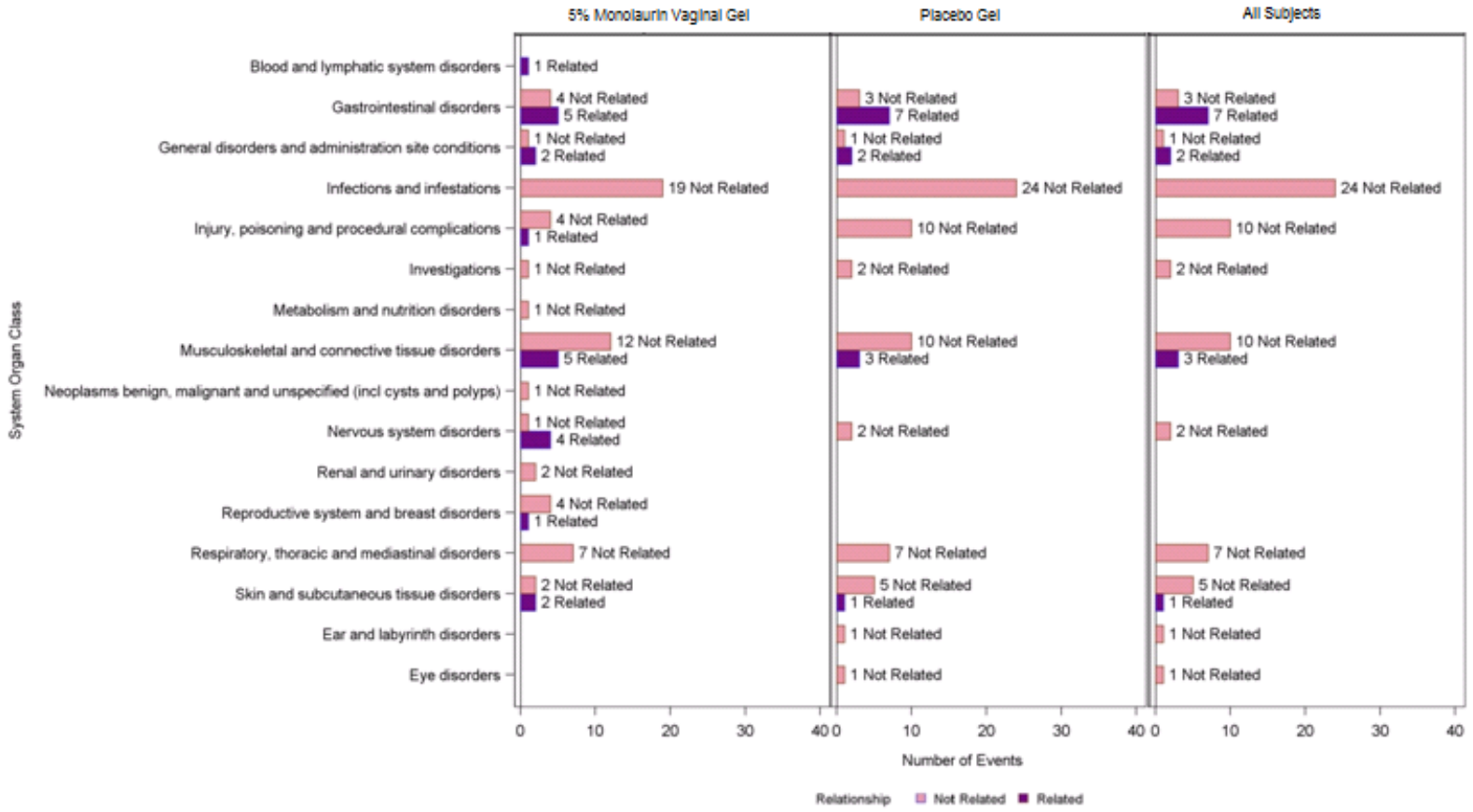


Figure 14: Incidence of Non-Solicited Non-Laboratory Adverse Events by MedDRA System Organ Class and Relationship to Treatment - Safety Population

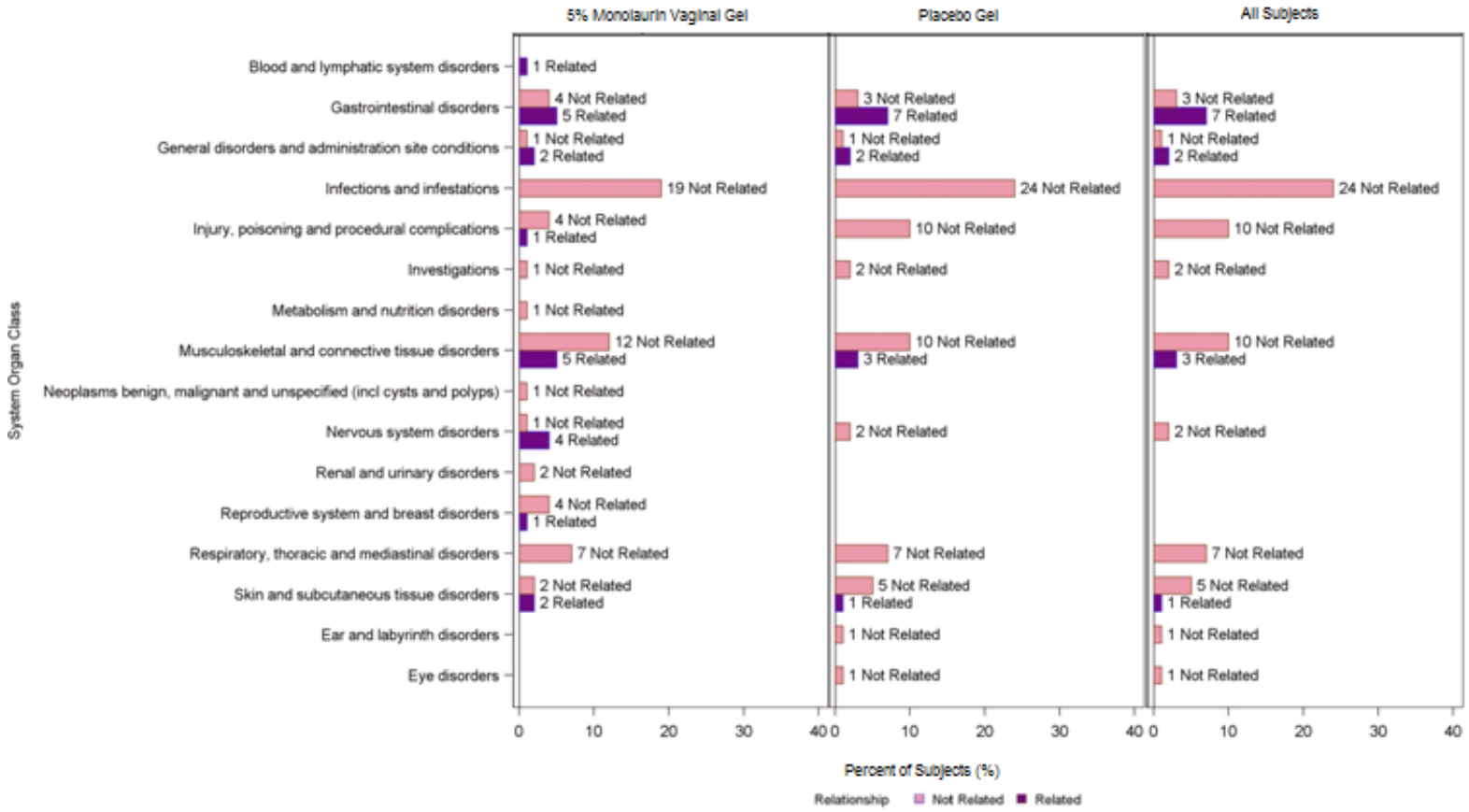
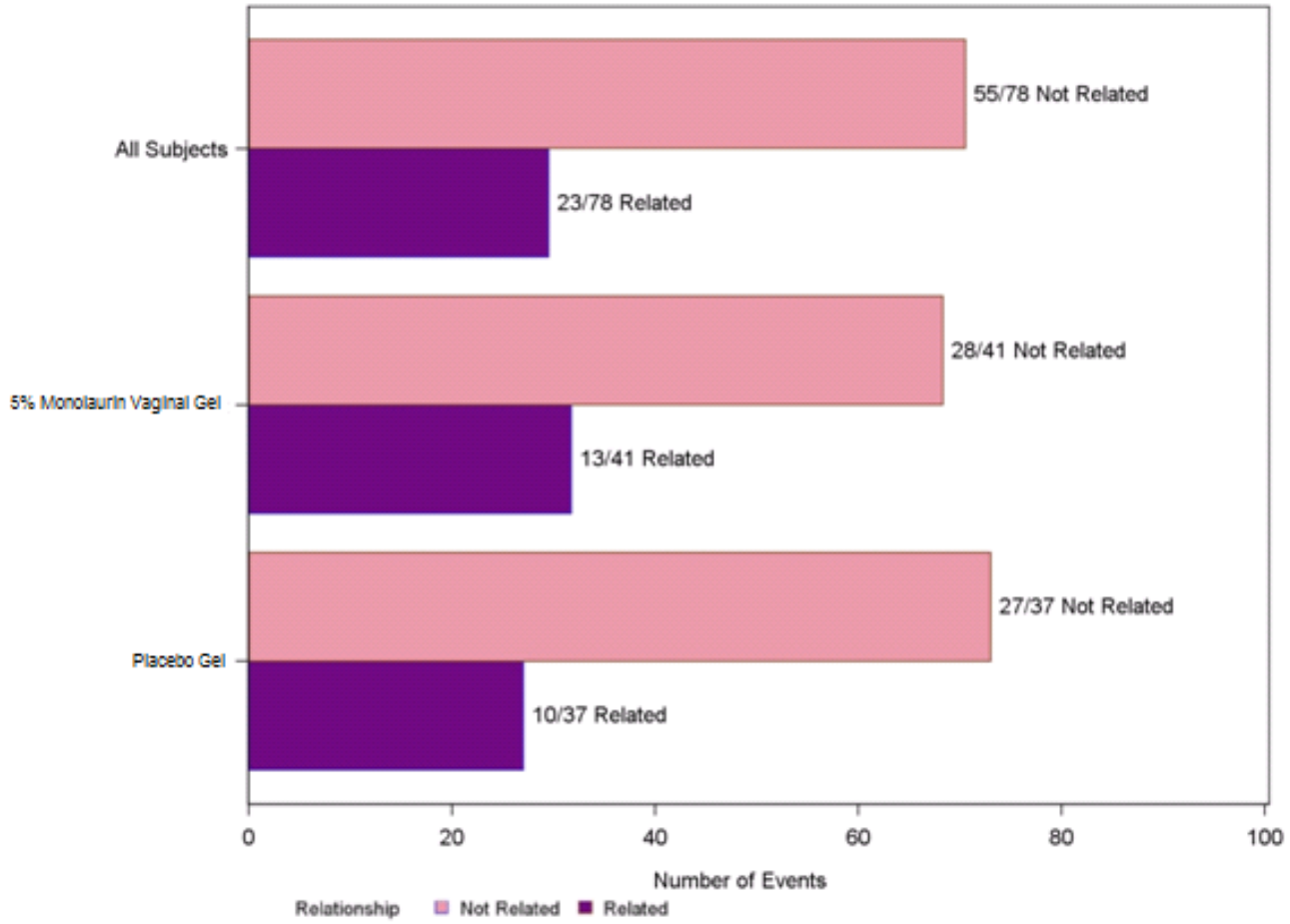


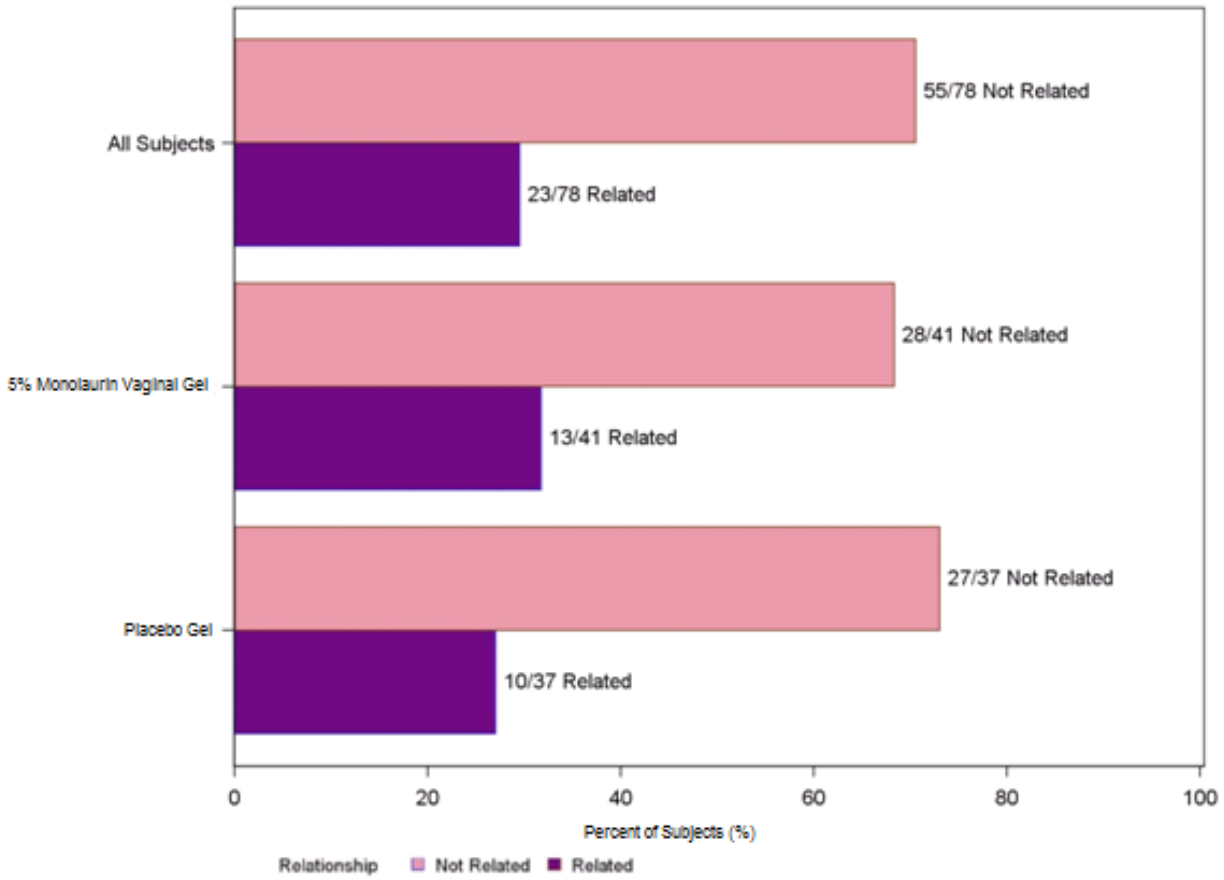
Figure 15: Frequency of Non-Solicited Non-Laboratory Adverse Events by Relationship to Treatment - Safety Population



Implementation Note:

Figures will be presented in the following order: 5% Monolaurin Vaginal Gel, Placebo Gel, All Subjects

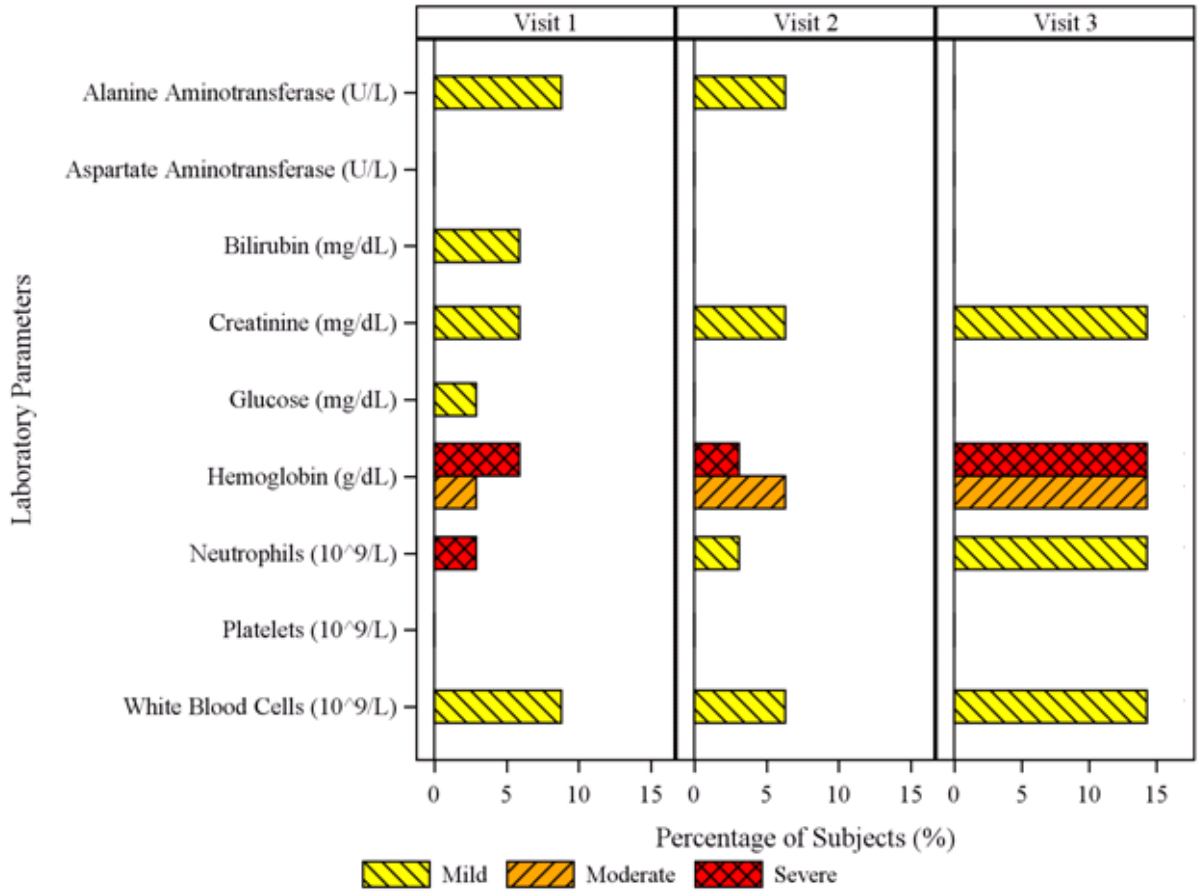
Figure 16: Incidence of Non-Solicited Non-Laboratory Adverse Events by Relationship to Treatment - Safety Population



Implementation Note:

Figures will be presented in the following order: 5% Monolaurin Vaginal Gel, Placebo Gel, All Subjects

Figure 17: Laboratory Results by Parameter, Severity, Visit - All Subjects

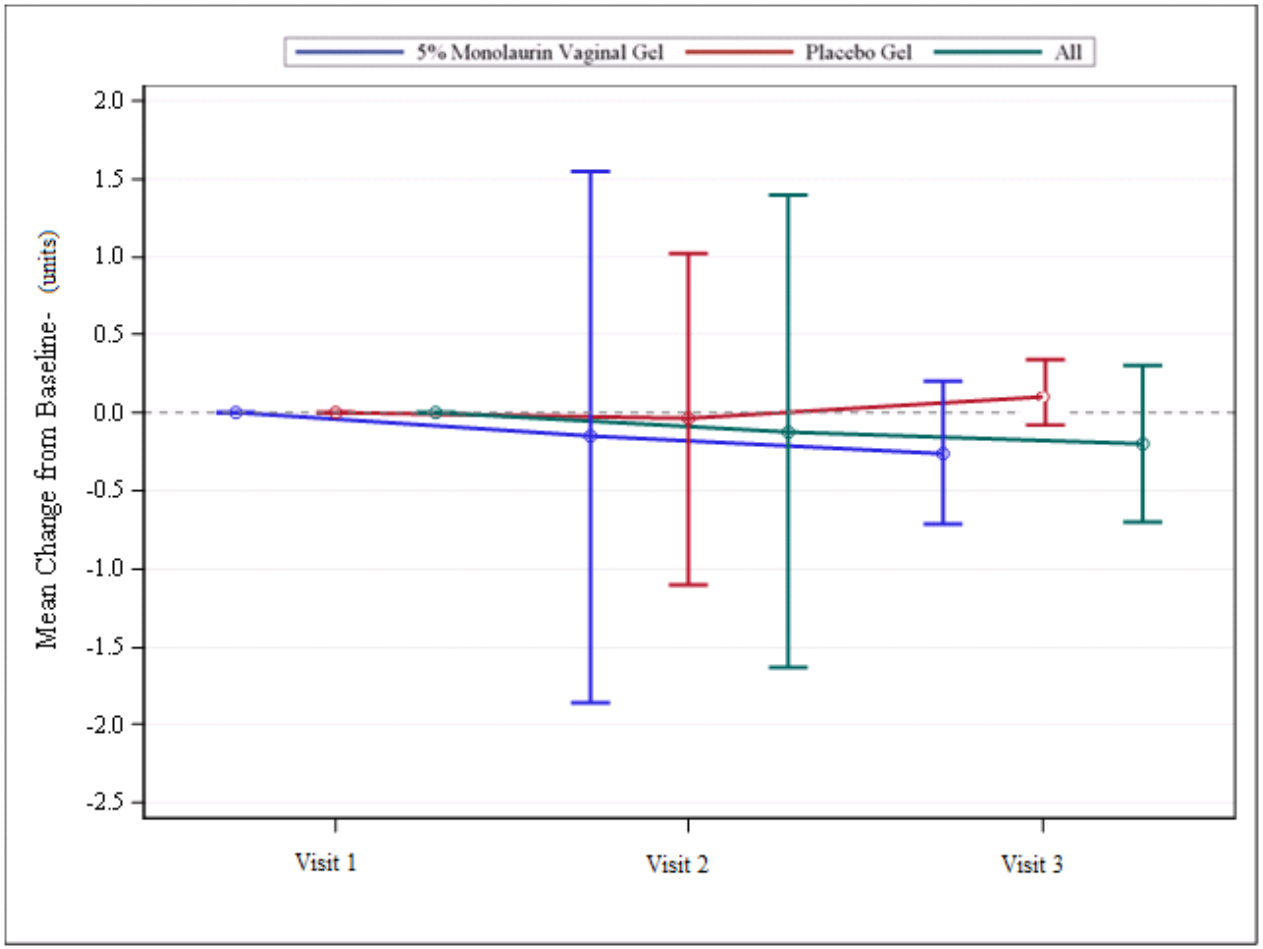


Figures with Similar Format:

Figure 18: Laboratory Results by Parameter, Severity, Visit - All Subjects - 5% Monolaurin Vaginal Gel

Figure 19: Laboratory Results by Parameter, Severity, Visit - All Subjects - Placebo Gel

Figure 20: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Alanine Aminotransferase (U/L)



Figures with Similar format:

Figure 21: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Aspartate Aminotransferase (U/L)

Figure 22: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Bilirubin (mg/dL)

Figure 23: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Creatinine (mg/dL)

Figure 24: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Glucose (mg/dL)

Figure 25: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Hemoglobin (g/dL)

Figure 26: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Neutrophils (10^9/L)

Figure 27: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - Platelets (10^9/L)

Figure 28: Summary of Mean Change from Baseline Clinical Laboratory Result - Safety Population - White Blood Cells (10^9/L)

Appendix III: Listings Mock-Ups

Programming Notes:

The following notes should be implemented on all listings:

1. If the actual treatment is not the same as the randomized treatment, then have a column for Randomized Treatment Group and Actual Treatment Group on all listings. If actual treatment equals randomized treatment, then will have one column labeled "Treatment Group".

2. For missing data, '-' will be used in blank cells.

Listing 1: 16.2.1 Early Terminations or Discontinued Subjects – All Enrolled Subjects

Subject ID	Randomized Treatment Group	Actual Treatment Group	Category	Study Day Corresponding to Early Termination/Treatment Discontinuation/Completion	Reason for Early Termination/ Treatment Discontinuation
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Early Termination/Treatment Discontinuation/Completion	xx	xxxxxxxxxxxxxxxx
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Early Termination/Treatment Discontinuation/Completion	xx	---

Implementation Notes:

1. Sort order will be by Subject ID, Category

2. Category will be "Early Termination", "Completion" or "Treatment Discontinuation". If a subject discontinued treatment, they will have two records.

3. In the “Reason” column, concatenate any “specify” fields, including AE number and DV number.

Listing 2: 16.2.2.1 Subject-Specific Protocol Deviations- All Enrolled Subjects

Subject ID	Randomized Treatment Group	Actual Treatment Group	Deviation Number	Study Day	Deviation Description	Deviation Category	Reason for Deviation	Deviation Affected Product Stability?	Deviation Resulted in AE?	Deviation Resulted in Subject Termination?	Deviation Resolution	Comments
Xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	xxxxxxx	xxxxxxxxxxx	xxxxxxx	Yes/No	Yes/No	Yes/No	Yes/No	xxxxxxxxxxx
Xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	xxxxxxx	xxxxxxxxxxx	xxxxxxx	Yes/No	Yes/No	Yes/No	Yes/No	--

Note: Deviation description column will contain all subfields concatenated together

Implementation Notes:

1. Sort order will be by Subject ID, Deviation Number
2. In the Deviation Category column concatenate any specify fields
3. In the Reason for Deviation column concatenate any specify fields.

Listing 3: 16.2.2.2 Non-Subject-Specific Protocol Deviations

Site	Deviation	Start Day	End Day	Reason for Deviation	Deviation Resulted in Subject Termination?	Deviation Affected Product Stability?	Deviation Category	Deviation Resolution	Comments
xxxx	xxxx	xx	xx	xxxx	Yes/No	Yes/No/NA	xxxx	xxxx	xxxx
xxxx	xxxx	xx	xx	xxxx	Yes/No	Yes/No/NA	xxxx	xxxx	xxxx

Note: Deviation column will contain all subfields concatenated together

Implementation Notes:

1. Sort order will be by Site Name, Start Date
2. In the Deviation Category column concatenate any specify fields
3. In the Reason for Deviation column concatenate any specify fields.

Listing 4: 16.2.3 Subjects Excluded from Analysis Populations

Randomized Treatment Group	Actual Treatment Group	Subject ID	Analyses in which Subject is Included	Analyses from which Subject is Excluded	Results Available?	Reason(s) Subject Excluded
5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxxxxx	[e.g., Safety, ITT, mITT, Evaluable, PP]	[e.g., Safety, ITT, mITT, Evaluable, PP, Visit x]	Yes/No	xxxxx
5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxxxxx	[e.g., Safety, ITT, mITT, Evaluable, PP]	[e.g., Safety, ITT, mITT, Evaluable, PP, Visit x]	Yes/No	xxxxx
5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxxxxx	[e.g., Safety, ITT, mITT, Evaluable, PP]	[e.g., Safety, ITT, mITT, Evaluable, PP, Visit x]	Yes/No	xxxxx

Note: "Yes" in the "Results available" column indicates that available data were removed from the analysis. If "Yes" the population in which data were removed will be listed in parenthesis. "No" indicates that no data were available for inclusion in the analysis.

Implementation Notes:

1. Sort order will be randomized treatment group, Subject ID
2. Reasons Subject Excluded should match the same verbiage that is used on the Analysis population tables (Tables 3 and 4)
3. For subjects excluded from the Per Protocol population, specify which visit's PP population (Visit 2 or Visit 3) the subject is excluded from

Listing 5: 16.2.4.1 Demographics Data - All Enrolled Subjects

Subject ID	Randomized Treatment Group	Actual Treatment Group	Age at Enrollment (years)	Ethnicity	Race
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xxxxxx	xxxxxx
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xxxxxx	xxxxxx
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xxxxxx	xxxxxx

Implementation Notes:

1. Sort order will be by Subject ID

2. For the Race column, if a subject is Multi-Racial, all races will be listed, separated by a comma

Listing 6: 16.2.4.2 Pre-Existing Medical Conditions – All Enrolled Subjects

Subject ID	Randomized Treatment Group	Actual Treatment Group	MH Number	Medical History Term	Condition Start Day	Condition End Day	MedDRA System Organ Class	MedDRA Preferred Term
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxx	xxxxxx	xx	xx	xxxxxx	xxxxxx
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxx	xxxxxx	xx	xx	xxxxxx	xxxxxx

Implementation Notes:

1. Sort order is Subject ID, MH Number.

2. "Condition Start Day" and "Condition End Day" are relative to enrollment (which is Day 1, day before enrollment is Day -1). Rather than use exact study days, categorize as follows:

- > 5 years prior to enrollment

- 1-5 years prior to enrollment

-1-12 months prior to enrollment

-Within 1 month of enrollment

-During Study

-If Ongoing at the end of the study, display "Ongoing' in the "Condition End Day" column.

-If ending is unknown at the end of the study, display "Unknown" in the "Condition End Day" column.

Listing 7: 16.2.4.3 Baseline Sexual History – All Enrolled Subjects

Subject ID	Randomized Treatment Group	Actual Treatment Group	Number of episodes of BV in last 12 months	Received treatment for previous episodes of BV in the previous 12 months?	Sexually active?	Sexual Orientation	Sex with men or women in the past 12 months?	Vaginal intercourse in the past 12 months?	Receptive oral intercourse in the past 12 months?	Receptive anal intercourse in the past 12 months?
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	Yes/No	Yes/No/Unknown	Heterosexual/ Gay/ Homosexual/ Bisexual/ Unknown	Men/Women/Both/ Neither/Unknown	Yes/No/ Unknown	Yes/No/ Unknown	Yes/No/ Unknown
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	Yes/No	Yes/No/Unknown	Heterosexual/ Gay/ Homosexual/ Bisexual/ Unknown	Men/Women/Both/ Neither/Unknown	Yes/No/ Unknown	Yes/No/ Unknown	Yes/No/ Unknown

Implementation Notes:

1. Sort order is Subject ID.

2. If answer to Sexually Active is 'No', then the remaining columns ('Sexual Orientation' through 'Receptive anal intercourse in the past 12 months?" should be blank. Fill with a '-'.

Listing 8: 16.2.4.4 Follow-up Sexual History - Safety Population

			Since First Dose of Treatment			48 Hours Prior to Visit 3		
Subject ID	**Randomized Treatment Group**	**Actual Treatment Group**	**Engaged in vaginal intercourse?**	**Received oral intercourse?**	**Inserted any intravaginal substances or objects other than the study treatment?**	**Engaged in vaginal intercourse?**	**Received oral intercourse?**	**Inserted any intravaginal substances or objects other than the study treatment?**
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Yes/No/ Unknown [Condom: xxx]	Yes/No/Unknown [Barrier: xxx]	Yes/No/ Unknown [Substance(s): xxx]	Yes/No/Unknown [Condom: xxx]	Yes/No/Unknown [Barrier: xxx]	Yes/No/Unknown [Substance(s): xxx]
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Yes/No/ Unknown [Condom: xxx]	Yes/No/Unknown [Barrier: xxx]	Yes/No/ Unknown [Substance(s): xxx]	Yes/No/Unknown [Condom: xxx]	Yes/No/Unknown [Barrier: xxx]	Yes/No/Unknown [Substance(s): xxx]

Note: If Condoms, barriers, or substances were used, they will be listed in the cell

Implementation Notes:

1. Sort order is Subject ID.

2. If answer to 'Engaged in vaginal intercourse?' is 'Yes', then concatenate answer to whether a condom was used 'Yes/No' (i.e. Yes [Condom: Yes]).

If answer is 'No' or 'Unknown', there will be no answer to condom usage.

3. If answer to 'Received oral intercourse?' is 'Yes', then concatenate answer to whether a barrier was used 'Yes/No' (i.e. Yes [Barrier: No]). If answer is 'No' or 'Unknown', there will be no answer to barrier usage.

4. If answer to 'Inserted any intravaginal substances or objects other than the study treatment? ' is 'Yes', then concatenate answer to the substances that were inserted : Tampons, Spermicide, Douche, Diaphragm, Feminine deodorant product, Other: Other, specify. For example, if a subject marked Yes to Tampons, Douche and Other, where other specify is metronidazole gel, this column would be: Yes [Substances: Tampons, Douche, Other: metronidazole gel]. If answer is 'No' or 'Unknown', there will be no answer to substances.

Listing 9: 16.2.5 Compliance Data - Safety Population

			Subject Report			Clinic Assessment of Product Accountability	
Subject ID	**Randomized Treatment Group**	**Actual Treatment Group**	**Number of Doses Taken as Scheduled**	**Number of Doses Taken Out of Window**	**Number of Doses Not Taken**	**Returned Used Applicators**	**Returned Unused Applicators**
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	x	x	x	x	x
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	x	x	x	x	x
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	x	x	x	x	x

Implementation Notes:

1. Sort order is Subject ID.

2. Total number of doses is 6. Number of doses not taken will be calculated as 6 - Number of doses taken as scheduled - Number of doses taken out of window.

3. A dose will be considered 'Taken as Scheduled' on a given day if there are 2 doses taken on the same day at least 8 hours a part. The doses should be taken within 72 hours from first dose at least 8 hours apart and not more than 2 doses in a 24 hour period to be counted as all 6 being 'Taken as Scheduled". If only one dose is taken on a day, then the first dose will be considered 'Taken as Scheduled'. If the first dose is taken after 3 pm, then only 1 dose will be taken on Day 1 and 1 dose on Day 4. Otherwise, a subject should have 2 doses taken on Day 1, 2 doses taken on Day 2 and 2 doses taken on Day 3. Any doses taken outside these time limits will be considered to be 'Taken Out of Window'.

4. If a subject does not have a record for 'Returned Used Applicators' or 'Returned Unused Applicators', then an 'Unknown' will be placed in those columns.

Listing 10: 16.2.6 Individual Efficacy Response Data

Subject ID	Randomized Treatment Group	Actual Treatment Group	Analysis Population	Visit Number	Study Day	Clinical Cure	Bacteriologic Cure	Therapeutic Cure
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	ITT, mITT, Evaluable, PP	xx	xx	Y/N	Y/N	Y/N
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	ITT, mITT, Evaluable, PP	xx	xx	Y/N	Y/N	Y/N
xxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	ITT, mITT, Evaluable, PP	xx	xx	Y/N	Y/N	Y/N

Implementation Notes:

1. Sort order is Subject ID, Analysis Population, Visit Number.

2. For Analysis Population, sort in the following order (will have to create a dummy sort variable): ITT, mITT, Evaluable, PP.

3. A subject will have one row for each analysis population/visit combination. So if a subject is in all 4 populations, that subject will have 8 rows in this table. One for ITT - Visit 2, ITT - Visit 3, mITT - Visit 2, mITT - Visit 3, Evaluable - Visit 2, Evaluable - Visit 3, PP - Visit 2, PP - Visit 3.

Listing 11: 16.2.7.1 Clinical Assessment - Safety Population

Study Day	Vaginal Odor	Vaginal Pain	Vaginal Tenderness	Vulvar/Vaginal Itching	Vaginal Dryness	Vaginal Discharge	Vulvar Inflammation
Subject ID: , Randomized Treatment Group: , Actual Treatment Group:							
xx	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]
xx	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]
xx	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]

Note: Vaginal Dryness and Vaginal Discharge are graded on a two-point scale (mild, moderate).

Implementation Notes:

1. Sort order is Subject ID.

2. Data from Visits 1, 2, and 3 will be listed

Listing 12: 16.2.7.2 Solicited Symptoms - Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Study Day	Vaginal Odor	Vaginal Pain	Vaginal Tenderness	Vulvar/Vaginal Itching	Vaginal Dryness	Vaginal Discharge	Vulvar Inflammation
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]	[severity]

Note: * means symptom qualifies as a treatment emergent solicited adverse event.

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. If a symptom is ongoing after day 5, add a row for Day 6 and for each day until the end date of the symptom. The severity will be the maximum severity reported for that symptom.

3. Mark all severities with an asterisk, *, that are considered treatment emergent solicited adverse events.

Listing 13: 16.2.7.3 Unsolicited Adverse Event - Safety Population

Adverse Event	Study Day	Severity	SAE?	Relationship to Study Treatment	In Not Related, Alternative Etiology	Action Taken with Study Treatment	Subject Discontinued Due to AE	Outcome	MedDRA System Organ Class	MedDRA Preferred Term
Subject ID: , Randomized Treatment Group: , Actual Treatment Group: , AE Number:										
xxxxxxx	**xx**	**xxxxxx**	**xxxxxx**	**xxxxxx**	**xxxxx**	**xxxxxx**	**Y/N**	**xxxxx**	**xxxxx**	**xxxxx**
Comments: xxxxxxxxxxxxx										
Subject ID: , Randomized Treatment Group: , Actual Treatment Group: , AE Number:										
xxxxxxx	**xx**	**xxxxxx**	**xxxxxx**	**xxxxxx**	**xxxxx**	**xxxxxx**	**Y/N**	**xxxxx**	**xxxxx**	**xxxxx**
Comments: xxxxxxxxxxxxx										

Note: For additional details about SAEs, see Table 79.

Implementation Notes:

1. Sort order is Subject ID, AE Number.

2. Shaded rows will be in the SAS color LTGRAY light gray #C0C0C0

Listing 14: 16.2.8.1 Clinical Laboratory Results – Hematology - Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Age (years)	Study Day	Hemoglobin (g/dL)	Neutrophils (10^9/L)	Platelets (10^9/L)	White Blood Cell Count (10^9/L)
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	XX.X	XX.XX	XXX	XX.XX
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	XX.X	XX.XX	XXX	XX.XX

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. Toxicity grades can be found in Appendix B of the Protocol. If a lab has a toxicity Grade of 1, 2, or 3, then put grade in parenthesis after the result. (i.e. 90 (Gr 3). If the toxicity grade is an increase, then add a "+" to the grade (i.e. +Gr 3). If a toxicity grade is a decrease, then add a '-' to the grade (i.e. -Gr 3). Note: all of the above hematology labs have a toxicity grading scale.

Listing 15: 16.2.8.2 Clinical Laboratory Results – Biochemistry - Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Age (years)	Study Day	Alanine Aminotransferase (U/L)	Aspartate Aminotransferase (U/L)	Bilirubin (mg/dL)	Creatinine (mg/dL)	Glucose (mg/dL)
xxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	XXXX	XXXX	X.X	X.XX	XXX
xxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xx	XXXX	XXXX	X.X	X.XX	XXX

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. Toxicity grades can be found in Appendix B of the Protocol. If a lab has a toxicity Grade of 1, 2, or 3, then put grade in parenthesis after the result. (i.e. 90 (Gr 3). If the toxicity grade is an increase, then add a "+" to the grade (i.e. +Gr 3). If a toxicity grade is a decrease, then add a '-' to the grade (i.e. -Gr 3). Note: all of the above biochemistry labs have a toxicity grading scale.

Listing 16: 16.2.9.1 Physical Exam Findings

Subject ID	Randomized Treatment Group	Actual Treatment Group	Study Day	Body System	Abnormal Finding	Reported as an AE? (AE Description; AE Number)
xxxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxx	xxxxxxxx	xxxxxxxx	Yes/No xxxxxx; xx

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. Only abnormal findings will be presented.

3. If the physical exam was reported as an AE, then concatenate the Physical exam with the Adverse Events by AENUM and report the AETERM, plus the AE Number.

Listing 17: 16.2.9.2 Pelvic Exam Findings

				Objective Signs of Inflammation									Vaginal Discharge			
				Cervix			Vagina			Vulva						
Subject ID	**Randomized Treatment Group**	**Actual Treatment Group**	**Study Day**	**Edema**	**Erythema**	**Excoriation**	**Edema**	**Erythema**	**Excoriation**	**Edema**	**Erythema**	**Excoriation**	**Quantity**	**Color**	**Consistency**	**Odor**
xxxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No	xxxxx	xxxxx	xxxxx	xxxxx

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. If Discharge is not present, populate cells with '-'.

Listing 18: 16.2.9.3 Additional Gynecological Test Results

Subject ID	Randomized Treatment Group	Actual Treatment Group	Study Day	Motile flagellated protozoa on saline wet mount?	Rapid Trichomonas test result	Pseudohyphae or budding spores on KOH wet mount?
xxxxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	Negative/Positive	Negative/Positive	Negative/Positive

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. 'Rapid Trichomonas test' was only collected on Day 1 and only conducted if the 'Motile flagellated protozoa' test was negative. Put a 'N/A' if test was not collected .

Listing 19: 16.2.10.1 Concomitant Medications - Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Concomitant Medication Number	Medication	Medication Start Day	Medication End Day	Indication	Taken for an AE? (AE Description; AE Number)	Taken for a condition on Medical History? (MH Description; MH Number)
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xxxxxx	xx	xx	xxxxxx	Yes/No xxxxx; xx	Yes/No xxxxx; xx
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xx	xxxxxx	xx	xx	xxxxxx	Yes/No xxxxx; xx	Yes/No xxxxx; xx

Implementation Notes:

1. Sort order is Subject ID, concomitant medication number.

2. 'Medication Start Day' and 'Medication End Day' are relative to enrollment (which is Day 1, day before enrollment is Day -1). For medication start dates that are > 30 days prior to enrollment, rather than use exact days, categorize as follows:

- > 5 years prior to enrollment

- 1- 5 years prior to enrollment

- 1-12 months prior to enrollment.

- For 'Medication End Day', if medication is Ongoing, display 'Ongoing' in the Medication End Day' column.

- For 'Medication End Day', if end of medication is unknown, display 'Unknown' in the 'Medication End Day' column.

3. If a Medication is taken for an AE, then concatenate the conmed with the Adverse Events by AENUM and report the AETERM, plus the AE Number.

4. If a Medication is taken for an MH, then concatenate the conmed with the Medical History event by MHNUM and report the MHTERM, plus the MH Number.

5. Include the birth control information in this dataset. The birth control information is coming from the RP/SUPPRP or BC1 dataset.

Listing 20: 16.2.10.2 Subjects Whose Assigned Treatment Group Does Not Match Their Randomized Treatment Group

Subject ID	Treatment Group at Randomization	Treatment Actually Received
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel

Implementation Note:

1. Sort order is Subject ID.

Listing 21: 16.2.10.3 Subjects Product Administration Position- Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Dose 1 Status	Dose 2 Status	Dose 3 Status	Dose 4 Status	Dose 5 Status	Dose 6 Status	Total Number of Doses Taken in the Recumbent Position (%)
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	xx (xx)
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	Recumbent/Not Recumbent/Missing	xx (xx)

Implementation Note:

1. Sort order is Subject ID.

Listing 22: 16.2.10.4 Amsel Criteria - mITT population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Visit	Study Day	Amine ("whiff") test on KOH wet mount	Off-white (milky or gray), thin, homogenous discharge	Percentage of clue cells on saline wet mount	Vaginal pH	Number of Amsel Criteria Met	Clinical Cure Determination
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	01	xx	Positive/Negative/Not Assessed	Yes/No/Not Assessed	x/Not Assessed	xx.x/Not Assessed	xx	--
			02	xx	Positive/Negative/Not Assessed	Yes/No/Not Assessed	x/Not Assessed	xx.x/Not Assessed	xx	Cure/Failure/Not Evaluable
			03	xx	Positive/Negative/Not Assessed	Yes/No/Not Assessed	x/Not Assessed	xx.x/Not Assessed	xx	Cure/Failure/Not Evaluable

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2, Unscheduled visits will be included

3. Clinical Cure Determination will be based on the mITT population

Listing 23: 16.2.10.5 Nugent Scores, Bacterial Morphotypes, and Yeast - mITT Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Visit	Study Day	Lactobacillus Culture Count	Gardnerella Culture Count	Mobiluncus Culture Count	Candida Culture Count	Budding Yeast	Nugent Score	Bacteriological Cure Determination
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	01	xx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	Few/Moderate/ Many/No organisms seen	0-10	--
			02	xx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	Few/Moderate/ Many/No organisms seen	0-10	Cure/Failure
			03	xx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	Few/Moderate/ Many/No organisms seen	0-10	Cure/Failure

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2, Unscheduled visits will be included

3. Bacteriological Cure Determination will be based on the mITT population

Listing 24 16.2.10.6 Clinical Failures-Safety Population

					Reason for Clinical Failure				
Subject ID	**Randomized Treatment Group**	**Actual Treatment Group**	**Visit**	**Study Day**	**Lack of resolution of one or more signs or symptoms in the Amsel criteria**	**Presentation of new signs or symptoms meeting the Amsel criteria**	**Early discontinuation of study therapy due to lack of treatment effect**	**Use of any vaginosis therapy or systemic antimicrobial therapy other than study product**	**Requires additional treatment for vaginosis**
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	02	xx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
			03	xx	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Implementation Notes:

1. Sort order is Subject ID, Study Day.

2. These reasons come from the eCRF and are not calculated (GYN) dataset.

Listing 25 16.2.10.7 BV Infection Status - Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	BV Infection Subgroup	If Recurrent, Number of Episodes in previous 12 months
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	First time Infection	NA
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	Recurrent Infection	xx

Implementation Notes:

1. Sort order is Subject ID.

2.The infection status comes from Question 1 of the Sexual History CRF. If a subject answers 1, then they have 'First time infection'. If they answer 2 or more, then they have Recurrent Infection.

Listing 26 16.2.11.1 Pregnancy Reports – Maternal Information - Safety Population

Subject ID	Randomized Treatment Group	Actual Treatment Group	Pregnancy Number	Study Day Corresponding to Estimated Date of Conception	Source of Maternal Information	Pregnancy Status	Mother's Pre-Pregnancy BMI	Mother's Weight Gain During Pregnancy	Tobacco, Alcohol, or Drug Use During Pregnancy?	Medications During Pregnancy?	Maternal Complications During Pregnancy?	Maternal Complications During Labor, Delivery, or Post-Partum?
xxxxxx	5% Monolaurin Vaginal Gel/Placebo Gel	5% Monolaurin Vaginal Gel/Placebo Gel	xxx	xxx	xxx	xxx	xxx	xxx	Y/N	Y/N	Y/N	Y Y/N /N

Note: Maternal Complications are included in the Adverse Event listing. Medications taken during pregnancy are included in the Concomitant Medications Listing.

Implementation Notes:

1. Sort order is Subject ID, Pregnancy Number

Listing 27 16.2.11.2 Pregnancy Reports – Gravida and Para

			Live Births												
Subject ID	**Pregnancy Number**	**Gravida**	**Extremely Preterm Births**	**Very Preterm Births**	**Early Preterm Births**	**Late Preterm Births**	**Early Term Births**	**Full Term Births**	**Late Term Births**	**Post Term Births**	**Still Births**	**Spontaneous Abortion/ Miscarriage**	**Elective Abortions**	**Therapeutic Abortions**	**Major Congenital Anomaly with Previous Pregnancy?**
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Y/N

Note: Gravida includes the current pregnancy, para events do not.

Listing 28 16.2.11.3 Pregnancy Reports – Live Birth Outcomes

Subject ID	**Pregnancy Number**	**Fetus Number**	**Pregnancy Outcome (for this Fetus)**	**Fetal Distress During Labor and Delivery?**	**Delivery Method**	**Gestational Age at Live Birth**	**Size for Gestational Age**	**Apgar Score, 1 minute**	**Apgar Score, 5 minutes**	**Cord pH**	**Congenital Anomalies?**	**Illnesses/ Hospitalizations within 1 Month of Birth?**
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	Y/N	xxx

Note: Congenital Anomalies are included in the Adverse Event listing.

Listing 29 16.2.11.4 Pregnancy Reports – Still Birth Outcomes

Subject ID	**Day of Initial Report**	**Fetus Number**	**Pregnancy Outcome (for this Fetus)**	**Fetal Distress During Labor and Delivery?**	**Delivery Method**	**Gestational Age at Still Birth**	**Size for Gestational Age**	**Cord pH**	**Congenital Anomalies?**	**Autopsy Performed?**	**If Autopsy, Etiology for Still Birth Identified?**
xxxxxx	xx	xxx	xxxxxxx	Y/N	xxxxxxx	xxx	xxx	xx	Y/N	Y/N	xxxxxxx

Listing 30 16.2.11.5 Pregnancy Reports – Spontaneous, Elective, or Therapeutic Abortion Outcomes

Subject ID	Day of Initial Report	Fetus Number	Pregnancy Outcome (for this Fetus)	Gestational Age at Termination	Abnormality in Product of Conception?	Reason for Therapeutic Abortion
xxxxxx	xx	xxx	xxxxx	xxxx	Y/N	xxxxxxx

Appendix IV: Clinical Lab Reference Ranges

Site	Test	Sex	Age (yrs)	Lower Limit	Upper Limit	Units
Cincinnati Children's Hospital	Alanine Aminotransferase	Female	All	12	78	U/L
Cincinnati Children's Hospital	Aspartate Aminotransferase	Female	All	9	37	U/L
Cincinnati Children's Hospital	Bilirubin	Both	All	0.1	1.1	mg/dL
Cincinnati Children's Hospital	Creatinine	Female	All	0.51	0.95	mg/dL
Cincinnati Children's Hospital	Glucose	Female	All	65	106	mg/dL
Cincinnati Children's Hospital	Hemoglobin	Female	All	11.7	15.7	g/dL
Cincinnati Children's Hospital	Neutrophils	Both	10 - 20	1.8	8	10^9/L
Cincinnati Children's Hospital	Neutrophils	Both	21+	1.8	7.7	10^9/L
Cincinnati Children's Hospital	Platelets	Both	All	135	466	10^9/L
Cincinnati Children's Hospital	White Blood Cell Counts	Both	16 - 20	4.5	13	10^9/L
Cincinnati Children's Hospital	White Blood Cell Counts	Both	21+	4.5	11	10^9/L
University of Iowa	Alanine Aminotransferase	Female	10 - 18	5	20	U/L
University of Iowa	Alanine Aminotransferase	Female	19+	0	33	U/L
University of Iowa	Aspartate Aminotransferase	Both	13 - 18	10	35	U/L
University of Iowa	Aspartate Aminotransferase	Female	19+	0	32	U/L
University of Iowa	Bilirubin	Both	18+		1.2	mg/dL
University of Iowa	Creatinine	Female	16+	0.5	1	mg/dL
University of Iowa	Glucose	Both	All	65	99	mg/dL
University of Iowa	Hemoglobin	Female	18+	11.9	15.5	g/dL
University of Iowa	Neutrophils	Both	5 - 18	1.7	7.5	10^9/L
University of Iowa	Neutrophils	Both	19+	2.188	7.8	10^9/L
University of Iowa	Platelets	Both	All	150	400	10^9/L
University of Iowa	White Blood Cell Counts	Both	18+	3.7	10.5	10^9/L
Duke University	Alanine Aminotransferase	Female	12+	14	54	U/L
Duke University	Aspartate Aminotransferase	Female	2+	15	41	mg/dL
Duke University	Bilirubin	Female	All	0.4	1.5	mg/dL
Duke University	Creatinine	Female	16+	0.4	1.0	mg/dL
Duke University	Glucose	Female	All	70	140	mg/dL
Duke University	Hemoglobin	Female	12-18	12.0	16.0	g/dL
Duke University	Hemoglobin	Female	19+	12.0	15.5	g/dL
Duke University	Neutrophils	Female	12-18	1.8	7.2	10^9/L
Duke University	Neutrophils	Female	19+	2.0	8.6	10^9/L
Duke University	Platelets	Female	12-18	150	400	10^9/L
Duke University	Platelets	Female	19+	150	450	10^9/L
Duke University	White Blood Cell Counts	Female	18+	3.2	9.8	10^9/L