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STATISTICAL ANALYSIS PLAN

Evaluation of the Effectiveness, Safety and Tolerability of LevoCept (Levonorgestrel-Releasing Intrauterine System) for Long-Acting Reversible Contraception

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Evaluation of the Effectiveness, Safety and Tolerability of LevoCept (Levonorgestrel-Releasing Intrauterine System) for Long-Acting Reversible Contraception

Protocol Number: CMDOC-0022

Sponsor: Sebela Pharmaceuticals Development LLC
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Document Version History

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1.5	To incorporate sponsor's comments and Protocol Version 4.0	[redacted]	14 November 2017
2.0	To incorporate sponsor's comments	[redacted]	20 July 2018

CONFIDENTIAL

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List of Abbreviations

ADaM	Analysis Data Model
AE	Adverse Event
ATC	Anatomical Therapeutic Classification
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
ECYC	Evaluable for Cycle Control
EP	Evaluable for pregnancy
ICH	International Conference on Harmonisation
safety	Intent to Treat
LTFU	Long Term Follow up
Max	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
n	Number of Patients with an Observation
N	Number of Patients in the Dataset
PD	Protocol Deviation
PT	Preferred Term
SAE	Serious AE
SD	Standard Deviation
SDTM	Standard Data Tabulation Model
SOC	System Organ Class
TLFs	Tables, Listings, and Figures
TEAE	Treatment-emergent AE
WHO DDE	World Health Organization Drug Dictionary Enhanced

1 Introduction

This document details the criteria to be used for the definition of the analysis populations, the statistical methodology for final analysis, and the proposed tabular, graphical and listing presentation of data from Study CMDOC-0022 of Sebela Pharmaceuticals Development LLC (Sebela). This document has been written based on information contained in the final study protocol (version 4.0) dated 18 October 2017.

1.1 Responsibilities

The Biostatistics Department at Synteract Inc. will be responsible for the formal statistical analyses and for the production of the summary tables, data listings, and figures.

1.2 Definitions

The following visits are scheduled in the study protocol:

- Visit 1(Screening Visit);
- Visit 2 (LevoCept Placement Visit): Day1;
- Follow up Visit 3 - 6 : Week 6±1w,13±2w, 26±2w and 52±2w;
- Long term follow up (LTFU): Every 6 months post 52 weeks (max 3 years post insertion)±2w.

Day 1 is defined as the date of study device successful deployed.

Based on the visit window in the study protocol, new analysis visit windows are redefined as follows to cover every data point, including unscheduled visits. Also note that if there are 2 or more non-missing records in the same analysis visit window, only the last one (by the assessment date) will be used for summary table, but data listings will include all records for all enrolled subjects, unless stated otherwise. For clinical data, visits will be referred to by their study day throughout this document.

The visit windows and study days are presented in Table 1:

Table 1 Visit windows and study days

Visit	Visit (Window) in Protocol	Study Day	Visit (Window) in Protocol in study day	Analysis Visit Window in study day
Visit 1(Screening)	Visit 1/Screening		-1 or earlier	-1 or earlier
Visit 2(Placement)	Visit 2 (Day 1)	1	1	1
Visit 3	Visit 3 (Week 6±1w)	43	36-56	2 – 68
Visit 4	Visit 4 (Week 13±2w)	92	78-112	69 – 138
Visit 5	Visit 5 (Week 26±2w)	183	169-203	139 – 274
Visit 6	Visit 6 (Week 52±2w)	365	351-385	275 – 385
Visit 7 Long Term FU 1	Visit 7 LTFU 1/Year 2 Month 6 (Week 78±2w)	547	533-567	386 – 638
Visit 8 Long Term FU 2	Visit 8 LTFU 2/Year 2 Month 12 (Week 104±2w)	729	715-749	639 – 821
Visit 9 Long Term FU 3	Visit 9 LTFU 3/Year 3 Month 6 (Week 130±2w)	912	897-930	822 – 1003
Visit 10 Long Term FU 4	Visit 10 LTFU 4/Year 3 Month 12 (Week 156±2w)	1093	1079-1113	1004 +

The analysis cycles and study days are presented in Table 2:

Table 2 Analysis cycles and study days

Year	Analysis Cycle	Study Day	Year	Analysis Cycle	Study Day	Year	Analysis Cycle	Study Day
Year 1	Cycle 1	1-28	Year 2	Cycle 14	365-392	Year 3	Cycle 27	729-756
Year 1	Cycle 2	29-56	Year 2	Cycle 15	393-420	Year 3	Cycle 28	757-784
Year 1	Cycle 3	57-84	Year 2	Cycle 16	421-448	Year 3	Cycle 29	785-812
Year 1	Cycle 4	85-112	Year 2	Cycle 17	449-476	Year 3	Cycle 30	813-840
Year 1	Cycle 5	113-140	Year 2	Cycle 18	477-504	Year 3	Cycle 31	841-868
Year 1	Cycle 6	141-168	Year 2	Cycle 19	505-532	Year 3	Cycle 32	869-896
Year 1	Cycle 7	169-196	Year 2	Cycle 20	533-560	Year 3	Cycle 33	897-924
Year 1	Cycle 8	197-224	Year 2	Cycle 21	561-588	Year 3	Cycle 34	925-952
Year 1	Cycle 9	225-252	Year 2	Cycle 22	589-616	Year 3	Cycle 35	953-980
Year 1	Cycle 10	253-280	Year 2	Cycle 23	617-644	Year 3	Cycle 36	981-1008
Year 1	Cycle 11	281-308	Year 2	Cycle 24	645-672	Year 3	Cycle 37	1009-1036
Year 1	Cycle 12	309-336	Year 2	Cycle 25	673-700	Year 3	Cycle 38	1037-1064
Year 1	Cycle 13	337-364	Year 2	Cycle 26	701-728	Year 3	Cycle 39	1065-1092
						Year 3+	Cycle 40	1093-1120

2 Objectives

The scientific objective of this study is to evaluate the effectiveness, study device placement, safety, and tolerability of the LevoCept Intrauterine Contraceptive as birth control in parous and nulliparous women of child-bearing age.

The purpose of the study is to obtain the safety and effectiveness data necessary to support initiation of a longer-term Phase III Pivotal Clinical Study for LevoCept.

3 Study Design

3.1 Brief Description

This is a prospective, multi-center, single-arm, open-label, Phase II clinical study. Each subject will be followed for 12 months after device placement for the protocol endpoints, and then every 6 months thereafter for those subjects who wish to continue study device use up to a maximum of 3 years.

Follow up office visits will occur at weeks 6, 13, 26 and 52 after study device placement, with monthly contact. For those subjects who wish to continue study device use after 12 months (up to 2 additional years for a total maximum of 3 years), long term follow up office visits will occur every 6 months with contact at the end of each 28-day cycle beginning after the 52-week visit. Additional visits will be conducted if necessary for safety issues.

The study will be conducted at approximately 16 centers in the U.S. It is estimated that approximately 250 subjects will be enrolled to have 2240 evaluable cycles at 12 months. It is planned that 225 of the 250 subjects will be within the 18-35 year age range, with a total of 2015 evaluable cycles. The remaining 25 subjects will be within the 36-40 year age range.

The overall schedule of assessments is presented in table 3:

Table 3: Schedule of Assessments

	Screening	LevoCept Placement	Follow up				Monthly Contact	Exit Visit	Long Term Follow up(max 3 yrs. post insertion)	End of each 28-day Cycle Contact	Exit Visit
Assessments	Visit 1	Visit 2 Day 1	Visit 3 6 ± 1w	Visit 4 13 ± 2w	Visit 5 26 ± 2w	Visit 6 52 ± 2w	up to 52 ± 1 w	Visit 2 – Visit 6/Week 52	Every 6 Months post 52± 2 w	Post 52 ± 1 w	Post Visit 6/ Week 52- Year 3
Initiation/Subject Characteristics											
Assessment of Eligibility	X	X									
Distribution of information	X										
Informed consent, PHI and Bill of Rights forms	X										
Demographics and baseline characteristics	X										
Medical/surgical, gynecologic and menstrual history	X										
Safety and Effectiveness											
Vital signs and weight	X	X	X	X	X	X		X	X		X
Height	X										
General physical exam	X					X		X			X
Pelvic exam	X	X	X[1]	X[1]	X[1]	X[1]		X[1]	X[1]		X[1]
Cervical cytology	X[6]										
Cervical infection test (gonorrhea and chlamydia)	X[5,7]										
Transvaginal ultrasound (for verifying study device position)		X	X[2]	X[2]	X[2]	X		X[1]	X[2]		X[2]
Pregnancy test-urine	X	X	X	X	X	X		X[4, 9]	X		X[4, 9]
Prior and interval concurrent medication	X	X	X	X	X	X	X	X	X		X

Adverse events		X	X	X	X	X	X	X	X		X
Other											
IUD placement		X									
IUD placement ease		X									
IUD placement pain		X									
IUD removal ease						X					X
IUD removal pain						X					X
Concomitant contraception		X	X	X	X	X	X	X	X	X	X
Need for contraception	X	X[8]	X[8]	X[8]	X[8]	X[8]	X	X[8]	X[8]	X[8]	X[8]
Patient trained on E-diary	X[3]	X	X	X	X						
E-diary reviewed with subject		X[3]	X	X	X	X	X				
End of study medication								X			X

Note: Screening and enrollment visit may be combined if the subject requests and all labs and screening exams are documented as normal.
1. Pelvic exam for LevoCept string check.
2. Transvaginal Ultrasound performed at Visit 6 or Exit visit or indicated.
3. First week of e-diary training, prior to LevoCept placement, to be used as training with the subject. This e-diary data is not a part of data collection or analysis. It is intended to ensure the subject understands how to complete the e-diary during the follow up period.
4. Urine pregnancy test will be done 17 days after removal/study exit by the subject at home, with a follow up call by the study coordinator or PI required to document the results. Note: If LevoCept is removed before 52+2 weeks, Visit 6 activities should be completed for Exit Visit.
5. Screening for cervical infections is required unless negative results have been obtained within three months of the screening visit.
6. Current with ASCCP cervical cancer screening guidelines for subjects who will be 21 or older at time of informed consent.
7. Insertion can occur without receipt of test results if there is no clinical evidence of infection.
8. If a subject believes the study device may have been expelled or is no longer in place, the subject should call for an urgent study visit and refrain from having sex or use appropriate non-hormonal contraception until further evaluation is completed.
9. For subjects exiting the study due to IUD expulsion: A urine pregnancy test will be done approximately 6-8 weeks after the exit visit by the subject at home, with a follow up call by the study coordinator or PI required to document results.

3.2 Study Sample Size

No formal sample size calculations were performed for the study. It is estimated that with 225 subjects enrolled with ages 18-35, a 12-month (13 cycles) Pearl Index of 0.6 (1 observed pregnancy), and 2,015 evaluable cycles, we will observe a 95% confidence interval (CI) for the 12-month Pearl Index of (0.1, 3.3).

4 Primary Efficacy and Safety Variables

For all change from baseline variables, baseline is defined as the last non-missing value on or before the day of study device successful placement. Change from baseline to post-baseline will be calculated as the post-baseline value minus the baseline value. If either the baseline or post-baseline value is missing for a particular variable, change from baseline will be missing.

4.1 Efficacy Variable

The primary outcome measure is effectiveness and will be evaluated as absence of pregnancy during study device use.

E-Diary data from the day of study placement to end of study/exit will collect the following information:

1) Menstrual and intermenstrual bleeding;
2) Vaginal intercourse;
3) Pain with intercourse;
4) Use of additional contraception;
5) Menstrual pain or cramping;
6) LevoCept expulsion

When data is still missing for a day after final attempt to have subject complete E-Diary, Vaginal intercourse, Pain with intercourse and Use of additional contraception will be collected for that specific missing day during monthly contact. The CRF collected data is used as a back-up. It is always preferred for the subject to complete the E-Diary data. If it occurs for a particular day that there is both subject data and CRF collected data, the subject data will take precedence and be used.

1. Pearl index

The primary efficacy variable is Pearl index. The Pearl index based on 28-day cycles and defined as the number of pregnancies per 100 woman-years (with one year comprising 13 28-day cycles). It will be calculated as:

$$\text{Pearl index} = \frac{\text{N} \times 1300}{\text{L}} = \frac{\text{Number of pregnancies} \times 1300}{\text{Number of woman-cycles of pregnancy at risk}}$$

Where n is the number of pregnancies, L is the number of woman-cycles of pregnancy at risk.

Only pregnancies judged to have occurred during study device use, or for which the estimated date of conception was within 7 days after study device removal or calculated date of expulsion are counted.

The number of woman-cycles of pregnancy at risk is the sum of the number of 28-day cycles for each subjects from the date of study device successful placement through the date of study device removal/expulsion or pregnancy, whichever comes earlier, excluding the following (unless the subject became pregnant in the cycle):

• Cycles where back-up contraception or emergency contraception use was reported by the subject;

• Cycles with no intercourse.

The cycle is defined as 28 days with the day of study device successful placement as cycle 1 day 1. The last cycle of pregnancy risk can be a partial cycle and the number of cycles can have one decimal place. The number of cycles (NC) of pregnancy risk for each subject will be calculated as:

$$\mathrm{NC} = \frac{\min(\text{Date of removal/expulsion, Date of conception }) - \text{Date of placement}}{28}$$

The NC is zero for subjects who failed in both study device insertion attempts.

2. Pregnancy rate

Pregnancy rate is defined as the success rate for getting pregnant. Time to pregnancy is defined as the number of days from the first day of study device use to the first documented estimated date of conception.

4.2 Safety and other Variables

Safety and other measures are study device placement, safety, and tolerability.

1. Placement success

Device successfully deployed at first try rate is defined as the percentage of the number of subjects with successful deployment at first attempt among the total number of subjects with first attempt.

Device successfully deployed at second try rate is defined as the percentage of the number of subjects with successful deployment at second attempt among the total number of subjects with second attempt.

Device successfully deployed rate is defined as the percentage of the number of subjects with successful deployment in either first or second attempt among the total number of subjects enrolled.

2. Ease of placement

Five categories of how easy the device placement have been collected: Very easy, Easy, Neither Easy nor Hard, Hard and Very Hard.

Five categories of device placement pain as rated by the subject: No Pain, Some Pain, Painful, Moderately Painful and Very Painful.

Question of insertions requiring mechanical cervical dilatation has been collected.

3. Adverse events

All Adverse Events (AEs) will be coded from verbatim text to PTs and grouped by system organ class (SOC) using the Medical Dictionary for Regulatory Activities (MedDRA) (version 17.0). AEs will be collected from the beginning of the study device placement procedure through to study exit. Pre-existing conditions that worsen during a study are to be reported as AEs.

Throughout the study, all AEs will be evaluated by the investigator and noted in the AE section of the CRF.

AEs will be classified as not related, unlikely related, probably related, or related events when considering their relationship to study device, study device placement/removal procedure. Also, AEs will be classified as mild, moderate, severe when considering their severity. If the severity or relationship of an AE is missing, the severity/relationship will be coded as severe, related, respectively, i.e. worst case scenario.

Treatment-emergent AEs (TEAEs): AEs that develop or that worsen in intensity during or after the exposure to the study device.

See Appendix 1 for handling of partial dates for AEs. If it cannot be determined whether the AE is treatment emergent due to a partial onset date then it will be counted as such.

Other AE variables include study device related AEs, AEs leading to study withdrawal, AEs leading to deaths, life threatening AEs, and serious AEs (SAEs).

4. Bleeding and spotting

The total number of bleeding or spotting days for each subject at each cycle will be counted. The total number of bleeding and spotting days for each subject at each cycle will also be counted separately.

5. Discontinuation rate and reasons for discontinuation

Removal rates

The removal rate is defined as the percentage of the number of subjects with device removed among the total number of subjects enrolled in the study by that time-point.

Expulsion rates

The expulsion rate is defined as the percentage of the number of subjects with device expulsion among the total number of subjects enrolled in the study by that time-point.

Discontinuation rate

The discontinuation rate is defined as the percentage of the number of subjects discontinued study among the total number of subjects enrolled in the study by that time-point.

Reasons for discontinuation

The following reasons have been collected for exiting study:

- Adverse Event;
- Withdrew Consent;
- Protocol Violation;
- Lost to Follow-up;
- Investigator/Sponsor Decision;
- Pregnancy;
- Screen Failure;
- Other.

5 Analysis Populations

Data analyses will be based on the analysis populations defined below. Analysis populations, including exclusions based on major protocol deviations (PDs), will be reviewed and approved by the Sebela and its designee. Excluded cases will be documented together with the reason for exclusion.

5.1 All Screened

Screened subjects are all subjects who have signed informed consent, PHI and Bill of Rights forms (if applicable) and being found eligible based on their history, physical examination, screening tests. Patients who withdraw consent before insertion for any reason would be considered a screen failure.

5.2 All Enrolled

Enrolled subjects are all screened subjects who underwent the study device placement procedure, regardless of whether the study device was successfully placed or not.

5.3 Safety Population

The safety analysis population will include all enrolled subjects who underwent a successful study device placement procedure.

5.4 Extension Analysis Population

Extension subjects are those who agree to continue study device use after 12 months, up to 2 additional years for a total maximum of 3 years.

5.5 Evaluable for Pregnancy Analysis Population

Evaluable for pregnancy (EP) analysis population will include only those safety subjects who underwent the study device placement successfully, and must meet requirements 1, 2 and 3 as follows. Subjects must also meet either requirement 4 or 5 to be EP.

The requirements are

1. between 18 to 35 years of age (inclusive) at enrolment;
2. at least one report of pregnancy status after being enrolled;
3. do not have pre-treatment pregnancy, which is defined as the estimated conception date being before the insertion date.

AND
4. have at least 1 cycle with intercourse and without any backup contraception or emergency contraception;
OR
5. became pregnant while study device LevoCept was in place.

Certain protocol deviations (PDs) are major in which they may affect the ability to assess the true effect of the trial device. Major protocol violations will be those reasonably considered to have had a material impact on the primary efficacy assessment. Subjects with major protocol violations will be excluded from EP analysis population.

5.6 Evaluable for Cycle Control Analysis Population

Evaluable for Cycle Control (ECYC) analysis population will include only those safety subjects with at least one cycle for which: A) a pregnancy did not occur; and B) there is bleeding related e-diary data.

6 Analysis Methods

6.1 General Methodology

Analyses will be implemented using SAS® 9.4 or above. In general, all efficacy and safety variables will be summarised using descriptive statistics and graphs as appropriate. Continuous variables will be summarised by descriptive statistics (sample size (n), mean, standard deviation (SD), minimum, median, and maximum). Categorical variables will be summarised in frequency tables (frequencies and percentages). Time to event variables will be summarised by Kaplan-Meier estimates of median and quartile time to events. Individual data will be presented in subject listings.

Means and medians will be displayed with one more decimal place than the collected data, and SDs will have one more decimal place than the means and medians. Minimum and maximum will be displayed with the same number of decimal places as the collected data. Percentages will be rounded to one decimal place.

No formal statistical testing will be performed on subject disposition, demographic, baseline characteristic, and safety data. Where appropriate, point estimates, together with their 95% confidence intervals will be presented.

Only observed data, with no data imputation, will be used for the efficacy analyses unless otherwise specified. Safety analyses will also be conducted on the observed data. However, for the start date/time of an AE or medication being partially or completely missing, the worst case scenario will be applied. That is, the AE will be assumed to be treatment emergent, and the medication will be considered to be concomitant.

6.2 Analysis Methods

6.2.1 Patient Disposition and Withdrawals

The number and percentage of screen failure, subjects enrolled, subjects with study device successfully deployed, discontinued 1-Year study prematurely, completed 1-year study, reason for discontinuation of 1-year study, entered the extension study, discontinued extension study prematurely, completed extension study, reason for discontinuation of extension studywill be presented. Selected information will also be summarized by site.

The number and percentage of subjects at each scheduled visit will be presented.

The number and percentage of subjects in each population will be presented.

Details of all subjects who violated the inclusion/exclusion criteria will be listed.

A listing will be presented to describe site number, date of study device placement, study completion or discontinuation, and primary reason for existing study for each screened subject.

6.2.2 Demographic and Baseline Characteristics

Demographic and other baseline characteristics, such as age at date of informed consent, age groups, ethnicity, race, marital status, parity status, weight, height, and body mass index (BMI) at baseline as well as uterine length will be summarised for all enrolled subjects.

Age will be categorized by two groups, 18 - 35 and 36 - 40 years.

BMI will be categorized by Underweight (< 18.5), Normal (18.5 – 24.9), Overweight (25.0 – 29.9), and Obese (≥ 30.0).

All demographic and baseline characteristics will be presented in a data listing.

6.2.3 Medical / Surgical History

Medical / Surgical history will be summarized given the number and percentage by body system for the safety population. Subject reporting the same body system multiple times will be counted only once for that body system.

All history will be presented in a data listing.

6.2.4 Gynecological History

Gynecological history data will be summarized for all questions collected on the CRF.

All gynecological history will be presented in a data listing.

6.2.5 Menstrual History

Menstrual history data will be summarized for all questions collected on the CRF.

All menstrual history will be presented in a data listing.

6.2.6 Cervical Cytology

Cervical cytology test results will be summarized in table and presented in a data listing.

6.2.7 Prior and Concomitant Medications

All medications (excluding rescue medications) collected will be coded to Anatomical Therapeutic Classification (ATC) Chemical subgroup (ATC 4th level code) and PT using the World Health Organization Drug Dictionary Enhanced (WHO DDE) Drug Reference List (Version Mar.1.2014).

Prior medications are defined as those taken by the subject prior to the study device placement. Concomitant medications are defined as those taken by the subject from the date of the study device placement to study completion/discontinuation. See Appendix 1 for handling of partial dates for medications. In cases where it is not possible to define a medication as prior or concomitant, the medication will be classified as concomitant.

Prior and concomitant medications will be summarised by ATC and PT for safety population. The number and percentage of subjects using each medication will be presented. Patients may have more than one medication per ATC class and generic drug name. At each level of subject summarization, a subject is counted once if she reported one or more medications at that level. Each summary will be ordered by descending order of incidence of ATC class and generic drug name within each ATC class.

All prior and concomitant medications will be presented in a data listing.

6.2.8 Efficacy Analysis

The primary efficacy variables, the Pearl index with 95% CI and pregnancy rate, will be summarised for each of the 3 years and cumulatively for EP population.

The 95% CI for Pearl Index will be approximated by Poisson distribution and Chi-square distribution. It will be calculated as:

$$\left(\frac{\frac{\chi^2\left(\frac{\alpha}{2};2n\right)}{2}}{\mathrm{L}}\times 1300,\ \frac{\frac{\chi^2\left(1-\frac{\alpha}{2};2n+2\right)}{2}}{\mathrm{L}}\times 1300\right)$$

where α is 0.05, n is the number of pregnancies and L is the number of woman-cycles of pregnancy at risk during the study device use.

The summary table will present the number of pregnancies and the number of cycles of risk in addition to the Pearl Index with 95% CI through 1-year, 2-year and 3-year.

Pregnancy rate analysis will include the number of subjects with pregnancy and the number of subjects who were not pregnant (censored). If a subject discontinues the study her time will be censored at the time of study discontinuation.

The distribution of pregnancy rate will be summarized using Kaplan-Meier method through 1-year, 2-year and 3-year intervals. Kaplan-Meier graph of pregnancy rate will also be generated.

The primary efficacy variable will also be examined for the following subgroups:

- By parity: parous and nulliparous women.
- By BMI group at baseline: Underweight (<18.5), Normal (18.5-24.9), Overweight (25.0-29.9), Obese (>=30)

Subject who has been pregnant and has at least one live birth is defined as parous, otherwise is defined as nulliparous.

Descriptive statistics will be presented for each subgroup.

6.2.9 Safety Variables

All safety analyses will be based on safety analysis population unless otherwise specified. Descriptive statistics will be used to summarise the safety outcomes No inferential analyses of safety data are planned.

6.2.9.1 Adverse Events

Number of AEs will be summarised by SOC and/or PT for the following categories of TEAEs: all AEs, SAEs, AEs related to study device, AEs related to study device placement/removal procedure, AEs leading to death, AEs leading to study device removal and AEs as primary reason for exiting study. Patients with more than one occurrence of the same SOC (PT) will be counted only once within the SOC (PT) categorisation.

AEs will also be summarised similarly by severity (i.e. mild, moderate, severe), relationship to study device (i.e. not related, unlikely related, probably related, related), relationship to placement/removal procedure (i.e. not related, unlikely related, probably related, related) and onset time frame (i.e.0-3 months, >3-6 months, >6-12 months, >12 months). Should a subject experience more than one occurrence of the same SOC (PT), the subject's worst occurrence (worst intensity/most related causality) will be retained in the tabulation.

All AEs, including AEs that started prior to the study device placement, will be presented in data listings. In addition, separate listings of all SAEs, AEs related to study device, AEs related to study device placement/removal procedure, AEs leading to death, AEs leading to study device removal and AEs as primary reason for exiting study will be provided. In case of any AEs reported from study device insertion failure subjects, selected AE tables will be repeated for all enrolled subjects for all AEs.

6.2.9.2 Extent of Exposure

The number of subjects with study device deployed and number of cycles of use to the study device will be summarized in enrolled subjects regardless of whether the study device was successfully placed or not. For subjects without successful placement, the number of cycles of use for the study device will be zero.

6.2.9.3 Device Placement & Removal, Subject Pain

The ease of study device placement and removal, subject pain, medication, as well as insertions requiring cervical dilation during the procedure, will be summarized categorically with number and percentages of subjects in each category for all enrolled subjects.

All device placement and removal data will be presented in data listings.

6.2.9.4 Device Subject Discomfort

Experience of any menstrual pain or cramping will be recorded daily by the subject in the e-diary. The occurrence and severity of discomfort will be summarized for each cycle in safety and ECYC population. The summary will present the number of days, the worst pain grade and the highest frequency occurrence pain grade in each cycle with menstrual pain or cramping.

If a cycle has less than 28 days but at least 14 days data, missing value will be imputed by the average in the same cycle for the subject, and then rounded to nearest integer.

For example, a subject at Cycle 6 has only 20 days data, of which 3 days with "Cramping". Total number of "Cramping" days at this cycle for her will be estimated as:

$$3 + (3 / 20 \times (28 - 20)),$$

which will be 4 after rounding.

If a cycle has less than 14 days data, no imputation for missing value, number of days for this cycle would be treated as missing.

All device subject discomfort e-diary data will be presented in data listings.

6.2.9.5 Occurrence and Severity of Dyspareunia

Pain with intercourse will be recorded daily by the subject in the e-diary and collected as missed diary review data in the CRF during monthly contact when not entered by the subject within the 10 day window. The occurrence and severity of dyspareunia will be summarized for each cycle in safety and ECYC population. The summary will present the number of days in each cycle with dyspareunia. The worst pain grade and the highest frequency occurrence pain grade in each cycle will be summarized using shift tables to assess changes from baseline. The missing value imputation at cycles will be calculated similarly as the above Section 6.2.9.4.

All occurrence and severity of dyspareunia e-diary data and daily missed diary review data from monthly contact will be presented in data listings.

6.2.9.6 Bleeding and Spotting

Vaginal bleeding and spotting will be recorded daily by subjects in e-diary. The total number of bleeding or spotting days will be summarized for each cycle in safety and ECYC population. The missing value imputation at cycles will be calculated similarly as the above Section 6.2.9.4.

In addition, bleeding and spotting will be summarized separately (i.e. none, spotting, light bleeding, medium bleeding, heavy bleeding). Subjects who discontinue the study due to bleeding complaints prior to completing one 28-day cycle will be included in the bleeding analysis.

When bleeding occurred, flows heavier than when not using hormones will also be summarized by cycle.

All bleed and spotting e-diary data will be presented in data listings.

6.2.9.7 Device Expulsion and Removal

Device expulsion will be recorded daily by the subject in e-diary. Device removal procedure will be recorded in the CRF. Cumulative study device removal rates and expulsion rates will be summarized at 1-year (study day 1 - 364), 2-year (study day 365 - 728), and 3-year (study day 729 +).

6.2.9.8 Vital Signs

Vital signs (temperature, heart rate, respiration, blood pressure), weight and BMI will be summarized using descriptive statistics at baseline and at each post-baseline time point. Changes from baseline will also be summarized by visit for heart rate, blood pressure, weight and BMI.

Vital signs, weight and BMI will be included in data listings.

6.2.9.9 Physical Examination

Physical examination results will be included in data listings only.

7 Interim Analyses

Interim analyses are planned for this study when all subjects have completed one year of treatment. The analyses for the interim CSR is the same as the planned analyses for the final CSR.

8 Changes in the Conduct of the Study or Planned Analysis

8.1 Changes in the Conduct of the Study

8.2 Changes to the Planned Analyses

- In the protocol, safety and enrolled subjects are defined as the same, all enrolled subjects who underwent the study device placement procedure, regardless of whether the study device was successfully placed or not. In this analysis plan, the safety analysis population will include all enrolled subjects who underwent a successful study device placement procedure.
- In the protocol, pre-treatment and on-treatment subjects are not specified in EP analysis population. In this analysis plan, pre-treatment subjects are excluded from EP.

9 SAS Data Transfer

All SAS reported study data will be transferred to Sebela and will be performed in compliance with CDISC (Clinical Data Interchange Standards Consortium) on issue of the final draft clinical study report (CSR). Synteract will provide metadata files along with the clinical and efficacy data.

All study data will be transferred as SAS transport files in standard SDTM/ADaM (Study Data Tabulation Model/Analysis Data Model) dataset format.

10 Reporting Conventions

The following reporting conventions will be adopted for the presentation of study data. These conventions will enhance the review process and help to standardise presentation with common notations.

10.1 General Reporting Conventions

- All tables and data listings will be developed in Landscape Orientation.
- Figures will be presented in Landscape Orientation, unless presented as part of the text in a CSR.
- Legends will be used for all figures with more than one variable or item displayed.
- Figures will be in black and white. Lines in figures should be wide enough to view the line after being photocopied.
- Specialised text styles, such as bolding, italics, borders, shading, superscripted and subscripted text will not be used in tables, figures, and data listings.
- Only standard keyboard characters should be used in tables and data listings. Special characters, such as non-printable control characters, printer specific, or font specific characters, will not be used on a table, figure, or data listing. Hexadecimal character representations are allowed.
- All titles will be centered on a page. The ICH (International Conference on Harmonisation) numbering convention is to be used for all TLFs.
- All footnotes will be left justified and displayed at the bottom of a page. Footnotes should be used sparingly and must add value to the table, figure, or data listing.
- Missing values for both numeric and character variables will be presented as “---“ in a table or data listing. A zero (0) may be used if appropriate to identify when the frequency of a variable is not observed.

- All date values will be presented as YYYY-MM-DD (e.g., 2001-10-23) format. A four-digit year is preferred for all dates.
- All observed time values will be presented using a 24-hour clock HH:MM:SS format (e.g., 01:35:45 or 11:26). Seconds should only be reported if they were measured as part of the study.
- All tables, figure, and data listings will have the name of the program, location, and a date stamp on the bottom of each output.
- All analysis programs developed for a table, figure, or data listing display will be self-contained to facilitate transfer of programs to multiple computing environments and transfer to a regulatory agency (if requested).
- Listings will be sorted by subject ID number.

10.2 Population Summary Conventions

- Population(s) represented on the tables or data listings will be clearly identified in the last title of the Table as "Population: <name of population>" and will be identical in name to that identified in the protocol or SAP.
- Population sizes may be presented in the column header as (N=xxxx), where appropriate.
- Population sizes shown with summary statistics are the samples sizes (n) of subjects with non-missing values.
- All population summaries for categorical variables will include all categories that were planned and for which the subjects may have had a response. Percentages corresponding to null categories (cells) will be suppressed.
- All population summaries for continuous variables will include: N, mean, median, SD, minimum, maximum and n. Other summaries (e.g., number missing, quartiles, 95% intervals) may be used as appropriate.
- All percentages are rounded and reported to a single decimal point (xx.x). A percentage of 100% will be reported as (100). No value of 0% will be reported. Any computation of percent that results in 0% is to be presented as a blank.

10.3 Standard Calculations

Variables requiring calculation will be derived using the following formula.

- **Study Day** – Study Day 1 is defined as the date of the study device placement; the day before the study device placement is defined as Study Day -1. For a given event date, Study Day is calculated relative to the date of study device placement.
  Study Day = [Event Date – Study Device Placement Date] (in days) + 1 day,
  where the event date is on or after the study device placement date.
  Study Day = [Event Date – Study Device Placement Date] (in days),
  where the event date is before the study device placement date.

- **Age (Years)** – Age is calculated as the number of years from the date of birth to the date of informed consent using the following formula and rounded down to the nearest year.

$$\text{Age (years)} = \frac{\text{Date of informed consent} - \text{date of birth}}{365.25}$$

- **Height** – Height entries made in inches (in) are converted to centimeters using the following formula:
  Height (cm) = Height (in) * 2.54, rounded to the one decimal place.

- **Weight** – Weight entries made in pounds (lbs) are converted to kilograms (kgs) using the following formula:
  Weight (kg) = Weight (lb) / 2.2046, rounded to the one decimal place.

- **Body Mass Index (BMI)** – BMI is derived using following formula and rounded to one decimal place.

$$\text{BMI } (\text{kg/m}^2) = \frac{\text{weight(kg)}}{[\text{height(cm)}/100]^2}.$$

BMI categorized by Underweight (< 18.5), Normal (18.5 – 24.9), Overweight (25.0 – 29.9), and Obese (≥ 30.0).

11 Appendix 1: Partial Date Conventions

Imputed dates will NOT be presented in the listings.
Algorithm for Treatment Emergence of Adverse Events:

Start Date	Stop Date	Action
Known	Known/Partial/Missing	If start date < study med start date, then not TEAE; If start date ≥ study med start date, then TEAE.
Partial, but known components show that it cannot be on or after study med start date	Known/Partial/Missing	Not TEAE
Partial, could be on or after study med start date	Known	If stop date < study med start date, then not TEAE; If stop date ≥ study med start date, then TEAE.
	Partial	Impute stop date as latest possible date (i.e. last day of month if day is unknown or 31 December if day and month are unknown), then: If stop date < study med start date, then not TEAE; If stop date ≥ study med start date, then TEAE.
	Missing	Assumed TEAE
Missing	Known	If stop date < study med start date, then not TEAE; If stop date ≥ study med start date, then TEAE.
	Partial	Impute stop date as latest possible date (i.e. last day of month if day is unknown or 31 December if day and month are unknown), then: If stop date < study med start date, then not TEAE; If stop date ≥ study med start date, then TEAE.
	Missing	Assumed TEAE

Algorithm for Prior/Concomitant Medications:

Start Date	Stop Date	Action
Known	Known/Partial/Missing	If start date < study med start date, then assign as prior; If start date ≥ study med start date, then assign as concomitant.
Partial	Known/Partial/Missing	Impute start date as earliest possible date (i.e. first day of month if day is unknown or 1st January if day and month are unknown), then: If start date < study med start date, then assign as prior; If start date ≥ study med start date, then assign as concomitant.
Missing	Known	If stop date < study med start date, then assign as prior; If stop date ≥ study med start date, then assign as concomitant.
	Partial	Impute stop date as latest possible date (i.e. last day of month if day is unknown or 31 December if day and month are unknown), then: If stop date < study med start date, then assign as prior; If stop date ≥ study med start date, then assign as concomitant.
	Missing	Assign as concomitant

12 Appendix 2 List of Tables, Figures, and Listings

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	14.1.1	Subject Disposition (All Screened Subjects)
	14.1.2	Disposition by Site (All Enrolled Subjects)
	14.1.3	Summary of Subjects at Each Scheduled Study Visit (All Enrolled Subjects)
	14.1.4	Summary of Subjects with Protocol Deviations (All Enrolled Subjects)
	14.1.5	Analysis Populations (All Enrolled Subjects)
	14.1.6	Demographics and Baseline Characteristics (All Enrolled Subjects)
	14.1.7	Medical History (All Enrolled Subjects)
	14.1.8	Gynecological History (All Enrolled Subjects)
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	14.1.11.3	Both Prior and Concomitant Medication (All Enrolled Subjects)
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	14.2.1	Pearl Index (EP Population)
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14.3.1		**Displays of Adverse Event**
	14.3.1.1.1	Overall Summary of Treatment-Emergent Adverse Events (Safety Population)
	14.3.1.1.2	Overall Summary of Adverse Events (All Enrolled Subjects)
	14.3.1.2.1	Overall Summary of Treatment-Emergent Adverse Events by Severity and Relatedness to the Study Product (Safety Population)
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	14.3.1.3.1	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
	14.3.1.3.2	Adverse Events by System Organ Class and Preferred Term (All Enrolled Subjects)
	14.3.1.4.1	Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Population)
	14.3.1.4.2	Serious Adverse Events by System Organ Class and Preferred Term (All Enrolled Subjects)
	14.3.1.5	Treatment-Emergent Adverse Events Leading to Study Device Removal (Safety Population)
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	14.3.1.8	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity (Safety Population)
	14.3.1.9	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relatedness to Study Device (Safety Population)
	14.3.1.10	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and by Relatedness to Study Device Placement/Removal Procedure (Safety Population)
	14.3.1.11	Treatment-Emergent Adverse Events by Preferred Term (Safety Population)
	14.3.1.12	Treatment-Emergent Adverse Events by Preferred Term by Onset Time Frame for the First Year (Safety Population)
	14.3.1.13	Treatment-Emergent Adverse Events by Preferred Term by Onset Time Frame (Safety Population)
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ICH Heading	Table Number	Table Description
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	14.3.5.2	Device Placement and Subject Pain During the Procedure (All Enrolled Subjects)
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16.2.4		**Demographics and Baseline Characteristics**
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13 Appendix 3 Table Layouts

Table 14.1.1
Subject Disposition (All Screened Subjects)

Description	Enrolled [1] (N=xx) n (%)	All Subjects (N=xx) n (%)
Screen Failure		n (%)
Safety Population [2]	n (%)	n (%)
Discontinued 1-Year Study Prematurely	n (%)	n (%)
Completed 1-Year Study	n (%)	n (%)
Entered the Extension Study	n (%)	n (%)
Discontinued Extension Study Prematurely	n (%)	n (%)
Completed Extension Study	n (%)	n (%)
Reason for Discontinuation of 1-Year Study		
Adverse Event	n (%)	n (%)
Withdrew Consent	n (%)	n (%)
Protocol Violation	n (%)	n (%)
Lost to Follow-up	n (%)	n (%)
Investigator/Sponsor Decision	n (%)	n (%)
Pregnancy	n (%)	n (%)
Other	n (%)	n (%)
Screen Failure [3]		n (%)
Reason for Discontinuation of Extension Study		
Adverse Event	n (%)	n (%)
Withdrew Consent	n (%)	n (%)
Protocol Violation	n (%)	n (%)
Lost to Follow-up	n (%)	n (%)
Investigator/Sponsor Decision	n (%)	n (%)
Pregnancy	n (%)	n (%)
Other	n (%)	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless otherwise specified.
[1] Enrolled subjects are all screened subjects who underwent the study device placement procedure, regardless of whether the study device was successfully placed or not.
[2] Safety population will include all enrolled subjects who underwent a successful study device placement procedure.
[3] Screen failure as primary reason for exiting study collected on the study exit status form.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.2
Subject Disposition by Site (All Enrolled Subjects)

Description	All Subjects (N=xx) n (%)
Site 1 xxx	
Enrolled	n (%)
Discontinued 1-Year Study Prematurely	n (%)
Completed 1-Year Study	n (%)
Entered the Extension Study	n (%)
Discontinued Extension Study Prematurely	n (%)
Completed Extension Study	n (%)
Site 2 xxx	
Enrolled	n (%)
Discontinued 1-Year Study Prematurely	n (%)
Completed 1-Year Study	n (%)
Entered the Extension Study	n (%)
Discontinued Extension Study Prematurely	n (%)
Completed Extension Study	n (%)

Note: Completed the study are subjects who completed 1-Year study but did not entered extension study or who completed extension study.
Note: Subjects who transferred to another site are included only in their initial site.
Note: Subject [redacted] transferred to site [redacted] subject [redacted] transferred to site [redacted], subject [redacted] transferred to site [redacted].
Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes: Sort by site ID and repeat for all other sites.

Table 14.1.3
Subjects at Each Scheduled Study Visit (All Enrolled Subjects)

Study Visit	All Subjects (N=xx) n (%)
Visit 1/Screening	n (%)
Visit 2 (Day 1)	n (%)
Visit 3 (Week 6±1)	n (%)
Visit 4 (Week 13±2)	n (%)
Visit 5 (Week 26±2)	n (%)
Visit 6 (Week 52±2)	n (%)
Visit 7 LTFU1	n (%)
Visit 8 LTFU2	n (%)
Visit 9 LTFU3	n (%)
Visit 10 LTFU4	n (%)
Follow Up	
Early Termination	

Note: LTFU1= Month 18, LTFU2= Month 24, LTFU3= Month 30, LTFU4=Month 36.
Note: Follow Up is the CRF collected visit after IUD removal.
LTFU= Long Term Follow up.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.4
Subjects with Protocol Deviations (All Enrolled Subjects)

	All Subjects (N=xx)	
	Events	Subjects
Type of Deviation	n	n (%)
Number of Events / Subjects with any deviation	n	n (%)
Subject not consented properly	n	n (%)
Scheduled visit completed out of specified window	n	n (%)
Deviation from protocol-defined procedure	n	n (%)
...	n	n (%)
<All categories on source listing>	n	n (%)

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.5
Analysis Populations (All Enrolled Subjects)

Description	All Subjects (N=xx) n (%)
Enrolled [1]	n (%)
Safety [2	n (%)
Evaluable for Pregnancy (EP) [3]	n (%)
Evaluable for Cycle Control (ECYC) [4]	n (%)
Extension[5]	n (%)

[1] Enrolled subjects are all screened subjects who underwent the study device placement procedure, regardless of whether the study device was successfully placed or not.
[2] Safety analysis population will include all enrolled subjects who underwent a successful study device placement procedure.
[3] Evaluable for pregnancy (EP) analysis population will include only those safety subjects who underwent the study device placement successfully, and must meet requirements 1(between 18 to 35 years of age (inclusive) at enrolment), 2 (at least one report of pregnancy status after being enrolled) and 3 (do not have pre-treatment pregnancy, which is defined as the estimated conception date being before the insertion date) to be EP. Subjects must also meet either requirement 4 (have at least 1 cycle of e-diary with intercourse and without any backup contraception or emergency contraception) or 5 (became pregnant while LevoCept was in place) to be EP.
[4] Evaluable for Cycle Control (ECYC) analysis population will include only those safety subjects with at least one cycle for which: A) a pregnancy did not occur; and B) there is bleeding related e-diary data.
[5] Extension population will include all safety subjects who agree to continue study device use after 12 months, up to 2 additional years for a total maximum of 3 years.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.6
Demographics and Baseline Characteristics (All Enrolled Subjects)

Characteristic	All Subjects (N=xx)
Age (years)[1]	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min	xx
Max	xx
Age Group	
18 - 35	n (%)
36 - 40	n (%)
Ethnicity	
Hispanic or Latino	n (%)
Not Hispanic or Latino	n (%)
Unknown	n (%)
Race[2]	
American Indian or Alaskan Native	n (%)
Asian	n (%)
Black or African American	n (%)
Native Hawaiian or Other Pacific Islander	n (%)
White	n (%)
More than one race	n (%)
Unknown	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless otherwise specified.

Note: For subjects ([redacted]) without study device successfully placed, baseline weight, height and BMI are defined as last non-missing value on or before the day of later study device placement attempt.
[1] Age (years) = (Date of informed consent - Date of birth) / 365.25, rounded down to the nearest year.
[2] Subjects could mark more than one race.
BMI = Body Mass Index; Max = Maximum; Min = Minimum; SD = Standard Deviation.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmers note: Table will continue summary statistics for Weight, height, and BMI, as shown for Age.

Table 14.1.6
Demographics and Baseline Characteristics (All Enrolled Subjects)

Programmers note: Continued table

Characteristic	All Subjects (N=xx)
Marital Status	
Married	n (%)
Divorced	n (%)
Separated	n (%)
Single	n (%)
Widowed	n (%)
Parity	
Parous	n (%)
Nulliparous	n (%)
Weight (kg)	
…	
Height (cm)	
…	
BMI (kg/m2)	
…	
BMI Category	
Underweight (<18.5)	n (%)
Normal (18.5-24.9)	n (%)
Overweight (25.0-29.9)	n (%)
Obese (>=30)	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless otherwise specified.

Note: For subjects [redacted] without study device successfully placed, baseline weight, height and BMI are defined as last non-missing value on or before the day of later study device placement attempt.
[1] Age (years) = (Date of informed consent - Date of birth) / 365.25, rounded down to the nearest year.
[2] Subjects could mark more than one race.
BMI = Body Mass Index; Max = Maximum; Min = Minimum; SD = Standard Deviation.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmers note: Table will continue summary statistics for Weight, height, and BMI, as shown for Age.

Table 14.1.7
Medical History (All Enrolled Subjects)

Body System	All Subjects (N=xx) n (%)
Allergies (including intolerance to nickel and copper)	n (%)
Cardiovascular	n (%)
Gastrointestinal	n (%)
Thyroid	n (%)
HEENT	n (%)
Hematological	n (%)
Hepatobiliary	n (%)
Immunological	n (%)
Integumentary	n (%)
Lymphatic	n (%)
Musculoskeletal	n (%)
Neurological	n (%)
Reproductive/Gynecologic	n (%)
Respiratory	n (%)
Urinary	n (%)
Endocrine	n (%)
Other	n (%)

Note: Subject reporting the same body system multiple times will be counted only once for that body system.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.8
Gynecological History (All Enrolled Subjects)

Description	All Subjects (N=xx) n (%)
Pain During Intercourse	
No Pain	n (%)
Some Pain	n (%)
Painful	n (%)
Moderately Painful	n (%)
Very Painful	n (%)
Missing	n (%)
Prior Contraception[1]	
Oral Contraception	n (%)
Double Barrier Method	n (%)
Injectable	n (%)
Implantable	n (%)
Condom	n (%)
IUD	n (%)
None	n (%)
Other	n (%)
Currently use Birth Control	
Yes	n (%)
No	n (%)
Current Contraception[1]	
n	n
Oral Contraception	n (%)
Double Barrier Method	n (%)
Injectable	n (%)
Implantable	n (%)
Condom	n (%)
IUD	n (%)
Other	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
[1] Subjects could mark more than one contraception method.
[2] Has the subject had any vaginal infections or yeast infections in the past 30 days?
[3] If the subject had any vaginal infections or yeast infections in the past 30 days, were any medications taken for the infection?
[4] If the subject currently breastfeeding, has the subject had two consecutive menses since the last pregnancy?
[5] Is there daily discomfort that can be attributed to gynecological issues (non-menstrual)

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.8
Gynecological History (All Enrolled Subjects)

Programmers note:Continued table

Description	All Subjects (N=xx) n (%)
Infections[2]	
Yes	n (%)
No	n (%)
Medications[3]	
n	n
Yes	n (%)
No	n (%)
Ever been Pregnant	
n	n
Yes	n (%)
No	n (%)
Number of Live Births (Natural)	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min	xx
Max	xx
Number of Live Births (C-Section)	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min	xx
Max	xx

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
[1] Subjects could mark more than one contraception method.
[2] Has the subject had any vaginal infections or yeast infections in the past 30 days?
[3] If the subject had any vaginal infections or yeast infections in the past 30 days, were any medications taken for the infection?
[4] If the subject currently breastfeeding, has the subject had two consecutive menses since the last pregnancy?
[5] Is there daily discomfort that can be attributed to gynecological issues (non-menstrual)

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.8
Gynecological History (All Enrolled Subjects)

Programmers note: Continued table

Description	All Subjects (N=xx) n (%)
Currently breastfeeding	
Yes	n (%)
No	n (%)
Two Consecutive Menses[4]	
n	n
Yes	n (%)
No	n (%)
Daily discomfort[5]	
Yes	n (%)
No	n (%)
If Yes, level of this daily discomfort	
n	n
No Pain	n (%)
Some Pain	n (%)
Painful	n (%)
Moderately Painful	n (%)
Very Painful	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
[1] Subjects could mark more than one contraception method.
[2] Has the subject had any vaginal infections or yeast infections in the past 30 days?
[3] If the subject had any vaginal infections or yeast infections in the past 30 days, were any medications taken for the infection?
[4] If the subject currently breastfeeding, has the subject had two consecutive menses since the last pregnancy?
[5] Is there daily discomfort that can be attributed to gynecological issues (non-menstrual)

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.9
Menstrual History (All Enrolled Subjects)

Description	All Subjects (N=xx) n (%)
Menstrual Cycle Over The Past 3 Months	
Regular	n (%)
Irregular	n (%)
If Regular, had 3 Consecutive Periods	
n	n
Yes	n (%)
No	n (%)
Frequency	
Less than 25 days	n (%)
25-30 days	n (%)
31-40 days	n (%)
More than 40 days	n (%)
Average length	
Irregular	n (%)
Less than 3 days	n (%)
3-5 days	n (%)
More than 5 days	n (%)
Usual flow	
None	n (%)
Light	n (%)
Moderate	n (%)
Heavy	n (%)
Usual level of discomfort caused by cramping	
None	n (%)
Mild	n (%)
Moderate	n (%)
Severe	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
[1] When not using Hormonal Contraception.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.9
Menstrual History (All Enrolled Subjects)

Programmers note: Continued table

Description	All Subjects (N=xx) n (%)
Spotting between periods	
None	n (%)
Occasionally	n (%)
Regularly	n (%)
Day in current menstrual cycle	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min	xx
Max	xx
Used Hormonal Contraception in the Last 3 Months	
Yes	n (%)
No	n (%)
Menstrual Cycles Regular[1]	
n	n
Yes	n (%)
No	n (%)
Frequency[1]	
n	n
Less than 25 days	n (%)
25-30 days	n (%)
31-40 days	n (%)
More than 40 days	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
[1] If used hormonal contraception in the last 3 Months, when not using Hormonal Contraception.
Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.9
Menstrual History (All Enrolled Subjects)

Programmers note: Continued table

Description	All Subjects (N=xx) n (%)
Average length[1]	
n	n
Irregular	n (%)
Less than 3 days	n (%)
3-5 days	n (%)
More than 5 days	n (%)
Usual flow[1]	
n	n
None	n (%)
Light	n (%)
Moderate	n (%)
Heavy	n (%)
Usual level of discomfort caused by cramping[1]	
n	n
None	n (%)
Mild	n (%)
Moderate	n (%)
Severe	n (%)
Spotting between periods[1]	
n	n
None	n (%)
Occasionally	n (%)
Regularly	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
[1] If used hormonal contraception in the last 3 Months, when not using Hormonal Contraception.
Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.10
Cervical Cytology (All Enrolled Subjects)

Description	All Subjects (N=xx) n (%)
Gonorrhea Test	
Positive	n (%)
Negative	n (%)
Not Done	n (%)
Chlamydia Test	
Positive	n (%)
Negative	n (%)
Not Done	n (%)
PAP Test	
Normal	n (%)
Abnormal: ASCUS, HPV Negative	n (%)
Abnormal: ASCUS, HPV Positive	n (%)
LSIL	n (%)
HSIL	n (%)
Cancer	n (%)
Not Done	n (%)

[1] Has the subject had a normal PAP or ASC-US with negative high-risk HPV test result within the appropriate screening timeframe?

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.1.11.1
Prior Medication (All Enrolled Subjects)

Anatomical Therapeutic Classification/ Preferred Term	All Subjects (N=xx) n (%)
Patients with any Prior Medications	n (%)
MEDICATION 1 ATC LEVEL	n (%)
Medication 1 PT LEVEL4	n (%)
Medication 1 PT LEVEL4	n (%)
…	
<All applicable PT LEVEL 4>	
MEDICATION x ATC LEVEL	
Medication x PT LEVEL4	n (%)
Medication x PT LEVEL4	n (%)
…	
<All applicable PT LEVEL 4>	
	n (%)

Note: At each level of summation subjects reporting more than one medication are counted only once.
Note: Medications are coded using WHO DDE Drug Reference List (Version xxx).

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming notes:
1. Sort data by descending order of incidence of ATC class and generic drug name within each ATC class at each level of summary.
2. Following the similar structure presentation as Table 14.1.11.1 for
14.1.11.2 Concomitant Medication (All Enrolled Subjects)
Update the cell at first column first row to 'Patients with any Concomitant Medications'.

3. Following the similar structure presentation as Table 14.1.11.1 for
14.1.11.3 Both Prior and Concomitant Medication (All Enrolled Subjects)
Update the cell at first column first row to 'Patients with both prior and Concomitant Medications'.

Table 14.2.1
Pearl Index (EP Population)

	Number of Subjects	Number of Pregnancies	Number of Woman-Cycles at Risk	Pearl Index	95% CI for Pearl Index
1-Year					
All EP Subjects	n	n	n	x.xx	x.xx, x.xx
EP Subjects by Parity					
Parous	n	n	n	x.xx	x.xx, x.xx
Nulliparous	n	n	n	x.xx	x.xx, x.xx
EP Subjects by BMI					
Underweight (<18.5)	n	n	n	x.xx	x.xx, x.xx
Normal (18.5-24.9)	n	n	n	x.xx	x.xx, x.xx
Overweight (25.0-29.9)	n	n	n	x.xx	x.xx, x.xx
Obese (>=30)	n	n	n	x.xx	x.xx, x.xx
2-Year					
All EP Subjects	n	n	n	x.xx	x.xx, x.xx
EP Subjects by Parity					
Parous	n	n	n	x.xx	x.xx, x.xx
Nulliparous	n	n	n	x.xx	x.xx, x.xx
EP Subjects by BMI					
Underweight (<18.5)	n	n	n	x.xx	x.xx, x.xx
Normal (18.5-24.9)	n	n	n	x.xx	x.xx, x.xx
Overweight (25.0-29.9)	n	n	n	x.xx	x.xx, x.xx
Obese (>=30)	n	n	n	x.xx	x.xx, x.xx
Cumulative 2-Year					
……					
3-Year					
……					
Cumulative					

EP=Evaluable for Pregnancy.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with for Cumulative 2-Year, 3-Year,Cumulative

Table 14.2.2
Pregnancy Rate (EP Population)

	Parous (N=xx)	Nulliparous (N=xx)	All Subjects (N=xx)
Number of Subjects with Pregnancy	n (%)	n (%)	n (%)
Number of subjects who was not Pregnant(Censored)	n (%)	n (%)	n (%)
Pregnancy Free (Days)			
Pregnancy Rate[1]			
1-Year	xx	xx	xx
2-Year	xx	xx	xx
Cumulative 2-Year	xx	xx	xx
3-Year	xx	xx	xx
Cumulative	xx	xx	xx
Range (Subjectswith Pregnancy)	xx -xx	xx -xx	xx -xx
Range (All Subjects)	xx -xx	xx -xx	xx -xx

[1] Kaplan-Meier product-limit estimates.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.1.1
Overall Summary of Treatment-Emergent Adverse Events (Safety Population)

	Events (N=xx) n	Subjects (N=xx) n (%)
Onset Time Frame:		
Missing	n	n (%)
From Day 1 through Day 42(Week 6)	n	n (%)
From Day 43 through Day 91(Week 13)	n	n (%)
From Day 92 through Day 182(Week 26)	n	n (%)
From Day 183 through Day 364(Week 52)	n	n (%)
From Day 365 through Day 546(LTFU 1)	n	n (%)
From Day 547 through Day 728(LTFU 2)	n	n (%)
From Day 729 through Day 911(LTFU 3)	n	n (%)
Day 912 and Later	n	n (%)
At least one AE	n	n (%)
An AE related to Study Device	n	n (%)
An AE related to Study Device Placement/Removal Procedure	n	n (%)
A serious AE	n	n (%)
An AE leading to death	n	n (%)
An AE leading to study device removal	n	n (%)
An AE as Primary Reason for Exiting Study	n	n (%)

Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: LTFU1= Month 18, LTFU2= Month 24, LTFU3= Month 30, LTFU4=Month 36.
LTFU=Long Term Follow Up.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming notes:
Following the similar structure presentation as Table 14.3.1.1.1 for 14.3.1.1.2 Overall Summary of Adverse Events (All Enrolled Subjects)

Table 14.3.1.2.1
Overall Summary of Treatment-Emergent Adverse Events by Severity and Relatedness to the Study Device (Safety Population)

	Events (N=xx) n			Total n (%)
Relatedness	Mild	Moderate	Severe	
Relatedness to Study Device				
Not Related	n	n	n	n (%)
Unlikely Related	n	n	n	n (%)
Probably Related	n	n	n	n (%)
Related	n	n	n	n (%)
Not Applicable	n	n	n	n (%)
Relatedness to Study Device Placement/Removal Procedure				
Not Related	n	n	n	n (%)
Unlikely Related	n	n	n	n (%)
Probably Related	n	n	n	n (%)
Related	n	n	n	n (%)
Not Applicable	n	n	n	n (%)

Note: The denominator for the percentages is the number of events (N) for the subjects in the safety population.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programming notes:
Following the similar structure presentation as Table 14.3.1.2.1 for
14.3.1.2.2 Overall Summary of Adverse Events by Severity and Relatedness to the Study Product (All Enrolled Subjects)

Table 14.3.1.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class / Preferred Term	Events (N=xx) n	Subjects (N=xx) n (%)
Number (%) of subjects with any AEs		n (%)
System Organ Class 1	n	n (%)
Preferred Term 1	n	n (%)
Preferred Term 2	n	n (%)
System Organ Class 2	n	n (%)
Preferred Term 1	n	n (%)
Preferred Term 2	n	n (%)

Note: Only treatment-emergent AEs are summarised in this table. An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: AEs are coded using MedDRA v xxx.
Note: System organ classes are listed in descending order based on the subjects column; within each system organ class, preferred terms are listed in descending order based on the subjects column.
Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one AE are counted only once.
AE=adverse event; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = Treatment-Emergent Adverse Event.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes: The following tables will follow a similar format as Table 14.3.1.3.1
14.3.1.3.2 Adverse Events by System Organ Class and Preferred Term (All Enrolled Subjects)
14.3.1.4.1 Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Population)
14.3.1.4.2 Serious Adverse Events by System Organ Class and Preferred Term (All Enrolled Subjects)
14.3.1.5 Treatment-Emergent Adverse Events Leading to Study Device Removal (Safety Population)
14.3.1.6 Treatment-Emergent Adverse Events as Primary Reason for Exiting Study (Safety Population)
14.3.1.7 Treatment-Emergent Adverse Events Leading to Death (Safety Population)

Table 14.3.1.8
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity (Safety Population)

System Organ Class / Preferred Term	Events (N=xx) n			Subjects (N=xx) n(%)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Number (%) of subjects with any AEs				n (%)	n (%)	n (%)
System Organ Class 1	n	n	n	n (%)	n (%)	n (%)
Preferred Term 1	n	n	n	n (%)	n (%)	n (%)
Preferred Term 2	n	n	n	n (%)	n (%)	n (%)
System Organ Class 2	n	n	n	n (%)	n (%)	n (%)
Preferred Term 1	n	n	n	n (%)	n (%)	n (%)
Preferred Term 2	n	n	n	n (%)	n (%)	n (%)

Note: Only treatment-emergent AEs are summarised in this table. An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: AEs are coded using MedDRA v xxx.
Note: System organ classes are listed in descending order based on the subjects column; within each system organ class, preferred terms are listed in descending order based on the subjects column.
Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one AE are counted only once using the highest severity.
AE=adverse event; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = Treatment-Emergent Adverse Event.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.9
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relatedness to Study Device (Safety Population)

System Organ Class / Preferred Term	Events (N=xx) n					Subjects (N=xx) n(%)				
	Not Related	Unlikely Related	Probably Related	Related	Not Applicable	Not Related	Unlikely Related	Probably Related	Related	Not Applicable
Number (%) of subjects with any AEs						n (%)	n (%)	n (%)	n (%)	n (%)
System Organ Class 1	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
System Organ Class 2	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)

Note: Only treatment-emergent AEs are summarised in this table. An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: AEs are coded using MedDRA v xxx.
Note: System organ classes are listed in descending order based on the subjects column; within each system organ class, preferred terms are listed in descending order based on the subjects column.
Note: At each level of summation (overall, system organ class, preferred term), subjects reporting more than one AE are counted only once using the closest relationship.
AE=adverse event; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = Treatment-Emergent Adverse Event.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes: The following table will follow a similar format as Table 14.3.1.9
Table 14.3.1.10 Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and by Relatedness to Study Device Placement/Removal Procedure (Safety Population)

Table 14.3.1.11
Treatment-Emergent Adverse Events by Preferred Term(Safety Population)

Preferred Term	Events (N=xx) n	Subjects (N=xx) n (%)
Number (%) of subjects with any AEs	n	n (%)
Preferred Term 1	n	n (%)
Preferred Term 2	n	n (%)
Preferred Term 3	n	n (%)
Preferred Term 4	n	n (%)

Note: Only treatment-emergent AEs are summarised in this table. An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: AEs are coded using MedDRA v xxx.
Note: Preferred terms are listed in descending order based on the subjects column.
Note: At each preferred term, subjects reporting more than one AE are counted only once.
AE=adverse event; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = Treatment-Emergent Adverse Event.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.12
Treatment-Emergent Adverse Events by Preferred Term by Onset Time Frame for the First Year (Safety Population)

	Events (N=xx) n				Subjects (N=xx) n(%)			
Preferred Term	0 – 3 Months	>3 – 6 Months	>6 – 12 Months	Overall	0 – 3 Months	>3 – 6 Months	>6 – 12 Months	Overall
Number (%) of subjects with any AEs	n	n	n	n	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n	n	n	n	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n	n	n	n	n (%)	n (%)	n (%)	n (%)
Preferred Term 3	n	n	n	n	n (%)	n (%)	n (%)	n (%)
Preferred Term 4	n	n	n	n	n (%)	n (%)	n (%)	n (%)

Note: Only treatment-emergent AEs are summarised in this table. An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: AEs are coded using MedDRA v xxx.
Note: Preferred terms are listed in descending order based on the overall subjects column.
Note: At each level of summation (overall, time frame, preferred term), subjects reporting more than one AE are counted only once.
AE=adverse event; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = Treatment-Emergent Adverse Event.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.1.13
Treatment-Emergent Adverse Events by Preferred Term by Onset Time Frame (Safety Population)

	Events (N=xx) n					Subjects (N=xx) n(%)				
Preferred Term	0 – 3 Months	>3 – 6 Months	>6 – 12 Months	>12 Months	Overall	0 – 3 Months	>3 – 6 Months	>6 – 12 Months	>12 Months	Overall
Number (%) of subjects with any AEs	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 1	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 2	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 3	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)
Preferred Term 4	n	n	n	n	n	n (%)	n (%)	n (%)	n (%)	n (%)

Note: Only treatment-emergent AEs are summarised in this table. An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: The denominator for the percentages is the number of subjects (N) in the safety population.
Note: AEs are coded using MedDRA v xxx.
Note: Preferred terms are listed in descending order based on the overall subjects column.
Note: At each level of summation (overall, time frame, preferred term), subjects reporting more than one AE are counted only once.
AE=adverse event; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = Treatment-Emergent Adverse Event.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.2.1
Deaths (All Enrolled Subjects)

Subject ID	Date of Death	Cause of Death	Primary Adverse Event #[1]	Comment
xxx-xxx	YYYY-MM-DD	SAE	xx	xxxxx
xxx-xxx	YYYY-MM-DD	Unknown		xxx
xxx-xxx	YYYY-MM-DD	Other, specify		xxx

[1] If subject's death was due to a SAE, provide primary Adverse Event.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.2.2
Serious Adverse Events (All Enrolled Subjects)

Programmer notes
This listing will follow a similar format as Listing 16.2.7.1

Table 14.3.2.3
Adverse Events as Primary Reason for Exiting Study (All Enrolled Subjects)

Programmer notes:
The following listings will follow a similar format as Listing 16.2.7.1:

Table 14.3.5.1
Treatment Exposure (All Enrolled Subjects)

	All Subjects (N=xx)
Device Deployed at First Attempt	
Yes	n (%)
No	n (%)
If No, Made a Second Attempt	
n	n
Yes	n (%)
No	n (%)
Device Deployed at Second Attempt	
n	n
Yes	n (%)
No	n (%)
Device Deployed in either Attempt	
Yes	n (%)
No	n (%)
Number of Cycles with Device Use	
n	xx
Mean	xx.x
SD	xx.xx
Median	xx.x
Min	xx
Max	xx

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.5.2
Device Placement and Subject Pain During the Procedure (All Enrolled Subjects)

	All Subjects (N=xx) n (%)
Difficulties with the Device Deployment	
n	n
Yes	n (%)
No	n (%)
Ease of Device Placement	
n	n
Very easy	n (%)
Easy	n (%)
Neither easy nor hard	n (%)
Hard	n (%)
Very hard	n (%)
Device Placement Pain	
n	n
No Pain	n (%)
Some Pain	n (%)
Painful	n (%)
Moderately Painful	n (%)
Very Painful	n (%)
Medication given during the procedure	
n	n
Yes	n (%)
No	n (%)
Mechanical Dilatation	
n	n
Yes	n (%)
No	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.5.3
Device Expulsion/Removal and Subject Pain During the Procedure (Safety Population)

Description	All Subjects (N=xx) n (%)
Cumulative 1-Year Device Expulsion Rate	n (%)
Cumulative 1-Year Device Removal Rate	n (%)
Cumulative 2-Year Device Expulsion Rate	n (%)
Cumulative 2-Year Device Removal Rate	n (%)
Cumulative 3-Year Device Expulsion Rate	n (%)
Cumulative 3-Year Device Removal Rate	n (%)
Device Expel Prior to This Visit	
n	n
Yes	n (%)
No	n (%)
If Yes, Expulsion Status	
n	n
Complete	n (%)
Partial	n (%)
Was removal accomplished by pulling the strings Without Difficulty	
n	n
Yes	n (%)
No	n (%)
If No, Select All That Apply:	
n	n (%)
Required significant force to pull out with strings	n (%)
Required use of ultrasound guidance	n (%)
Required use of Alligator forceps	n (%)
Required use of IUD hook	n (%)
Required use of other instrument	n (%)
Unable to remove in office initially, required second office visit for successful removal	n (%)
Unable to remove in office - removed in OR	n (%)
Other	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.5.3
Device Expulsion/Removal and Subject Pain During the Procedure (Safety Population)

Programmers note: Continued table

Description	All Subjects (N=xx) n (%)
Ease of Device Removal	
n	n
Very Easy	n (%)
Easy	n (%)
Neither Easy nor Difficult	n (%)
Difficult	n (%)
Very Difficult	n (%)
Device Removal Pain	
n	n
No Pain	n (%)
Some Pain	n (%)
Painful	n (%)
Moderately Painful	n (%)
Very Painful	n (%)
Medication Given During the Procedure	
n	n
Yes	n (%)
No	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.5.4
Transvaginal Ultrasound (Safety Population)

	All Subjects (N=xx)
Device in Place	
n	n (%)
Yes	n (%)
No	n (%)

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Table 14.3.6.1.1
Bleeding and Spotting by Cycle (Safety Population)

Number of Days With	Cycle Statistic	All Sujects (N=xx)
Bleeding or Spotting	Cycle 1	
	n	xx
	Mean	xx.x
	SD	xx.xx
	Median	xx.x
	Min	xx
	Max	xx
	xxxxx	
	n	xx
	Mean	xx.x
	SD	xx.xx
	Median	xx.x
	Min	xx
	Max	xx
None		
Spotting		
Light Bleeding		
Medium Bleeding		
Heavy Bleeding		
Bleeding		
Heavier Flow than when not Using Hormones		
Heavier Flow than when not Using Hormones when Bleeding occurred		

Note: Bleeding include Light Bleeding, Medium Bleeding and Heavy Bleeding.
Note: Menses question has the following choices: None, Spotting (minimal bleeding, no sanitary products required), Light Bleeding (pad, liner, or tampon used), Medium Bleeding (pad, liner, or tampon used), Heavy Bleeding (pad, liner, or tampon used).
Note: The heavy flow question is only asked when the subject responds with Spotting, Light Bleeding, Medium Bleeding, or Heavy Bleeding to the menses question.
Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with all cycles and remaining symptom.
2. Follow a similar format as Table 16.3.6.1.1 for:
Table 16.3.6.1.2 Bleeding and Spotting by Cycle (ECYC Population

Table 14.3.6.2.1
Occurrence and Severity of Dyspareunia in Number of Days by Cycle (Safety Population)

Cycle Statistic	All Subjects (N=xx) No Pain	Some Pain	Painful	Moderately Painful	Very Painful	Not Applicable
Cycle 1						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx	xx	xx	xx	xx	xx
Max	xx	xx	xx	xx	xx	xx
xxxxx						
n	xx	xx	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min	xx	xx	xx	xx	xx	xx
Max	xx	xx	xx	xx	xx	xx

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with all cycles.
2. Follow a similar format as Table 16.3.6.2.1 for:
Table 16.3.6.2.2 Occurrence and Severity of Dyspareunia in Number of Days by Cycle (ECYC Population)

Table 14.3.6.2.3
Occurrence and Severity of Dyspareunia – Worst Pain Grade Shift from Baseline by Cycle (Safety Population)

Cycle Worst Post-Baseline Pain Grade	Baseline				
	No Pain	Some Pain	Painful	Moderately Painful	Very Painful
Cycle 1 (n=xx)					
No Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Some Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Moderately Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Very Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Cycle 2 (n=xx)					
No Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Some Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Moderately Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Very Painful	n (%)	n (%)	n (%)	n (%)	n (%)

Note: At each cycle, subjects reporting more than one pain grade are counted only once using the worst severity.
Note: The denominator of the percentages is the number of subjects who have baseline and non-missing post-baseline at the corresponding cycle.

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with all cycles.
2. Follow a similar format as Table 16.3.6.2.3 for:
Table 16.3.6.2.4 Occurrence and Severity of Dyspareunia – Worst Pain Grade Shift from Baseline by Cycle (ECYC Population)

Table 14.3.6.2.5
Occurrence and Severity of Dyspareunia – Highest Frequency of Occurrence Pain Grade Shift from Baseline by Cycle (Safety Population)

Cycle Highest Frequency of Occurrence Post-Baseline Pain Grade	Baseline				
	No Pain	Some Pain	Painful	Moderately Painful	Very Painful
Cycle 1 (n=xx)					
No Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Some Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Moderately Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Very Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Cycle 2 (n=xx)					
No Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Some Pain	n (%)	n (%)	n (%)	n (%)	n (%)
Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Moderately Painful	n (%)	n (%)	n (%)	n (%)	n (%)
Very Painful	n (%)	n (%)	n (%)	n (%)	n (%)

Note: At each cycle, subjects reporting more than one pain grade are counted only once using the highest frequency of severity and worst severity, in case of ties.
Note: The denominator of the percentages is the number of subjects who have baseline and non-missing post-baseline at the corresponding cycle.

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with all cycles.
2. Follow a similar format as Table 16.3.6.2.5 for:
Table 16.3.6.2.6 Occurrence and Severity of Dyspareunia – Highest Frequency of Occurrence Pain Grade Shift from Baseline by Cycle (ECYC Population)

Table 14.3.6.3.1
Occurrence and Severity of Menstrual Pain or Cramping in Number of Days by Cycle (Safety Population)

Cycle Statistic	All Subjects (N=xx) None	Mild	Moderate	Severe
Cycle 1				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min	xx	xx	xx	xx
Max	xx	xx	xx	xx
xxxxx				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min	xx	xx	xx	xx
Max	xx	xx	xx	xx

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with all cycles.
2. Follow a similar format as Table 16.3.6.3.1 for:
Table 16.3.6.3.2 Occurrence and Severity of Menstrual Pain or Cramping in Number of Days by Cycle (ECYC Population)

Table 14.3.6.3.3
Occurrence and Severity of Menstrual Pain or Cramping by Cycle (Safety Population)

	All Subjects (N=xx)							
	Worst Pain Grade[1]				Highest Frequency of Occurrence Pain Grade[2]			
Cycle	None	Mild	Moderate	Severe	None	Mild	Moderate	Severe
Cycle 1	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Cycle 2	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

[1]: At each cycle, subjects reporting more than one pain grade are counted only once using the worst severity.
[2]: At each cycle, subjects reporting more than one pain grade are counted only once using the highest frequency of severity and worst severity, in case of ties.

Reference: Listing xxx.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note:
1.Table will continue with all cycles.
2. Follow a similar format as Table 16.3.6.3.3 for:
Table 16.3.6.3.4 Occurrence and Severity of Menstrual Pain or Cramping by Cycle (ECYC Population)

Table 14.3.7.1
Vital Signs and Weight by Analysis Visit (Safety Subjects)

		All Subjects (N=xx)	
Parameter (Unit)	Visit Statistic	Result	Change from Baseline
Heart Rate (bpm)	Baseline		
	n	xx	
	Mean	xx.x	
	SD	xx.xx	
	Median	xx.x	
	Min	xx	
	Max	xx	
	xxxxx		
	n	xx	xx
	Mean	xx.x	xx.x
	SD	xx.xx	xx.xx
	Median	xx.x	xx.x
	Min	xx	xx
	Max	xx	xx
Respiration (breaths/min)			
SBP (mmHg)			
DBP (mmHg)			
Temperature (F)			
Weight (kg)			
BMI (kg/m2)			

Note: LTFU1= Month 18, LTFU2= Month 24, LTFU3= Month 30, LTFU4=Month 36.
DBP = Diastolic Blood Pressure; SBP = Systolic Blood Pressure; LTFU=Long Term Follow Up.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note: Table will continue with all visits and remaining vital signs.

Table 14.3.7.2
BMI Category by Analysis Visit (Safety Subjects)

Visit Statistic	All Subjects (N=xx) n (%)
Baseline	
n	n
Underweight (<18.5)	n (%)
Normal (18.5-24.9)	n (%)
Overweight (25.0-29.9)	n (%)
Obese (>=30)	n (%)
xxxxx	
n	n
Underweight (<18.5)	n (%)
Normal (18.5-24.9)	n (%)
Overweight (25.0-29.9)	n (%)
Obese (>=30)	n (%)

Note: Percentages are based on the number of subjects specified in the column header, i.e. N, unless small n is specified for each category.
Note: LTFU1= Month 18, LTFU2= Month 24, LTFU3= Month 30, LTFU4=Month 36.
LTFU=Long Term Follow Up.

Reference: Listing xxx.
Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer note: Table will continue with all visits.

14 Appendix 4 Listing Layouts

Listing 16.2.1.1
Subject Disposition (All Screened Subjects)

Site ID	Subject ID	Date of Placement/ Date of Second Placement Attempt	Complete 12 months of the study	Date of Week 52 Follow-Up Visit or Early Termination/ Subject Status	Transvaginal Ultrasound performed/ Device in Place	Date of Last Exposure to Device/ # of Days on Device [1] Date of Study Completion or Discontinuation/ Date of Last Contact/ # of Days on Study [2]	Primary Reason for Exiting Study/ Desire for pregnancy[3]
xxx	xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	Yes	YYYY-MM-DD/ Continuing With Long-Term Follow-Up	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Completed Study
	xxx-xxx	YYYY-MM-DD/ ---	Yes	YYYY-MM-DD/ Completing Study and Removing Device	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Adverse Event: #
xxx	xxx-xxx	YYYY-MM-DD/. YYYY-MM-DD	Yes	YYYY-MM-DD/ Continuing With Long-Term Follow-Up	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Withdrew Consent, specify/ Yes
	xxx-xxx	YYYY-MM-DD/ ---	Yes	YYYY-MM-DD/ Completing Study and Removing Device	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Protocol Violation, specify
xxx	xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	Yes	YYYY-MM-DD/ Completing Study and Removing Device	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Lost to Follow-up, specify
	xxx-xxx	YYYY-MM-DD	No	YYYY-MM-DD/ Early Termination	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Investigator/Sponsor Decision, specify

xxx	xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	No	YYYY-MM-DD/ Early Termination	Yes/ No, Explain	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Pregnancy
	xxx-xxx	---/ ---	---	---/ ---	---/ ---	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Screen Failure
xxx	xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	No	YYYY-MM-DD/ Early Termination	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Other, specify
	xxx-xxx	YYYY-MM-DD/ YYYY-MM-DD	No	YYYY-MM-DD/ Early Termination	Yes/ Yes	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Withdrew Consent, specify/ No

[1] # of Days on Device = Date of Last Exposure to Device – Placement Successful Deployment Date + 1.
[2] # of Days on Study = Date of Study Completion or Discontinuation – Placement Successful Deployment Date + 1.
[3] If Withdrew Consent is marked, did the subject withdraw consent due to a desire for pregnancy?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.1.2
Subjects Who Prematurely Discontinued the 1-Year Study (All Enrolled Subjects)

Site ID	Subject ID	Age	Race	Date of Placement/ Date of Second Placement Attempt	Date of Last Exposure to Device/ # of Days on Device [1] Date of Study Discontinuation/ Date of Last Contact/ # of Days on Study [2]	Primary Reason for Exiting Study/ Desire for pregnancy[3]
xxx	xxx-xxx	xx	xx	YYYY-MM-DD/ ---	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Investigator/Sponsor Decision, specify
	xxx-xxx	xx	xx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Lost to Follow-up, specify
xxx	xxx-xxx	xx	xx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Other, specify
	xxx-xxx	xx	xx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Withdrew Consent, specify/ No

[1] # of Days on Device = Date of Last Exposure to Device – Placement Successful Deployment Date + 1.
[2] # of Days on Study = Date of Study Completion – Placement Successful Deployment Date + 1.
[3] If Withdrew Consent is marked, did the subject withdraw consent due to a desire for pregnancy?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.1.3
Subjects Who Prematurely Discontinued the Extension Study (Extension Population)

Site ID	Subject ID	Age	Race	Date of Placement/ Date of Second Placement Attempt	Date of Last Exposure to Device/ # of Days on Device [1]/ Date of Discontinuation/ Date of Last Contact/ # of Days on Study [2]	Primary Reason for Exiting Study/ Desire for pregnancy[3]
xxx	xxx-xxx	xx	xx	YYYY-MM-DD/ ---	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Investigator/Sponsor Decision, specify
	xxx-xxx	xx	xx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Lost to Follow-up, specify
xxx	xxx-xxx	xx	xx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Other, specify
	xxx-xxx	xx	xx	YYYY-MM-DD/ YYYY-MM-DD	YYYY-MM-DD/ xx / YYYY-MM-DD/ YYYY-MM-DD/ xx	Withdrew Consent, specify/ No

[1] # of Days on Device = Date of Last Exposure to Device – Placement Successful Deployment Date + 1.
[2] # of Days on Study = Date of Study Discontinuation – Placement Successful Deployment Date + 1.
[3] If Withdrew Consent is marked, did the subject withdraw consent due to a desire for pregnancy?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.1.4
Study Exit Status (All Screened Subjects)

Site ID	Subject ID	Age	Date of Last Contact	Primary Reason for Exiting Study	Complete 12 months of the study
xxx	xxx-xxx	xx	YYYY-MM-DD	Completed Study	Yes
	xxx-xxx	xx	YYYY-MM-DD	Adverse Event: # xx	Yes

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.2.1
Eligibility (All Screened Subjects)

Subject ID	Informed Consent Date	Reconsent Date [1]	Protocol Version	Date Eligibility Confirmed	Eligibility Status	Screen Failure	Criteria were NOT met or Exclusion Criteria MET
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	Protocol Version 1	YYYY-MM-DD	Eligible	No	
xxx-xxx	YYYY-MM-DD	---	Protocol Version 1	YYYY-MM-DD	Ineligible	Yes	Incl 4
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	Protocol Version 1	YYYY-MM-DD	Eligible	No	
xxx-xxx	YYYY-MM-DD	---	Protocol Version 1	YYYY-MM-DD	Ineligible	Yes	Incl 4, Incl 7
xxx-xxx	YYYY-MM-DD	YYYY-MM-DD	Protocol Version 2	YYYY-MM-DD	Eligible	No	
xxx-xxx	YYYY-MM-DD	---	Protocol Version 3	YYYY-MM-DD	Ineligible	Yes	Incl 4, Excl 16

[1] Date Reconsent Form signed if subject is continuing with Long-Term Follow-Up.

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Listing 16.2.2.2
Protocol Deviations (All Screened Subjects)

	Subjects Excluded from						
Subject ID	Safety	EP	ECYC	Seq #	Deviation Category	Deviation Details/Reason	Classification
xxx-xxx	No	No	Yes	1	xxxxx	xxxxx	Significant
	No	No	No				
	No	Yes	Yes				
xxx-xxx							Insignificant

Safety= intention-to-treat, EP= evaluable for pregnancy, ECYC= evaluable for cycle control.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.3.1
Subject Status on Analysis Population (All Screened Subjects)

Subject ID	Enrolled	Screen Failure	Safety	EP	ECYC	Extension	If No for EP inclusion, deviation specification [1]					If No for ECYC inclusion, deviation specification [2]	
							Requirement 1	Requirement 2	Requirement 3	Requirement 4	Requirement 5	Requirement 1	Requirement 2
xxx-xxx	Yes	No	Yes	Yes	Yes	Yes							
xxx-xxx	Yes	No	Yes	No	No	No	Meet	Meet	Meet	Not Meet	Not Meet	Not Meet	Meet
xxx-xxx	Yes	No	Yes	No	No	No	Meet	Not Meet	Not Meet	Meet	Not Meet	Not Meet	Not Meet
xxx-xxx	Yes	No	Yes	No	Yes	No	Not Meet	Meet	Meet	Meet	Meet		
xxx-xxx	Yes	No	Yes	No	Yes	No	Not Meet	Meet	Meet	Meet	Not Meet		

[1] EP include safety subjects who meet requirements 1, 2, 3 and 4 or 5. Requirement 1 = between 18 to 35 years of age (inclusive) at enrolment; Requirement 2 = at least one report of pregnancy status after being enrolled; Requirement 3 = do not have pre-treatment pregnancy, which is defined as the estimated conception date being before the insertion date; Requirement 4 = have at least 1 cycle with intercourse and without any backup contraception or emergency contraception; Requirement 5 = became pregnant while study device LevoCept was in place.
[2] ECYC include only those safety subjects with at least one cycle for which: A) a pregnancy did not occur; and B) there is bleeding related e-diary data. Requirement 1 = At least one cycle without pregnancy but with bleeding related e-diary data; Requirement 2 = Bleeding related e-diary data;
Safety= intention-to-treat, EP= evaluable for pregnancy, ECYC= evaluable for cycle control.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Sebela Pharmaceuticals Development LLC
CMDOC-0022

Listing 16.2.4.1
Demographics (All Enrolled Subjects)

Site ID	Site	Subject ID	Date of Birth	Age (years)[1]	Race[2]	Ethnicity	Marital Status	Parity
xxx	xxxxx	xxx-xxx	YYYY-MM-DD	xx	White	Hispanic or Latino	Married	Parous
xxx	xxxxx	xxx-xxx	YYYY-MM-DD	xx	Black or African American	Not Hispanic or Latino	Divorced	Nulliparous
xxx	xxxxx	xxx-xxx	YYYY-MM-DD	xx	Asian	Not Hispanic or Latino	Separated	Parous
xxx	xxxxx	xxx-xxx	YYYY-MM-DD	xx	White, Asian	Not Hispanic or Latino	Single	Nulliparous
xxx	xxxxx	xxx-xxx	YYYY-MM-DD	xx	White	Hispanic or Latino	Widowed	

Note: Subjects who transferred to another site are included only in their initial site.
Note: Subject [redacted] transferred to site [redacted], subject [redacted] transferred to site [redacted] subject [redacted] transferred to site [redacted].
[1] Age (years) = (Date of informed consent - Date of birth) / 365.25, rounded down to the nearest year.
[2] Subjects could mark more than one race.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.4.2
Medical History (All Enrolled Subjects)

Subject ID	Any Clinically Relevant MH	MH #	Body System	Condition/Event/Procedure	Date of Onset	Ongoing	End Date
xxx-xxx	No						
xxx-xxx	Yes	1	Allergies (including intolerance to nickel and copper)	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		2	Cardiovascular	xxxxx	YYYY-MM-DD	Yes	
		3	Gastrointestinal	xxxxx	YYYY		YYYY
		4	Thyroid	xxxxx	YYYY-MM		YYYY-MM
		5	HEENT	xxxxx	UNKNOWN		UNKNOWN
		6	Hematological	xxxxx	YYYY-MM-DD	Yes	
		7	Hepatobiliary	xxxxx	YYYY-MM-DD	Yes	
		8	Immunological	xxxxx	YYYY-MM-DD	Yes	
		9	Integumentary	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		10	Lymphatic	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		11	Musculoskeletal	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		12	Neurological	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		13	Reproductive/Gynecologic	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		14	Respiratory	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		15	Urinary	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		16	Endocrine	xxxxx	YYYY-MM-DD		YYYY-MM-DD
		17	Other,Specify	xxxxx	YYYY-MM-DD		YYYY-MM-DD

MH = medical history.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes: Sort by MH # within each subject.

Listing 16.2.4.3
Gynecological History (All Enrolled Subjects)
Part 1 of 2

Subject ID	History collected	Pain During Intercourse	Prior Contraception	Currently Use Birth Control	Current Primary Contraception	Date of Last Contraception Use	Infections[1]/ Medications[2]
xxx-xxx	No						
xxx-xxx	Yes	No Pain	Oral Contraception/ Double Barrier Method/ Injectable/ Implantable/ Condom/ IUD,Type/ None/ Other, Specify	Yes	Oral Contraception/ Double Barrier Method/ Injectable/ Implantable/ Condom/ IUD,Type/ Other, Specify	YYYY-MM-DD	No
xxx-xxx	Yes	Some Pain	Condom	No		YYYY	No
xxx-xxx	Yes	Painful	IUD,Type	Yes	IUD,Type	YYYY-MM	Yes/ No
xxx-xxx	Yes	Moderately Painful	None	Yes	None	UNKNOWN	Yes/ Yes
xxx-xxx	Yes	Very Painful	Other, Specify	Yes	Other, Specify	YYYY-MM-DD	Yes/ ---

[1] Has the subject had any vaginal infections or yeast infections in the past 30 days?
[2] If the subject had any vaginal infections or yeast infections in the past 30 days, were any medications taken for the infection?
[3] If the subject currently breastfeeding, has the subject had two consecutive menses since the last pregnancy?
[4] Is there daily discomfort that can be attributed to gynecological issues (non-menstrual).
MH = medical history.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.4.3
Gynecological History (All Enrolled Subjects)
Part 2 of 2

Subject ID	History collected	Ever been Pregnant	If Yes, End Date of Last Pregnancy	Number of Live Births		Currently breastfeeding	Two Consecutive Menses[3]	Daily discomfort[4]	If Yes, level of this daily discomfort
				Natural	C-Section				
xxx-xxx	No								
xxx-xxx	Yes	No						No	
xxx-xxx	Yes	Yes	YYYY-MM-DD	0	3	Yes	No	Yes	Some Pain
xxx-xxx	Yes	Yes	YYYY-MM-DD	2	1	Yes	Yes	Yes	Painful
xxx-xxx	Yes	Yes	UNKNOWN	0	0	No		Yes	Moderately Painful

[1] Has the subject had any vaginal infections or yeast infections in the past 30 days?
[2] If the subject had any vaginal infections or yeast infections in the past 30 days, were any medications taken for the infection?
[3] If the subject currently breastfeeding, has the subject had two consecutive menses since the last pregnancy?
[4] Is there daily discomfort that can be attributed to gynecological issues (non-menstrual)
MH = medical history.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.4.4
Menstrual History (All Enrolled Subjects)
Part 1 of 2

Subject ID	Menstrual Cycle Over The Past 3 Months	Had 3 consecutive periods	Frequency	Average length	Usual flow	Usual level of discomfort caused by cramping	Spotting between periods	Day in current menstrual cycle
xxx-xxx	Irregular	Yes	Less than 25 days	Irregular	None	None	None	
xxx-xxx	Regular	No	25-30 days	Less than 3 days	Light	Mild	Occasionally	1
xxx-xxx	Irregular	Yes	31-40 days	3-5 days	Moderate	Moderate	Regularly	10
xxx-xxx	Regular	Yes	More than 40 days	More than 5 days	Heavy	Severe		26

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Listing 16.2.4.4
Menstrual History (All Enrolled Subjects)
Part 2 of 2

		When not using Hormonal Contraception					
Subject ID	Used Hormonal Contraception in the Last 3 Months	Menstrual Cycles Regular	Frequency	Average length	Usual flow	Usual level of discomfort caused by cramping	Spotting between periods
xxx-xxx	No						
xxx-xxx	Yes	Yes	Less than 25 days	Irregular	None	None	None
xxx-xxx	Yes	No	25-30 days	Less than 3 days	Light	Mild	Occasionally
xxx-xxx	Yes	Yes	31-40 days	3-5 days	Moderate	Moderate	Regularly
xxx-xxx	Yes	Yes	More than 40 days	More than 5 days	Heavy	Severe	

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.4.5
Cervical Cytology (All Enrolled Subjects)

		Gonorrhea Test			Chlamydia Test			PAP Test	
Subject ID	Visit	Performed	Date of Collection	Result	Performed	Date of Collection	Result	Date of Last PAP Cytology	Result
xxx-xxx	xxx	No			No				
xxx-xxx	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive	YYYY-MM-DD	Normal
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		
xxx-xxx	xxx	Yes	YYYY-MM-DD	Negative	Yes	YYYY-MM-DD	Negative	YYYY-MM-DD	Abnormal: ASCUS, HPV Negative
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		
xxx-xxx	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive	YYYY-MM-DD	Abnormal: ASCUS, HPV Positive
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		
xxx-xxx	xxx	Yes	YYYY-MM-DD	Negative	Yes	YYYY-MM-DD	Negative	YYYY-MM-DD	Abnormal: ASCUS, HPV Negative
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		
xxx-xxx	xxx	Yes	YYYY-MM-DD	Negative	Yes	YYYY-MM-DD	Negative	YYYY-MM-DD	HSIL
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		
xxx-xxx	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive	YYYY-MM-DD	Cancer
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		
xxx-xxx	xxx	Yes	YYYY-MM-DD	Negative	Yes	YYYY-MM-DD	Negative	YYYY-MM-DD	Not Done
	xxx	Yes	YYYY-MM-DD	Positive	Yes	YYYY-MM-DD	Positive		

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes:
Please check data from two forms: Cervical Cytology and Unscheduled Cervical Infect Test.

Listing 16.2.4.6
Prior and Concomitant Medications (All Enrolled Subjects)

Subject ID	Any CM	CM #	ATC Class // Preferred Name // Verbatim	Prior	Concomitant	Start Date/ Stop Date	Dose (Units)	Dose Form	Route/ Frequency	Used for Emergency Contraception	Indications
xxx-xxx	No										
xxx-xxx	Yes	1	xxxxx// xxxxx// xxxxx	No	Yes	YYYY-MM-DD / Ongoing	4 (mg)	Powder	Oral / QD	No	MH # 21
		2	xxxxx// xxxxx// xxxxx	Yes	Yes	YYYY-MM-DD / YYYY-MM-DD	5 (mL)	Other, Specify	Intramuscular/ PRN	Yes	Primary AE #3/ Additional AE(s): #1, 2
xxx-xxx	Yes	1	xxxxx// xxxxx// xxxxx			YYYY-MM-DD / YYYY-MM-DD	3 (Other, Specify)	Tablet	Topical/ Other, Specify	No	MH # 21/ Other: xxxxx

CM= Concomitant Medications.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes:
1. Sort by CM #.
2. Show the unit, dose form, route and frequency, not the codes.
3. Use XMED dataset.

Listing 16.2.5.1
Device Placement (All Enrolled Subjects)
Part 1 of 2

		First Attempt				Second Attempt				
Subject ID	Placement Performed	Device Lot Number	Date	Day of Current Menstrual Cycle[1]	Deployed	Device Lot Number	Attempt	Date	Day of Current Menstrual Cycle[1]	Deployed
xxx-xxx	Yes	xxx	YYYY-MM-DD	1	No, Explain		No	YYYY-MM-DD	1	No, Explain
xxx-xxx	Yes	xxx	YYYY-MM-DD	2	No	xxx	Yes	YYYY-MM-DD	2	No, Explain
xxx-xxx	Yes	xxx	YYYY-MM-DD	8	No	xxx	Yes	YYYY-MM-DD	8	Yes
xxx-xxx	Yes	xxx	YYYY-MM-DD	12	Yes			YYYY-MM-DD	12	Yes

[1] If subject has not been menstruating regularly due to hormonal contraception use or a recent pregnancy, day of current menstrual cycle is record as 00.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.5.1
Device Placement (All Enrolled Subjects)
Part 2 of 2

Subject ID	Difficulties with the Device Deployment	How easy was the device placement	Device Placement Pain	Medication given during the procedure	Mechanical Dilatation	Transvaginal Ultrasound		
						TVUS Performed	Date	Device in Place
xxx-xxx	No	Very easy	No Pain	Yes	Yes			
xxx-xxx	No	Easy	Some Pain	No	No	Yes	YYYY-MM-DD	No, Explain
xxx-xxx	Yes, Explain	Very hard	Very Painful	Yes	Yes	Yes	YYYY-MM-DD	Yes
xxx-xxx	Yes, Explain	Neither easy nor hard	Moderately Painful	Yes	Yes	Yes	YYYY-MM-DD	Yes

[1] If subject has not been menstruating regularly due to hormonal contraception use or a recent pregnancy, day of current menstrual cycle is recored as 00.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.5.2
Device Removal (All Enrolled Subjects)

Subject ID	Visit	Device Expel Prior to this visit/ Status	Date of Expulsion	Date of Procedure	Without Difficulty[1]	If No, Explain	Medication given during the procedure	Ease of Device Removal	Device Removal Pain
xxx-xxx	WEEK 52 - FOLLOW UP	Yes/ Complete	YYYY-MM-DD	YYYY-MM-DD			Yes	Very easy	No Pain
xxx-xxx	WEEK 52 - FOLLOW UP	Yes/ Partial	YYYY-MM-DD	YYYY-MM-DD	No	Required significant force to pull out with strings	No	Easy	Some Pain
xxx-xxx	WEEK 52 - FOLLOW UP	No		YYYY-MM-DD	No	Required use of IUD hook/ Other, Specify	Yes	Very hard	Very Painful
xxx-xxx	WEEK 52 - FOLLOW UP	No		YYYY-MM-DD	No	Required use of Alligator forceps	Yes	Neither easy nor hard	Moderately Painful
xxx-xxx	WEEK 52 - FOLLOW UP	No		YYYY-MM-DD	Yes				

[1] Was removal accomplished by pulling the strings without difficulty?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.5.3
Transvaginal Ultrasound (All Enrolled Subjects)

Subject ID	Visit	Date of Procedure	Device in Place	If No, Explain
xxx-xxx	xxxxx	YYYY-MM-DD		
xxx-xxx	xxxxx	YYYY-MM-DD	Yes	
	xxxxx	YYYY-MM-DD	No	xxxxx
xxx-xxx	xxxxx	YYYY-MM-DD	No	xxxxx

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.1
Pregnancy Test (All Enrolled Subjects)

Subject ID	Visit	Urine Pregnancy Test Performed	If No, Explain	Collection Date	Test Result
xxx-xxx	xxxxx	Yes		YYYY-MM-DD	Negative
	xxxxx	Yes		YYYY-MM-DD	Negative
	xxxxx	Yes		YYYY-MM-DD	Negative
	xxxxx	No	xxxxx		
xxx-xxx	xxxxx	Yes		YYYY-MM-DD	Positive
xxx-xxx	xxxxx	No	xxxxx		

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.2
Post-Expulsion Pregnancy Test (All Enrolled Subjects)

Subject ID	Phone Contact Completed [1]	If No, Explain	Date of Contact	Pregnancy Test Performed [2]	Date of Test Completed	Test Result
xxx-xxx	Yes		YYYY-MM-DD	Yes	YYYY-MM-DD	Negative
	Yes		YYYY-MM-DD	Yes	YYYY-MM-DD	Negative
	Yes		YYYY-MM-DD	No		
	No	xxxxx		No		
xxx-xxx	Yes		YYYY-MM-DD	Yes	YYYY-MM-DD	Positive
xxx-xxx	No	xxxxx				

[1] Was a Post-Expulsion Follow-up phone contact completed?
[2] Did the subject complete the 6-8-Week Post-Expulsion Pregnancy Test?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.3
Post-Removal Pregnancy Test (All Enrolled Subjects)

Subject ID	Post-Removal Follow-up phone contact completed	Date of Contact	If No, Explain	Complete the 17-Day Post-Removal Pregnancy Test	Date Pregnancy Test Was Completed	Test Result
xxx-xxx	No		xxxxx			
xxx-xxx	Yes	YYYY-MM-DD		Yes	YYYY-MM-DD	Negative
xxx-xxx	Yes	YYYY-MM-DD		Yes	YYYY-MM-DD	Positive
xxx-xxx	Yes	YYYY-MM-DD		No		

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.4
Pregnancy Notification (All Enrolled Subjects)

Subject ID	Serum Collection Performed	Collection Date	Test Result	Serum Test Result (mIU/L)	Date of Last Menstrual Period Before Pregnancy	Method [1]	Date Gestational Age Determined	Estimated		
								Date of Conception	Date of Delivery	Gestational Age (weeks)
xxx-xxx	No, Explain									
xxx-xxx	Yes	YYYY-MM-DD	Negative	xx	YYYY-MM-DD		YYYY-MM-DD	YYYY-MM-DD	YYYY-MM-DD	2
xxx-xxx	Yes	YYYY-MM-DD	Positive	xx	YYYY-MM-DD	Abdominal/Pelvic Exam, Ultrasound	YYYY-MM-DD	YYYY-MM-DD	YYYY-MM-DD	3
xxx-xxx	Yes	YYYY-MM-DD	Positive	xx	YYYY-MM-DD	Investigator Estimation, Specify	YYYY-MM-DD	YYYY-MM-DD	YYYY-MM-DD	8

[1] Method used to determine gestational age.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.5
Pregnancy Outcome (All Enrolled Subjects)

										Second Baby	
Subject ID	Date of Birth or Termination	Fetal Status	Gestational Age (weeks)	Weight (lbs) / Weight (ozs) / Height (inches)	Sex/ Apgar Score (1 minute)/ Apgar Score (5 minutes)	Maternal Complications	Prenatal Events	Postnatal Events	Multiple Birth	Weight (lbs) / Weight (ozs) / Height (inches)	Sex/ Apgar Score (1 minute)/ Apgar Score (5 minutes)
xxx-xxx	YYYY-MM-DD	PreTerm Birth	xx	xx/ xx/ xx	xx/ xx/ xx	xxxxx	xxxxx	xxxxx	No		
xxx-xxx	YYYY-MM-DD	Full Term Birth	xx	xx/ xx/ xx	xx/ xx/ xx	xxxxx	xxxxx	xxxxx	Yes	xx/ xx/ xx	xx/ xx/ xx
xxx-xxx	YYYY-MM-DD	Spontaneous Termination	xx	xx/ xx/ xx	xx/ xx/ xx	xxxxx	xxxxx	xxxxx	Yes	xx/ xx/ xx	xx/ xx/ xx
xxx-xxx	YYYY-MM-DD	Unknown	xx	xx/ xx/ xx	xx/ xx/ xx	xxxxx	xxxxx	xxxxx	Yes	xx/ xx/ xx	xx/ xx/ xx

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.6.6
Return to Fertility (All Enrolled Subjects)

Subject ID	Subject Desire Pregnancy	If Yes, Mark Outcome	Date of Conception (If Pregnancy Occurred)
xxx-xxx	No		
xxx-xxx	Yes	Pregnancy Occurred	YYYY-MM-DD
xxx-xxx	Yes	Pregnancy Did Not Occur	
xxx-xxx	Yes	Lost To Follow-up	

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.7.1
Adverse Events (All Enrolled Subjects)
Part 1 of 2

Subject ID	Any AE	AE #	System Organ Class // Preferred Term // Verbatim Text	Start Date(Study Da)/ End Date (Study Day)/ Duration/ TEAE	Severity	Worsening of Pre-existing Condition	Related to Bleeding	Relationship to Study Device	Relationship to Placement/ Removal Procedure	Action Taken with Study Device	Treatment of Event	Outcome
xxx-xxx	No											
xxx-xxx	Yes	1	xxxxx// xxxxx// xxxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)/ xx/ No	Mild	No	No	Not Related	Not Related	None	Medication	Recovered
		2	xxxxx// xxxxx// xxxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)/ xx/ Yes	Moderate	Yes	Yes	Unlikely Related	Unlikely Related	Removed	Non-Drug Treatment	Resolved with Sequelae
		3	xxxxx// xxxxx// xxxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)/ xx/ Yes	Life Threatening	No	No	Probably Related	Probably Related	Expelled	Hospitalization	Ongoing
		4	xxxxx// xxxxx// xxxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)/ xx/ Yes	Fatal	Yes	Yes	Related	Related	Not Applicable	None	Fatal
xxx-xxx	Yes	1	xxxxx// xxxxx// xxxxx	YYYY-MM-DD (xx)/ YYYY-MM-DD (xx)/ xx/ Yes	Moderate	No	No	Not Applicable	Not Applicable	Expelled	Hospitalization	Unknown

[1] Did the AE require inpatient hospitalization or prolong an existing hospitalization?
[2] Did the AE result in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions?
[3] Did the AE result in a congenital anomaly or birth defect?
Note: An AE that stared on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: AEs are coded using MedDRA v xxx.
Note: Study day is relative to the date of study device successfully deployed. Duration in days is calculated as end date –start date +1.
AE = Adverse Event; MedDRA = Medical Dictionary for Drug Activities; TEAE = Treatment-Emergent Adverse Event.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes: Sort by AE # within each subject.

Listing 16.2.7.1
Adverse Events (All Enrolled Subjects)
Part 2 of 2

Subject ID	Any AE	AE #	Serious	Result in Death	Date of Death/ Death Certificate/ Autopsy	Life-threatening	Hospitalization[1]/ Date of Admission/ Date of Discharge	Life functions[2]	Birth Defect[3]	Important Medical Event	Intervention
xxx-xxx	No										
xxx-xxx	Yes	1	No	No		No		No		No	No
		2	No	No		Yes	Yes/ YYYY-MM-DD/ YYYY-MM-DD	Yes		Yes	Yes
		3	Yes	No		No		No		No	No
		4	Yes	Yes	YYYY-MM-DD/ Yes/ --	Yes	Yes/ YYYY-MM-DD/ YYYY-MM-DD	Yes		Yes	Yes
xxx-xxx	Yes	1	No	No	YYYY-MM-DD/ Yes/ Yes	No		No	Unknown	No	No

[1] Did the AE require inpatient hospitalization or prolong an existing hospitalization?
[2] Did the AE result in persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions?
[3] Did the AE result in a congenital anomaly or birth defect?
Note: An AE that started on or after the date/time of study device placement, or an AE with an unknown/not reported onset date/time is defined as a TEAE.
Note: AEs are coded using MedDRA v xxx.
Note: Study day is relative to the date of study device successfully deployed. Duration in days is calculated as end date –start date +1.
AE = Adverse Event; MedDRA = Medical Dictionary for Drug Activities; TEAE = Treatment-Emergent Adverse Event.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes:
1. Sort by AE # within each subject.
2. The following listings will follow a similar format as Listing 16.2.7.1:

16.2.7.2 Adverse Events Related to Study Device (All Enrolled Subjects)
16.2.7.3 Adverse Events Related to Study Device Placement/Removal Procedure (All Enrolled Subjects)
16.2.7.4 Adverse Events Leading to Study Device Removal (All Enrolled Subjects)
16.2.7.5 Adverse Events Leading to Death (All Enrolled Subjects)

Listing 16.2.8.1
Subject Diary (All Enrolled Subjects)
Part 1 of 2

Question ID	Question Description	Responses Description
QS1	Did you have a period (Menses) or other vaginal bleeding today?	None - None(No bleeding or spotting); Spotting - Spotting(minimal bleeding, no sanitary products required); Light Bleeding - Light Bleeding(pad, liner, or tampon used); Medium Bleeding - Medium Bleeding(pad, liner, or tampon used); Heavy Bleeding - Heavy Bleeding(pad, liner, or tampon used).
QS2	If vaginal bleeding occurred, was the flow today heavier than when you are not using hormones?	Yes; No.
QS3	Do you have vaginal intercourse today?	Yes; No.
QS4	If you have vaginal intercourse, did you experience pain during intercourse?	No Pain; Some Pain; Painful; Moderately Painful; Very Painful; Not Applicable.
QS5	If you had pain with incourse, was the pain worse than before IUD insertion?	Yes; No.
QS6	If you have vaginal intercourse, did you use any additional birth control methods?	Yes; No.
QS7	If additional birth control methods were used, please mark all that apply:	Hormonal contraception (e.g., pill, patches, ring); Emergency contraception (e.g., Plan B, Ella); Female barrier (e.g., condom, Spermicide, cap); Male condom Alone; Male condom with Spermicide; Withdrawal; Other(specify).
QS8	Have you experienced any menstrual pain or cramping?	None; Mild; Moderate; Severe.
QS9	If pain or cramping occurred, was the cramping worse than when you are not using hormones?	Yes; No.
QS10	Did the LevoCept device expel?	Yes; No; Suspected.

Listing 16.2.8.1
Subject Diary (All Enrolled Subjects)
Part 2 of 2

Subject ID	Date	Sequence #	Cycle #	Day #	QS1	QS2	QS3	QS4	QS5	QS6	QS7	QS8	QS9	QS10
xxx-xxx	YYYY-MM-DD	xx	xx	xx	None		Yes	No Pain	Yes	Yes	Hormonal contraception	None	Yes	Yes
	YYYY-MM-DD	xx	xx	xx	Spotting		Yes	Some Pain	Yes	Yes	Emergency contraception	Mild	Yes	Yes
	YYYY-MM-DD	xx	xx	xx	Light Bleeding	Yes	Yes	Painful	Yes	Yes	Female barrier	Moderate	Yes	Yes
	YYYY-MM-DD	xx	xx	xx	Medium Bleeding	No	No	Not Applicable	Yes	Yes	Male condom Alone	Severe	Yes	Yes
	YYYY-MM-DD	xx	xx	xx	Heavy Bleeding	Yes	No	Not Applicable	Yes	Yes	Male condom with Spermicide		Yes	Yes
	YYYY-MM-DD	xx	xx	xx	None		Yes	No Pain	Yes	Yes	Withdrawal			
	YYYY-MM-DD	xx	xx	xx	None		Yes	Moderately Painful	No	No	Other, specify			
	YYYY-MM-DD	xx	xx	xx	None			Very Painful	No	No				
xxx-xxx	YYYY-MM-DD	xx	xx	xx	None		Yes	No Pain	Yes	Yes	Hormonal contraception/ Other, specify	None	No	No
	YYYY-MM-DD	xx	xx	xx	Spotting		Yes	No Pain	Yes	Yes	Female barrier/ Male condom with Spermicide	Mild	No	No

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.8.2
Subject Missed Diary Review (All Enrolled Subjects)

Subject ID	At least one Diary Missed	Date of Missed	Sequence #	CRF Cycle #	Cycle #	Day #	Vaginal intercourse	Additional Birth Control [1]	Pain[2]	Pain Worse[3]
xxx-xxx	Yes	YYYY-MM-DD	xx	xx	xx	xx	Yes	Yes	No Pain	Yes
	Yes	YYYY-MM-DD	xx	xx	xx	xx	Yes	No	Some Pain	No
	Yes	YYYY-MM-DD	xx	xx	xx	xx	Yes	Yes	Painful	Yes
xxx-xxx	Yes	YYYY-MM-DD	xx	xx	xx	xx	Yes	Yes	Moderately Painful	Yes
	Yes	YYYY-MM-DD	xx	xx	xx	xx	No		Not Applicable	No
	Yes	YYYY-MM-DD	xx	xx	xx	xx	Yes	Yes	Very Painful	Yes
xxx-xxx	No									

[1] If yes, did the subject use any additional birth control methods?
[2] Did the subject experience pain during intercourse?
[3] If the subject experienced pain during intercourse, was the pain worse than before IUD insertion

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.8.3
Monthly Phone Contact (All Enrolled Subjects)

Subject ID	Contact Conducted	Date of Contact	Cycle #	Intercourse[1]	Additional Birth Control [2]	Medications[3]	Adverse Events[4]	Resolve or Change[5]
xxx-xxx	Yes	YYYY-MM-DD	xx	Yes	Yes	Yes	Yes	Yes
		YYYY-MM-DD	xx	No	No	No	No	No
		YYYY-MM-DD	xx	Yes	Yes	Yes	Yes	Yes
xxx-xxx	No							
xxx-xxx	Yes	YYYY-MM-DD	xx	Yes	Yes	Yes	Yes	Yes
		YYYY-MM-DD	xx	No	No	No	No	No
		YYYY-MM-DD	xx	Yes	Yes	Yes	Yes	Yes

[1] Did subject have intercourse at least one time during the previous Cycle?
[2] Did the subject use any additional forms of birth control or emergency contraception during the previous Cycle?
[3] Has subject taken any medications since the last contact?
[4] Did subject experience any Adverse Events since the last contact?
[5] Did any prior Adverse Events resolve or change since the last contact?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.8.4
Subject Study Visits (All Enrolled Subjects)

Subject ID	Visit	Date	Not Done	If Not Done, Specify Reason
xxx-xxx	xxxxx	YYYY-MM-DD		
	xxxxx		Yes	Subject Discontinued Prior to this Visit
xxx-xxx	xxxxx	YYYY-MM-DD		
	xxxxx		Yes	Other, Specify
xxx-xxx	xxxxx	YYYY-MM-DD		
	xxxxx	YYYY-MM-DD		

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.8.5
Long Term Follow-up (Extension Population)

Subject ID	Visit	Date	Additional Birth Control [1]	Vaginal Intercourse [2]	Frequency[3]
xxx-xxx	xxxxx	YYYY-MM-DD	Yes	No	
	xxxxx	YYYY-MM-DD	Yes	Yes	Several times a month
xxx-xxx	xxxxx	YYYY-MM-DD	Yes	Yes	Once or twice a week
	xxxxx	YYYY-MM-DD	Yes	Yes	Several times a week
xxx-xxx	xxxxx	YYYY-MM-DD	Yes	Yes	Once a month or less
	xxxxx	YYYY-MM-DD	Yes	Yes	At least once a day

[1] Did subject use additional birth control in the past 6 months?
[2] Did subject have vaginal intercourse at least once since last visit?
[3] If Yes, how often did the subject have vaginal intercourse in the past 6 months?

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Programmer notes: Date is not shown on this form, recorded on VISIT form.

Listing 16.2.9.1
Height (All Enrolled Subjects)

Subject ID	Visit	Measured	Date of Measurement	Height (cm)
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx.x
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx.x

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Listing 16.2.9.2
Vital Signs (All Enrolled Subjects)

Subject ID	Visit	Collected	Assessment Date	Heart Rate (bpm)	Respiration (breaths/min)	SBP (mmHg)	DBP (mmHg)	Temperature (F)	Weight (kg)	BMI (kg/m2)	BMI category[1]
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx*	xx*	xx*	xx*	xx*	xx.x*	xx.x*	Underweight
	xxxxx	Yes	YYYY-MM-DD	xx	xx	xx	xx	xx	xx.x	xx.x	Normal
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx*	xx*	xx*	xx*	xx*	xx.x*	xx.x*	Overweight
	xxxxx	Yes	YYYY-MM-DD	xx	xx	xx	xx	xx	xx.x	xx.x	Obese

Note: * Baseline value.
[1] BMI categorized by Underweight (< 18.5), Normal (18.5 – 24.9), Overweight (25.0 – 29.9), and Obese (≥ 30.0).
DBP = Diastolic Blood Pressure; SBP = Systolic Blood Pressure.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.9.3
Vital Signs - Change from Baseline Results (All Enrolled Subjects)
Part 1 of 2

				Heart Rate (bpm)		SBP (mmHg)		DBP (mmHg)	
Subject ID	Visit	Collected	Assessment Date	Result	Change from Baseline	Result	Change from Baseline	Result	Change from Baseline
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx*		xx*		xx.x*	
	xxxxx	Yes	YYYY-MM-DD	xx		xx	xx	xx.x	xx
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx *		xx*		xx.x*	
	xxxxx	Yes	YYYY-MM-DD	xx		xx	xx	xx.x	xx

Note: * Baseline value.
DBP = Diastolic Blood Pressure; SBP = Systolic Blood Pressure.

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Listing 16.2.9.3
Vital Signs - Change from Baseline Results (All Enrolled Subjects)
Part 2 of 2

				Weight (kg)		BMI (kg/m2)	
Subject ID	Visit	Collected	Assessment Date	Result	Change from Baseline	Result	Change from Baseline
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx.x*		xx.x*	
	xxxxx	Yes	YYYY-MM-DD	xx.x	xx	xx.x	xx
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	xx.x*		xx.x*	
	xxxxx	Yes	YYYY-MM-DD	xx.x	xx	xx.x	xx

Note: * Baseline value.
DBP = Diastolic Blood Pressure; SBP = Systolic Blood Pressure.

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.9.4
Physical Examination (All Enrolled Subjects)

Subject ID	Visit	Performed	Date of Examination	Any Clinically Significant Abnormalities
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	No
	xxxxx	Yes	YYYY-MM-DD	Yes
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	No
	xxxxx	Yes	YYYY-MM-DD	No

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time

Listing 16.2.9.5
Pelvic Examination (All Enrolled Subjects)

Subject ID	Visit	Performed	Date of Examination	Any Clinically Significant Abnormalities
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	No
	xxxxx	Yes	YYYY-MM-DD	Yes
xxx-xxx	xxxxx	Yes	YYYY-MM-DD	No
	xxxxx	Yes	YYYY-MM-DD	No

Program Location: \\xx\xxx\xxx\xxx\xxxxxx\xxxxxxxxxxxxxxxx\xxxx\xxxxx.sas date time