



STATISTICAL ANALYSIS PLAN

**A Multi-Center, Open-Label Trial Investigating
Behavior Related to ella[®] Use in a Simulated OTC Environment
(LIBRella)**

151032-001

**Final Version 2.0
Date: 16 November 2018**

PEGUS Research, Inc.

CONFIDENTIAL

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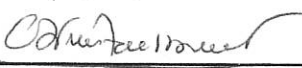
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Glossary and Abbreviations

aCRF	Annotated Case Report Form
ADaM	Analysis Data Model
AE	Adverse Event
AUT	Actual Use Trial
CDISC	Open-Clinical Data Interchange Standards Consortium
CSR	Clinical Study Report
CI	Confidence Interval
CIL	Consumer Information Leaflet
DCI	Data Collection Instrument
DFL	Drug Facts Label
DMP	Data Management Plan
EC	Emergency Contraceptive
EDC	Electronic Data Capture
EOS	End-of-Study
FDA	Food and Drug Administration
HBC	Hormonal Birth Control
ICF	Informed Consent Form
IP	Investigational Product
MedDRA	Medical Dictionary for Regulatory Activities
OTC	Over-the-Counter
PT	Preferred Term
REALM	Rapid Estimate of Adult Literacy in Medicine
REALM-Teen	Rapid Estimate of Adolescent Literacy in Medicine
Rx	Prescription
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SOC	System Organ Class
SOP	Standard Operating Procedure
UPA	Ulipristal Acetate

1 Introduction

This Actual Use Trial (AUT) is designed to evaluate consumers' use of ella® (ulipristal acetate [UPA]) under conditions that emulate actual over-the-counter (OTC) use. The study will assess whether consumers use the product in a manner consistent with the labeling and provide measures of how and when consumers select to use and use the product. AUT design is somewhat different than efficacy trials in that the study looks at subject compliance to directions and dosing information. Where applicable, descriptions have been included where language from efficacy trials may be used in slightly different ways for compliance measures.

The purpose of this document is to provide a more technical and detailed elaboration of the principal features of the analysis described in the protocol, and to include detailed procedures for executing the statistical analysis of the primary and secondary endpoints and other data.

This Statistical Analysis Plan (SAP) assumes familiarity with the final Protocol v3.2 dated 15 Dec 2017 titled "A Multi-Center, Open-Label Trial Investigating Behavior Related to ella® Use in a Simulated OTC Environment (LIBRella). In particular, the SAP is based on the planned analysis specification as written in LIBRella Protocol Section 9 "Data Analysis/Statistical Methods". Therefore, SAP readers may consult the LIBRella Protocol for more background information on the study, e.g., on study objectives, study design and population, treatments, definition of measurements and variables, and planning of sample size. However, it is important to note that the updated study design elements related to the addition of adolescent-only clinic sites described in Protocol v3.2 were never implemented prior to this trial being placed on a Partial Clinical Hold by the Food and Drug Administration (FDA) on 18 January 2017. Therefore, these changes to the study are not reflected within the SAP (i.e., change to exclusion criteria and removal of requirement to purchase the product at the adolescent-only sites).

The following flow chart in Figure 1 below is included to provide an overview of data collection and analysis populations, see Section 5 for additional description of the analysis populations.

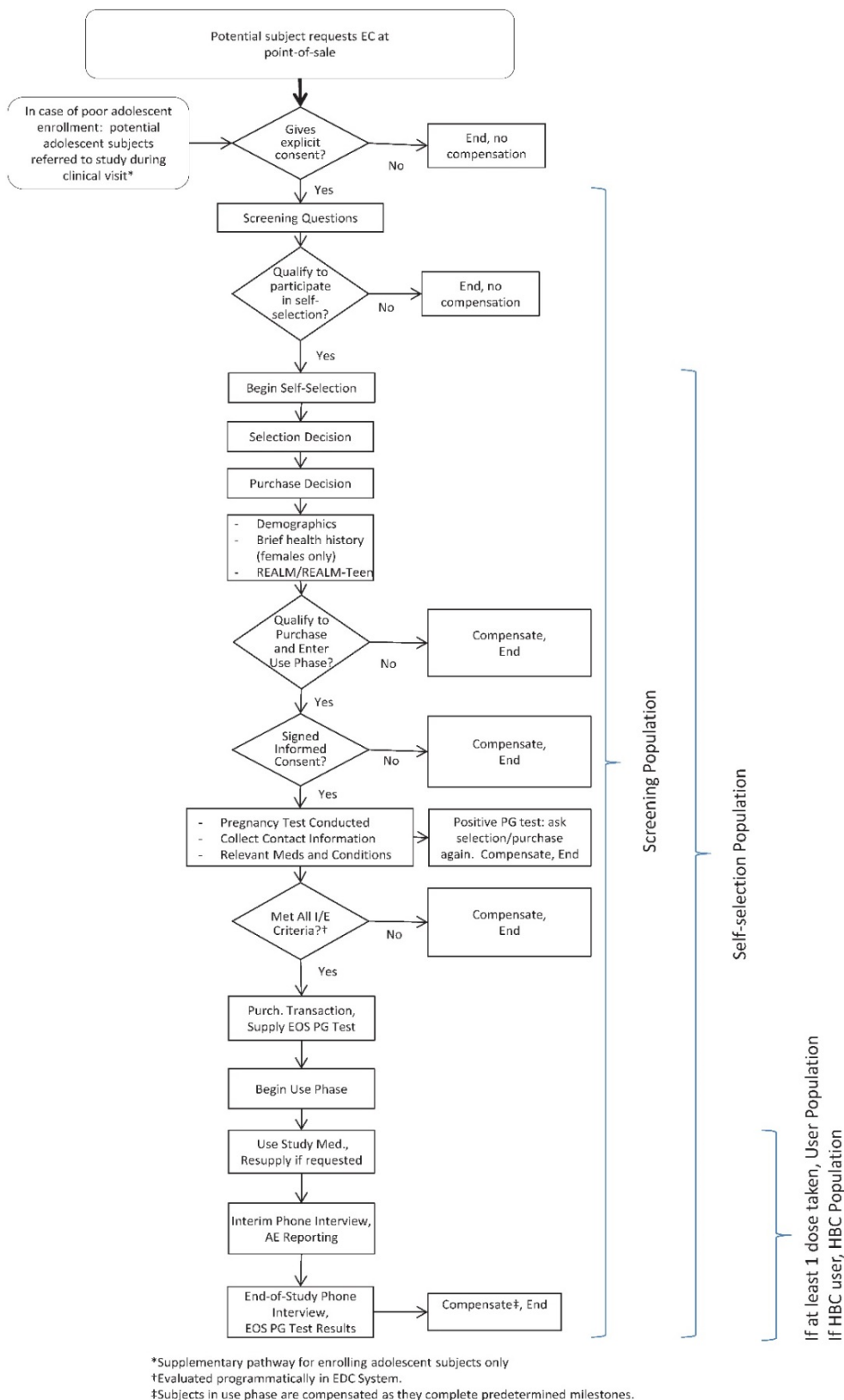


Figure 1. Flow Chart of Study Procedures

2 Trial Objectives

The overall purpose of this study is to evaluate the adequacy of the proposed OTC labeling to guide appropriate consumer behavior in an OTC-like setting when selecting and using ella®. The behavior will be measured by pre-specified endpoints. The determination of the endpoints and other measures is based on the potential clinical consequences of a consumer failing to heed each key label instruction and concerns raised with regard to the potential misuse of the product in an OTC setting. Endpoints are designated either as Actual Use endpoints or Self-Selection endpoints. Note that the “Other Measures” listed below are not endpoints but rather will be used to help characterize the study population in the analysis.

Actual use endpoints measure compliance with label directions for correct use of the investigational product (IP). Self-selection endpoints measure the ability of subjects who review the label information and make a decision about whether the investigational product is appropriate for their use. This is a complex behavior that requires the subject to synthesize information and directions on the label with the knowledge of their current health status and any previous experience with the product class. There are populations of interest that are excluded from the use phase of this study (women who are pregnant or breastfeeding, males). To address Food and Drug Administration (FDA) requests for information on the ability of these potential consumers to correctly identify that it would not be appropriate for them to use the product, they are instructed to review the label information, make a selection and purchase decision and demographics are collected. These subject data are used for analysis of the self-selection endpoints but not to have use data to be included in the actual use endpoints. See Section 5: Analysis sets for further description on the study populations. For detail on the classification of subjects as appropriate for use and correct/acceptable/incorrect self-selection, see Section 6.4.2.1.

Primary Endpoints

- A. Actual Use: Proportion of dosing instances (each recorded use/dose of the study medication) among user population taken within 120 hours (5 days) of most recent episode of unprotected sex. (Compliance with timing)
- B. Actual Use: Proportion of dosing instances among user population in which no more than one tablet was taken. (Compliance with dose)
- C. Self-Selection: Proportion of female selectors (those who selected to use the product during the self-selection interview) who are not pregnant at the time of selection decision. (Indirect measure of intended compliance with absence of pregnancy)

Secondary Endpoints

- D. Self-Selection: Proportion of females in the self-selection population (any female who completed the self-selection interview) who make a correct selection decision with regards to breastfeeding at the time of selection decision. (Indirect measure of intended compliance with absence of breastfeeding)
- E. Self-Selection: Proportion of self-selection population who make a correct selection decision regarding use of the product. (Compliance with Do Not Use and Ask a Doctor Before Use Drug Facts Label directions)

F. Actual Use: Proportion of dosing instances among user population in which hormonal birth control (HBC) is not taken for 5 days after taking ella®. (Compliance with post-dose instruction)

G. Actual Use: Proportion of dosing instances among user population associated with use of hormonal contraceptives in the same cycle after taking ella® in which subject reports using a condom (or other barrier method) every time they have sex until their next menstrual period. (Compliance with post-dose instruction)

H. Actual Use: Proportion of user population who do not use the study product more than once in the same menstrual cycle. (Compliance with post-dose instruction)

I. Self-Selection/Actual Use: Proportion of self-selection population taking one of the “ask a doctor or pharmacist before use” products who do not select, who select but do not use or who report contacting a healthcare provider or pharmacist. (Compliance with possible Drug-drug Interaction directions)

Other Measures

J. Actual Use: Proportion of user population who used a HBC method sometime during the past two months.

K. Actual Use: Proportion of user population who used any emergency contraceptive (EC) on more than one occasion within the study period.

L. Actual Use: Proportion of user population who report becoming pregnant within the study period.

3 Trial Design

This is an observational open-label, multicenter, 6-week study designed to create as much as possible an OTC-like environment in which subjects will make a self-selection and purchase decision about ella® based only on their reading of the outside of the package including the Drug Facts Label (DFL). This is not a randomized trial and there is only one study product that subjects will use based on their own understanding of the directions included on the DFL and Consumer Information Leaflet (CIL); there is no protocol-directed dosing schedule. Qualified subjects who choose to purchase the study medication will do so, then leave the study site and use the product on their own. The study is designed to assess if, when and how subjects use the medication in an OTC-like environment.

This trial is a multi-center trial conducted in a naturalistic environment. Study characteristics and procedures were designed to make it as naturalistic as possible. Some of the key naturalistic elements include the following:

- There are minimal study exclusionary criteria imposed on subjects, making this trial nearly an all-comers study to mimic the likely OTC population.
- The study will be conducted in women’s health clinics and pharmacies, representing typical locations where consumers now commonly purchase EC in an OTC-like setting.
- The proposed OTC packaging and labeling is the only product information provided to subjects during the study. Subjects will only review the outer packaging at the initial visit. Study staff will not provide any additional information or encouragement regarding

product selection at that visit. Staff will not answer subject questions but will redirect them to the outer package.

- After purchasing the study product, subjects will take the package with them when they leave the site; the package will include the outer packaging and, inside the package, the consumer information leaflet (CIL) and study medication.
- Subject characteristics and how they might be related to behaviors directed by the DFL that are gathered at screening, enrollment, or during the 6-week study period will not be discussed directly with subjects until the end of study (EOS) interview.

3.1 Eligibility Criteria

For the self-selection phase, subjects must meet the following screening inclusion criteria to begin the enrollment interview:

- 1) Able to read, speak and understand English
- 2) Can see well enough to read information on the label
- 3) Another member of the respondent's family has not participated in this study
- 4) Consumer or someone else in the household does not work for a market research or advertising company, public relations firm, news organization, pharmacy or pharmaceutical company, medicine manufacturer, as a healthcare professional, or as part of a health care practice, managed care or health insurance company, trained or worked as a healthcare professional or market research professional (eliminated for reasons of confidentiality and increased awareness of medicines and their labels)
- 5) Has not participated in a health-related market research or product label study in the past 12 months
- 6) Has not participated in a clinical trial in the past 12 months
- 7) Has never participated in a study about EC
- 8) Seeking the use of emergency contraception

Additionally, subjects must meet all of the following inclusion criteria to be eligible for enrollment into the use phase of the study:

- 1) Evidence of a personally signed and dated informed consent form (ICF) indicating that the subject (or a legal representative) has been informed of all pertinent aspects of the study.
- 2) Willing and able to comply with the initial visit and planned phone calls and other study procedures.

All subjects will then be asked to make a selection decision. Those presenting with any of the following will not be included, so the exclusion criteria for Use Phase:

- 1) Unwilling to purchase study medication.
- 2) Unwilling to provide written informed consent.
- 3) Unwilling or unable to provide contact information.
- 4) Unwilling to state that the product is for their own use and no one else's.
- 5) Pregnant, by self-report or by a urine pregnancy test.
- 6) Male.

- 7) Known allergy to ulipristal acetate or inactive ingredients.
- 8) Currently breastfeeding.
- 9) Premenarchal (have not experienced a first menstrual cycle).

Subject eligibility will be reviewed and documented by the Investigator or his/her designee before subjects are allowed to purchase and/or begin the use phase of the study.

3.2 Sample Size

The planned sample size for this study is approximately 950 use phase participants. Given that subjects are recruited after independently seeking EC, most of those who enter the self-selection phase are expected to purchase, and most use phase participants are expected to actually use the study product (UPA 30mg) during the study. If approximately 75% of subjects pass the screening criteria, self-select and both qualify and agree to purchase and enter the use phase, it is expected that up to 1270 subjects will need to be interviewed to yield 950 purchasers.

Assuming approximately 950 use phase participants, if 80% of those use the product within the study period, that would yield a user population of 760. Estimating approximately 40% of users will have had recent hormonal contraceptive use would yield a recent hormonal contraceptive user population of 305. Allowing for a further 20% loss to follow-up yields a user population of approximately 608 and a recent hormonal contraceptive user population of 245.

Given that adolescents are a subgroup of interest in the study, adult subjects will be constrained to no more than 775 subjects, allowing for an adolescent subgroup number of approximately 175. Further, the group of older adolescents (age 15 and older) will be constrained to 125, to allow for approximately 50 subjects under the age of 15. If 15% of 950 subjects are classified as low literacy by the Rapid Estimate of Adult Literacy in Medicine (REALM)¹ (for adults) or Rapid Estimate of Adolescent Literacy in Medicine (REALM-Teen)² (for adolescents under age 18), the cohort of low literacy subjects will be approximately 143 subjects, representing a low literacy subgroup of sufficient size.

Because actual use trials are not hypothesis-testing comparative trials, study sample size is designed to allow for adequate evaluation of key endpoints across all subjects and among several subgroups. As the analysis of actual use trials typically focuses on estimating the proportion (and associated 95% confidence intervals) of individual endpoints, sample size is most often based on the number of subjects needed to constrain the confidence interval (CI) to a limited range. For this study, assuming 85% correct compliance behavior (the confidence interval depends on the actual point estimate), a sample of 608 subjects would constrain the CI to $\pm 3.1\%$. For purposes of illustration, **Table 1** provides the 2-sided exact 95% confidence interval for various sample sizes around a point estimate of 85%.

Table 1 Two-sided 95% CIs for Various Sample Sizes Around 85% Point Estimate

	N=760^a	N=608^b	N=245^c	N=143^d
95% CI around a point estimate of 85%	$\pm 2.7\%$	$\pm 3.1\%$	$\pm 5.1\%$	$\pm 7.0\%$

a Approximate user population (maximum)

b Approximate user population (allowing for loss-to-follow up)

- c Approximate recent hormonal contraceptive users
- d Approximate low-literacy subjects (8th grade-level as measured by the REALM or REALM-Teen Test)

3.3 Randomization

There is no randomization in this study.

4 General Statistical Considerations

4.1 General Principles

Statistical analyses of the data will be performed by PEGUS Research using the SAS System for Windows v 9.4 (SAS Institute, Cary, NC). All analyses performed in this study will be descriptive.

4.2 Handling of Dropouts

For subjects that choose to withdraw at any point during the study, an attempt to collect End-of-study (EOS) information and the reasons for the subject's early termination will be conducted. Data gathered prior to subject withdrawal and any ongoing data collection will be included in the analysis for completed questions, unless the subject withdraws consent or requests otherwise. Subjects who do not complete the study will be described in a disposition table, which will provide complete traceability of all subjects who began the screening process and detail of those subjects who qualified, the number that went on to select, purchase, and use the IP. Any subjects who withdrew their consent or were determined to be lost to follow-up will be described in the disposition table as well. Drop-outs will not be replaced.

4.3 Handling of Missing Data

Missing data will not be imputed; the statistical analyses will be based on cases with relevant data available. For endpoint calculations, if missing data makes it so a case (subject or a dosing instance) cannot be classified as to whether or not it belongs in the numerator, that case will also be excluded from the denominator. All missing data will be flagged, and a reason for why the data are missing will be described in a footnote in each applicable statistical table.

4.4 Protocol Violations

Potential subjects will be screened for inclusion and exclusion criteria for the different interview phases described in Section 3.1. Subjects who enter the use phase in violation of the inclusion/exclusion criteria is a protocol violation. In these cases, subjects will be included in the relevant analysis population unless the inclusion/exclusion criteria that were violated would bias the analysis of a study endpoint. However, these subjects would be included in safety analyses if they had taken the study drug.

All violations to the study procedures are tracked/managed by the project manager. Of note, because use of the product is not driven by protocol, non-compliance with the label is not a protocol violation and are captured in relevant study endpoints. All protocol violations will be reviewed by the study team before database lock to evaluate violation magnitude as major or minor, based on the impact on analysis of the endpoints, and therefore the subject's eligibility for any analysis population. Subjects with protocol violations will be summarized by the violation severity and category. In the instance of any duplicate subjects enrolling in the trial, both

records will be retained in the database for the duplicate subject, but only the first instance will be used in the analysis.

4.5 Interim Analyses and Data Monitoring

No designed interim analyses will be conducted. Reviews on progress of enrollment and characteristics of enrollees and other data points important to this study will be looked at periodically from the source data being collected.

Note that a targeted analysis and reporting activity was completed at the request of the FDA while study data were still being collected from subjects and data review and cleaning were ongoing. FDA notified HRA on 18 Jan 2018 that the LIBRella study (and any others investigating UPA) was placed on a Partial Clinical Hold, and requested that no additional subjects enroll into the study, for all subjects to return any unused IP, and that additional data be gathered to determine if there was any detectable safety signal related to liver function in the user population. Subjects who were still enrolled in the study were asked additional targeted health questions in a telephone interview conducted by PEGUS Research nurses, and were then directed to return to the study site for a liver function blood test. These additional study procedures were described in an Administrative Letter to the study protocol. The data were summarized and provided to FDA in March 2018. No safety signal was detected. The Liver Safety Report will be included as an Appendix to the Clinical Study Report (CSR), but will not be described within the body of the CSR. In addition, all liver safety data will be included in the raw, source datasets. No interim analysis of protocol-defined study endpoints was conducted during the liver safety analysis.

4.6 Electronic Data Capture and Data Entry Rules

Information collected during the subject interviews will be entered directly into an Electronic Data Capture (EDC) application (DATATRAK ONE, DATATRAK International, Inc.). Automatic data checks will alert users of discrepancies and inconsistencies, where applicable. In the event of a data entry error, trained study staff interviewers conducting enrollment and follow-up interviews will have the ability to correct information previously entered. Data Management will review the information entered as defined in the study protocol and Data Management Plan (DMP).

All system users will have a unique login user name and password, and system access privileges will be strictly controlled and documented. Whenever data is modified after the initial data entry process, a computer-generated audit trail entry will be created. The audit trail, user access privilege processes, and electronic signatures collected by the system will be compliant with 21 CFR Part 11 requirements.

If an internet connection is not available, the interview will not be started. If the internet connection is lost during the course of an interview, a paper copy of the electronic forms will be available to complete the interview. When the Internet connection is restored, study staff at the site will enter the data from the paper forms into the EDC system. If this were to occur, the completed paper copy of the electronic forms is the source document. Otherwise, the electronic record is the source.

A detailed DMP describes procedures to ensure the proper management and quality of study data and additional PEGUS Standard Operating Procedures (SOPs) specify the activities performed to ensure the quality, accuracy and reliability of the statistical analysis and the final study report.

4.7 Data Review

Data review will be ongoing during the course of this study. Data will be reviewed by PEGUS Research for accuracy and all validation and documentation will be done before database lock. Study Data Tabulation Model (SDTM) datasets will also be created from the source data and Analysis Data Model (ADaM) datasets for analysis will be created from the SDTM datasets. Review cycles will be established to maintain integrity with standard SDTM and ADaM domains. Open-Clinical Data Interchange Standards Consortium (CDISC) validator software will be used to flag for errors and inconsistencies to help in creating FDA compliant datasets.

5 Analysis Sets

The statistical analysis will be based on the following populations of interests. The operational definition for each population is included, and is based on the final Data Collection Instrument (DCI; see Appendix 11.1):

- Responder Population: Subjects who accept the invitation to participate and begin the screening process (including those who do not meet screening criteria for proceeding to the self-selection phase).
 - Section 3, Question 2 not blank
- Self-Selection Population: Subjects who accept the invitation to participate and meet study inclusion screening criteria, participate in a face-to-face interview at the study site and make a self-selection decision (including purchase decision when relevant). Both the self-selection decision and the purchase decision are used to classify subjects as to whether they are a selector or a non-selector.
 - Subjects coded as selector or non-selector in manual coding process (described in study protocol)
- Purchasers (Use Phase Participants): Subjects who meet study enrollment criteria and purchase/obtain the study medication.
 - Section 14, Question 41 answered “Yes”
- User Population: Subjects who take at least one dose of study medication during the study.
 - Section 19, Question 1 answered “Yes” OR Section 21, Question 1 answered “Yes”
- Recent hormonal contraceptive users: Subjects in the user population who also report recent hormonal contraceptive use (i.e., use of a hormonal contraceptive within the previous two months).
 - (Section 19, Question 1 answered “Yes” OR Section 21, Question 1 answered “Yes”) AND [(Section 7, Question 30 answered “Yes” AND Section 7, Question 30a answered one or more of boxes 1-6) OR (Section 7, Question 32 answered “Yes” AND Section 7, Question 32a answered one or more of boxes 1-6 AND Section 7, Question 32b answered ≤60 Days ago OR ≤8 Weeks ago OR ≤2 Months ago)]

6 Statistical Methodology

Frequencies and percentages will be presented for categorical data, mean, standard deviation (SD); median, and range will be presented for numerical data. Percentages will be rounded to one decimal place. The category of missing data will be displayed only if there are actually missing values. Frequencies, percentages and 2-sided 95% CI will be calculated for the primary

and secondary endpoints using the exact method. For the primary endpoints, it will be concluded that the established target threshold is reached if the lower limit of the CI of the point estimate is equal to or exceeds the value of the pre-determined threshold (thresholds for primary endpoints are presented below in Section 6.4.1).

Note that Statistical Table Shells are available for review as a separate study document.

6.1 Population Characteristics

A summary of the disposition of subjects (including responders, self-selection population, purchasers and users) and reasons for exclusion from these populations will be provided. Demographic characteristics, medical history and other background information will be summarized for the responder, self-selection, purchaser, and user populations.

Demographics and endpoint results will be presented for subgroups of interest, with subjects dichotomized on the corresponding variables, which include (but are not necessarily limited to) literacy, gender, age (adolescent vs. adult women, and women <20 years of age vs ≥20 years of age), and history of HBC use.

In addition, all self-selection endpoint results for adolescents will be presented separately for adolescents recruited via clinician referral vs. adolescents recruited in other ways in order to estimate any impact of clinician referral on self-selection endpoints.

6.2 Efficacy

Not applicable to this study.

6.3 Pharmacokinetics / Pharmacodynamics

Not applicable to this study.

6.4 Evaluation of Use

Several of the endpoints are based on dosing instance, rather than by subject, as subjects have the potential to take more than one dose over the course of the study. However, for each of those endpoints a secondary analysis by subject will also be presented as applicable.

6.4.1 Primary Analysis

Frequencies, percentages and two-sided exact 95% confidence intervals will be calculated for the endpoints for the applicable study populations (as defined in Section 5) and for selected subgroups (as described in Section 6.1). The target threshold for the three primary endpoints is 90%. The objective will be considered met for these endpoints if the lower bound of the 2-sided 95% CI for each endpoint evaluated for the entire study population meets or exceeds the established threshold.

- A. Actual Use: Proportion of dosing instances among user population taken within 120 hours (5 days) of most recent episode of unprotected sex.

The first primary endpoint is the proportion in which the denominator includes all dosing instances of the IP and the numerator includes all dosing instances of the IP which were taken within 120 hours (5 days) of the subject's most recent episode of unprotected sex. A time parameter will not be used in collecting the dates for the calculation of the numerator. Rather, as subjects are more likely to focus on the larger time blocks (days), the numerator will be calculated as all dosing instances where (date of ingestion of

tablet-date of most recent unprotected sex ≤ 5 days). It is possible that this type of date comparison may lead to the inclusion of a few subjects who took the IP within 5 calendar days, but more than 120 hours after unprotected sex (depending on time of day for the two dates). However, given that it will be within the labeled 5 calendar days, inclusion of these subjects in the numerator will be acceptable. Additionally, frequencies of number of days between unprotected sex and use of EC will be presented.

Endpoint operationally defined as follows: Total dosing instances (denominator) is the count of all discrete instances of Section 19, Question 3 plus all discrete instances of Section 21, Question 3. Total dosing instances where the IP was taken within 120 hours (5 days) of the subject's most recent episode of unprotected sex (numerator) is the count of all discrete instances where Section 19, Question 3b minus Section 19 Question 3 ≤ 120 hours OR ≤ 5 days plus all discrete instances where Section 21, Question 3b minus Section 21 Question 3 ≤ 120 hours OR ≤ 5 days.

- B. Actual Use: Proportion of dosing instances among user population in which no more than one tablet was taken.

The second primary endpoint is the proportion in which the denominator is all discrete dosing instances of the IP and the numerator includes all dosing instances where no more than one tablet of UPA (IP or prescription (Rx)) was taken.

Endpoint operationally defined as follows: Total dosing instances (denominator) is the count of all discrete dosing instances of Section 19, Question 3 plus all discrete instances of Section 21, Question 3, plus all discrete instances of Section 19, Question 5c, plus all discrete instances of Section 21, Question 5c. Total dosing instances where no more than one tablet was taken (numerator) is the count of all discrete instances where Section 19, Question 3a = 1, plus all discrete instances where Section 21, Question 3a = 1, plus all discrete instances where Section 19, Question 5d = 1, plus all discrete instances where Section 21, Question 5d = 1.

Results for this endpoint will also be presented by subject, expressed by the proportion in which the denominator is all subjects in the user population, and the numerator includes all subjects who took no more than one tablet in all of their dosing instances.

Endpoint operationally defined as follows: User population (denominator) is the count of all subjects who answered "Yes" to Section 19, Question 1 OR answered "Yes" to Section 21, Question 1. Total number of subjects who took no more than one tablet of UPA (numerator) is the count of all subjects for whom any responses provided to Section 19, Question 3a, Section 21, Question 3a, Section 19, Question 5d, and Section 21, Question 5d all = 1.

- C. Self-Selection: Proportion of female selectors (those who selected to use the product) who are not pregnant at the time of selection decision.

The third primary endpoint is the proportion in which the denominator includes all females who selected to use the product (regardless of whether they purchased/used) and the numerator includes all female selectors who were not pregnant at the time of the selection decision. Pregnancy status will be based on results of the pregnancy test, if available. For subjects who did not proceed far enough in the interview to take the

pregnancy test, their self-reported pregnancy status will be used. In the case of subjects that report not being pregnant, sign consent and then receive a positive result on the pregnancy test, their selection decision made prior to the pregnancy test will be used for formal analysis of this endpoint, though this measure will also be presented taking into account their selection decision made after the pregnancy test for informational purposes only.

Endpoint operationally defined as follows: Selector population (denominator) is the count of all subjects who were coded as a selector in selector coding. Selectors who were not pregnant at selection (numerator) includes all subjects who were coded as a selector in selector coding AND ((Section 12, Question 36b answered “Negative”) OR (Section 12, Question 36b is null and Section 7, Question 27 is not answer “Yes”) OR (Section 12, Question 36b is “Positive” but subject indicates she had a very recent abortion)).

6.4.2 Secondary Analysis

- D. Self-Selection: Proportion of females in the self-selection population who make a correct selection decision with regard to breastfeeding.

The first secondary endpoint is the proportion in which the denominator includes all females in the self-selection population and the numerator includes those who made a correct decision with regard to breastfeeding, specifically, all women in the self-selection population minus any selectors who were breastfeeding at the time of the selection decision.

Endpoint operationally defined as follows: Self-selection population (denominator) defined as Section 4, Question 13 not blank. Those who made a correct decision with regards to breastfeeding (numerator) includes the Self-selection population minus any subjects who were coded as a selector in selector coding. AND who answered “Yes” to Section 7, Question 29.

- E. Self-Selection: Proportion of self-selection population who make a correct selection decision.

This endpoint is the proportion of those subjects making the self-selection decision who make a correct decision about whether the product is right for them to use, as outlined below. Operational definitions of Correct, Acceptable and Incorrect Selectors are detailed in Section 6.4.2.1 below.

6.4.2.1 Conceptual Approach to Self-Selection

Conceptually, the selection decision can be characterized as a 2x2 table (**Table 2** below) where the participant's decision to select or not select the study product for use is crossed with whether or not it is appropriate to use, based on participant's self-reported health status and clinical characteristics.

Table 2 Self-Selection Decision Outcomes

Participant's Selection Decision	Appropriate to Use	
	YES	NO
YES (selectors)	Cell A Correct Decision	Cell B Incorrect Decision
NO (non-selectors)	Cell C Incorrect Decision	Cell D Correct Decision

The four cells in the self-selection matrix can be characterized as follows.

Cell A: Participants who say the study product is right for them to use and based on their self-reported medical and demographic information, the study product is right for them to use.

Cell B: Participants who say the study product is right for them to use and based on their self-reported medical and demographic information, the study product is not right for them to use.

Cell C: Participants who say the study product is not right for them to use and based on their self-reported medical and demographic information, the study product is right for them to use.

Cell D: Participants who say the study product is not right for them to use and based on their self-reported medical and demographic information, the study product is not right for them to use.

Each subject will be classified on two key variables: (1) the selection decision and (2) the appropriateness of use given the selection decision, in order to populate the typical 2x2 self-selection table.

Selection Decision: The selection phase of the interview consists of the self-selection and purchase questions, with accompanying neutral follow-up questions. All subjects who go on to actually purchase the study product will be categorized as selectors in selector coding. Even subjects who do not eventually complete the purchase of the product will be classified as a selector or a non-selector primarily on the basis of the initial self-selection and purchase questions. However, all information recorded during the selection phase of the interview will be considered in the classification of subjects as selectors or non-selectors. This is completed in a manual coding process, where subjects are coded as selectors and non-selectors.

Appropriate to Use:

Non-selectors will be classified on the variable Appropriate for Use as follows:

Yes: meets the label criteria for use, representing those who could have selected appropriately, but did not (**Cell C**).

No: does not meet the label requirements for use, and appropriately did not select (**Cell D**). This includes those subjects who otherwise might have met the strict criteria for appropriate use according to the DFL, but who give a medically

appropriate rationale for their non-selection decision. For example, if a subject who otherwise meets the labeled criteria for use does not select the product and cites the fact that they are taking a medicine for Human Immunodeficiency Virus (HIV) as their reason for not selecting (which otherwise does not disqualify a subject from using, but rather suggests that they talk to a doctor), that subject will be re-classified from Cell C to Cell D. A physician will review the casebook for each subject who falls into Cell C to determine if any subjects meet that criterion.

Selectors will be classified on the variable Appropriate for Use as follows:

Yes: either meets the strict label criteria for use (1-Correct Selectors) or reported and measured characteristics justify the selection decision (2-Acceptable Selectors), representing those who chose to use the product who made a clinically acceptable decision despite not meeting the strict label criteria for use (**Cell A**).

No: does not meet strict label criteria and reported and measured characteristics do not justify the selection decision (3-Incorrect Selectors), representing those who chose to use the product, but should not have (**Cell B**).

Complete definitions of Correct, Acceptable, and Incorrect Selectors follow:

1) Correct Selectors. Subject meets the strict criteria of the Drug Facts label, including:

- a) No contraindications (not pregnant or breastfeeding, no known allergy to any of the ingredients, no previous use of ella[®] within the same menstrual cycle)

Operationally defined as follows:

- Not Pregnant: Section 12, Question 36b is “Negative” OR (Section 12, Question 36b is null and Section 7, Question 27 not answered “Yes”) OR Section 12, Question 36b is “Positive” but subject indicates she had a very recent abortion
- Not Breastfeeding: Answered “No” to Section 7, Question 29.
- No Allergy: Answered “No” to all parts of Section 7, Question 25 and 25a.
- No previous use of ella[®] within the same menstrual cycle: Did not answer “No” to Section 19, Question 10d OR did answer “Advance provision” to Section 5, Question 15.

- b) Is a woman of childbearing potential. This would include all women who do not report any of the following: surgical sterilization (tubal ligation, hysterectomy, or bilateral oophorectomy), congenital malformation/defect, endometrial ablation, or postmenopausal for at least one year

Operationally defined as follows: Answered “Yes” to Section 7, Question 28 OR none of boxes 1-6 checked in Section 7, Question 28a.

- c) Has had unprotected sex in the 5 days prior to purchase of the product or is purchasing for future use

Operationally defined as follows: Checked box 2 to Section 5, Question 15 OR answered ≤ 120 hours or ≤ 5 days to Section 5, Question 17.

- 2) Acceptable Selectors. Subject does not meet the strict criteria of the Drug Facts label, but selection is classified as appropriate because they are judged clinically (see Section 8.4.3 of the Protocol) to be an appropriate selector by an independent panel of physician reviewers. This group is expected to be quite small.
- 3) Incorrect Selectors. This group includes selectors who are not correct or acceptable, including having any of the following:
 - a. A contraindication to the product (are pregnant or breastfeeding, has an allergy to one of the ingredients, or previously used ella® within the same menstrual cycle)

Operationally defined as follows:

- Pregnant: Answered “Yes” to Section 7, Question 27 OR Section 12, Question 36b is “Positive”.
- Breastfeeding: Answered “Yes” to Section 7, Question 29.
- Allergy: Answered “Yes” to any part of Section 7, Question 25 or 25a.
- Previous use of ella® within the same menstrual cycle: Answered “No” to Section 19, Question 10d AND did not answer “Advance provision” to Section 5, Question 15.

- b. Is a man

Operationally defined as follows: Answered “Male” to Section 3, Question 3.

- c. Is a woman without childbearing potential. This would include all women who report any of the following: surgical sterilization (tubal ligation, hysterectomy, or bilateral oophorectomy), congenital malformation/defect, endometrial ablation, or postmenopausal for at least one year

Operationally defined as follows: Answered “No” to Section 7, Question 28 AND at least one of boxes 1-6 checked in Section 7, Question 28a.

- d. Has not had unprotected sex in the 5 days prior to purchase of the product and is not purchasing for future use

Operationally defined as follows: (Answered >120 hours or >5 days to Section 5, Question 17 or did not answer Section 5, Question 17) AND did not answer “Advance provision” to Section 5, Question 15.

Cell A represents a correct decision, namely consumers for whom the study product is right to use who choose to use it, and therefore presents very little potential adverse clinical consequences.

Cell C, while not technically correct, is a decision that accrues no health risk, but rather is a missed opportunity to use the drug. Thus, these subjects are considered neither correct nor incorrect and are usually left out of the primary self-selection analysis.

The most critical self-selection decision is made by subjects who, based on their health status, should not use the study drug (cells B and D). Unlike an incorrect decision by consumers for whom this product is appropriate (cell C), an incorrect decision (cell B) by these consumers has potential efficacy or safety implications. Because of the point of sale recruitment study design, it is expected that very few subjects will be inappropriate for use, therefore this endpoint will be measured by the following proportion, taken from the self-selection table $[(\text{cell A} + \text{cell D}) / (\text{cell A} + \text{cell B} + \text{cell D})]$. Again, note that this does not take into account cell C, as those subjects could have chosen to use the product, but did not (for whatever reason).

Other proportions will also be presented, including the total correct selectors as described by the equation $[(\text{cell A} + \text{cell D}) / (\text{cell A} + \text{cell B} + \text{cell C} + \text{cell D})]$ and the typical self-selection metric, namely the proportion described by the equation $[\text{cell D} / (\text{cell B} + \text{cell D})]$. This proportion represents a correct non-selection decision. In other words, this is the proportion of those who should not select the product who correctly do not select it.

Please note, for the purposes of this study, for all subjects who qualify to purchase the product, self-selection will be evaluated at the time of purchase. Each purchase will be independently evaluated for the self-selection endpoints. Because the timing of the most recent episode of unprotected sex is one of the elements of appropriate use, a subject who does not meet the label criteria of having had unprotected sex within 120 hours of purchase would be categorized as an acceptable selector if it is demonstrated that she is purchasing for future use and meets all other requirements for correct selection.

- F. Actual Use: Proportion of dosing instances among user population in which HBC is not taken for 5 days after taking ella®.

This secondary endpoint is the proportion in which the denominator includes all dosing instances of the IP and the numerator includes all dosing instances in which there is no reported use of intermittently dosed HBC (i.e. pill, patch, or ring) for at least 5 days. The numerator will be defined as all dosing instances where a daily- or weekly-dosed HBC method (i.e., pill, patch, or ring) was not subsequently started, plus all those where a HBC method was started and $(\text{date of HBC method started} - \text{date of IP ingestion}) \geq 5$ days).

Operationally defined as follows: Total dosing instances (denominator) is the count of all discrete instances of Section 19, Question 3 plus all discrete instances of Section 21, Question 3. Total dosing instances where there is no reported use of pill, patch or ring for 5 days (numerator) is the total dosing instances minus the count of all discrete instances where Section 19, Question 4d minus Section 19, Question 3 is <5 days plus discrete instances where Section 21, Question 4d minus Section 21, Question 3 is <5 days.

- G. Actual Use: Proportion of dosing instances among user population associated with use of hormonal contraceptives in the same cycle after taking ella® in which subject reports using a condom (or other barrier method) every time they have sex until their next menstrual period.

This secondary endpoint is the proportion in which the denominator includes all dosing instances of the IP among those who start or restart hormonal contraception in the same menstrual cycle and the numerator includes dosing instances where the subject reports using condoms every time they have sex during the remainder of that menstrual period.

Operationally defined as follows:

Total dosing instances among those who started or restarted hormonal contraception in the same menstrual cycle (denominator) is the count of all discrete instances where (a date is given in Section 19, Question 4d AND Section 19, Question 7 is answered “No”) OR (a date is given in Section 19, Question 4d AND Section 19, Question 7 is answered “Yes” and the date in Section 19, Question 4d is before the date given in Section 19, Question 7a) PLUS discrete instances where (a date is given in Section 21, Question 4d AND Section 21, Question 7 is answered “No”) OR (a date is given in Section 21, Question 4d AND Section 21, Question 7 is answered “Yes” and the date in Section 21, Question 4d is before the data given in Section 21, Question 7a) AND (Section 19 Question 8 was answered “Yes” or Section 21, Question 9 answered “Yes”).

The numerator includes all instances of the denominator in which the subject reports use of a condom each time they had sex during the remainder of that menstrual cycle (numerator) is the total dosing instances among those who started or restarted hormonal contraception in the same menstrual cycle (i.e., the denominator, operationally defined above) minus (the count of all discrete instances where Section 19, Question 8 is answered “Yes” AND Section 19, Question 8c is answered “No” or Question 8d is not answered “Every time”) PLUS (the count of all discrete instances where Section 21, Question 9 is answered “Yes” AND Section 21, Question 9c is answered “No” or Question 9d is not answered “Every time”).

This endpoint will also be presented by subject, expressed as the proportion in which the denominator includes all subjects who start or restart hormonal contraception in the same menstrual cycle on at least one occasion and the numerator includes the subjects who also reported using condoms each time they had sex during the remainder of that menstrual cycle.

Operationally defined as follows:

Total number of subjects who started or restarted hormonal contraception in the same menstrual cycle (denominator) is the count of all subjects who (provided a date in Section 19, Question 4d AND Section 19, Question 7 is answered “No”) OR (provided a date in Section 19, Question 4d AND Section 19, Question 7 is answered “Yes” and the date in Section 19, Question 4d is before the date given in Section 19, Question 7a) PLUS subjects who (provided a date in Section 21, Question 4d AND Section 21, Question 7 is answered “No”) OR (provided a date in Section 21, Question 4d AND Section 21, Question 7 is answered “Yes” and the date in Section 21, Question 4d is before the data given in Section 21, Question 7a) AND .

The numerator includes all subjects in the denominator who report use of a condom each time they had sex during the remainder of that menstrual cycle who started or restarted hormonal contraception in the same menstrual cycle (i.e., the denominator,

operationally defined above) minus (the count of all subjects where Section 19, Question 8 is answered “Yes” AND Section 19, Question 8c is answered “No” or Question 8d is not answered “Every time”) PLUS (the count of all subjects where Section 21, Question 9 is answered “Yes” AND Section 21, Question 9c is answered “No” or Question 9d is not answered “Every time”) AND (Section 19 Question 8 was answered “Yes” or Section 21, Question 9 answered “Yes”).

- H. Actual Use: Proportion of user population who do not use the study product more than once in the same menstrual cycle.

This secondary endpoint is the proportion in which the denominator includes all subjects who take at least one dose of the product (user population) and the numerator includes all subjects who do not use more than one dose(s) of the study product within the same menstrual cycle after taking the initial dose of ella®.

Operationally defined as follows: All subjects who take at least one dose of the product (denominator) is the count of all subjects in the user population (Section 19, Question 1 answered “Yes” or Section 21, Question 1 answered “Yes”). All subjects who do not use more than one dose(s) of the study product within the same menstrual cycle after taking the initial dose of ella® (numerator) is the denominator minus the count of all subjects who take a second dose within the same menstrual cycle as defined by any subject who took more than one dose of IP (Section 19, Question 2 >1 or Section 21, Question 2 >1, OR Section 19, Question 3 and Section 21, Question 3 represent different dates) AND the second reported date occurred before the date of any reported menstrual period (Section 19, Question 7a; Section 21, Question 7a).

- I. Self-Selection/Actual Use: Proportion of self-selection population taking one of the “ask a doctor or pharmacist before use” products who do not select, who select but do not use or who report contacting a healthcare provider or pharmacist.

This secondary endpoint is the proportion defined by the denominator including all subjects who participate in the self-selection interview who report taking one of the “ask a doctor or pharmacists before use” compounds (including barbiturates, carbamazepine, felbamate, oxcarbazepine, phenytoin, topiramate, rifampin, griseofulvin, a prescription drug to treat HIV/AIDS, bosentan, or a supplement containing St. John’s Wort) and the numerator is all such subjects who either do not select or use or who report talking with a doctor or pharmacist about it use during the course of the study.

Operationally defined as follows: All subjects who participate in the self-selection interview who report taking one of the “ask a doctor or pharmacists before use” compounds (including barbiturates, carbamazepine, felbamate, oxcarbazepine, phenytoin, topiramate, rifampin, griseofulvin, a prescription drug to treat HIV/AIDS, bosentan, or a supplement containing St. John’s Wort) (denominator) as defined by subjects reporting any of the listed drugs in Section 13, Question 38a. The numerator is all of the subjects in the denominator who are also not included in the User Population or who responded “Yes to Section 22, Question 11.

6.4.3 Other Analyses

The other measures are all simple proportions where the user population represents the denominator.

- J. Proportion of user population who use an HBC method sometime during the past two menstrual cycles.

Operationally defined as follows: Denominator is count of subjects in the User Population. Numerator includes all those in the denominator who answered “Yes” to Section 7, Question 30 OR (who answer “Yes” to Section 7, Question 32 AND who answer ≤ 56 Days ago or ≤ 8 Weeks ago or ≤ 2 Months ago to Section 7, Question 32b) or who answer “Yes” to Question 4 in Section 19 or Section 21.

- K. Proportion of user population who used any EC on more than one occasion within the study period.

Operationally defined as follows: Denominator is count of subjects in the User Population. Numerator includes all those in the denominator who report more than one discrete date in iterations of Section 19, Question 3 and/or Section 21, Question 3 OR who answer “Yes” to Section 19, Question 5 or Section 21, Question 5.

- L. Proportion of user population who report becoming pregnant within the study period.

This will include all pregnancies that are reported during or after completion of the study where conception was judged by the medical monitor to have likely taken place during participation, based on all that is known about the pregnancy (e.g. last menstrual period, medical records, ultrasound results, etc.). Further, pregnancies will be classified as likely EC failure or not.

6.4.4 Adverse Events

Adverse event (AE) analyses will include all events which initially occurred, or worsened following treatment. Adverse events will be summarized by the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC) and Preferred Term (PT) and classified according to their severity (mild, moderate, or severe) and relationship (related or not related) to study product. For the summary by severity, subjects who have multiple occurrences of the same AE will be classified according to the worst reported severity of the AE. Similarly, for the summary by relationship to the study product, the AE will be classified according to the worst relationship.

7 Changes to Planned Analysis

In the study protocol, the label direction of “do not use for regular birth control” is included in the list of labeled contraindications for use in the context of evaluation of a correct selection decision. It was later determined that compliance with this label direction would be better assessed by examining the reasons for frequent purchase or use of ella® during the study period rather than considering this a selection issue. Therefore, this was not included in the operational definition of a correct or incorrect selection decision in Section 6.4.2.1, and will instead be evaluated by summarizing any reasons provided for attempting to purchase more than three packages at one time, or more than nine packages total, over the course of the study period (i.e., any answers provided to the open-ended questions in Section 15/Drug Purchase Log).

In addition, based on interactions with the FDA, several other behaviors of interest will be analyzed and described in the study report, such as the proportion of subjects in the user population who report:

- using another form of EC during the study;
 - Operationally defined as levonorgestrel or a verbatim response in Section 19, Question 5a OR Section 21, Question 5a.
- using ella® (IP or prescription) multiple times in the same menstrual cycle;
 - Operationally defined as (data present in Section 22, Question 10a) OR any dates provided in Section 19, Question(s) 3, Section 19 Question(s) 5c, Section 21, Question(s) 3, and Section 21, Question(s) 5c are less than 28 days apart.
- re-starting their regular form of hormonal birth control during the study period.
 - Operationally defined as providing a date in Section 19, Question 4d or Section 21, Question 4d.

8 Datasets and Supporting Documentation

8.1 Datasets

Source data (SDTM) and analysis (ADaM) datasets will conform to CDISC requirements.

8.2 Supporting Documentation

Supporting documentation will include annotated case report forms (aCRFs) and specifications for SDTM and ADaM datasets.

9 Document History and Changes in the Planned Statistical Analysis

Document	Version / Date	Summary of Changes
Final SAP	Final v1.0_31OCT2018	N/A
Amended SAP	Final v2.0_16NOV2018	<p>Correction was made to the title of one of the HRA signatories.</p> <p>All references to the operational definition of a selector or non-selector were updated to reflect that selector status was based on selector coding, as described in the protocol. The previous version had erroneously used a programmatic definition.</p> <p>Endpoint C: Section 7, Question 27 not answered “Yes” was added to the operational definition. Also updated to include that a false positive on a pregnancy test due to</p>

		<p>a very recent abortion would be treated as “not pregnant” in the analysis.</p> <p>Correct Selectors: Section 7, Question 27 not answered “Yes” was added to the operational definition. Also updated to include that a false positive on a pregnancy test due to a very recent abortion would be treated as “not pregnant” in the analysis.</p> <p>In item D under Incorrect selectors was corrected due to errors in syntax and the omission of “or did not answer Section 5, Question 17”</p> <p>Endpoint G: The operational definition for the “by subject” analysis of this endpoint was added, and the denominator updated to only instances that were associated with sex in that menstrual cycle.</p> <p>Other Measure J: numerator in operational definition was updated to also include “OR who answer “Yes” to Question 4 in Section 19 or Section 21.”</p> <p>The descriptor “hormonal” was added to the third bulleted item under Changes to Planned Analysis.</p>
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10 References

1. Murphy, Peggy W.; Davis, Terry C.; Long, Sandra W.; Jackson, Robert H.; Decker, Barbara C. Rapid Estimate of Adult Literacy in Medicine (REALM): a quick reading test for patients. *Journal of Reading* 1993 Oct; 37(2):124-30.
2. Davis TC, Wolf MS, Arnold CL, Byrd RS, Long SW, Springer T, Kennen E, Bocchini JA. Development and validation of the Rapid Estimate of Adolescent Literacy in Medicine (REALM-Teen): a tool to screen adolescents for below-grade reading in health care settings. *Pediatrics*. 2006 Dec 1;118(6):e1707-14.

11 Appendices

11.1 Final Data Collection Instrument (DCI)

SUBJECT NUMBER

(subnum, <subnum>)

SUBJECT NUMBER

Subject ID:

(partId, <partId>)

(String, Text)

Screening Date (DD-MMM-YYYY):

(scrDt, <scrDt>)

(Date, Text)

(dd-MMM-yyyy)

Programming Vars (DON'T MAKE VISIBLE)

(prog, <prog>)

used for EOS Q2 (e2)

Any AE 1b contains "Talk to a HCP"

(AE1Bhcp, <AE1Bhcp>)

(String, PlainText)

AE 1b WAS ASKED

(AE1Bask, <AE1Bask>)

(String, PlainText)

Site Number

(siteNum, <siteNum>)

(String, PlainText)

Final Dispos Date Set

(DspDtSet, <DspDtSet>)

(String, PlainText)

Enrollment

(enroll, <enroll>)

Sub Forms

3 SCREENING

4 PURCHASE QUESTION / 5 REASON FOR PURCHASE / 6 DEMO

7 CURRENT / REGULAR RELEVANT MEDICATIONS AND ASSOCIATED CONDITIONS

8 REALM TEST

9 REALM TEEN TEST

11 INFORMED CONSENT

12 ENROLLMENT PREGNANCY TEST

13 MEDICATIONS AT ENROLLMENT

14 CONTACT INFORMATION AND PURCHASE TRANSACTION

15 DRUG PURCHASE LOG

16 DRUG RETURN LOG

17 ENROLLMENT END-OF-STUDY QUESTIONS

18 FINAL SUBJECT ENROLLMENT DISPOSITION

3 SCREENING

(screener, <screener>)

3 SCREENING

Read: Thank you for your interest in this study. I first want to take a minute to give you some information about our privacy policies, so you can be assured that we are committed to protecting your personal information. Here is a copy of our privacy notice for you to take with you today that explains how we use and protect your personal information.

☐ Yes Continue. (1)

☐ No Stop. (2)

1. Interviewer: Was the written privacy notice given to the subject?

(priv, <priv>)

(Integer, RadioCheckbox)

Read: Next, I need to ask you some questions to see if you qualify for the study. The information you provide to us is used strictly for the purposes of the study, and is stored in secure databases that are only accessible to our employees and other study staff who have a need to know this information. Demographic and health information you provide to us may be shared with the study sponsor or regulatory agencies, but it will always remain anonymous, unless otherwise required by law.

☐ Yes Continue. (1)

☐ No Stop. (2)

2. Do I have your permission to continue?

(perm, <perm>)

(Integer, RadioCheckbox)

2a. How did you hear about this study?

Do not read answer options

Check all that apply

(hear, <hear>)

(String, MultiCheckbox)

☐ Front desk told me about it when I asked for emergency contraceptive (1)

☐ Word of mouth (friend told me about it) (2)

☐ Saw a study flier at the research site (3)

☐ Saw a study flier somewhere else in the community (4)

☐ Saw an ad on social media (Facebook, Twitter, Instagram, etc.) (5)

☐ Saw an ad online (6)

☐ Clinician referral during other clinical visit (7)

☐ Other: (8)

If Other, please specify:

(hearO, <hearO>)

(String, Text)

Read: **Thank you. Now that you have been informed about our privacy policies, let's see if you qualify for the study.**

☐ Female (1)

☐ Male (2)

3. Interviewer, please indicate subject's gender:

If necessary, ask: **Are you male or female?**

(If further clarification is needed based on gender identity sensitivities, sites may ask: **Do you have a female reproductive system?** or **What was your gender assignment at birth?**)

(sex, <sex>)

(Integer, RadioCheckbox)

4. How old are you?

yrs.

(age, <age>)

(Integer, Text)

☐ Refused exact age – verified subject age 18 or older (1)

☐ Refused to answer (2)

(ageRf, <ageRf>)

(Integer, RadioCheckbox)

5. Are you able to read, speak and understand English?

☐ Yes (1)

☐ No (2)

(suLang, <suLang>)

(Integer, RadioCheckbox)

6. Do you normally wear corrective lenses, contacts or glasses to read?

☐ Yes (1)

☐ No (2)

(glass, <glass>)

(Integer, RadioCheckbox)

6a. If Yes to Q6: Do you currently have them with you?

☐ Yes (1)

☐ No (2)

(glassA, <glassA>)

(Integer, RadioCheckbox)

6b. If No to Q6a, show mock package: Can you see well enough without them to read text of this size?

☐ Yes (1)

☐ No (2)

(glassB, <glassB>)

(Integer, RadioCheckbox)

7. Has any member of your family participated in this study?

☐ Yes (1)

☐ No (2)

(famPct, <famPct>)

(Integer, RadioCheckbox)

8. Do you, or does anyone in your household, work... ☐ Yes (1)

Ask one at a time and wait for a 'yes'/'no' response. ☐ No (2)

8a. For a market research or advertising company, public relations firm, or news organization?

(MrkAd, <MrkAd>)

(Integer, RadioCheckbox)

8b. For a pharmacy or pharmaceutical company, or for a ☐ Yes (1)

medicine manufacturer? ☐ No (2)

(pharm, <pharm>)

(Integer, RadioCheckbox)

8c. As a healthcare professional or as part of a healthcare ☐ Yes (1)

practice, managed care or health insurance company? ☐ No (2)

(HCP, <HCP>)

(Integer, RadioCheckbox)

8d. Have you been trained or worked as a healthcare ☐ Yes (1)

professional or market research professional? ☐ No (2)

(trnHCP, <trnHCP>)

(Integer, RadioCheckbox)

9. Have you participated in a health-related market ☐ Yes (1)

research or product label study in the past 12 months? ☐ No (2)

(PctMR12, <PctMR12>)

(Integer, RadioCheckbox)

10. Have you participated in a clinical trial in the past 12 ☐ Yes (1)

months? ☐ No (2)

(PctCLN12, <PctCLN12>)

(Integer, RadioCheckbox)

11. Have you ever participated in a study about emergency ☐ Yes (1)

contraception? ☐ No (2)

(PctCont, <PctCont>)

(Integer, RadioCheckbox)

If age <18 ☐ Yes (1)

12. Interviewer, please note: Is the subject accompanied ☐ No (2)

by a parent/guardian?

(acPar, <acPar>)

(Integer, RadioCheckbox)

☐ Qualified Continue. (1)

(scrQualT, <scrQualT>)
(Integer, RadioCheckbox)

.
(scrTermT, <scrTermT>)
(Integer, RadioCheckbox)

☐ Not Qualified Read: I'm sorry, but you do not qualify to be in the study. There are other prescription and over-the-counter emergency contraceptives available to you today. Provide EC alternatives. Thank you for your interest in participating. (1)

4 PURCHASE QUESTION / 5 REASON FOR PURCHASE / 6 DEMO

(purchDemo, <purchDemo>)

4 SELECTION AND PURCHASE QUESTIONS

Read: Next, I'd like you to take a look at this over-the-counter medicine packaging. The name of this product is ella, and it is an emergency contraceptive pill that is currently available by prescription only. This box is what the over-the-counter package would look like if it were to be available without a doctor's prescription. I want you to imagine that you see this product on the shelf in the store where you normally shop for over-the-counter products.

Show the empty ella package to the subject.

Please review and handle the product as you normally would if you were looking to purchase a new OTC product that you haven't used before. You can take as much time as you need to review the information on the package. Please let me know when you are finished and I'll have some questions to ask you. Your task is to decide whether this medicine is right for you to use and whether you would like to purchase it for your own use.

Give the package to the subject.

While the subject is reading, look busy to avoid unwittingly putting pressure on him/her to read quickly or incompletely.

When finished reading: **Keep the package for now. You may look at it if you need to while answering my questions.**

13. Given what you have read on the label and your own ☐ Okay/Yes (1)
current health conditions, is this medicine okay or not okay ☐ Not okay / No (2)
for you to use? ☐ Don't know (3)

Do not read answer options

☐ Would talk to a doctor (4)

Check only one

☐ Would talk to a pharmacist (5)

(okNok, <okNok>)

(Integer, RadioCheckbox)

13-a. If Q13=Would talk to a doctor OR Would talk to a ☐ Okay/Yes (1)
pharmacist: If you couldn't talk to your doctor/pharmacist ☐ Not okay / No (2)
and had to make a decision on your own, do you think this ☐ Don't know (3)
medication is ok or not ok for you to use?

Do not read answer options

Check only one

(okNokA, <okNokA>)

(Integer, RadioCheckbox)

13-b. Q13=Okay/Yes OR Q13a=Okay/Yes: **Please tell me why you decided this medication is right for you to use today.**

Example neutral probing questions:

(What things did you consider?)

(Are there any reasons it is not OK for you to use?)

(What things on the label did you consider?)

Record verbatim response

(okNokB, <okNokB>)

(String, MultiLineText)

13-c. Q13=Not okay/No or Q13a=Not okay/No: **Tell me why you think this medication is not ok for you to use today?**

Example neutral probing questions:

(What things did you consider?)

(What things on the label did you consider?)

(What things on the label helped you make this decision?)

Record verbatim response

(okNokC, <okNokC>)

(String, MultiLineText)

13-d. If Q13=Would talk to a doctor OR Would talk to a pharmacist: **Why would you want to talk to a doctor/pharmacist? What would you talk to your doctor/pharmacist about?**

Record verbatim response

(okNokD, <okNokD>)

(String, MultiLineText)

13-e. If Q13=Don't know or Q13a=Don't know: **Can you tell me why you are uncertain?**

Record verbatim response

(okNokE, <okNokE>)

(String, MultiLineText)

14. If Q13=Okay/Yes or Q13a=Okay/Yes: **Would you like to purchase ella today for your own use? It costs \$10.00 for a package containing 1 tablet.**

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

Do not read answer options

Check only one

(purch, <purch>)

(Integer, RadioCheckbox)

14a. If Q14 = No: Please explain why not.

Do not read answer options

Check all that apply

Probe: Probe to get as much information as possible with neutral questions such as “are there any other reasons?” or “anything else?”

(purchA, <purchA>)

(String, MultiCheckbox)

(specify which contraindication(s))

(purchAC, <purchAC>)

(String, Text)

If Other, please specify:

(purchAO, <purchAO>)

(String, Text)

14b. If Q14 = Don't know: Can you please explain why you are unsure if you would like to purchase ella?

Probe: Probe to get as much information as possible with neutral questions such as “are there any other reasons?” or “anything else?”

Record verbatim response

(purchB, <purchB>)

(String, MultiLineText)

☐ Cost of product (1)

☐ Does not have money with them (2)

☐ Unwilling to pay for study product / expected product to be free (3)

☐ Product is not right for me / has contraindication on the label (specify which contraindication(s)) (4)

☐ Decided not to take emergency contraception (5)

☐ Decided to use a different kind of emergency contraception (6)

☐ Other (specify): (7)

5 REASON FOR PURCHASE

15. Why did you come to purchase emergency contraception today?

Do not read answer options

Check all that apply

(whyBuy, <whyBuy>)

(String, MultiCheckbox)

If Other, please specify:

(whyBuyO, <whyBuyO>)

(String, Text)

☐ I had unprotected sex/contraception failed (1)

☐ I want to have some at home in case I need it (advanced provision) (2)

☐ Other: specify: (3)

The next few questions ask about unprotected sex. When I ask about unprotected sex, I am talking about vaginal intercourse that could lead to pregnancy. This includes sex where you did not use any birth control or sex where your contraception failed (for example, your partner did not use a condom or a condom broke during sex).

16.If Q15 box 1 is not checked: Have you had unprotected sex recently? ☐ Yes (1)
☐ No (2)
☐ Don't know (3)
Do not read answer options
Check only one
(unpSex, <unpSex>)
(Integer, RadioCheckbox)

If Q15 =I had unprotected sex/contraception failed OR
Q16=Yes

17. How long ago was your most recent episode of unprotected sex?

Do not read answer options
Probe as needed to get best estimate
Indicate a number and a time unit:
(recUsex, <recUsex>)
(Integer, Text)

(recUsexD, <recUsexD>)
(Integer, RadioCheckbox)

- ☐ Hours (1)
☐ Days (2)
☐ Weeks (3)
☐ Months (4)

6 DEMOGRAPHICS

Read: I am now going to ask you a few questions to help us understand the people taking our survey.

18. What is the highest level of education you have completed? I will read the options and you tell me which one applies to you.
Read answer options except 'Refused'
Check only one
(edu, <edu>)
(Integer, RadioCheckbox)

☐ 8th grade or less (1)
☐ Some high school (2)
☐ High school graduate, GED, or certificate (3)
☐ Some college or technical school (4)
☐ College graduate (5)
☐ Post-graduate degree (6)
☐ Refused (7)

19. Do you consider yourself Hispanic or Latino?
Do not read answer options
Check only one
(hisp, <hisp>)

☐ Yes (1)
☐ No (2)
☐ Don't know / Refused (3)

(Integer, RadioCheckbox)

20. Which of the following five racial designations best describe you? More than one choice is acceptable.

Read answer options except 'Other, specify' and 'Refused'

Check all that apply and avoid using Other unless necessary

(race, <race>)

(String, MultiCheckbox)

If Other, please specify:

(raceO, <raceO>)

(String, Text)

☐ American Indian or Alaska Native (1)

☐ Asian (2)

☐ Black or African American (3)

☐ Native Hawaiian or Other Pacific Islander (4)

☐ White (5)

☐ Other, specify: (6)

☐ Refused (7)

21. What would you estimate your annual household income to be? Is it:

Read answer options except 'Refused' and 'Don't Know'

Check only one

(income, <income>)

(Integer, RadioCheckbox)

☐ Less than \$25,000 per year (1)

☐ \$25,000 to \$34,999 per year (2)

☐ \$35,000 to \$49,999 per year (3)

☐ \$50,000 to \$74,999 per year (4)

☐ \$75,000 to \$99,999 per year (5)

☐ \$100,000 to \$149,999 per year (6)

☐ \$150,000 or more per year (7)

☐ Refused (8)

☐ Don't know/Not Sure (9)

22. If age <18, ask: What is the highest level of education either of your parents has completed? I will read the options and you tell me which one applies to your parent.

Read answer options except 'Refused' and 'Don't Know'

Check only one

(eduPar, <eduPar>)

(Integer, RadioCheckbox)

☐ 8th grade or less (1)

☐ Some high school (2)

☐ High school graduate, GED, or certificate (3)

☐ Some college or technical school (4)

☐ College graduate (5)

☐ Post-graduate degree (6)

☐ Refused (7)

☐ Don't know/Not sure (8)

23. What is your height?

Feet

(htF, <htF>)

(Integer, Text)

Inches

(htI, <htI>)

(Integer, Text)

.

(htRef, <htRef>)

☐ Refused (1)

(String, MultiCheckbox)

24. What is your weight?

Pounds

(wt, <wt>)

(Integer, Text)

.

☐ Refused (1)

(wtRef, <wtRef>)

(String, MultiCheckbox)

7 CURRENT / REGULAR RELEVANT MEDICATIONS AND ASSOCIATED CONDITIONS

(crMeds, <crMeds>)

7 CURRENT / REGULAR RELEVANT MEDICATIONS AND ASSOCIATED CONDITIONS

SECTION 7 - FEMALES ONLY

Read: Now I have a few questions about your health and some medicines you may be taking. For some of these I will ask if you are taking them right now or if you have ever taken them. Don't be shy to ask me to repeat a question if you aren't sure which I have asked about.

Point out the active ingredient on the mock package: ☐ Yes (1)
☐ No (2)

25. Do you have a known allergy to the active ingredient in ella, ulipristal acetate?

Do not read answer options

Check only one

(aIElla, <aIElla>)

(Integer, RadioCheckbox)

Point out the inactive ingredients on the mock package: ☐ Yes (1)
☐ No (2)

25a. Do you have a known allergy to any of these inactive ingredients?

Allow subject to review the list on the package and check 'yes' or 'no' for each sub-question.

Read answer options

A Croscarmellose sodium

(aIEllaA, <aIEllaA>)

(Integer, RadioCheckbox)

B Lactose monohydrate

(aIEllaB, <aIEllaB>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

C Magnesium stearate

(aIEllaC, <aIEllaC>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

D Povidone

(aIEllaD, <aIEllaD>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

26. Show calendar: On what date did you start your last

(dd-MMM-yyyy)

menstrual period? If unable to give exact date: **What is your best guess about when your last period started?**

Enter date (DD-MMM-YYYY):

(lstM, <lstM>)

(Date, Text)

(lstMUK, <lstMUK>)

(Integer, RadioCheckbox)

☐ Unknown (1)

☐ Has not had a first menstrual period (premenarchal) (2)

26a. If Unknown checked in Q26: Can you tell me approximately how many weeks ago you started your last menstrual period?

weeks ago

(lstM2, <lstM2>)

(Integer, Text)

(lstM2A, <lstM2A>)

(Integer, RadioCheckbox)

☐ Other: specify (1)

☐ Don't know (2)

☐ Has not had a first menstrual period (premenarchal) (3)

If Other, please specify:

(lstM2AO, <lstM2AO>)

(String, Text)

27. Are you currently pregnant?

Do not read answer options

Check only one

(prego, <prego>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

27a. If Q27=Yes: How do you know that you are pregnant?

Do not read answer options

Check all that apply

(pregA, <pregA>)

(String, MultiCheckbox)

☐ I missed periods / My period is late (1)

☐ Positive pregnancy test (2)

☐ Doctor told me I'm pregnant (3)

☐ Other: specify (4)

If Other, please specify:

(pregAO, <pregAO>)

(String, Text)

27b. If Q27=Don't know: Can you tell me why you say you don't know, or what you mean by that? Do you have a reason to believe that you may already be pregnant?

Record verbatim response, probe to find out if they have reasons in addition to the recent unprotected intercourse for which they came seeking EC to think they may be pregnant

(pregB, <pregB>)

(String, MultiLineText)

28. Is it physically possible for you to become pregnant? ☐ Yes (1)

(posPg, <posPg>) ☐ No (2)

(Integer, RadioCheckbox) ☐ Don't know (3)

28a. If Q28=No: Can you tell me why you cannot physically ☐ Tubal ligation (1)

become pregnant? ☐ Hysterectomy (2)

Interviewer: If subject responds "No" to Q28, but provides a birth control method as a reason below, correct Q28 to 'Yes' and proceed to Q29. ☐ Postmenopausal (for at least one year) (3)

Do not read answer options ☐ Bilateral oophorectomy (ovariectomy) (4)

Check all that apply ☐ Congenital malformation/ defect (5)

(posPgA, <posPgA>)

(String, MultiCheckbox)

If Other, please specify:

(posPgAO, <posPgAO>)

(String, Text)

29. Are you currently breastfeeding?

Do not read answer options

Check only one

(brstFd, <brstFd>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

30. Right now, are you using a birth control pill, vaginal ring, patch, implant, or injection or an IUD (intra-uterine device)? ☐ Yes (1)

Do not read answer options ☐ No (2)

Check only one ☐ Don't know (3)

(bc, <bc>)

(Integer, RadioCheckbox)

30a. If Q30=Yes: Which of those are you currently using? ☐ Birth control pill (1)

Do not read answer options ☐ Vaginal ring (2)

Check all that apply ☐ Birth control patch (3)

(bcA, <bcA>)

☐ Implant (4)

(String, MultiCheckbox)

- ☐ Injection (5)
- ☐ IUD (6)
- ☐ Don't know / Not sure (7)
- ☐ Other: (8)

If Other, please specify:

(bcAO, <bcAO>)

(String, Text)

30b. If Q30=Yes: Which of those have you ever used?

Do not read answer options

Check all that apply

(bcB, <bcB>)

(String, MultiCheckbox)

- ☐ Birth control pill (1)
- ☐ Vaginal ring (2)
- ☐ Birth control patch (3)
- ☐ Implant (4)
- ☐ Injection (5)
- ☐ IUD (6)
- ☐ Don't know / Not sure (7)
- ☐ Other: (8)

If Other, please specify:

(bcBO, <bcBO>)

(String, Text)

31. Right now do you use any other method or protection to prevent pregnancy?

(oMth, <oMth>)

(Integer, RadioCheckbox)

- ☐ Yes (1)
- ☐ No (2)
- ☐ Don't know (3)

31a. If Q31=Yes: What are you using?

Do not read answer options

Check all that apply

(oMthA, <oMthA>)

(String, MultiCheckbox)

- ☐ Male condoms (01)
- ☐ Female condoms (02)
- ☐ Diaphragm (03)
- ☐ Sponge (04)
- ☐ Spermicide (05)
- ☐ Partner vasectomy/Partner is sterile (06)
- ☐ Rhythm method (07)
- ☐ Withdrawal (08)
- ☐ Abstinence (09)
- ☐ Partner is not male (10)
- ☐ Don't know / Not sure (11)
- ☐ Other: (12)

If Other, please specify:

(oMthAO, <oMthAO>)

(String, Text)

32. If Q30=No: Have you ever used a birth control pill,

- ☐ Yes (1)

vaginal ring, patch, implant, or injection or an IUD (intra-uterine device)?

(evrBC, <evrBC>)

(Integer, RadioCheckbox)

☐ No (2)

☐ Don't know (3)

32a. If Q32=Yes: Which of those have you used in the past?

Do not read answer options

Check all that apply

(evrBCA, <evrBCA>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Vaginal ring (2)

☐ Birth control patch (3)

☐ Implant (4)

☐ Injection (5)

☐ IUD (6)

☐ Don't know / Not sure (7)

☐ Other: (8)

If Other, please specify:

(evrBCAO, <evrBCAO>)

(String, Text)

32b. If Q32=Yes: When was the last time you used one of those birth control methods?

If subject is unsure, probe to get their best guess

Indicate a number and a time unit:

(evrBCn, <evrBCn>)

(Integer, Text)

(evrBCd, <evrBCd>)

(Integer, RadioCheckbox)

☐ Days ago (1)

☐ Weeks ago (2)

☐ Months ago (3)

☐ Years ago (4)

8 REALM TEST

(realm, <realm>)

8 REALM TEST

Read: It would be helpful for us to get an idea of what medical words you are familiar with. What I need you to do is look at this list of words, beginning here.

Point to the first word in List 1 on the purple card.

Say all of the words out loud. If you come to a word you don't know, you can sound it out or just skip it and go on.

Give subject the purple card.

- Click on the "Correct" box for each word the subject pronounces correctly.
- Click on the "Not Correct" box for each word the subject does not attempt or mispronounces.
- Make sure there is an entry for every word; there must be no blanks.
- If the subject refused to take the REALM Test, click on the box just above the beginning of the test.

Subject refused to take REALM Test

☐ Refused (1)

(rlmRf, <rlmRf>)

(Integer, RadioCheckbox)

fat:

☐ Correct (1)

(fat, <fat>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

flu:

☐ Correct (1)

(flu, <flu>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

pill:

☐ Correct (1)

(pill, <pill>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

dose:

☐ Correct (1)

(dose, <dose>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

eye:

☐ Correct (1)

(eye, <eye>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

stress:

☐ Correct (1)

(stress, <stress>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

smear: ☐ Correct (1)

(smear, <smear>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

nerves: ☐ Correct (1)

(nerves, <nerves>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

germs: ☐ Correct (1)

(germs, <germs>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

meals: ☐ Correct (1)

(meals, <meals>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

disease: ☐ Correct (1)

(disease, <disease>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

cancer: ☐ Correct (1)

(cancer, <cancer>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

caffeine: ☐ Correct (1)

(caffeine, <caffeine>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

attack: ☐ Correct (1)

(attack, <attack>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

kidney: ☐ Correct (1)

(kidney, <kidney>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

hormones: ☐ Correct (1)

(hormones, <hormones>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

herpes: ☐ Correct (1)

(herpes, <herpes>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

seizure:

☐ Correct (1)

(seizure, <seizure>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

bowel:

☐ Correct (1)

(bowel, <bowel>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

asthma:

☐ Correct (1)

(asthma, <asthma>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

rectal:

☐ Correct (1)

(rectal, <rectal>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

incest:

☐ Correct (1)

(incest, <incest>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

fatigue:

☐ Correct (1)

(fatigue, <fatigue>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

pelvic:

☐ Correct (1)

(pelvic, <pelvic>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

jaundice:

☐ Correct (1)

(jaundice, <jaundice>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

infection:

☐ Correct (1)

(infect, <infect>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

exercise:

☐ Correct (1)

(exercise, <exercise>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

behavior:

☐ Correct (1)

(behavior, <behavior>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

prescription: ☐ Correct (1)
(prescrip, <prescrip> ☐ Not Correct (0)
(Integer, RadioCheckbox)

notify: ☐ Correct (1)
(notify, <notify> ☐ Not Correct (0)
(Integer, RadioCheckbox)

gallbladder: ☐ Correct (1)
(gall, <gall>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

calories: ☐ Correct (1)
(calories, <calories>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

depression: ☐ Correct (1)
(depress, <depress>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

miscarriage: ☐ Correct (1)
(miscar, <miscar>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

pregnancy: ☐ Correct (1)
(preg, <preg>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

arthritis: ☐ Correct (1)
(arth, <arth>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

nutrition: ☐ Correct (1)
(nutrit, <nutrit>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

menopause: ☐ Correct (1)
(meno, <meno>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

appendix: ☐ Correct (1)
(appendix, <appendix>) ☐ Not Correct (0)
(Integer, RadioCheckbox)

abnormal: ☐ Correct (1)

(abnormal, <abnormal>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

syphilis: ☐ Correct (1)

(syph, <syph>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

hemorrhoids: ☐ Correct (1)

(hemorr, <hemorr>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

nausea: ☐ Correct (1)

(nausea, <nausea>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

directed: ☐ Correct (1)

(directed, <directed>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

allergic: ☐ Correct (1)

(allergic, <allergic>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

menstrual: ☐ Correct (1)

(menstr, <menstr>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

testicle: ☐ Correct (1)

(testicle, <testicle>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

colitis: ☐ Correct (1)

(colitis, <colitis>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

emergency: ☐ Correct (1)

(emerg, <emerg>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

medication: ☐ Correct (1)

(medic, <medic>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

occupation: ☐ Correct (1)

(occup, <occup>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

sexually:

(sexually, <sexually>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

alcoholism:

(alcohol, <alcohol>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

irritation:

(irritat, <irritat>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

constipation:

(constipa, <constipa>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

gonorrhea:

(gonorr, <gonorr>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

inflammatory:

(inflam, <inflam>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

diabetes:

(diab, <diab>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

hepatitis:

(hepa, <hepa>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

antibiotics:

(antibi, <antibi>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

diagnosis:

(diagnos, <diagnos>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

potassium:

(potas, <potas>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

anemia:
(anemia, <anemia>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

obesity:
(obesity, <obesity>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

osteoporosis:
(osteo, <osteo>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

impetigo:
(impetigo, <impetigo>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

REALM Score:
(lit, <lit>
(String, PlainText)

You have left one or more words blank. DO NOT SAVE.

Check for missing words

(noRealm, <noRealm>
(String, PlainText)

REALM Complete

(yesRealm, <yesRealm>
(String, PlainText)

9 REALM TEEN TEST

(realmT, <realmT>)

9 REALM TEEN TEST

Read: It would be helpful for us to get an idea of what medical words you are familiar with. What I need you to do is look at this list of words, beginning here.

Point to the first word in List 1 on the green card.

Say all of the words out loud. If you come to a word you don't know, you can sound it out or just skip it and go on.

- Give subject the green card.
- Click on the "Correct" box for each word the subject pronounces correctly.
- Click on the "Not Correct" box for each word the subject does not attempt or mispronounces.
- Make sure there is an entry for every word; there must be no blanks.
- If the subject refused to take the REALM Teen Test, click on the box just above the beginning of the test.

Subject refused to take REALM-Teen Test

☐ Refused (1)

(rlmtRf, <rlmtRf>)

(Integer, RadioCheckbox)

eye:

☐ Correct (1)

(rt1, <rt1>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

pill:

☐ Correct (1)

(rt2, <rt2>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

fat:

☐ Correct (1)

(rt3, <rt3>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

skin:

☐ Correct (1)

(rt4, <rt4>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

throat:

☐ Correct (1)

(rt5, <rt5>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

blood:

☐ Correct (1)

(rt6, <rt6>)

☐ Not Correct (0)

(Integer, RadioCheckbox)

weight:

(rt7, <rt7>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

stress:

(rt8, <rt8>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

death:

(rt9, <rt9>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

liquid:

(rt10, <rt10>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

disease:

(rt11, <rt11>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

drug:

(rt12, <rt12>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

mouth:

(rt13, <rt13>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

ounce:

(rt14, <rt14>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

heart:

(rt15, <rt15>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

risks:

(rt16, <rt16>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

diet:

(rt17, <rt17>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

teaspoon:
(rt18, <rt18>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

period:
(rt19, <rt19>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

cancer:
(rt20, <rt20>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

stomach:
(rt21, <rt21>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

headache:
(rt22, <rt22>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

fever:
(rt23, <rt23>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

pimple:
(rt24, <rt24>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

virus:
(rt25, <rt25>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

calories:
(rt26, <rt26>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

allergy:
(rt27, <rt27>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

marijuana:
(rt28, <rt28>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

pelvic: ☐ Correct (1)

(rt29, <rt29>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

asthma: ☐ Correct (1)

(rt30, <rt30>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

emergency: ☐ Correct (1)

(rt31, <rt31>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

infection: ☐ Correct (1)

(rt32, <rt32>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

exercise: ☐ Correct (1)

(rt33, <rt33>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

medicine: ☐ Correct (1)

(rt34, <rt34>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

violence: ☐ Correct (1)

(rt35, <rt35>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

prevention: ☐ Correct (1)

(rt36, <rt36>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

suicide: ☐ Correct (1)

(rt37, <rt37>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

depression: ☐ Correct (1)

(rt38, <rt38>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

prescription: ☐ Correct (1)

(rt39, <rt39>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

abnormal: ☐ Correct (1)

(rt40, <rt40>) ☐ Not Correct (0)

(Integer, RadioCheckbox)

injury:

(rt41, <rt41>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

ointment:

(rt42, <rt42>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

seizure:

(rt43, <rt43>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

diabetes:

(rt44, <rt44>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

nutrition:

(rt45, <rt45>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

alcoholism:

(rt46, <rt46>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

antibiotic:

(rt47, <rt47>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

complications:

(rt48, <rt48>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

delinquency:

(rt49, <rt49>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

penicillin:

(rt50, <rt50>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

puberty:

(rt51, <rt51>)

(Integer, RadioCheckbox)

☐ Correct (1)

☐ Not Correct (0)

menstrual:
(rt52, <rt52>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

pneumonia:
(rt53, <rt53>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

constipation:
(rt54, <rt54>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

diagnosis:
(rt55, <rt55>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

nausea:
(rt56, <rt56>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

acne:
(rt57, <rt57>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

anemia:
(rt58, <rt58>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

hepatitis:
(rt59, <rt59>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

adolescent:
(rt60, <rt60>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

bulimia:
(rt61, <rt61>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

fatigue:
(rt62, <rt62>
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

anorexia:
☐ Correct (1)

(rt63, <rt63>)
(Integer, RadioCheckbox)

☐ Not Correct (0)

tetanus:
(rt64, <rt64>)
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

bronchial:
(rt65, <rt65>)
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

obesity:
(rt66, <rt66>)
(Integer, RadioCheckbox)

☐ Correct (1)
☐ Not Correct (0)

Realm score:
(litT, <litT>)
(String, PlainText)

You have left one or more words blank. DO NOT SAVE.

Check for missing words
(noRealmT, <noRealmT>)
(String, PlainText)

REALM Complete
(ysRealmT, <ysRealmT>)
(String, PlainText)

11 INFORMED CONSENT

(ic, <ic>)

11 INFORMED CONSENT

Read: Thank you. Now, I would like you to read this Informed Consent Document that explains all about your participation in this study today. Please read it very carefully; take as much time as you need. If you have any questions, please ask me. Also, please don't sign anything until we have a chance to talk after you've read it.

33. Interviewer: Was the subject allowed to ask questions about the study and were questions addressed and answered to the subject's satisfaction prior to obtaining written informed consent?

(alAsk, <alAsk>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

34. Interviewer: Did the subject (or parent/guardian of an adolescent subject) sign the informed consent document?

(IC, <IC>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

34a. If Yes to Q34: Record the date of consent signature.

(DD/MMM/YYYY)

(icDT, <icDT>)

(Date, Text)

(dd-MMM-yyyy)

34b. If Yes to Q34: Record first initial and last name of study staff member conducting consent, as qualified per the Site Signature and Responsibility Log.

(icIntl, <icIntl>)

(String, Text)

35. Interviewer, if subject is ≤ 17 years old or enrolls with a parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(assPG, <assPG>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

35. Interviewer, if subject is ≤ 17 years old or enrolls with a parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(ass18, <ass18>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

35. Interviewer, if subject is ≤ 14 years old or enrolls with a

☐ Yes: Continue (1)

parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(ass15, <ass15>)

(Integer, RadioCheckbox)

35. Interviewer, if subject is ≤ 15 years old or enrolls with a parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(ass16, <ass16>)

(Integer, RadioCheckbox)

35. Interviewer, if subject is ≤ 16 years old or enrolls with a parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(ass17, <ass17>)

(Integer, RadioCheckbox)

35a. If Yes to Q35: Record the date of assent signature.

(DD/MMM/YYYY)

(assDT, <assDT>)

(Date, Text)

☐ No STOP here. Subject does not qualify to continue.

Compensate subject for the visit and thank them for participating. (2)

☐ Yes: Continue (1)

☐ No STOP here. Subject does not qualify to continue.

Compensate subject for the visit and thank them for participating. (2)

☐ Yes: Continue (1)

☐ No STOP here. Subject does not qualify to continue.

Compensate subject for the visit and thank them for participating. (2)

(dd-MMM-yyyy)

12 ENROLLMENT PREGNANCY TEST

(enPreg, <enPreg>)

12 ENROLLMENT PREGNANCY TEST

Read: As we just talked about while going over the study information, I will now need you to provide a urine sample.

36. Interviewer: Was the pregnancy test conducted?

(enPregT, <enPregT>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: (2)

Specify:

(enPregTs, <enPregTs>)

(Integer, RadioCheckbox)

☐ Test malfunctioned or results unclear. (1)

☐ Subject unable to provide urine sample. (2)

☐ Subject declined to take test. STOP here. Subject does not qualify to continue. (3)

36a. If Yes to Q36: Record the date of test.

(DD/MMM/YYYY)

(enPregTa, <enPregTa>)

(Date, Text)

(dd-MMM-yyyy)

Q36b If Yes to Q36=Yes: What was the result of the pregnancy test?

(enPregTb, <enPregTb>)

(Integer, RadioCheckbox)

☐ Positive: Subject does not qualify to continue, continue to Q37 (1)

☐ Negative (2)

36c. If test result is negative: Did the subject request the result?

(enPregTc, <enPregTc>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If Q36b=Positive, read: Your urine sample was used to conduct a pregnancy test which came back with a positive result.

☐ Okay/Yes (1)

☐ Not okay / No (2)

☐ Don't know (3)

☐ Would talk to a doctor (4)

☐ Would talk to a pharmacist (5)

☐ Other, specify: (6)

37. Given what you have read on the label and this new information about your current health conditions, is this medicine okay or not okay for you to use?

Do not read answer options

Check only one

(enPrg37, <enPrg37>)

(Integer, RadioCheckbox)

If Other, please specify:

(enPrg37O, <enPrg37O>)

(String, Text)

37a. If Q37=Would talk to a doctor OR Would talk to a pharmacist: **If you couldn't talk to your doctor/pharmacist and had to make a decision on your own, do you think this medication is ok or not ok for you to use?**

☐ Okay/Yes (1)

☐ Not okay / No (2)

☐ Don't know (3)

Do not read answer options

Check only one

(enPrg37a, <enPrg37a>)

(Integer, RadioCheckbox)

37b. Q37=Okay/Yes OR Q37a=Okay/Yes: **Please tell me why you decided this medication is right for you to use today.**

Example neutral probing questions:

(What things did you consider?)

(Are there any reasons it is not OK for you to use?)

(What things on the label did you consider?)

Record verbatim response

(enPrg37b, <enPrg37b>)

(String, MultiLineText)

37c. Q37=Not okay/No or Q37a=Not okay/No: **Please tell me why you think this medication is not ok for you to use today?**

Example neutral probing questions:

(What things did you consider?)

(What things on the label did you consider?)

(What things on the label helped you make this decision?)

Record verbatim response

(enPrg37c, <enPrg37c>)

(String, MultiLineText)

37d. If Q37=Don't know or Q37a=Don't know: **Can you tell me why you are uncertain?**

Record verbatim response

(enPrg37d, <enPrg37d>)

(String, MultiLineText)

37e. If Q37=Okay/Yes or Q37a=Okay/Yes: **Would you still like to purchase ella today for your own use?**

☐ Yes (1)

☐ No (2)

Do not read answer options

☐ Don't know (3)

Check only one

(enPrg37e, <enPrg37e>)

(Integer, RadioCheckbox)

37f. If Q37e=No: Please explain why not.

Do not read answer options

Check all that apply

Probe: Probe to get as much information as possible with neutral questions such as “are there any other reasons?” or “anything else?”

(enPrg37f, <enPrg37f>)

(String, MultiCheckbox)

☐ Should not use if already pregnant (1)

☐ Does not have money with them (2)

☐ Unwilling to pay for study product / expected product to be free (3)

☐ Product is not right for me / has contraindication on the label (specify which contraindication(s)) (4)

☐ Decided not to take emergency contraception (5)

☐ Decided to use a different kind of emergency contraception (6)

☐ Other (specify): (7)

please specify:

(enP37fC, <enP37fC>)

(String, Text)

If Other, please specify:

(enP37fO, <enP37fO>)

(String, Text)

37g. If Q37e=Don't know: Can you please explain why you are unsure if you would like to purchase ella?

Probe: Probe to get as much information as possible with neutral questions such as “are there any other reasons?” or “anything else?”

Record verbatim response

(enPrg37g, <enPrg37g>)

(String, MultiLineText)

13 MEDICATIONS AT ENROLLMENT

(medEn, <medEn>)

13 MEDICATIONS AT ENROLLMENT

38. Are you currently taking any prescription medications, or are there over-the-counter or herbal products that you take regularly?

☐ Yes (1)
☐ No (2)
☐ Don't know (3)

Do not read answer options

Check only one

(presc, <presc>)

(Integer, RadioCheckbox)

38a. If Q38=Yes: What are you currently taking? Why are you taking that?

List each medication and the associated indication

1

(med1, <med1>)

(String, Text)

Indication:

(med1I, <med1I>)

(String, Text)

2

(med2, <med2>)

(String, Text)

Indication:

(med2I, <med2I>)

(String, Text)

3

(med3, <med3>)

(String, Text)

Indication:

(med3I, <med3I>)

(String, Text)

4

(med4, <med4>)

(String, Text)

Indication:

(med4I, <med4I>)

(String, Text)

5

(med5, <med5>)

(String, Text)

Indication:

(med5I, <med5I>)

(String, Text)

6

(med6, <med6>)

(String, Text)

Indication:

(med6I, <med6I>)

(String, Text)

7

(med7, <med7>)

(String, Text)

Indication:

(med7I, <med7I>)

(String, Text)

8

(med8, <med8>)

(String, Text)

Indication:

(med8I, <med8I>)

(String, Text)

9

(med9, <med9>)

(String, Text)

Indication:

(med9I, <med9I>)

(String, Text)

10

(med10, <med10>)

(String, Text)

Indication:

(med10I, <med10I>)

(String, Text)

14 CONTACT INFORMATION AND PURCHASE TRANSACTION

(conPurch, <conPurch>)

14 CONTACT INFORMATION AND PURCHASE TRANSACTION

Collect contact information for subjects who qualify for the use period and who sign consent. Also, collect contact information for a person who does not live with the subject, but will know how to contact the subject. Or for an adolescent subject with a parent/guardian present, collect the parent's information as an alternate contact.

Read: I would now like to collect some contact information. Your contact information is necessary for the purposes of conducting the telephone follow-up interviews and compensating you for those interviews.

39. Interviewer: Did the subject provide contact information?

(contact, <contact>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

Read: The study product costs \$10.00 for a package of 1 tablet.

40. Study product is only for use by study subjects. Do you confirm that you will not allow anyone else to use your study product?

Do not read answer options

Check only one

(elsUse, <elsUse>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

Read: Would you like to purchase the product today?

41. Did the subject purchase the study drug?

(purch2, <purch2>)

(Integer, RadioCheckbox)

☐ Yes – Continue to Drug Purchase log to conduct and record the purchase transaction (1)

☐ No (2)

41a. If Q41=No: Why did you decide not to purchase this product today?

Do not read answer options

Check all that apply

Probe: Probe to get as much information as possible with neutral questions such as “are there any other reasons?” or “anything else?”

(noPur, <noPur>)

(String, MultiCheckbox)

☐ Cost of product (1)

☐ Does not have money with them (2)

☐ Unwilling to pay for study product / expected product to be free (3)

☐ Product is not right for me / has contraindication on the label (Specify which contraindication(s)) (4)

☐ Decided not to take emergency contraception (5)

☐ Decided to use a different kind of emergency contraception (6)

☐ Other (specify) (7)

Specify which contraindication:

(noPurC, <noPurC>)

(String, Text)

If Other, please specify:

(noPurO, <noPurO>)

(String, Text)

If Q41=No: End of Enrollment Interview Script for Non-purchasers:

☐ Yes (1)

Read: **Thank you for your interest in this study, but you do not qualify to continue. If you feel you need emergency contraception, it is advised you speak to a doctor or pharmacist about your options, or look into an over-the-counter emergency contraceptive. Thanks again for your participation and have a nice day.**

Verify that script was read and compensate subject

(verSc2, <verSc2>)

(Integer, RadioCheckbox)

15 DRUG PURCHASE LOG

(dpl, <dpl>)

15 DRUG PURCHASE LOG

Instructions:

- Use one entry for each package purchased
- Enter date of purchase
- Write subject number on the outer carton and inner foil blister sheet of each package purchased.

Pack 1 ☐ (1)

(pack1, <pack1>)

(Integer, RadioCheckbox)

Date of Purchase

(pack1Dt, <pack1Dt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 2 ☐ (1)

(pack2, <pack2>)

(Integer, RadioCheckbox)

Date of Purchase

(pack2Dt, <pack2Dt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 3 ☐ (1)

(pack3, <pack3>)

(Integer, RadioCheckbox)

Date of Purchase

(pack3Dt, <pack3Dt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 4 ☐ (1)

(pack4, <pack4>)

(Integer, RadioCheckbox)

Date of Purchase

(pack4Dt, <pack4Dt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 5 ☐ (1)

(pack5, <pack5>)

(Integer, RadioCheckbox)

Date of Purchase
(pack5Dt, <pack5Dt>)
(Date, Text)

(dd-MMM-yyyy)

Pack 6
(pack6, <pack6>)
(Integer, RadioCheckbox)

☐ (1)

Date of Purchase
(pack6Dt, <pack6Dt>)
(Date, Text)

(dd-MMM-yyyy)

Pack 7
(pack7, <pack7>)
(Integer, RadioCheckbox)

☐ (1)

Date of Purchase
(pack7Dt, <pack7Dt>)
(Date, Text)

(dd-MMM-yyyy)

Pack 8
(pack8, <pack8>)
(Integer, RadioCheckbox)

☐ (1)

Date of Purchase
(pack8Dt, <pack8Dt>)
(Date, Text)

(dd-MMM-yyyy)

Pack 9
(pack9, <pack9>)
(Integer, RadioCheckbox)

☐ (1)

Date of Purchase
(pack9Dt, <pack9Dt>)
(Date, Text)

(dd-MMM-yyyy)

Total number of packages purchased:
(totPacks, <totPacks>)
(Integer, PlainText)

(expression, pack1 +
pack2 +
pack3 +
pack4 +
pack5 +
pack6 +
pack7 +
pack8 +
pack9)

Attempted to purchase more than 3 packages at any one time during the study. ☐ (1)

(att3, <att3>)

(Integer, RadioCheckbox)

Number of packages requested on one occasion:

(att3num, <att3num>)

(Integer, Text)

If attempted to purchase more than 3 packages at any one encounter: **I can only sell you 3 packages at any one time. Can you tell me why you wanted to purchase more than 3 packages today?**

(att3Why, <att3Why>)

(String, MultiLineText)

Attempted to purchase more than 9 packages over the course of the study. ☐ (1)

(att9, <att9>)

(Integer, RadioCheckbox)

Number of packages requested in total over the course of the study:

(att9num, <att9num>)

(Integer, Text)

If attempted to purchase more than 9 packages over the course of study participation: **I can only sell you a total of 9 packages over the course of the study. Can you tell me why you wanted to purchase more than 9 packages over the course of the study?**

(att9Why, <att9Why>)

(String, MultiLineText)

Continue to Enrollment Disposition and Compensation

16 DRUG RETURN LOG

(dr, <dr>)

16 DRUG RETURN LOG

Drug Return Instructions:

- Use one entry for each package returned
- Enter date of return

Pack 1 Date of Drug Return

(pack1RDt, <pack1RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 2 Date of Drug Return

(pack2RDt, <pack2RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 3 Date of Drug Return

(pack3RDt, <pack3RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 4 Date of Drug Return

(pack4RDt, <pack4RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 5 Date of Drug Return

(pack5RDt, <pack5RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 6 Date of Drug Return

(pack6RDt, <pack6RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 7 Date of Drug Return

(pack7RDt, <pack7RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 8 Date of Drug Return

(pack8RDt, <pack8RDt>)

(Date, Text)

(dd-MMM-yyyy)

Pack 9 Date of Drug Return

(pack9RDt, <pack9RDt>)

(Date, Text)

(dd-MMM-yyyy)

17 ENROLLMENT END-OF-STUDY QUESTIONS

(enEOS, <enEOS>)

17 ENROLLMENT END-OF-STUDY QUESTIONS

Read: You do not qualify to purchase and use this product, because it is not medically suitable for you for one or more reasons. I'd like to ask you some additional questions about why you wanted to purchase.

42. If ((Q13 or Q13a=Yes)) and male (Q3=Male): You are male, and this product is only for females. Why did you say this product was right for you?

(enEMale, <enEMale>)

(String, MultiLineText)

43. If ((Q13 or Q13a=Yes)) and allergic (Q25=Yes or Q25a=Yes to any of A, B, C or D): You told me that you are allergic to one or more of the ingredients of this product. Why did you say that it was right for you to use?

(enEalrg, <enEalrg>)

(String, MultiLineText)

44. If (((Q13 or Q13a=Yes)) and pregnant (Q27=Yes)) OR (Q37=Okay/yes): You told me that you are pregnant and that this product would be ok for you to use. The label for this product says 'do not use if you are already pregnant' because the product is intended to prevent pregnancy. Why did you say that it was right for you?

(enEpreg, <enEpreg>)

(String, MultiLineText)

45. If ((Q13 or Q13a=Yes)) and breastfeeding (Q29=Yes): You told me that you are breastfeeding. The label says that this product should not be used while breastfeeding. Why did you say that it was right for you to purchase?

(enEBF, <enEBF>)

(String, MultiLineText)

Read: Thank you for your interest in this study, but you do not qualify to continue. If you feel you need emergency contraception, it is advised you speak to a doctor or pharmacist about your options, or look into an over-the-counter emergency contraceptive. Thanks again for your participation and have a nice day.

☐ Yes (1)

Verify that script was read and compensate subject

(verSc3, <verSc3>)

(Integer, RadioCheckbox)

18 FINAL SUBJECT ENROLLMENT DISPOSITION

(enDISP, <enDISP>)

18 FINAL SUBJECT ENROLLMENT DISPOSITION / COMPENSATION

Interviewer: Verify correct disposition, enter any other/specify.

Check only one

. ☐ Disqualified during screening (1)
(enDisp1, <enDisp1>)
(Integer, RadioCheckbox)

. ☐ Qualified after screening but did not start the interview
(1)
(enDisp2, <enDisp2>)
(Integer, RadioCheckbox)

. ☐ Disqualified during enrollment interview, not allowed to
purchase (1)
(enDisp3, <enDisp3>)
(Integer, RadioCheckbox)

. ☐ Started but did not complete the interview (specify why
not): (1)
(enDisp4, <enDisp4>)
(Integer, RadioCheckbox)

. ☐ Completed interview: Eligible to purchase but did not
purchase (1)
(enDisp5, <enDisp5>)
(Integer, RadioCheckbox)

. ☐ Completed interview and purchased (1)
(enDisp6, <enDisp6>)
(Integer, RadioCheckbox)

. ☐ Other (1)
(enDisp7, <enDisp7>)
(Integer, RadioCheckbox)

specify why not

(enDspl, <enDspl>)
(String, Text)

If Other, please specify:

(enDspO, <enDspO>)
(String, Text)

Read: Thank you for participating in this study. Your compensation for participation is a \$75 prepaid Visa card. Please note that it expires in a few months.

☐ Yes (1)

Verify that script was read and compensate subject
(vrCmpS, <vrCmpS>)
(Integer, RadioCheckbox)

Please record the last 5 digits from the card used to compensate the subject, complete the compensation acknowledgment form with subject signature to document receipt:

(cardVer, <cardVer>)
(Integer, Text)

Please record the last 5 digits from the card used to compensate the subject, complete the compensation acknowledgment form with subject signature to document receipt: :

(cardVerV, <cardVerV>)
(Integer, Text)

For purchasers, read: **As we discussed when we went over the consent document, after you complete the telephone interviews in two and six weeks that are part of this study, you can choose to be compensated with a digital prepaid Visa card that you will receive in your email. Once you've received it in your email you can either use it for online purchases or over the phone, or you can choose to have a physical card sent to you.**

☐ Yes (1)

☐ No (2)

Are you okay with your payment being sent to the email you gave us?

If No: **Ok, then you will receive your prepaid Visa card in the mail.**

Read: **If you have any questions, please call the number listed on page one of your consent document. If you need to come back to purchase any additional study medication, please call first to make sure a member of the study staff will be available.**

For enrolled subjects, provide them with enrollment compensation, pink copy of the informed consent, the purchased study drug, pre-paid return envelope, home pregnancy test, and administrative information card with subject number recorded on all materials. Show subject all materials and explain use.

Thank you again for your participation. Have a nice day.

(prcPay, <prcPay>)

(Integer, RadioCheckbox)

Use

(use, <use>)

Sub Forms

- *19 NURSE FOLLOW-UP INTERVIEW (WEEK 2)*
 - *20 CONCOMITANT MEDICATIONS*
 - *21 NURSE FOLLOW-UP INTERVIEW (WEEK 6)*
 - *22 END-OF-STUDY OR EARLY TERMINATION INTERVIEW*
 - *23 END OF STUDY PREGNANCY TEST RESULTS*
 - *24 AE / SAE / EIU FORMS*
 - *Pregnancy Collection Form (emergency contraception)*
 - *25 FINAL SUBJECT DISPOSITION – ENROLLED SUBJECTS*
-

19 NURSE FOLLOW-UP INTERVIEW (WEEK 2)

(fu2, <fu2>)

19 NURSE FOLLOW-UP INTERVIEW (WEEK 2)

Read: Hello, my name is _____. I am a nurse from PEGUS Research calling about the study that you enrolled in at (study site) on (date of enrollment). I have some questions about your use of the ella emergency contraception pill(s) that you purchased at that time. This phone interview usually takes about 20 minutes and you will be paid for your time. May I go ahead now? (If no, ask when would be a good time to call back)

Subject Number:

(w2Sub, <w2Sub>)

(String, Text)

Date of interview:

(w2DT, <w2DT>)

(Date, Text)

(dd-MMM-yyyy)

Read: The following questions are about your use of the study medicine ella. I will also be asking a few questions about unprotected sex. The next few questions ask about unprotected sex. When I ask about unprotected sex, I am talking about heterosexual vaginal sexual intercourse that could lead to pregnancy. This includes sex where you did not use any birth control or sex where your contraception failed (for example, your partner did not use a condom or a condom broke during sex).

☐ Yes (1)

☐ No (2)

1. Have you taken the ella tablet (any of the ella tablets) that you purchased as part of this study?

(w2Tak, <w2Tak>)

(Integer, RadioCheckbox)

1a. If Q1=No: Why haven't you taken ella?

Do not read responses

Check all that apply

(w2TakN, <w2TakN>)

(String, MultiCheckbox)

☐ I haven't needed it / Didn't have unprotected sex (1)

☐ Bought it for advance provision / for future use in case the need arises (2)

☐ I decided against it (3)

☐ I started my period (4)

☐ I forgot / misplaced it (5)

☐ Other (6)

If Other, please specify:

(w2TakNo, <w2TakNo>)

(String, Text)

2. How many different times did you take ella?
times

(w2Tab, <w2Tab>)

(Integer, Text)

(w2TabA, <w2TabA>)

(Integer, RadioCheckbox)

If Other, please specify:

(w2TabAo, <w2TabAo>)

(String, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

3. On what date did you first take ella? (work to a date /
prompt with date of enrollment/purchase / number of days
after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt1, <w23Dt1>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w23T1, <w23T1>)

(Integer, Text)

(w23TA1, <w23TA1>)

(Integer, RadioCheckbox)

If Other, please specify:

(w23TAo1, <w23TAo1>)

(String, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

3b. On what date did you have unprotected sex? I'm
asking about the unprotected sex that led you to take this
dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase /
number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U1, <w23U1>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w23UA1, <w23UA1>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA11, <w23UA11>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C1, <w23C1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co1, <w23Co1>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w241, <w241>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w24A1, <w24A1>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B1, <w24B1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C1, <w24C1>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w24CN1, <w24CN1>)

(Integer, Text)

If Other, please specify:

(w24Co1, <w24Co1>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt1, <w24DDt1>)

(Date, Text)

(w24D1, <w24D1>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: Did you start with a new pill pack, patch or vaginal ring?

Do not read responses

Check all that apply

(w24E1, <w24E1>)

(String, MultiCheckbox)

If Other, please specify:

(w24Eo1, <w24Eo1>)

(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt2, <w23Dt2>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w23T2, <w23T2>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

(w23TA2, <w23TA2>)

☐ Other: (2)

(Integer, RadioCheckbox)

If Other, please specify:

(w23TAo2, <w23TAo2>)

(String, Text)

3b. On what date did you have unprotected sex? I'm

asking about the unprotected sex that led you to take this (dd-MMM-yyyy)

dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase /
number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U2, <w23U2>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w23UA2, <w23UA2>)

(Integer, RadioCheckbox)

**3b-1. If Q3b='Did not have unprotected sex': If you did not
have unprotected sex, why did you use ella?**

Enter verbatim response:

(w23UA12, <w23UA12>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C2, <w23C2>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co2, <w23Co2>)

(String, Text)

**4. Were you taking a daily birth control pill, or using a birth
control patch or vaginal ring at the time you took this dose
of ella?**

☐ Yes (1)

☐ No (2)

(w242, <w242>)

(Integer, RadioCheckbox)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w24A2, <w24A2>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B2, <w24B2>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C2, <w24C2>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w24CN2, <w24CN2>)

(Integer, Text)

If Other, please specify:

(w24Co2, <w24Co2>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt2, <w24DDt2>)

(Date, Text)

(w24D2, <w24D2>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4dDid not restart that method: **Can you please tell me HOW you restarted your pill, patch or vaginal ring?**

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E2, <w24E2>)

(String, MultiCheckbox)

If Other, please specify:

(w24Eo2, <w24Eo2>)

(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. **On what date did you next take ella?** (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt3, <w23Dt3>)

(Date, Text)

(dd-MMM-yyyy)

3a. **How many tablets did you take on that date?**

tablets

(w23T3, <w23T3>)

(Integer, Text)

(w23TA3, <w23TA3>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w23TAo3, <w23TAo3>)

(String, Text)

3b. **On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.**

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U3, <w23U3>)

(Date, Text)

(dd-MMM-yyyy)

☐ Did not have unprotected sex (1)

(w23UA3, <w23UA3>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA13, <w23UA13>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C3, <w23C3>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co3, <w23Co3>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w243, <w243>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w24A3, <w24A3>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B3, <w24B3>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C3, <w24C3>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking

ella?

(w24CN3, <w24CN3>)

(Integer, Text)

If Other, please specify:

(w24Co3, <w24Co3>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt3, <w24DDt3>)

(Date, Text)

(w24D3, <w24D3>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E3, <w24E3>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w24Eo3, <w24Eo3>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt4, <w23Dt4>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w23T4, <w23T4>)

(Integer, Text)

.
(w23TA4, <w23TA4>)

(Integer, RadioCheckbox)

If Other, please specify:

(w23TAo4, <w23TAo4>)

(String, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U4, <w23U4>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w23UA4, <w23UA4>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA14, <w23UA14>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C4, <w23C4>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co4, <w23Co4>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w244, <w244>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were

☐ Birth control pill (1)

you using?

Do not read responses

Check all that apply

(w24A4, <w24A4>)

(String, MultiCheckbox)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B4, <w24B4>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C4, <w24C4>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w24CN4, <w24CN4>)

(Integer, Text)

If Other, please specify:

(w24Co4, <w24Co4>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt4, <w24DDt4>)

(Date, Text)

(w24D4, <w24D4>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4dDid not restart that method: **Can you please tell me HOW you restarted your pill, patch or vaginal ring?**

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E4, <w24E4>)

(String, MultiCheckbox)

If Other, please specify:

(w24Eo4, <w24Eo4>)

(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. **On what date did you next take ella?** (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt5, <w23Dt5>)

(Date, Text)

(dd-MMM-yyyy)

3a. **How many tablets did you take on that date?**

tablets

(w23T5, <w23T5>)

(Integer, Text)

(w23TA5, <w23TA5>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w23TAo5, <w23TAo5>)

(String, Text)

3b. **On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.**

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U5, <w23U5>)

(Date, Text)

(dd-MMM-yyyy)

(w23UA5, <w23UA5>)

(Integer, RadioCheckbox)

☐ Did not have unprotected sex (1)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA15, <w23UA15>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C5, <w23C5>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co5, <w23Co5>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w245, <w245>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w24A5, <w24A5>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B5, <w24B5>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C5, <w24C5>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking

ella?

(w24CN5, <w24CN5>)

(Integer, Text)

If Other, please specify:

(w24Co5, <w24Co5>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt5, <w24DDt5>)

(Date, Text)

(w24D5, <w24D5>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E5, <w24E5>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w24Eo5, <w24Eo5>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt6, <w23Dt6>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w23T6, <w23T6>)

(Integer, Text)

.
(w23TA6, <w23TA6>)

(Integer, RadioCheckbox)

If Other, please specify:

(w23TAo6, <w23TAo6>)

(String, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U6, <w23U6>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w23UA6, <w23UA6>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA16, <w23UA16>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C6, <w23C6>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co6, <w23Co6>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w246, <w246>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were

☐ Birth control pill (1)

you using?

Do not read responses

Check all that apply

(w24A6, <w24A6>)

(String, MultiCheckbox)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B6, <w24B6>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C6, <w24C6>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w24CN6, <w24CN6>)

(Integer, Text)

If Other, please specify:

(w24Co6, <w24Co6>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt6, <w24DDt6>)

(Date, Text)

(w24D6, <w24D6>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4dDid not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?
Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E6, <w24E6>)

(String, MultiCheckbox)

If Other, please specify:

(w24Eo6, <w24Eo6>)

(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt7, <w23Dt7>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w23T7, <w23T7>)

(Integer, Text)

(w23TA7, <w23TA7>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w23TAo7, <w23TAo7>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U7, <w23U7>)

(Date, Text)

(dd-MMM-yyyy)

(w23UA7, <w23UA7>)

(Integer, RadioCheckbox)

☐ Did not have unprotected sex (1)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA17, <w23UA17>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C7, <w23C7>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co7, <w23Co7>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w247, <w247>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w24A7, <w24A7>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B7, <w24B7>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C7, <w24C7>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking

ella?

(w24CN7, <w24CN7>)

(Integer, Text)

If Other, please specify:

(w24Co7, <w24Co7>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt7, <w24DDt7>)

(Date, Text)

(w24D7, <w24D7>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E7, <w24E7>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w24Eo7, <w24Eo7>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt8, <w23Dt8>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w23T8, <w23T8>)

(Integer, Text)

.
(w23TA8, <w23TA8>)

(Integer, RadioCheckbox)

If Other, please specify:

(w23TAo8, <w23TAo8>)

(String, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U8, <w23U8>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w23UA8, <w23UA8>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA18, <w23UA18>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C8, <w23C8>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co8, <w23Co8>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w248, <w248>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were

☐ Birth control pill (1)

you using?

Do not read responses

Check all that apply

(w24A8, <w24A8>)

(String, MultiCheckbox)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B8, <w24B8>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C8, <w24C8>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w24CN8, <w24CN8>)

(Integer, Text)

If Other, please specify:

(w24Co8, <w24Co8>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt8, <w24DDt8>)

(Date, Text)

(w24D8, <w24D8>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4dDid not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E8, <w24E8>)

(String, MultiCheckbox)

If Other, please specify:

(w24Eo8, <w24Eo8>)

(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w23Dt9, <w23Dt9>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w23T9, <w23T9>)

(Integer, Text)

(w23TA9, <w23TA9>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w23TAo9, <w23TAo9>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w23U9, <w23U9>)

(Date, Text)

(dd-MMM-yyyy)

☐ Did not have unprotected sex (1)

(w23UA9, <w23UA9>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w23UA19, <w23UA19>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w23C9, <w23C9>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w23Co9, <w23Co9>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w249, <w249>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w24A9, <w24A9>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w24B9, <w24B9>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

Check all that apply

(w24C9, <w24C9>)

(String, MultiCheckbox)

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking

ella?

(w24CN9, <w24CN9>)

(Integer, Text)

If Other, please specify:

(w24Co9, <w24Co9>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w24DDt9, <w24DDt9>)

(Date, Text)

(w24D9, <w24D9>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w24E9, <w24E9>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w24Eo9, <w24Eo9>)

(String, Text)

5. Since you enrolled in the study on (date of enrollment), have you taken any other form of emergency contraception, other than the ella you purchased as part of this study?

(w25, <w25>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

5a. If Q5=Yes: What other kind of emergency contraception did you take?

Do not read responses

☐ prescription ulipristal acetate (ella), not the study drug (1)

☐ levonorgestrel (Plan B, My Way, Next Choice) (2)

Check all that apply

(w25A, <w25A>)

(String, MultiCheckbox)

☐ Other: (3)

If Other, please specify:

(w25Ao, <w25Ao>)

(String, Text)

5b. If Q5a Box 1 checked: How many times did you take ella or ulipristal acetate that you got from somewhere other than this study? Times

(w25BN, <w25BN>)

(Integer, Text)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w25Bo, <w25Bo>)

(String, Text)

5c. If Q5a Box 1 checked: On what date did you first take ella that you got from somewhere other than this study?

Enter date:_____ (MM/DD/YYYY)

(w25C1, <w25C1>)

(Date, Text)

☐ Don't know / Not sure /Don't remember (1)

(w25C1dk, <w25C1dk>)

(Integer, RadioCheckbox)

5d. How many ella tablets did you take on that date?
tablets

(w25DN1, <w25DN1>)

(Integer, Text)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

(w25D1, <w25D1>)

(Integer, RadioCheckbox)

If Other, please specify:

(w25Do1, <w25Do1>)

(String, Text)

5c. If Q5a Box 1 checked: On what date did you next take ella that you got from somewhere other than this study?

Enter date:_____ (MM/DD/YYYY)

(w25C2, <w25C2>)

(Date, Text)

5d. How many ella tablets did you take on that date?

tablets

(w25DN2, <w25DN2>)

(Integer, Text)

.

(w25D2, <w25D2>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w25Do2, <w25Do2>)

(String, Text)

5c. If Q5a Box 1 checked: On what date did you next take ella that you got from somewhere other than this study?

Enter date:_____ (MM/DD/YYYY)

(w25C3, <w25C3>)

(Date, Text)

(dd-MMM-yyyy)

5d. How many ella tablets did you take on that date?

tablets

(w25DN3, <w25DN3>)

(Integer, Text)

.

(w25D3, <w25D3>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w25Do3, <w25Do3>)

(String, Text)

6. If Q5=Yes AND Q5a =levonogestrel or other: How many times have you taken any other form of emergency contraception not including ella, either from this study or another source, since (date of enrollment).

Times

(w26N, <w26N>)

(Integer, Text)

.

(w26, <w26>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w26O, <w26O>)

(String, Text)

7. Since you enrolled in the study on (date of enrollment), have you had a menstrual period?

(w27, <w27>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

7a. If Q7=Yes: To the best of your recollection, what day did that menstrual period start?

Enter date, encourage best estimate if uncertain

(MM/DD/YYYY)

(w27A, <w27A>)

(Date, Text)

(dd-MMM-yyyy)

☐ Don't know / Not sure / Don't remember (1)

(w27dk, <w27dk>)

(Integer, RadioCheckbox)

Read: The next few questions I'll ask about sexual intercourse. When I ask about sexual intercourse, I am talking about heterosexual vaginal sex (not oral sex or same-gender partner sex).

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

If Q1=Yes

8. Between when you took the first dose of ella from this study and (Q7=Yes (date of last period) OR Q7=No (today's date)), did you have sexual intercourse?

(w28, <w28>)

(Integer, RadioCheckbox)

8a. If Q8=Yes: Did you use anything or take anything to prevent pregnancy when you had sex during that time (after you first took the study drug ella and (before your period started) or (now))?

(w28A, <w28A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

8b. If Q8a=Yes: What are all the birth control methods you were using to prevent pregnancy when you had sex during that time (after you first took the study drug ella and (before your period started) or (now))?

Do not read responses

☐ Condoms (01)

☐ Diaphragm (02)

☐ Sponge (03)

☐ Spermicide (04)

☐ Birth control pills/patch/vaginal ring (05)

Check all that apply
(w28B, <w28B>)
(String, MultiCheckbox)

- ☐ Long-acting contraceptives (implant/injection/IUD) (06)
- ☐ Partner wasn't male (07)
- ☐ Didn't have vaginal intercourse (08)
- ☐ Withdrawal (09)
- ☐ Natural family planning/rhythm method (10)
- ☐ Don't know / Not sure / Don't remember (11)
- ☐ Other (specify): (12)

If Other, please specify:
(w28Bo, <w28Bo>)
(String, Text)

8c. If ((Q8=Yes AND Q8a=No) OR (Q8b Condoms or Diaphragm or Sponge)): **Have you used a condom or other barrier method of birth control (like a sponge or diaphragm) during intercourse since you first used ella that you got from this study?**

(w28C, <w28C>)
(Integer, RadioCheckbox)

- ☐ Yes (1)
- ☐ No (2)
- ☐ Don't know / Not sure / Don't remember (3)

8d. If (Q8b=Condoms or Diaphragm or Sponge) OR Q8c=Yes: **How often did you use (a condom/diaphragm/sponge) when you had sex after first using ella and (before your menstrual period started) or (now)?**

(w28D, <w28D>)
(Integer, RadioCheckbox)

- ☐ Every time (1)
- ☐ Most of the time (more than 50% of the time) (2)
- ☐ Some of the time (less than 50% of the time) (3)

The next question is about unprotected sex. The next few questions ask about unprotected sex. When I ask about unprotected sex, I am talking about heterosexual vaginal sexual intercourse that could lead to pregnancy. This includes sex where you did not use any birth control or sex where your contraception failed (for example, your partner did not use a condom or a condom broke during sex).

- ☐ Yes (1)
- ☐ No (2)
- ☐ Don't know / Not sure / Don't remember (3)

If Q1=Yes

9. **Have you had unprotected sex since enrolling in the study?**

(w29, <w29>)
(Integer, RadioCheckbox)

10. **Before participating in this study, had you ever used an emergency contraceptive?**

- ☐ Yes (1)
- ☐ No (2)

(w210, <w210>)
(Integer, RadioCheckbox)

10a. If Q10=Yes: **What kind of emergency contraception did you take?**

Do not read responses

Check all that apply

(w210a, <w210a>)
(String, MultiCheckbox)

- ☐ prescription ulipristal acetate (ella), not the study drug (1)
☐ levonorgestrel (Plan B, My Way, Next Choice) (2)
☐ Other: (3)

If Other, please specify:

(w210aO, <w210aO>)
(String, Text)

10b. If Q10a Box 1 not checked: **Have you ever used ella before participating in this study?**

(w210b, <w210b>)
(Integer, RadioCheckbox)

- ☐ Yes (1)
☐ No (2)
☐ Don't know / Not sure (3)
☐ Other (4)

If Other, please specify:

(w210bO, <w210bO>)
(String, Text)

10c. If Q10a Box 1 or Q10b Box 1 checked: **Before you enrolled in this study when did you last use ella?**

(w210cN, <w210cN>)
(Integer, Text)

.
(w210cD, <w210cD>)
(Integer, RadioCheckbox)

- ☐ Days ago (1)
☐ Weeks ago (2)
☐ Months ago (3)
☐ Years ago (4)
☐ Don't know / Not sure / Don't remember (5)
☐ Other: (6)

If Other, please specify:

(w210cO, <w210cO>)
(String, Text)

10d. If Q10c Box 1 or 2 checked: **Did you have a period between taking that dose of ella and the study medicine ella that you got as part of this study?**

(w210d, <w210d>)
(Integer, RadioCheckbox)

- ☐ Yes (1)
☐ No (2)
☐ Don't know / Not sure (3)
☐ Other (4)

If Other, please specify:

(w210dO, <w210dO>)

(String, Text)

Adverse Event Trigger Questions

These questions should be asked of everybody to determine if any adverse events need to be recorded.

Now I'm going to ask you some questions about any other health problems you may have had during the study.

Since you enrolled in the ella study, have you been to the doctor for any reason not already discussed?

Since you enrolled in the ella study, have you developed any new medical problems not already discussed?

Since you enrolled in the ella study, have you been to a hospital as a patient for any reason?

Also consider new medications or changes in medications reported.

Based on the responses to all questions go to the Adverse Events Form and complete as necessary.

Complete Concomitant Medication Form

☐ Yes (1)

☐ No (2)

11. Since you enrolled in this study on (date of enrollment), have you started taking any new medications?

☐ Don't know / Not sure / Don't remember (3)

(w211, <w211>)

(Integer, RadioCheckbox)

Tab Total from week 2 interview:

(totTabs, <totTabs>)

(Integer, PlainText)

(expression, w23T1 +

w23T2 +

w23T3 +

w23T4 +

w23T5 +

w23T6 +

w23T7+

w23T8 +

w23T9 +

w25DN1 +

w25DN2 +

w25DN3)

Read: **That concludes our telephone interview for today.**

☐ Not contacted (1)

Your compensation for this interview will come to you in the (mail in the next 2 weeks) or (as an e-card in your email in the next week). A nurse from PEGUS Research will contact you again in approximately one month for your final interview. Remember that the pregnancy test that you

☐ Refused Interview (2)

were given at the site will need to be taken just before that interview. Thank you for your time and have a nice day.

(w2NC, <w2NC>)

(Integer, RadioCheckbox)

20 CONCOMITANT MEDICATIONS

(cm, <cm>)

20 CONCOMITANT MEDICATIONS

Please review all Enrollment medications and update as necessary.

1

(c1, <c1>)

(String, Text)

Indication:

(c1l, <c1l>)

(String, Text)

Ongoing?

(c1A, <c1A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c1aAE, <c1aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c1aeRef, <c1aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c1SDt, <c1SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c1EDt, <c1EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c1Ds, <c1Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c1Rt, <c1Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c1Caus, <c1Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

2

(c2, <c2>)

(String, Text)

Indication:

(c2I, <c2I>)

(String, Text)

Ongoing?

(c2A, <c2A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c2aAE, <c2aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c2aeRef, <c2aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c2SDt, <c2SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c2EDt, <c2EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c2Ds, <c2Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c2Rt, <c2Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c2Caus, <c2Caus>)

☐ Yes (1)

☐ No (2)

(Integer, RadioCheckbox)

3

(c3, <c3>)

(String, Text)

Indication:

(c3I, <c3I>)

(String, Text)

Ongoing?

(c3A, <c3A>)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

(c3aAE, <c3aAE>)

(Integer, RadioCheckbox)

If yes, select:

(c3aeRef, <c3aeRef>)

(Reference, Select)

If Associated with an AE = Yes

Start date:

(c3SDt, <c3SDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c3EDt, <c3EDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c3Ds, <c3Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c3Rt, <c3Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c3Caus, <c3Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

4

(c4, <c4>
(String, Text)

Indication:

(c4I, <c4I>
(String, Text)

Ongoing?

(c4A, <c4A>
(Integer, RadioCheckbox)

Associated with an AE? (specify)

(c4aAE, <c4aAE>
(Integer, RadioCheckbox)

If yes, select:

(c4aeRef, <c4aeRef>
(Reference, Select)

If Associated with an AE = Yes

Start date:

(c4SDt, <c4SDt>
(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c4EDt, <c4EDt>
(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c4Ds, <c4Ds>
(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c4Rt, <c4Rt>
(String, Text)

If Associated with an AE = Yes Causal relationship

(c4Caus, <c4Caus>
(Integer, RadioCheckbox)

5

(c5, <c5>

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Yes (1)

☐ No (2)

(String, Text)

Indication:

(c5I, <c5I>)

(String, Text)

Ongoing?

(c5A, <c5A>)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

(c5aAE, <c5aAE>)

(Integer, RadioCheckbox)

If yes, select:

(c5aeRef, <c5aeRef>)

(Reference, Select)

If Associated with an AE = Yes

Start date:

(c5SDt, <c5SDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c5EDt, <c5EDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c5Ds, <c5Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c5Rt, <c5Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c5Caus, <c5Caus>)

(Integer, RadioCheckbox)

6

(c6, <c6>)

(String, Text)

Indication:

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Yes (1)

☐ No (2)

(c6I, <c6I>)

(String, Text)

Ongoing?

(c6A, <c6A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c6aAE, <c6aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c6aeRef, <c6aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c6SDt, <c6SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c6EDt, <c6EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c6Ds, <c6Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c6Rt, <c6Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c6Caus, <c6Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

7

(c7, <c7>)

(String, Text)

Indication:

(c7I, <c7I>)

(String, Text)

Ongoing?

(c7A, <c7A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c7aAE, <c7aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c7aeRef, <c7aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c7SDt, <c7SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c7EDt, <c7EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c7Ds, <c7Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c7Rt, <c7Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c7Caus, <c7Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

8

(c8, <c8>)

(String, Text)

Indication:

(c8I, <c8I>)

(String, Text)

Ongoing?

(c8A, <c8A>)

☐ Yes (1)

☐ No (2)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

(c8aAE, <c8aAE>)

(Integer, RadioCheckbox)

If yes, select:

(c8aeRef, <c8aeRef>)

(Reference, Select)

If Associated with an AE = Yes

Start date:

(c8SDt, <c8SDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c8EDt, <c8EDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c8Ds, <c8Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c8Rt, <c8Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c8Caus, <c8Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Yes (1)

☐ No (2)

9

(c9, <c9>)

(String, Text)

Indication:

(c9I, <c9I>)

(String, Text)

Ongoing?

(c9A, <c9A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

☐ Yes (1)

(c9aAE, <c9aAE>)
(Integer, RadioCheckbox)

If yes, select:

(c9aeRef, <c9aeRef>)
(Reference, Select)

If Associated with an AE = Yes

Start date:

(c9SDt, <c9SDt>)
(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c9EDt, <c9EDt>)
(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c9Ds, <c9Ds>)
(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c9Rt, <c9Rt>)
(String, Text)

If Associated with an AE = Yes Causal relationship

(c9Caus, <c9Caus>)
(Integer, RadioCheckbox)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Yes (1)

☐ No (2)

10

(c10, <c10>)
(String, Text)

Indication:

(c10I, <c10I>)
(String, Text)

Ongoing?

(c10A, <c10A>)
(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c10aAE, <c10aAE>)
(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c10aeRef, <c10aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c10SDt, <c10SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c10EDt, <c10EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c10Ds, <c10Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c10Rt, <c10Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c10Caus, <c10Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Reviewed all Enrollment medications and updated as necessary?

(cRevMed, <cRevMed>)

(Integer, RadioCheckbox)

☐ Y (1)

☐ N (2)

Read: **What new medicines are you taking? Why did you start taking that medicine?**

(cRepNMed, <cRepNMed>)

(Integer, RadioCheckbox)

☐ Report New Medicine (1)

11

(c11, <c11>)

(String, Text)

Indication:

(c11I, <c11I>)

(String, Text)

Ongoing?

(c11A, <c11A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c11aAE, <c11aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c11aeRef, <c11aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c11SDt, <c11SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c11EDt, <c11EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c11Ds, <c11Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c11Rt, <c11Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c11Caus, <c11Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Baseline med not reported at enrollment?

(c11bnr, <c11bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

12

(c12, <c12>)

(String, Text)

Indication:

(c12I, <c12I>)

(String, Text)

Ongoing?

(c12A, <c12A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c12aAE, <c12aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c12aeRef, <c12aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c12SDt, <c12SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c12EDt, <c12EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c12Ds, <c12Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c12Rt, <c12Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c12Caus, <c12Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Baseline med not reported at enrollment?

(c12bnr, <c12bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

13

(c13, <c13>)

(String, Text)

Indication:

(c13l, <c13l>)

(String, Text)

Ongoing?

☐ Yes (1)

(c13A, <c13A>)

☐ No (2)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

☐ Yes (1)

(c13aAE, <c13aAE>)

☐ No (2)

(Integer, RadioCheckbox)

If yes, select:

(c13aeRef, <c13aeRef>)

Sample reference 1 ()

(Reference, Select)

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(dd[UNK]-MMM[UNK]-yyyy)

(c13SDt, <c13SDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(dd[UNK]-MMM[UNK]-yyyy)

(c13EDt, <c13EDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c13Ds, <c13Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c13Rt, <c13Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

☐ Yes (1)

(c13Caus, <c13Caus>)

☐ No (2)

(Integer, RadioCheckbox)

Baseline med not reported at enrollment?

☐ Yes (1)

(c13bnr, <c13bnr>)

☐ No (2)

(Integer, RadioCheckbox)

14

(c14, <c14>)

(String, Text)

Indication:

(c14I, <c14I>)

(String, Text)

Ongoing?

(c14A, <c14A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c14aAE, <c14aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c14aeRef, <c14aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c14SDt, <c14SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c14EDt, <c14EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c14Ds, <c14Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c14Rt, <c14Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c14Caus, <c14Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Baseline med not reported at enrollment?

(c14bnr, <c14bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

15

(c15, <c15>)

(String, Text)

Indication:

(c15I, <c15I>)

(String, Text)

Ongoing?

(c15A, <c15A>)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

(c15aAE, <c15aAE>)

(Integer, RadioCheckbox)

If yes, select:

(c15aeRef, <c15aeRef>)

(Reference, Select)

If Associated with an AE = Yes

Start date:

(c15SDt, <c15SDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c15EDt, <c15EDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c15Ds, <c15Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c15Rt, <c15Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c15Caus, <c15Caus>)

(Integer, RadioCheckbox)

Baseline med not reported at enrollment?

(c15bnr, <c15bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

(c16, <c16>)

(String, Text)

Indication:

(c16I, <c16I>)

(String, Text)

Ongoing?

(c16A, <c16A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c16aAE, <c16aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c16aeRef, <c16aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c16SDt, <c16SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c16EDt, <c16EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c16Ds, <c16Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c16Rt, <c16Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c16Caus, <c16Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Baseline med not reported at enrollment?

(c16bnr, <c16bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

17

(c17, <c17>)

(String, Text)

Indication:

(c17I, <c17I>)

(String, Text)

Ongoing?

(c17A, <c17A>)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

(c17aAE, <c17aAE>)

(Integer, RadioCheckbox)

If yes, select:

(c17aeRef, <c17aeRef>)

(Reference, Select)

If Associated with an AE = Yes

Start date:

(c17SDt, <c17SDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c17EDt, <c17EDt>)

(PartialDate, PartialDate)

If Associated with an AE = Yes

Daily dose:

(c17Ds, <c17Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c17Rt, <c17Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c17Caus, <c17Caus>)

(Integer, RadioCheckbox)

Baseline med not reported at enrollment?

(c17bnr, <c17bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

(dd[UNK]-MMM[UNK]-yyyy)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Yes (1)

☐ No (2)

☐ Yes (1)

☐ No (2)

18

(c18, <c18>)

(String, Text)

Indication:

(c18I, <c18I>)

(String, Text)

Ongoing?

(c18A, <c18A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c18aAE, <c18aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c18aeRef, <c18aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c18SDt, <c18SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c18EDt, <c18EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c18Ds, <c18Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c18Rt, <c18Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c18Caus, <c18Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Baseline med not reported at enrollment?

(c18bnr, <c18bnr>)

☐ Yes (1)

☐ No (2)

(Integer, RadioCheckbox)

19

(c19, <c19>)

(String, Text)

Indication:

(c19I, <c19I>)

(String, Text)

Ongoing?

(c19A, <c19A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Associated with an AE? (specify)

(c19aAE, <c19aAE>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select:

(c19aeRef, <c19aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c19SDt, <c19SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c19EDt, <c19EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c19Ds, <c19Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c19Rt, <c19Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

(c19Caus, <c19Caus>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Baseline med not reported at enrollment?

☐ Yes (1)

(c19bnr, <c19bnr>)

☐ No (2)

(Integer, RadioCheckbox)

20

(c20, <c20>)

(String, Text)

Indication:

(c20I, <c20I>)

(String, Text)

Ongoing?

☐ Yes (1)

(c20A, <c20A>)

☐ No (2)

(Integer, RadioCheckbox)

Associated with an AE? (specify)

☐ Yes (1)

(c20aAE, <c20aAE>)

☐ No (2)

(Integer, RadioCheckbox)

If yes, select:

(c20aeRef, <c20aeRef>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Associated with an AE = Yes

Start date:

(c20SDt, <c20SDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes AND If Ongoing = No

End date:

(c20EDt, <c20EDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Associated with an AE = Yes

Daily dose:

(c20Ds, <c20Ds>)

(String, Text)

If Associated with an AE = Yes

Route (e.g. iv, po)

(c20Rt, <c20Rt>)

(String, Text)

If Associated with an AE = Yes Causal relationship

☐ Yes (1)

(c20Caus, <c20Caus>)

☐ No (2)

(Integer, RadioCheckbox)

Baseline med not reported at enrollment?

(c20bnr, <c20bnr>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

.

(barb, <barb>)

(Integer, RadioCheckbox)

☐ Subject reported taking barbiturates, carbamazepine, felbamate, oxcarbazepine, phenytoin, or topiramate (1)

.

(rifa, <rifa>)

(Integer, RadioCheckbox)

☐ Subject reported taking rifampin (1)

.

(grise, <grise>)

(Integer, RadioCheckbox)

☐ Subject reported taking griseofulvin (1)

.

(bosn, <bosn>)

(Integer, RadioCheckbox)

☐ Subject reported taking bosentan (1)

.

(stJohn, <stJohn>)

(Integer, RadioCheckbox)

☐ Subject reported taking St. John's Wort or any herbal product containing hypericum perforatum (1)

.

(HIVm, <HIVm>)

(Integer, RadioCheckbox)

☐ Subject reported taking medicine to treat HIV/AIDS (1)

.

(nonAbove, <nonAbove>)

(Integer, RadioCheckbox)

☐ Subject did not report taking any of the above medications (1)

21 NURSE FOLLOW-UP INTERVIEW (WEEK 6)

(fu6, <fu6>)

21 NURSE FOLLOW-UP INTERVIEW (WEEK 6)

Read: Hello, my name is _____. I am a nurse from PEGUS Research calling about the study that you enrolled in at (study site) on (date of enrollment). I have some questions about your use of the ella emergency contraception pill that you purchased at that time. This phone interview usually takes about 20 minutes and you will be paid for your time. May I go ahead now?

(If no, ask when would be a good time to call back)

Subject Number:

(w6Sub, <w6Sub>)

(String, Text)

Date of interview:

(w6DT, <w6DT>)

(Date, Text)

(dd-MMM-yyyy)

Read: The following questions are about your use of the study medicine, ella. I will also be asking a few questions about unprotected sex. The next few questions ask about unprotected sex. When I ask about unprotected sex, I am talking about heterosexual vaginal sexual intercourse that could lead to pregnancy. This includes sex where you did not use any birth control or sex where your contraception failed (for example, your partner did not use a condom or a condom broke during sex).

☐ Yes (1)

☐ No (2)

If Q1 from Week 2 = Yes AND (number of tablets purchased – number of tablets previously reported to have been taken (total of Q3a in week-2 interview) = 0): **(Skip to Q5)**

If Q1 from Week 2 = No OR if Week 2 interview not completed, ask Q1-6, then skip to Q8:

1. Have you taken the ella tablet (any of the ella tablets) that you purchased as part of this study?

(w6Tak, <w6Tak>)

(Integer, RadioCheckbox)

1a. If Q1=No: Why haven't you taken ella?

Do not read responses

Check all that apply

(w6TakN, <w6TakN>)

(String, MultiCheckbox)

☐ I haven't needed it / Didn't have unprotected sex (1)

☐ Bought it for advance provision / for future use in case the need arises (2)

☐ I decided against it (3)

☐ I started my period (4)

☐ I forgot / misplaced it (5)

☐ Other (6)

If Other, please specify:

(w6TakNo, <w6TakNo>)

(String, Text)

(If Q1=No or blank Skip to Q5)

2. How many different times did you take ella?

times

(w6Tab, <w6Tab>)

(Integer, Text)

.

(w6TabA, <w6TabA>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w6TabAo, <w6TabAo>)

(String, Text)

3. On what date did you first take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc.)

Enter date:_____ (MM/DD/YYYY)

(w63Dt1, <w63Dt1>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w63T1, <w63T1>)

(Integer, Text)

.

(w63TA1, <w63TA1>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w63TAo1, <w63TAo1>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w63U1, <w63U1>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA1, <w63UA1>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA11, <w63UA11>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C1, <w63C1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co1, <w63Co1>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w641, <w641>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w64A1, <w64A1>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w64B1, <w64B1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that

Check all that apply
(w64C1, <w64C1>)
(String, MultiCheckbox)

worried me (for example: usually also use a condom, but it broke) (3)
☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)
☐ Other (specify): (5)
☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w64CN1, <w64CN1>)
(Integer, Text)

If Other, please specify:

(w64Co1, <w64Co1>)
(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: **To the best of your recollection, when did you start using that birth control method (again) after you took ella?**

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt1, <w64DDt1>)
(Date, Text)

.
(w64D1, <w64D1>)
(Integer, RadioCheckbox)

☐ Did not restart that method (1)
☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: **Can you please tell me HOW you restarted your pill, patch or vaginal ring?**

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply
(w64E1, <w64E1>)
(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)
☐ I picked up in the pack where I left off (2)
☐ Never stopped using HBC (3)
☐ Other (specify): (4)
☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w64Eo1, <w64Eo1>)
(String, Text)

3. **On what date did you next take ella?** (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: _____ (MM/DD/YYYY)

(w63Dt2, <w63Dt2>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w63T2, <w63T2>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w63TAo2, <w63TAo2>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(dd-MMM-yyyy)

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w63U2, <w63U2>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA2, <w63UA2>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA12, <w63UA12>)

(String, MultiLineText)

3c. Did you take the tablet with food?

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co2, <w63Co2>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

☐ Yes (1)

☐ No (2)

(w642, <w642>)

(Integer, RadioCheckbox)

4a. If Q4=Yes: Which of those birth control methods were you using?

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

Do not read responses

Check all that apply

(w64A2, <w64A2>)

(String, MultiCheckbox)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

(w64B2, <w64B2>)

(Integer, RadioCheckbox)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

Do not read responses

Check all that apply

(w64C2, <w64C2>)

(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN2, <w64CN2>)

(Integer, Text)

If Other, please specify:

(w64Co2, <w64Co2>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

(dd-MMM-yyyy)

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt2, <w64DDt2>)

(Date, Text)

(w64D2, <w64D2>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w64E2, <w64E2>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w64Eo2, <w64Eo2>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w63Dt3, <w63Dt3>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w63T3, <w63T3>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

(w63TA3, <w63TA3>)

(Integer, RadioCheckbox)

If Other, please specify:

(w63TAo3, <w63TAo3>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: (MM/DD/YYYY)

(w63U3, <w63U3>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA3, <w63UA3>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA13, <w63UA13>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C3, <w63C3>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co3, <w63Co3>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w643, <w643>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w64A3, <w64A3>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w64B3, <w64B3>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that

Check all that apply
(w64C3, <w64C3>
(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN3, <w64CN3>
(Integer, Text)

If Other, please specify:

(w64Co3, <w64Co3>
(String, Text)

worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt3, <w64DDt3>
(Date, Text)

.
(w64D3, <w64D3>
(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: Did you start with a new pill pack, patch or vaginal ring?

Do not read responses

Check all that apply
(w64E3, <w64E3>
(String, MultiCheckbox)

If Other, please specify:

(w64Eo3, <w64Eo3>
(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: _____ (MM/DD/YYYY)

(w63Dt4, <w63Dt4>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w63T4, <w63T4>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w63TAo4, <w63TAo4>)

(String, Text)

3b. On what date did you have unprotected sex? I'm

asking about the unprotected sex that led you to take this (dd-MMM-yyyy)

dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase /
number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w63U4, <w63U4>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA4, <w63UA4>)

(Integer, RadioCheckbox)

**3b-1. If Q3b='Did not have unprotected sex': If you did not
have unprotected sex, why did you use ella?**

Enter verbatim response:

(w63UA14, <w63UA14>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C4, <w63C4>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co4, <w63Co4>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

☐ Yes (1)

☐ No (2)

(w644, <w644>)

(Integer, RadioCheckbox)

4a. If Q4=Yes: Which of those birth control methods were you using?

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

Do not read responses

Check all that apply

(w64A4, <w64A4>)

(String, MultiCheckbox)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

(w64B4, <w64B4>)

(Integer, RadioCheckbox)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

Do not read responses

Check all that apply

(w64C4, <w64C4>)

(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN4, <w64CN4>)

(Integer, Text)

If Other, please specify:

(w64Co4, <w64Co4>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

(dd-MMM-yyyy)

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt4, <w64DDt4>)

(Date, Text)

(w64D4, <w64D4>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w64E4, <w64E4>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w64Eo4, <w64Eo4>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w63Dt5, <w63Dt5>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w63T5, <w63T5>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

(w63TA5, <w63TA5>)

(Integer, RadioCheckbox)

If Other, please specify:

(w63TAo5, <w63TAo5>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: (MM/DD/YYYY)

(w63U5, <w63U5>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA5, <w63UA5>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA15, <w63UA15>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C5, <w63C5>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co5, <w63Co5>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w645, <w645>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w64A5, <w64A5>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w64B5, <w64B5>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that

Check all that apply
(w64C5, <w64C5>
(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN5, <w64CN5>
(Integer, Text)

If Other, please specify:

(w64Co5, <w64Co5>
(String, Text)

worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt5, <w64DDt5>
(Date, Text)

.
(w64D5, <w64D5>
(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: Did you start with a new pill pack, patch or vaginal ring?

Do not read responses

Check all that apply

(w64E5, <w64E5>
(String, MultiCheckbox)

If Other, please specify:

(w64Eo5, <w64Eo5>
(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: _____ (MM/DD/YYYY)

(w63Dt6, <w63Dt6>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w63T6, <w63T6>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w63TAo6, <w63TAo6>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(dd-MMM-yyyy)

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w63U6, <w63U6>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA6, <w63UA6>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA16, <w63UA16>)

(String, MultiLineText)

3c. Did you take the tablet with food?

☐ Yes (1)

(w63C6, <w63C6>)

☐ No (2)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co6, <w63Co6>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

☐ Yes (1)

☐ No (2)

(w646, <w646>)

(Integer, RadioCheckbox)

4a. If Q4=Yes: Which of those birth control methods were you using?

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

Do not read responses

Check all that apply

(w64A6, <w64A6>)

(String, MultiCheckbox)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

(w64B6, <w64B6>)

(Integer, RadioCheckbox)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

Do not read responses

Check all that apply

(w64C6, <w64C6>)

(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN6, <w64CN6>)

(Integer, Text)

If Other, please specify:

(w64Co6, <w64Co6>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

(dd-MMM-yyyy)

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt6, <w64DDt6>)

(Date, Text)

(w64D6, <w64D6>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4dDid not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w64E6, <w64E6>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w64Eo6, <w64Eo6>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date:_____ (MM/DD/YYYY)

(w63Dt7, <w63Dt7>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w63T7, <w63T7>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

(w63TA7, <w63TA7>)

(Integer, RadioCheckbox)

If Other, please specify:

(w63TAo7, <w63TAo7>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: (MM/DD/YYYY)

(w63U7, <w63U7>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA7, <w63UA7>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA17, <w63UA17>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C7, <w63C7>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co7, <w63Co7>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w647, <w647>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w64A7, <w64A7>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w64B7, <w64B7>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that

Check all that apply
(w64C7, <w64C7>)
(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN7, <w64CN7>)
(Integer, Text)

If Other, please specify:

(w64Co7, <w64Co7>)
(String, Text)

worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt7, <w64DDt7>)
(Date, Text)

.
(w64D7, <w64D7>)
(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: Did you start with a new pill pack, patch or vaginal ring?

Do not read responses

Check all that apply
(w64E7, <w64E7>)
(String, MultiCheckbox)

If Other, please specify:

(w64Eo7, <w64Eo7>)
(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w63Dt8, <w63Dt8>)

(Date, Text)

3a. How many tablets did you take on that date?

tablets

(w63T8, <w63T8>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w63TAo8, <w63TAo8>)

(String, Text)

3b. On what date did you have unprotected sex? I'm

asking about the unprotected sex that led you to take this (dd-MMM-yyyy)

dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase /
number of days after purchase, etc)

Enter date: (MM/DD/YYYY)

(w63U8, <w63U8>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA8, <w63UA8>)

(Integer, RadioCheckbox)

**3b-1. If Q3b='Did not have unprotected sex': If you did not
have unprotected sex, why did you use ella?**

Enter verbatim response:

(w63UA18, <w63UA18>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C8, <w63C8>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co8, <w63Co8>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

☐ Yes (1)

☐ No (2)

(w648, <w648>)

(Integer, RadioCheckbox)

4a. If Q4=Yes: Which of those birth control methods were you using?

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

Do not read responses

Check all that apply

(w64A8, <w64A8>)

(String, MultiCheckbox)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

(w64B8, <w64B8>)

(Integer, RadioCheckbox)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

Do not read responses

Check all that apply

(w64C8, <w64C8>)

(String, MultiCheckbox)

How many were missed during the week before taking ella?

(w64CN8, <w64CN8>)

(Integer, Text)

If Other, please specify:

(w64Co8, <w64Co8>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: To the best of your recollection, when did you start using that birth control method (again) after you took ella?

(dd-MMM-yyyy)

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt8, <w64DDt8>)

(Date, Text)

(w64D8, <w64D8>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: Can you please tell me HOW you restarted your pill, patch or vaginal ring?

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w64E8, <w64E8>)

(String, MultiCheckbox)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

If Other, please specify:

(w64Eo8, <w64Eo8>)

(String, Text)

3. On what date did you next take ella? (work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

Enter date: _____ (MM/DD/YYYY)

(w63Dt9, <w63Dt9>)

(Date, Text)

(dd-MMM-yyyy)

3a. How many tablets did you take on that date?

tablets

(w63T9, <w63T9>)

(Integer, Text)

☐ Don't know / Not sure / Don't remember (1)

☐ Other: (2)

(w63TA9, <w63TA9>)

(Integer, RadioCheckbox)

If Other, please specify:

(w63TAo9, <w63TAo9>)

(String, Text)

3b. On what date did you have unprotected sex? I'm asking about the unprotected sex that led you to take this dose of the study drug ella.

(work to a date / prompt with date of enrollment/purchase / number of days after purchase, etc)

(dd-MMM-yyyy)

Enter date: (MM/DD/YYYY)

(w63U9, <w63U9>)

(Date, Text)

☐ Did not have unprotected sex (1)

(w63UA9, <w63UA9>)

(Integer, RadioCheckbox)

3b-1. If Q3b='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w63UA19, <w63UA19>)

(String, MultiLineText)

3c. Did you take the tablet with food?

(w63C9, <w63C9>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w63Co9, <w63Co9>)

(String, Text)

4. Were you taking a daily birth control pill, or using a birth control patch or vaginal ring at the time you took this dose of ella?

(w649, <w649>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

4a. If Q4=Yes: Which of those birth control methods were you using?

Do not read responses

Check all that apply

(w64A9, <w64A9>)

(String, MultiCheckbox)

☐ Birth control pill (1)

☐ Patch (2)

☐ Vaginal ring (3)

☐ Don't know / Not sure / Don't remember (4)

4b. If Q4a Box 1, 2 or 3 checked: Were you using that birth control method on any of the days in the week before you took this dose of ella?

(w64B9, <w64B9>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

4c. If Q4b=Yes: If you were using that birth control method at the time, why did you decide to take this dose of ella?

Do not read responses

☐ I wasn't using my method reliably (1)

☐ I missed pills (2)

☐ Was using pills/patch/ring but had intercourse that

Check all that apply
(w64C9, <w64C9>)
(String, MultiCheckbox)

worried me (for example: usually also use a condom, but it broke) (3)

☐ I took it as an extra precaution / to be 100% sure I didn't get pregnant (4)

☐ Other (specify): (5)

☐ Don't know / not sure / Don't remember (6)

How many were missed during the week before taking ella?

(w64CN9, <w64CN9>)

(Integer, Text)

If Other, please specify:

(w64Co9, <w64Co9>)

(String, Text)

4d. If Q4a Box 1, 2 or 3 checked: **To the best of your recollection, when did you start using that birth control method (again) after you took ella?**

Enter date, encourage best estimate if uncertain. If never stopped, date is same as study product use

Enter date: (MM/DD/YYYY)

(w64DDt9, <w64DDt9>)

(Date, Text)

.

(w64D9, <w64D9>)

(Integer, RadioCheckbox)

☐ Did not restart that method (1)

☐ Don't know / Not sure / Don't remember (2)

4e. If Q4d Did not restart that method: **Can you please tell me HOW you restarted your pill, patch or vaginal ring?**

Probe if needed: **Did you start with a new pill pack, patch or vaginal ring?**

Do not read responses

Check all that apply

(w64E9, <w64E9>)

(String, MultiCheckbox)

If Other, please specify:

(w64Eo9, <w64Eo9>)

(String, Text)

☐ I used a new pack/patch/ring (1)

☐ I picked up in the pack where I left off (2)

☐ Never stopped using HBC (3)

☐ Other (specify): (4)

☐ Don't know / Not sure / Don't remember (5)

5. Since you enrolled in the study on (date of enrollment), have you taken any other form of emergency contraception, other than the ella you purchased as part of

☐ Yes (1)

☐ No (2)

this study?

(w65, <w65>)

(Integer, RadioCheckbox)

5a. If Q5=Yes: **What other kind of emergency contraception did you take?**

Do not read responses

Check all that apply

(w65A, <w65A>)

(String, MultiCheckbox)

If Other, please specify:

(w65Ao, <w65Ao>)

(String, Text)

☐ prescription ulipristal acetate (ella), not the study drug (1)

☐ levonorgestrel (Plan B, My Way, Next Choice) (2)

☐ Other: (3)

5b. If Q5a=prescription ulipristal acetate (ella), not the study drug: **How many times did you take ella or ulipristal acetate that you got from somewhere other than this study?** Times

(w65BN, <w65BN>)

(Integer, Text)

.
(w65B, <w65B>)

(Integer, RadioCheckbox)

If Other, please specify:

(w65Bo, <w65Bo>)

(String, Text)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

5c. If Q5a=prescription ulipristal acetate (ella), not the study drug: **On what date did you first take ella that you got from somewhere other than this study?**

Enter date:_____ (MM/DD/YYYY)

(w65C1, <w65C1>)

(Date, Text)

.
(w65C1dk, <w65C1dk>)

(Integer, RadioCheckbox)

(dd-MMM-yyyy)

☐ Don't know / Not sure /Don't remember (1)

5d. **How many ella tablets did you take on that date?**

tablets

(w65DN1, <w65DN1>)

(Integer, Text)

☐ Don't know / Not sure /Don't remember (1)

(w65D1, <w65D1>
(Integer, RadioCheckbox)

☐ Other: (2)

If Other, please specify:

(w65Do1, <w65Do1>
(String, Text)

5c. If Q5a Box 1 checked: On what date did you next take ella that you got from somewhere other than this study?

(dd-MMM-yyyy)

Enter date:_____ (MM/DD/YYYY)

(w65C2, <w65C2>
(Date, Text)

5d. How many ella tablets did you take on that date?
tablets

(w65DN2, <w65DN2>
(Integer, Text)

(w65D2, <w65D2>
(Integer, RadioCheckbox)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w65Do2, <w65Do2>
(String, Text)

5c. If Q5a Box 1 checked: On what date did you next take ella that you got from somewhere other than this study?

(dd-MMM-yyyy)

Enter date:_____ (MM/DD/YYYY)

(w65C3, <w65C3>
(Date, Text)

5d. How many ella tablets did you take on that date?
tablets

(w65DN3, <w65DN3>
(Integer, Text)

(w65D3, <w65D3>
(Integer, RadioCheckbox)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w65Do3, <w65Do3>
(String, Text)

6. If Q5=Yes AND Q5a =levonogestrel or other: How many times have you taken any other form of emergency

contraception not including ella, either from this study or another source, since (date of enrollment).

Times

(w66N, <w66N>)

(Integer, Text)

.

(w66, <w66>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w66O, <w66O>)

(String, Text)

Tab Total from week 2 interview:

(w67tabC, <w67tabC>)

(String, PlainText)

If Q1 from Week 2 = Yes AND (number of tablets

☐ Yes (1)

purchased – number of tablets previously reported to have been taken ≥ 1):

☐ No (Skip to Q8) (2)

7. When we spoke approximately 4 weeks ago, you said that you had taken (number of tablets previously reported to have been taken) doses of ella. Have you taken any additional tablets of ella that you purchased as part of this study at any time since we last spoke on (date of week 2 interview)?

(w67, <w67>)

(Integer, RadioCheckbox)

7a. If Q7=Yes: Do you remember the date you took the study drug ella after our last interview?

Enter date : (MM/DD/YYYY)

(w67A, <w67A>)

(Date, Text)

(dd-MMM-yyyy)

.

☐ No (1)

(w67Ano, <w67Ano>)

(Integer, RadioCheckbox)

7b. If Q7a=No: If you don't recall a specific date, what can you tell me about WHEN you took the study drug ella after our last interview?

Record verbatim response, e.g. "I took it about a week after the last interview", "I took it a few days ago", "I don't remember".

(w67B, <w67B>)
(String, MultiLineText)

7c. How many ella tablets did you take on that date?

tablets

(w67Cn, <w67Cn>)
(Integer, Text)

- ☐ Don't know / Not sure / Don't remember (1)
☐ Other: (2)

(w67C, <w67C>)
(Integer, RadioCheckbox)

If Other, please specify:

(w67Co, <w67Co>)
(String, Text)

7d. How many days after you had unprotected sex did you use ella?

Enter date: _____ (MM/DD/YYYY)

(w67D, <w67D>)
(Date, Text)

(dd-MMM-yyyy)

- ☐ Did not have unprotected sex (1)

(w67Dno, <w67Dno>)
(Integer, RadioCheckbox)

7d-1. If Q7d='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w67D1, <w67D1>)
(String, MultiLineText)

7e. Do you remember if you took the tablet with food?

(w67E, <w67E>)
(Integer, RadioCheckbox)

- ☐ Yes (1)
☐ No (2)
☐ Don't know / Not sure / Don't remember (3)
☐ Other: (4)

If Other, please specify:

(w67Eo, <w67Eo>)
(String, Text)

7a. If Q7=Yes: Do you remember the date you took the study drug ella after our last interview?

Enter date : (MM/DD/YYYY)

(w67A2, <w67A2>)
(Date, Text)

(dd-MMM-yyyy)

☐ No (1)

(w67Ano2, <w67Ano2>)

(Integer, RadioCheckbox)

7b. If Q7a=No: If you don't recall a specific date, what can you tell me about WHEN you took the study drug ella after our last interview?

Record verbatim response, e.g. "I took it about a week after the last interview", "I took it a few days ago", "I don't remember".

(w67B2, <w67B2>)

(String, MultiLineText)

7c. How many ella tablets did you take on that date?

tablets

(w67Cn2, <w67Cn2>)

(Integer, Text)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

If Other, please specify:

(w67Co2, <w67Co2>)

(String, Text)

7d. How many days after you had unprotected sex did you use ella?

Enter date: _____ (MM/DD/YYYY)

(w67D2, <w67D2>)

(Date, Text)

(dd-MMM-yyyy)

☐ Did not have unprotected sex (1)

(w67Dno2, <w67Dno2>)

(Integer, RadioCheckbox)

7d-1. If Q7d='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w67D12, <w67D12>)

(String, MultiLineText)

7e. Do you remember if you took the tablet with food?

(w67E2, <w67E2>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w67Eo2, <w67Eo2>)

(String, Text)

7a. If Q7=Yes: Do you remember the date you took the study drug ella after our last interview?

Enter date : (MM/DD/YYYY)

(w67A3, <w67A3>)

(Date, Text)

(dd-MMM-yyyy)

☐ No (1)

(w67Ano3, <w67Ano3>)

(Integer, RadioCheckbox)

7b. If Q7a=No: If you don't recall a specific date, what can you tell me about WHEN you took the study drug ella after our last interview?

Record verbatim response, e.g. "I took it about a week after the last interview", "I took it a few days ago", "I don't remember".

(w67B3, <w67B3>)

(String, MultiLineText)

7c. How many ella tablets did you take on that date?

tablets

(w67Cn3, <w67Cn3>)

(Integer, Text)

☐ Don't know / Not sure /Don't remember (1)

☐ Other: (2)

(w67C3, <w67C3>)

(Integer, RadioCheckbox)

If Other, please specify:

(w67Co3, <w67Co3>)

(String, Text)

7d. How many days after you had unprotected sex did you use ella?

Enter date: _____ (MM/DD/YYYY)

(w67D3, <w67D3>)

(Date, Text)

(dd-MMM-yyyy)

☐ Did not have unprotected sex (1)

(w67Dno3, <w67Dno3>)

(Integer, RadioCheckbox)

7d-1. If Q7d='Did not have unprotected sex': If you did not have unprotected sex, why did you use ella?

Enter verbatim response:

(w67D13, <w67D13>)

(String, MultiLineText)

7e. Do you remember if you took the tablet with food?

(w67E3, <w67E3>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Other: (4)

If Other, please specify:

(w67Eo3, <w67Eo3>)

(String, Text)

If Q7 Week 2=No or Week 2 interview not conducted:

8. Since you enrolled in the study on (date of enrollment), have you had a menstrual period?

(w68, <w68>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

8a. If Q8=Yes: To the best of your recollection, what day did that menstrual period start?

Enter date, encourage best estimate if uncertain

(MM/DD/YYYY)

(w68A, <w68A>)

(Date, Text)

(dd-MMM-yyyy)

.

(w68dk, <w68dk>)

(Integer, RadioCheckbox)

☐ Don't know / Not sure / Don't remember (1)

Read: The next few questions I'll ask about sexual intercourse. When I ask about sexual intercourse, I am talking about heterosexual vaginal sex (not oral sex or same-gender partner sex).

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

If Q1=Yes or Q8=Yes AND (Week 2 Q8) not asked:

9. Between when you took the first dose of ella from this study and (Q8=Yes (date of last period) OR Q8=No (today's date)), did you have sexual intercourse?

(w69, <w69>)

(Integer, RadioCheckbox)

9a. If Q9=Yes: Did you use anything or take anything to prevent pregnancy when you had sex during that time

(after you first took the study drug ella and (before your

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

period started) or (now))?

(w69A, <w69A>)

(Integer, RadioCheckbox)

9b. If Q9a=Yes: What are all the birth control methods you were using to prevent pregnancy when you had sex during that time (after you first took the study drug ella and (before your period started) or (now))?

Do not read responses

Check all that apply

(w69B, <w69B>)

(String, MultiCheckbox)

☐ Condoms (01)

☐ Diaphragm (02)

☐ Sponge (03)

☐ Spermicide (04)

☐ Birth control pills/patch/vaginal ring (05)

☐ Long-acting contraceptives (implant/injection/IUD) (06)

☐ Partner wasn't male (07)

☐ Didn't have vaginal intercourse (08)

☐ Withdrawal (09)

☐ Natural family planning/rhythm method (10)

☐ Don't know / Not sure / Don't remember (11)

☐ Other (specify): (12)

If Other, please specify:

(w69Bo, <w69Bo>)

(String, Text)

9c. If ((Q9=Yes AND Q9a=No) OR (Q9b Condoms or Diaphragm or Sponge)): Have you used a condom or other barrier method of birth control (like a sponge or diaphragm) during intercourse since you first used ella from this study?

(w69C, <w69C>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

9d. If (Q9b=Condoms or Diaphragm or Sponge) OR Q9c=Yes: How often did you use (a condom/diaphragm/sponge) when you had sex after first using ella and (before your menstrual period started) or (now)?

(w69D, <w69D>)

(Integer, RadioCheckbox)

☐ Every time (1)

☐ Most of the time (more than 50% of the time) (2)

☐ Some of the time (less than 50% of the time) (3)

The next question is about unprotected sex. The next few questions ask about unprotected sex. When I ask about unprotected sex, I am talking about heterosexual vaginal sexual intercourse that could lead to pregnancy. This includes sex where you did not use any birth control or sex where your contraception failed (for example, your partner did not use a condom or a condom broke during sex).

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

10. If Q9=Yes: **Have you had unprotected sex since enrolling in the study?**

(w610, <w610>)

(Integer, RadioCheckbox)

Adverse Event Trigger Questions

These questions should be asked of everybody to determine if any adverse events need to be recorded.

Now I'm going to ask you some questions about any other health problems you may have had during the study.

Since you enrolled in the ella study, have you been to the doctor for any reason not already discussed?

Since you enrolled in the ella study, have you developed any new medical problems not already discussed?

Since you enrolled in the ella study, have you been to a hospital as a patient for any reason?

Also consider new medications or changes in medications reported.

Based on the responses to all questions go to the Adverse Events Form and complete as necessary.

Complete Concomitant Medication Form and Continue to ☐ Yes (1)

End of Study Interview ☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

11. Since you enrolled in this study on (date of enrollment), have you started taking any new medications?

(w611, <w611>)

(Integer, RadioCheckbox)

(w6NC, <w6NC>)

(Integer, RadioCheckbox)

☐ Not contacted (1)

☐ Refused Interview (2)

22 END-OF-STUDY OR EARLY TERMINATION INTERVIEW

(eos, <eos>)

22 END-OF-STUDY OR EARLY TERMINATION INTERVIEW

I would now like to continue and ask you some end-of-study questions we are asking of all participants in our study.

Subject Number:

(eSub, <eSub>)

(String, Text)

Date of interview:

(eDT, <eDT>)

(Date, Text)

(dd-MMM-yyyy)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes):

1. During the study, did you ever vomit within 3 hours of taking ella?

(e1, <e1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

1a. If Q1=Yes: Did you do anything in particular because you vomited within 3 hours of taking ella?

Do not read responses

Check all that apply

(e1a, <e1a>)

(String, MultiCheckbox)

☐ Talked to a healthcare professional (1)

☐ Took another tablet of ella (2)

☐ Took another form of emergency contraception (3)

☐ Did nothing (4)

☐ Other: (5)

When?

(e1aW, <e1aW>)

(Date, Text)

(dd-MMM-yyyy)

If Other, please specify:

(e1aO, <e1aO>)

(String, Text)

1b. If Q1=Yes AND Q1a Talked to a healthcare professional: Did you call a healthcare professional to find out if you should repeat the dose?

(e1b, <e1b>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

Why not?

(e1bW, <e1bW>)

(String, Text)

1c. If Q1=Yes AND (Q1a=Talked to a healthcare professional OR Q1b=Yes): **When you talked to your healthcare professional, did you tell him or her that you had taken ella and had vomited afterward?**

(e1c, <e1c>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

1d. If Q1=Yes AND (Q1a=Talked to a healthcare professional OR Q1b=Yes): **What did your healthcare professional tell you?**

(e1d, <e1d>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (EOS Q1b=NO OR AE Q1b does not contain 'Talked to a healthcare professional')

2. The instructions on the package say to call a healthcare professional to find out if you should repeat the dose if you vomit within 3 hours of taking ella. You told us that you vomited within 3 hours after taking ella. Why did you decide not to call a healthcare professional to find out if you should repeat the dose? Record verbatim response

(e2, <e2>)

(String, MultiLineText)

3. Did you ever breastfeed around the time you took the ella from this study?

(e3, <e3>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

3a. If Q3=Yes: **The instructions on the package say not to take ella if you are breastfeeding. Why did you decide to take ella even though you were breastfeeding?** Record verbatim response

(e3a, <e3a>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (Week 2 Q3b date-Q3 date is >5 days OR Week 6 Q3b date-Q3 date is >5 days OR Week 6 Q7d date-Q7a date >5 days):

4. The instructions on the package say to take ella as soon as possible and no later than 5 days after unprotected sex. You told us that you took ella more than 5 days after unprotected sex. Why did you decide to take

ella even though it was more than 5 days after unprotected sex? Record verbatim response

(e4, <e4>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND ((Week 2 Q4b=Yes AND Q4d date-Q3 date<5 days) OR (Week 6 Q4b=Yes AND Q4d date-Q3 date<5 days)):

5. The instructions on the package say not to use birth control pills, patch, or ring for 5 days after taking ella. You told us that you started using birth control pills, patch or ring sooner than 5 days after taking ella. Why did you decide to start using birth control pills/patches/rings sooner than 5 days after taking ella? Record verbatim response

(e5, <e5>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (Week 2 Q4e not contains box 1 OR Week 6 Q4e not contains box 1):

6. The instructions on the package insert say to restart with a new pack of pills (or a new patch or vaginal ring). Why did you decide not to follow this instruction? Record verbatim response

(e6, <e6>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (Week 2 Q4d= 'Date' OR 'Don't know / Not sure / Don't remember' OR Week 6 Q4d='Date' OR 'Don't know / Not sure / Don't remember') AND (((Week 2 (Q8b Condoms or Diaphragm or Sponge) OR Q8c=No) OR (Week 6 (Q9b Condoms or Diaphragm or Sponge) OR Q9c=No))):

7. The instructions on the package say to use condoms (or another barrier method, a sponge or diaphragm for example) every time you have sex from the time you take ella until the start of your next menstrual period, even if you start or restart birth control pills, patches, or rings. Why did you not use condoms or another barrier method every time you had sex until your next menstrual period? Record verbatim response

(e7, <e7>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (Week 2 Q4 = No OR Q4d= 'Did not restart that method' OR Week 6 Q4 = No OR Q4d='Did not restart that method') AND (((Week 2 (Q8b Condoms or Diaphragm or Sponge) OR Q8c=No) OR (Week 6 (Q9b Condoms or Diaphragm or Sponge) OR Q9c=No))):

8. The instructions on the package say to use condoms (or another barrier method) every time you have sex from the time you take ella until the start of your next menstrual period. Why did you not use condoms or another barrier method every time you had sex until your next menstrual period? Record verbatim response

(e8, <e8>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (Week 2 Q3a is >1 OR Week 6 Q3a is >1):

9. The instructions on the package say not to take more than one tablet of ella at a time. Why did you decide to take more than one tablet of ella at one time? Record verbatim response

(e9, <e9>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (any sum of number of tablets >1 reported in Week 2 (Q3a AND Q5d) AND Week 6 (Q3a AND Q5d AND Q7c):

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

10. You reported taking ella on more than two occasions during the course of the study. Did you have a menstrual cycle between each dose?

(e10, <e10>)

(Integer, RadioCheckbox)

10a. If Q10 = No or Don't know / Not sure / Don't remember: The instructions on the package say not to take more than one dose of ella in the same menstrual cycle. Why did you decide to take ella more than once within a single menstrual cycle? Record verbatim response

(e10a, <e10a>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (ConMed table box 7 not checked):

☐ Yes (1)

☐ No (2)

11. Did you talk to a healthcare professional or pharmacist ☐ Don't know / Not sure (3)

about the medicines you take before you took ella?

(e11, <e11>)

(Integer, RadioCheckbox)

reported ask a doctor or pharmacist drugs:

Subject reported taking barbiturates, carbamazepine, felbamate, oxcarbazepine, phenytoin, or topiramate

(cmMed1, <cmMed1>)

(String, PlainText)

Subject reported taking rifampin

(cmMed2, <cmMed2>)

(String, PlainText)

Subject reported taking griseofulvin

(cmMed3, <cmMed3>)

(String, PlainText)

Subject reported taking bosentan

(cmMed4, <cmMed4>)

(String, PlainText)

Subject reported taking St. John's Wort or any herbal product containing hypericum perforatum

(cmMed5, <cmMed5>)

(String, PlainText)

Subject reported taking medicine to treat HIV/AIDS

(cmMed6, <cmMed6>)

(String, PlainText)

11a. If Q11=No: The instructions inside the package tell you to talk to a healthcare professional or a pharmacist before you take ella if you are taking (reported ask a doctor or pharmacist drug). Why didn't you do that?

(e11a, <e11a>)

(String, MultiLineText)

. ☐ Reported starting this medication AFTER use of ella. (1)

(e11aR, <e11aR>)

(Integer, RadioCheckbox)

12. As far as you know, are you pregnant?

☐ Yes (1)

(e12, <e12>)

☐ No (2)

(Integer, RadioCheckbox)

☐ Don't know / Not sure (3)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes) AND (Week 2 ☐ Yes (1)

Q7 box 1 NOT checked AND Week 6 Q8 box 1 NOT checked) AND EOS Q12=No:

☐ No (2)

13. The instructions on the package say to do a pregnancy test if you are more than one week late getting your period. You told us that you haven't had a period since you enrolled in this study on (date of enrollment). Did you take any pregnancy test when your period was late?

(e13, <e13>)

(Integer, RadioCheckbox)

Why did you not take a pregnancy test? Record verbatim response

(e13a, <e13a>)

(String, MultiLineText)

If (Week 2 Q1=Yes OR Week 6 Q1=Yes)

☐ Yes (1)

14. At any time since you took ella have you had severe lower abdominal pain?

☐ No (2)

(e14, <e14>)

(Integer, RadioCheckbox)

14a. If Q14=Yes: Did you do anything in particular when you had lower abdominal pain any time after taking ella?

Check all that apply

(e14a, <e14a>)

(String, MultiCheckbox)

☐ Talked to a healthcare professional (1)

☐ Stopped taking ella (2)

☐ Did nothing (3)

☐ Other: (4)

When?

(e14aW, <e14aW>)

(Date, Text)

(dd-MMM-yyyy)

If Other, please specify:

(e14aO, <e14aO>)

(String, Text)

14b. If Q14=Yes AND Q14a Talked to a healthcare professional: Did you contact a healthcare professional about it?

☐ Yes (1)

☐ No (2)

(e14b, <e14b>)

(Integer, RadioCheckbox)

Why not?

(e14ba, <e14ba>)

(String, MultiLineText)

14c. If Q14=Yes AND (Q14a=Talked to a healthcare professional OR Q14b=Yes): **When you talked to your healthcare professional, did you tell him or her that you had taken ella?**

(e14c, <e14c>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

14d. If Q14=Yes AND (Q14a=Talked to a healthcare professional OR Q14b=Yes): **What did your healthcare professional tell you?**

(e14d, <e14d>)

(String, MultiLineText)

Complete End of Study Pregnancy Test Results form.

☐ All empty packaging reported disposed of by subject, none to return. (1)

Read: **That concludes this interview and your participation in the study. Your compensation for this interview will come to you (in the mail in the next 2 weeks) (or) (via email in the next few days). Please use the pre-addressed and stamped envelope provided to you when you enrolled to return ALL unused study medication or any empty medicine packaging. Thank you for your time today and for participating in our study. If you need any emergency contraception in the future, you can purchase over-the-counter options or talk to a healthcare provider.**

If subject indicates that empty medication packaging was thrown away and none will be returned, check box:

(eNonRtrn, <eNonRtrn>)

(Integer, RadioCheckbox)

.

(eNC, <eNC>)

(Integer, RadioCheckbox)

☐ Not contacted (1)

☐ Refused Interview (2)

23 END OF STUDY PREGNANCY TEST RESULTS

(epreg, <epreg>)

23 END OF STUDY PREGNANCY TEST RESULTS

1. Have you taken the pregnancy test provided to you when you enrolled in this study?

(ep1, <ep1>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No Read: **Do you have the test that you could take now while I wait?** If not able to take test now or needs another test provided: Read: **We will send you another test. Please take it when you receive it and call us back with the results.**

Confirm mailing address. (2)

☐ Don't know / Not sure / Don't remember (3)

☐ Refused (4)

1a. If Q1=Yes: To the best of your recollection, do you remember the date you took the pregnancy test?

(ep1a, <ep1a>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ I don't remember (3)

☐ Other (4)

Enter date:

(ep1aDT, <ep1aDT>)

(Date, Text)

(dd-MMM-yyyy)

If Other, please specify:

(ep1aO, <ep1aO>)

(String, Text)

1b. If Q1aYes: If you don't recall a specific date, what can you tell me about WHEN you took the pregnancy test?

days ago

(ep1bD, <ep1bD>)

(Integer, Text)

weeks ago

(ep1bW, <ep1bW>)

(Integer, Text)

.

(ep1b, <ep1b>)

(Integer, RadioCheckbox)

☐ Don't remember (1)

☐ Other: (2)

If Other, please specify:

(ep1bO, <ep1bO>)

(String, Text)

1c. If Q1=Yes: What was the result of the pregnancy test? ☐ Positive - Complete EIU form (1)

(ep1c, <ep1c>)
(Integer, RadioCheckbox)

- ☐ Negative (2)
- ☐ Test malfunctioned or results unclear. Read: **We will send you another test. Please take it when you receive it and call us back with the results.** Confirm mailing address.
(3)
- ☐ Don't know / Not sure / Don't remember Read: **We will send you another test. Please take it when you receive it and call us back with the results.** Confirm mailing address.
(4)

1d. If Q1c=Yes: Have you contacted a healthcare provider to confirm your pregnancy?

(ep1d, <ep1d>)
(Integer, RadioCheckbox)

- ☐ Yes (1)
- ☐ No (2)

Why not?

(ep1dW, <ep1dW>)
(String, MultiLineText)

1e. If Q1d=Yes: When you talked to your healthcare professional, did you tell him or her that you had taken ella?

(ep1e, <ep1e>)
(Integer, RadioCheckbox)

- ☐ Yes (1)
- ☐ No (2)

1f. If Q1e=Yes: What did your healthcare professional tell you? Record verbatim response

(ep1f, <ep1f>)
(String, MultiLineText)

24 AE / SAE / EIU FORMS

(aesum, <aesum>)

Sub Forms

[24 AE / SAE / EIU FORMS]

24 AE / SAE / EIU FORMS

(ae, <ae>)

24 AE / SAE / EIU FORMS

Follow up questions not to be asked directly to the subject, ☐ Yes (1)
unless prompted: ☐ No (2)

1. Did the subject spontaneously report any vomiting after
taking study drug ella?

(ae1, <ae1>)

(Integer, RadioCheckbox)

1a. If Q1=Yes: Was it within 3 hours of taking study drug
ella?

(ae1A, <ae1A>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know / Not sure / Don't remember (3)

If Q1 = Yes: When is this AE being collected?

☐ During the Week 2 Interview (1)

☐ During the Week 6 Interview (2)

☐ During the EOS interview (3)

☐ Spontaneously reported (4)

If 'During the EOS interview' skip to Q2

(ae1A2, <ae1A2>)

(String, MultiCheckbox)

1b. You mentioned you vomited within 3 hours of taking
ella from this study. Afterward, did you do anything in
particular because you vomited within 3 hours of taking
ella?

Do not read responses

Check all that apply

(ae1B1, <ae1B1>)

(Integer, RadioCheckbox)

☐ Talked to a healthcare professional: (1)

.

(ae1B, <ae1B>)

(String, MultiCheckbox)

☐ Took another ella tablet (2)

☐ Took another form of emergency contraception (3)

☐ Did nothing (4)

☐ Other: (5)

When?

(ae1Bw, <ae1Bw>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Other, please specify:

(ae1Bo, <ae1Bo>)

(String, Text)

1c. If Q1b=Talked to a healthcare professional: **When you** ☐ Yes (1)
talked to your healthcare professional, did you tell him or ☐ No (2)
her that you had taken ella and had vomited afterward?

(ae1C, <ae1C>)

(Integer, RadioCheckbox)

1d. If Q1c=Yes **What did your healthcare professional tell you?**

(ae1D, <ae1D>)

(String, MultiLineText)

2. Did the subject spontaneously report severe lower ☐ Yes (1)
abdominal pain any time during the study after taking study ☐ No (2)
drug ella?

(ae2, <ae2>)

(Integer, RadioCheckbox)

If Q2 = Yes: When is this AE being collected?

☐ During the Week 2 Interview (1)

☐ During the Week 6 Interview (2)

☐ During the EOS interview (3)

☐ Spontaneously reported (4)

If 'During the EOS interview' skip to Adverse Event Term

(ae2_2, <ae2_2>)

(String, MultiCheckbox)

2a. You mentioned you had severe lower abdominal pain
after taking ella from this study. What, if anything, did you
do about that?

☐ Talked to a healthcare professional: (1)

☐ Did nothing (2)

☐ Other: (3)

Do not read responses

Check all that apply

(ae2A, <ae2A>)

(String, MultiCheckbox)

When?

(ae2Aw, <ae2Aw>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

If Other, please specify:

(ae2Ao, <ae2Ao>)

(String, Text)

2b. If Q2a=Talked to a healthcare professional: **When you** ☐ Yes (1)

talked to your healthcare professional, did you tell him or ☐ No (2)

her that you had taken ella?

(ae2B, <ae2B>)

(Integer, RadioCheckbox)

2c. If Q2b=Yes What did your healthcare professional tell you or do for you? What did they say was causing your pain?

(ae2C, <ae2C>)

(String, MultiLineText)

Serious Adverse Event Report Form

Diagnosis/syndrome of AE:

(ae_evnt, <ae_evnt>)

(String, Text)

Is the event serious?

☐ No (1)

(aeSRS, <aeSRS>)

☐ Yes (2)

(Integer, RadioCheckbox)

Study No:

(stNo, <stNo>)

(String, Text)

Investigator's Name

(lname, <lname>)

(String, Text)

Centre No:

(CenNo, <CenNo>)

(String, Text)

Patient No.

(PatNo, <PatNo>)

(String, Text)

Treatment / Randomization No.

(TreRN, <TreRN>)

(String, Text)

Country

(Cntry, <Cntry>)

(String, Text)

Patient information

Patient Initials:

first

(piF, <piF>)

(String, Text)

mid

(piM, <piM>)

(String, Text)

last

(piL, <piL>)

(String, Text)

Date of Birth:

day month year

(aeDOB, <aeDOB>)

(PartialDate, PartialDate)

Age:

(aeAge, <aeAge>)

(String, Text)

Sex:

(aeSex, <aeSex>)

(Integer, RadioCheckbox)

☐ male (1)

☐ female (2)

Height (in):

(aeht, <aeht>)

(String, Text)

Weight (lbs):

(aewt, <aewt>)

(String, Text)

Adverse event information

Report type:

☐ initial (1)

*For follow-up report, give only changes to previous

☐ follow up* (2)

Onset of first signs/symptoms of SAE:

(aeRpTp, <aeRpTp>)

(Integer, RadioCheckbox)

day / month / year

(ae_st_dt, <ae_st_dt>)

(PartialDate, PartialDate)

Time since last dose of study medication:

(days) /

(ae_IsDa, <ae_IsDa>)

(String, Text)

(hours) /

(ae_IsHr, <ae_IsHr>)

(String, Text)

(minutes)

(ae_IsMn, <ae_IsMn>)

(String, Text)

or

☐ NA (1)

(ae_Is_na, <ae_Is_na>)

(Integer, RadioCheckbox)

Seriousness criteria (tick all that apply).

☐ Death (1)

☐ Life Threatening (2)

IF the event was serious or a protocol specified significant

☐ Hospitalization (required or prolonged) (3)

AE, please complete an SAE form

☐ Persistent or significant disability / in capacity (4)

(ae_ser, <ae_ser>)

(String, MultiCheckbox)


☐ Congenital anomaly / birth defect (5)

☐ Medically important event (6)

. day / month / year

(ae_serD, <ae_serD>)

(PartialDate, PartialDate)



Did the patient take a significant overdose?

☐ No (1)

(oDose, <oDose>)

☐ Yes (2)

(Integer, RadioCheckbox)

Is the event due to lack of efficacy?

☐ No (1)

(IEff, <IEff>)

☐ Yes (2)

(Integer, RadioCheckbox)

Description of adverse event

Description:

(ae_desc, <ae_desc>)

(String, MultiLineText)

Description(Cont.)

(ae_desc2, <ae_desc2>)

(String, MultiLineText)

Component signs or symptoms (only if applicable)

1.

(aeComp1, <aeComp1>)

(String, Text)

2.
(aeComp2, <aeComp2>)
(String, Text)

3.
(aeComp3, <aeComp3>)
(String, Text)

4.
(aeComp4, <aeComp4>)
(String, Text)

5.
(aeComp5, <aeComp5>)
(String, Text)

6.
(aeComp6, <aeComp6>)
(String, Text)

Study medication:
Date started day / month / year
(smStDt, <smStDt>)
(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Date ended day / month / year
(smSpDt, <smSpDt>)
(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Drug code broken:
(dcBrok, <dcBrok>)
(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

if yes result:
(dcBrokR, <dcBrokR>)
(String, Text)

Trial indication:
(trlInd, <trlInd>)
(String, MultiLineText)

Daily dose:
(dDos, <dDos>)
(String, Text)

Route of administration:
(Rt, <Rt>)
(String, Text)

Batch No.:

(BtchNo, <BtchNo>)

(String, Text)

Intensity of Event

(aeInt, <aeInt>)

(Integer, RadioCheckbox)

☐ Mild (1)

☐ Moderate (2)

☐ Severe (3)

Action Taken

Study medication :

(acMed, <acMed>)

(Integer, RadioCheckbox)

☐ No change in study medication (1)

☐ Dosage increased due to event (2)

☐ Dosage decreased due to event (3)

☐ Discontinued and reintroduced, no event recurred (4)

☐ Discontinued and reintroduced, same event recurred (5)

☐ Discontinued due to event (6)

Other measures than action on study medication?

(acOms, <acOms>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

If YES,

Medication :

(acOmsY, <acOmsY>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

(please specify):

(acOmsYS, <acOmsYS>)

(String, Text)

Other (please specify):

(acOmsYO, <acOmsYO>)

(String, Text)

Outcome of patient / SAE

(OtCome, <OtCome>)

(Integer, RadioCheckbox)

☐ Recovery without sequelae on: (1)

☐ Recovering/resolving (2)

☐ Ongoing at time of this report (3)

☐ Recovery with sequelae: (4)

☐ Subject died (5)

. day / month / year

(RwoSq, <RwoSq>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

. day / month / year

(RwSq, <RwSq>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

•Autopsy performed?

☐ No (1)

(autop, <autop>)
(Integer, RadioCheckbox)

•Death due to SAE?
(dDueAE, <dDueAE>)
(Integer, RadioCheckbox)

if No, cause of death:
(csDth, <csDth>)
(String, Text)

- ☐ Yes (if YES, please provide a copy of the autopsy report) (2)
☐ Planned (3)
☐ No (1)
☐ Yes (2)

Assessment of causality

In the investigator's opinion the relationship between the reported adverse event(s) and the study medication is:
(aeCas, <aeCas>)
(Integer, RadioCheckbox)

- ☐ Certain (1)
☐ Possible (2)
☐ Unlikely (3)
☐ Not related (4)

If unlikely or not related, in the investigator's opinion, the reported adverse event is:
(aeRel, <aeRel>)
(Integer, RadioCheckbox)

- ☐ related to study procedures (1)
☐ unrelated to study procedures (2)

Relevant medical history

(e.g. previous diseases, surgery, allergies, pregnancy)
(relMH, <relMH>)
(String, MultiLineText)

Tests / laboratory findings

(relevant for SAE diagnosis or course description)

Test/lab name
(tname1, <tname1>)
(String, Text)

Date
day / month / year
(tDt1, <tDt1>)
(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Unit
(tUnit1, <tUnit1>)
(String, Text)

Result / value
(tReslt1, <tReslt1>)
(String, Text)

Test/lab name

(tname2, <tname2>)

(String, Text)

Date

day / month / year

(tDt2, <tDt2>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Unit

(tUnit2, <tUnit2>)

(String, Text)

Result / value

(tReslt2, <tReslt2>)

(String, Text)

Test/lab name

(tname3, <tname3>)

(String, Text)

Date

day / month / year

(tDt3, <tDt3>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Unit

(tUnit3, <tUnit3>)

(String, Text)

Result / value

(tReslt3, <tReslt3>)

(String, Text)

Test/lab name

(tname4, <tname4>)

(String, Text)

Date

day / month / year

(tDt4, <tDt4>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Unit

(tUnit4, <tUnit4>)

(String, Text)

Result / value

(tReslt4, <tReslt4>)

(String, Text)

Test/lab name
(tname5, <tname5>)
(String, Text)

Date
day / month / year
(tDt5, <tDt5>)
(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Unit
(tUnit5, <tUnit5>)
(String, Text)

Result / value
(tReslt5, <tReslt5>)
(String, Text)

Investigator's Signature

Name:
(iName, <iName>)
(String, Text)

Address:
(iAddrs, <iAddrs>)
(String, Text)

Date of this report: day / month / year
(rptDT, <rptDT>)
(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Pregnancy Collection Form (emergency contraception)

(pr, <pr>)

Pregnancy Collection Form

(emergency contraception)

page : 1 of 6

Please return this form to HRA Pharma Pharmacovigilance 15 rue Beranger 75003 PARIS,

fax : 01.42.77.03.52, e-mail : pharmacovigilance@hra-pharma.com

For internal use only: Reception date of the information



(D0)

(dd[UNK]-MMM[UNK]-yyyy)

(prRdt, <prRdt>)

(PartialDate, PartialDate)

Case No:HRA-

(prCsNo1, <prCsNo1>)

(String, Text)

REPORTER INFORMATION

Last name :

(prLn, <prLn>)

(String, Text)

First name :

(prFn, <prFn>)

(String, Text)

Address :

(prAd, <prAd>)

(String, Text)

Phone:

(prPhn, <prPhn>)

(String, Text)

Fax :

(prFax, <prFax>)

(String, Text)

Date:



(prDt, <prDt>)

(dd[UNK]-MMM[UNK]-yyyy)

(PartialDate, PartialDate)

Signature :

(prSig, <prSig>)

(String, Text)

Health Care Professional

☐ Yes (1)

(prHCP, <prHCP>)

☐ No (2)

(Integer, RadioCheckbox)

Country:

(prCntry, <prCntry>)

(String, Text)

Email :

(prEml, <prEml>)

(String, Text)

PATIENT IDENTIFICATION

Initials :

(prIntls, <prIntls>)

(String, Text)

Height:

(prHt, <prHt>)

(String, Text)

Date of birth (DD/MM/YYYY):

(prDOB, <prDOB>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

or age:

(prAge, <prAge>)

(String, Text)

Weight:

(prWt, <prWt>)

(String, Text)

PREGNANCY INFORMATION

Date of last menstrual period :

(prLMPDt, <prLMPDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

Date of pregnancy diagnosis :

(prPDdt, <prPDdt>)

(dd[UNK]-MMM[UNK]-yyyy)

(PartialDate, PartialDate)

Pregnancy stage at time of diagnosis :

(prStage, <prStage>)

(String, Text)

Expected delivery date :

(prEDDdt, <prEDDdt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

EMERGENCY CONTRACEPTION EXPOSURE

Drug name :

(prDname, <prDname>)

(String, Text)

Total dose administered :

(prTdos, <prTdos>)

(String, Text)

Time from intercourse to drug intake (hours or days) :

(prTmint, <prTmint>)

(String, Text)

Date of intake:

(prIntkDt, <prIntkDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

Batch number:

(prBtchNo, <prBtchNo>)

(String, Text)

Exp. date:

(prExpDt, <prExpDt>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

Pregnancy status before emergency contraception intake : ☐ Not Pregnant / (1)

(prPreg, <prPreg>)

(Integer, RadioCheckbox)

☐ Pregnant (2)

If pregnant, pregnancy stage at drug exposure (in weeks of amenorrhea) :

(prPregst, <prPregst>)

(String, Text)

Additional intake of HRA Pharma emergency contraception ☐ No (1)

during pregnancy?

(prAdIn, <prAdIn>)

☐ Yes (2)

(Integer, RadioCheckbox)

: How many?

(prAdInH, <prAdInH>)

(String, Text)

Period of exposure:

(prPex, <prPex>)

(Integer, RadioCheckbox)

☐ 1ST TRIM. (1)

☐ 2ND TRIM. (2)

☐ 3RD TRIM. (3)

☐ UNK (4)

Use of hormonal contraception after emergency
contraception intake in the same menstrual cycle?

(prUHrm, <prUHrm>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

: Name

(prUHrmN, <prUHrmN>)

(String, Text)

Start date after emergency contraception intake:

(prUHrmD, <prUHrmD>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

PREGNANCY OUTCOME

.

(prLB, <prLB>)

(Integer, RadioCheckbox)

☐ Live birth (1)

.

(prHChld, <prHChld>)

(Integer, RadioCheckbox)

☐ Healthy child Thank you for completing this form.
No further information is requested (1)

Pregnancy term (weeks)

(prPrTrm, <prPrTrm>)

(String, Text)

Number of children born

(prNoOfC, <prNoOfC>)

(String, Text)

For each child, please specify :

Sex :

(prBsx1, <prBsx1>)

(String, Text)

Birth weight (kg) :

(prBwt1, <prBwt1>)

(String, Text)

Sex :

(prBsx2, <prBsx2>)

(String, Text)

Birth weight (kg) :

(prBwt2, <prBwt2>)

(String, Text)

Sex :

(prBsx3, <prBsx3>)

(String, Text)

Birth weight (kg) :

(prBwt3, <prBwt3>)

(String, Text)

Thank you for completing this form.
No further information is requested.

.
(prCong, <prCong>)
(Integer, RadioCheckbox)

☐ Congenital anomaly Please complete pages 2 and 4 (1)

.
(prNeoDth, <prNeoDth>)
(Integer, RadioCheckbox)

☐ Neonatal death Please complete pages 2 and 5 (1)

.
(prElAb, <prElAb>)
(Integer, RadioCheckbox)

☐ Elective abortion (no medical reason) please complete pages 2 and 3 (1)

.
(prMtDth, <prMtDth>)
(Integer, RadioCheckbox)

☐ Maternal death Thank you for completing this form.
You will be contacted very soon for further information. (1)

.
(prOthOt, <prOthOt>)
(Integer, RadioCheckbox)

- ☐ Induced therapeutic abortion (in case of anomaly discovered during a prenatal diagnosis) Please complete pages 2 and 6 (1)
- ☐ Spontaneous abortion (less than 20 completed weeks of pregnancy) Please complete pages 2 and 6 (2)
- ☐ Premature fetal death (20-27 completed weeks of pregnancy) Please complete pages 2 and 6 (3)
- ☐ Late fetal death (≥ 28 completed weeks of pregnancy) Please complete pages 2 and 6 (4)
- ☐ Ectopic pregnancy Please complete pages 2 and 6 (5)

Pregnancy Collection Form
(emergency contraception)
page : 2 of 6

Patient ID: Initials

(prPIDInt, <prPIDInt>)

(String, Text)

Date of birth:

(prDOB2, <prDOB2>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

For internal use only : Case No:HRA-

(prCsNo2, <prCsNo2>)

(String, Text)

MATERNAL HISTORY

History of pregnancy

(prHOP, <prHOP>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, how many :

(prHOPH, <prHOPH>)

(String, Text)

and number of live infants

(prHOPN, <prHOPN>)

(String, Text)

History of spontaneous abortion (miscarriage)

(prHOSA, <prHOSA>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, how many :

(prHOSAH, <prHOSAH>)

(String, Text)

History of fetal death ?

(prHOFD, <prHOFD>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, how many :

(prHOFDH, <prHOFDH>)

(String, Text)

History of elective abortion ?

(prHOEA, <prHOEA>)

☐ No (1)

☐ Yes (2)

(Integer, RadioCheckbox)

, how many :

(prHOEAH, <prHOEAH>)

(String, Text)

History of therapeutic abortion ?

☐ No (1)

☐ Yes (2)

(prHOTA, <prHOTA>)

(Integer, RadioCheckbox)

, how many :

(prHOTAH, <prHOTAH>)

(String, Text)

History of birth defect ?

☐ No (1)

☐ Yes (2)

(prHOBD, <prHOBD>)

(Integer, RadioCheckbox)

, how many :

(prHOBDH, <prHOBDH>)

(String, Text)

History of congenital anomaly ?

☐ No (1)

☐ Yes (2)

(prHOCA, <prHOCA>)

(Integer, RadioCheckbox)

, how many :

(prHOCAH, <prHOCAH>)

(String, Text)

RELEVANT DRUG(S) OTHER THAN HRA PHARMA EMERGENCY CONTRACEPTION RECEIVED DURING PREGNANCY

Medication Name

(prMnm1, <prMnm1>)

(String, Text)

Indication

(prInd1, <prInd1>)

(String, Text)

Daily dose

(prDaDos1, <prDaDos1>)

(String, Text)

Route of administration

(prRad1, <prRad1>)

(String, Text)

Periods of exposure during pregnancy

(prPOEx1, <prPOEx1>)

(Integer, RadioCheckbox)

☐ 1st trim. (1)

☐ 2nd trim. (2)

☐ 3rd trim. (3)

☐ Throughout pregnancy (4)

☐ Unknown (5)

Medication Name

(prMnm2, <prMnm2>)

(String, Text)

Indication

(prInd2, <prInd2>)

(String, Text)

Daily dose

(prDaDos2, <prDaDos2>)

(String, Text)

Route of administration

(prRad2, <prRad2>)

(String, Text)

Period of exposure during pregnancy

(prPOEx2, <prPOEx2>)

(Integer, RadioCheckbox)

☐ 1st trim. (1)

☐ 2nd trim. (2)

☐ 3rd trim. (3)

☐ Throughout pregnancy (4)

☐ Unknown (5)

Medication Name

(prMnm3, <prMnm3>)

(String, Text)

Indication

(prInd3, <prInd3>)

(String, Text)

Daily dose

(prDaDos3, <prDaDos3>)

(String, Text)

Route of administration

(prRad3, <prRad3>)

(String, Text)

Periods of exposure during pregnancy

(prPOEx3, <prPOEx3>)

(Integer, RadioCheckbox)

☐ 1st trim. (1)

☐ 2nd trim. (2)

☐ 3rd trim. (3)

☐ Throughout pregnancy (4)

☐ Unknown (5)

Recreational drug use

Tobacco

(prTab, <prTab>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Estimated weekly dose

(prTabD, <prTabD>)

(String, Text)

Period of exposure during pregnancy

(prTabP, <prTabP>)

(Integer, RadioCheckbox)

☐ 1st trim. (1)

☐ 2nd trim. (2)

☐ 3rd trim. (3)

☐ Throughout pregnancy (4)

☐ Unknown (5)

Alcohol

(prAlc, <prAlc>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Estimated weekly dose

(prAlcD, <prAlcD>)

(String, Text)

Period of exposure during pregnancy

(prAlcP, <prAlcP>)

(Integer, RadioCheckbox)

☐ 1st trim. (1)

☐ 2nd trim. (2)

☐ 3rd trim. (3)

☐ Throughout pregnancy (4)

☐ Unknown (5)

Illicit drugs

(prDrg, <prDrg>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

Estimated weekly dose

(prDrgD, <prDrgD>)

(String, Text)

Route of administration

(prDrgR, <prDrgR>)

(String, Text)

Period of exposure during pregnancy

(prDrgP, <prDrgP>)

(Integer, RadioCheckbox)

☐ 1st trim. (1)

☐ 2nd trim. (2)

☐ 3rd trim. (3)

☐ Throughout pregnancy (4)

☐ Unknown (5)

RELEVANT MEDICAL CONDITION(S) DURING PREGNANCY*

*diabetes, hypertension or any other significant medical condition

Medical condition

(prMC1, <prMC1>)

(String, Text)

Start date

(prMCst1, <prMCst1>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

Stop date

(prMCsp1, <prMCsp1>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

.

(prMCO1, <prMCO1>)

(Integer, RadioCheckbox)

☐ Ongoing at time of pregnancy outcome (1)

Medical condition

(prMC2, <prMC2>)

(String, Text)

Start date

(prMCst2, <prMCst2>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

Stop date

(prMCsp2, <prMCsp2>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

☐ Ongoing at time of pregnancy outcome (1)

(prMCO2, <prMCO2>)

(Integer, RadioCheckbox)

RESULTS OF SEROLOGY TESTS

Rubella test Date and Result

(prRubT, <prRubT>)

(String, MultiLineText)

Toxoplasmosis test Date and Result

(prToxT, <prToxT>)

(String, MultiLineText)

PRENATAL TESTS

Type of test

(prPTtp1, <prPTtp1>)

(String, Text)

Date and Result

(prPTdt1, <prPTdt1>)

(String, MultiLineText)

Type of test

(prPTtp2, <prPTtp2>)

(String, Text)

Date and Result

(prPTdt2, <prPTdt2>)

(String, MultiLineText)

Type of test

(prPTtp3, <prPTtp3>)

(String, Text)

Date and Result

(prPTdt3, <prPTdt3>)

(String, MultiLineText)

Pregnancy Collection Form

(emergency contraception)

page : 3 of 6

Patient ID: Initials

(prPIDin3, <prPIDin3>)

(String, Text)

Date of birth:

(prDOB3, <prDOB3>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

For internal use only : Case No:HRA-

(prCsNo3, <prCsNo3>)

(String, Text)

TO COMPLETE IN CASE OF ELECTIVE ABORTION

Date of elective abortion (no medical reason - patient's
elective choice):

(prDEA, <prDEA>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

Was an ultrasound performed

(prUper, <prUper>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, date:

(prUperD, <prUperD>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

What were the findings:

(prUfnd, <prUfnd>)

(String, MultiLineText)

Was there any evidence of heartbeat?

(prEvd, <prEvd>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

, reason (i.e. early stage of pregnancy):

(prEvdR, <prEvdR>)

(String, MultiLineText)

Fetus Crown Rump Length (CRL).....(mm)

(prCRL, <prCRL>)

(Integer, RadioCheckbox)

☐ Not conclusive (1)

☐ Normal for gestational age (2)

Biparietal diameter (BPD).....(mm)

(prBPD, <prBPD>)

(Integer, RadioCheckbox)

☐ Not conclusive (1)

☐ Normal for gestational age (2)

Please provide a copy of the medical report of this exam together with this completed form

Was a placental pathologic examination performed?

☐ No (1)

(prPthE, <prPthE>)

☐ Yes (2)

(Integer, RadioCheckbox)

, date:

(prPthED, <prPthED>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

What were the findings:

(prPthEF, <prPthEF>)

(String, MultiLineText)

Please provide a copy of the medical report of this exam together with this completed form

Was a pathologic examination of the products of
conception performed

☐ No (1)

☐ Yes (2)

(prPthE2, <prPthE2>)

(Integer, RadioCheckbox)

, date:

(prPthE2D, <prPthE2D>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

What were the findings:

(prPthE2F, <prPthE2F>)

(String, MultiLineText)

Please provide a copy of the medical report(s) of this exam together with this completed form

Thank you for completing this form

br> Pregnancy Collection Form

(emergency contraception)

page : 4 of 6

Patient ID: Initials

(prPIDin4, <prPIDin4>)

(String, Text)

Date of birth:

(prDOB4, <prDOB4>)

(PartialDate, PartialDate)

(dd[UNK]-MMM[UNK]-yyyy)

For internal use only : Case No:HRA-

(prCsNo4, <prCsNo4>)

(String, Text)

TO COMPLETE IN CASE OF CONGENITAL ANOMALY

Pregnancy term (in weeks) at time of diagnosis:

(prTrmDg, <prTrmDg>)

(String, Text)

Pregnancy term (in weeks) at time of delivery:

(prTrmDI, <prTrmDI>)

(String, Text)

Number of children born :

(prNoCb, <prNoCb>)

(String, Text)

Delivery method :

☐ Vaginal (1)

☐ Caesarean (2)

(prDMth, <prDMth>)

(Integer, RadioCheckbox)

LIST OF CONGENITAL ANOMALIES

CHILD 1

(prCong1, <prCong1>)

(String, Text)

CHILD 2

(prCong2, <prCong2>)

(String, Text)

CHILD 3

(prCong3, <prCong3>)

(String, Text)

CHILD 1 RELATIONSHIP TO

EMERGENCYCONTRACEPTION INTAKE

(certain/probable/possible/unlikely/not related)

(prRIECI1, <prRIECI1>)

(String, Text)

POSSIBLE CAUSES

1=MATERNAL AGE, 2=UNKNOWN

3=OTHER, SPECIFY

(prPosCs1, <prPosCs1>)

(String, Text)

CHILD 2 RELATIONSHIP TO

EMERGENCYCONTRACEPTION INTAKE

(certain/probable/possible/unlikely/not related)

(prRIECI2, <prRIECI2>)

(String, Text)

POSSIBLE CAUSES

1=MATERNAL AGE, 2=UNKNOWN

3=OTHER, SPECIFY

(prPosCs2, <prPosCs2>)

(String, Text)

CHILD 3 RELATIONSHIP TO

EMERGENCYCONTRACEPTION INTAKE

(certain/probable/possible/unlikely/not related)

(prRIECI3, <prRIECI3>)

(String, Text)

POSSIBLE CAUSES

1=MATERNAL AGE, 2=UNKNOWN

3=OTHER, SPECIFY

(prPosCs3, <prPosCs3>)

(String, Text)

APGAR SCORES

CHILD 1 APGAR1 MIN

(prAp1_1, <prAp1_1>)

(String, Text)

APGAR 5 MIN

(prAp5_1, <prAp5_1>)

(String, Text)

CHILD 2 APGAR1 MIN

(prAp1_2, <prAp1_2>)

(String, Text)

APGAR 5 MIN

(prAp5_2, <prAp5_2>)

(String, Text)

CHILD 3 APGAR1 MIN

(prAp1_3, <prAp1_3>)

(String, Text)

APGAR 5 MIN

(prAp5_3, <prAp5_3>)

(String, Text)

Please describe below any maternal and/or family history
of congenital anomaly

(prHist, <prHist>)

(String, MultiLineText)

Please describe below any other significant maternal
and/or family history

(prSgMat, <prSgMat>)

(String, MultiLineText)

Other comments

(prOcom, <prOcom>)

(String, MultiLineText)

Thank you for completing this form.

Pregnancy Collection Form

(emergency contraception)

page : 5 of 6

Patient ID: Initials

(prPIDin5, <prPIDin5>)

(String, Text)

Date of birth:

(prDOB5, <prDOB5>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

For internal use only : Case No:HRA-

(prCsNo5, <prCsNo5>)

(String, Text)

TO COMPLETE IN CASE OF NEONATAL DEATH

Pregnancy term (in weeks) :

(prTrmDI5, <prTrmDI5>)

(String, Text)

Number of children born :

(prNoCb5, <prNoCb5>)

(String, Text)

Delivery method :

☐ Vaginal (1)

(prDMth5, <prDMth5>)
(Integer, RadioCheckbox)

☐ Cesarean (2)

CHILD 1 AGE OF NEONATE AT DEATH

(prNeoA1, <prNeoA1>)
(String, Text)

CAUSE OF DEATH

(prNeoC1, <prNeoC1>)
(String, Text)

RELATIONSHIP TO EMERGENCY CONTRACEPTION
INTAKE

(certain/probable/possible/unlikely/not related)
(prNeoR1, <prNeoR1>)
(String, Text)

AUTOPSY PERFORMED

(YES/NO)*
(prNeoAu1, <prNeoAu1>)
(String, Text)

CHILD 2 AGE OF NEONATE AT DEATH

(prNeoA2, <prNeoA2>)
(String, Text)

CAUSE OF DEATH

(prNeoC2, <prNeoC2>)
(String, Text)

RELATIONSHIP TO EMERGENCY CONTRACEPTION
INTAKE

(certain/probable/possible/unlikely/not related)
(prNeoR2, <prNeoR2>)
(String, Text)

AUTOPSY PERFORMED

(YES/NO)*
(prNeoAu2, <prNeoAu2>)
(String, Text)

CHILD 3 AGE OF NEONATE AT DEATH

(prNeoA3, <prNeoA3>)

(String, Text)

CAUSE OF DEATH

(prNeoC3, <prNeoC3>)

(String, Text)

RELATIONSHIP TO EMERGENCY CONTRACEPTION

INTAKE

(certain/probable/possible/unlikely/not related)

(prNeoR3, <prNeoR3>)

(String, Text)

AUTOPSY PERFORMED

(YES/NO)*

(prNeoAu3, <prNeoAu3>)

(String, Text)

APGAR SCORES

CHILD 1 APGAR1 MIN

(prApN1_1, <prApN1_1>)

(String, Text)

APGAR 5 MIN

(prApN5_1, <prApN5_1>)

(String, Text)

CHILD 2 APGAR1 MIN

(prApN1_2, <prApN1_2>)

(String, Text)

APGAR 5 MIN

(prApN5_2, <prApN5_2>)

(String, Text)

CHILD 3 APGAR1 MIN

(prApN1_3, <prApN1_3>)

(String, Text)

APGAR 5 MIN

(prApN5_3, <prApN5_3>)

(String, Text)

Please describe below any maternal and/or family history

of congenital anomaly

(prHistN, <prHistN>)

(String, MultiLineText)

Please describe below any other significant maternal
and/or family history

(prSgMatN, <prSgMatN>)

(String, MultiLineText)

Other comments

(prOcomN, <prOcomN>)

(String, MultiLineText)

Thank you for completing this form.

Pregnancy Collection Form

(emergency contraception)

page : 6 of 6

Patient ID: Initials

(prPIDin6, <prPIDin6>)

(String, Text)

Date of birth:

(prDOB6, <prDOB6>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

For internal use only : Case No:HRA-

(prCsNo6, <prCsNo6>)

(String, Text)

TO COMPLETE IN CASE OF FOETAL LOSS

Pregnancy term (in weeks)

(prTrmDI6, <prTrmDI6>)

(String, Text)

Number of fetus :

(prNoCb6, <prNoCb6>)

(String, Text)

FACTORS THAT MAY HAVE HAD AN IMPACT ON
FOETAL LOSS

1

(prFctLs1, <prFctLs1>)

(String, Text)

2

(prFctLs2, <prFctLs2>)

(String, Text)

3

(prFctLs3, <prFctLs3>)

(String, Text)

4

(prFctLs4, <prFctLs4>)

(String, Text)

5

(prFctLs5, <prFctLs5>)

(String, Text)

In case of ectopic pregnancy, please specify below:

(prEctc, <prEctc>)

(String, MultiCheckbox)

☐ Salpingitis or known tubal anomaly (1)

☐ Previous ectopic pregnancy (2)

☐ Previous tubal surgery (3)

RELATIONSHIP BETWEEN FOETAL LOSS AND
EMERGENCY CONTRACEPTION INTAKE

(certain / probable / possible / unlikely / not related)

(prLossR, <prLossR>)

(String, Text)

Please describe below any maternal and/or family history
of foetal loss

(prHistL, <prHistL>)

(String, MultiLineText)

Please describe below any other significant maternal
and/or family history

(prSgMatL, <prSgMatL>)

(String, MultiLineText)

FOETAL LOSS COMPLICATIONS

Any vaginal bleeding?

(prVB, <prVB>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, please specify:

(prVBS, <prVBS>)

(Integer, RadioCheckbox)

☐ Spotting (1)

☐ Regular (2)

☐ Heavy (3)

Duration of bleedings:

(prVBD, <prVBD>)

(String, Text)

Were the bleedings clinically excessive?

(prVBex, <prVBex>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

Need for curettage?

(prNeCu, <prNeCu>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, please specify the gestational age:

(prNeCuS, <prNeCuS>)

(String, Text)

The curettage was performed:

(prNeCuP, <prNeCuP>)

(Integer, RadioCheckbox)

☐ following the usual protocol (1)

☐ because you were worried about excessive bleeding (2)

Any infection?

(prInfC, <prInfC>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

Location of infection

(prInfCL, <prInfCL>)

(String, Text)

Infectious agent

(prInfCL, <prInfCL>)

(String, Text)

Treatment given

(prInfCT, <prInfCT>)

(String, Text)

Was the infection a complication of pregnancy loss?

(prInfCC, <prInfCC>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

Any other complication?

(prOthC, <prOthC>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, please describe:

(prOthCD, <prOthCD>)

(String, MultiLineText)

Was a pathologic examination of the products of
conception performed

(prExPr, <prExPr>)

(Integer, RadioCheckbox)

☐ No (1)

☐ Yes (2)

, date:

(prExPrD, <prExPrD>)

(PartialDate, PartialDate)



(dd[UNK]-MMM[UNK]-yyyy)

What were the findings:

(prExPrF, <prExPrF>)

(String, MultiLineText)

Please Provide a copy of the medical report(s) of this
exam together with this completed form

OTHER COMMENTS

(prOcom6, <prOcom6>)

(String, MultiLineText)

Thank you for completing this form.

25 FINAL SUBJECT DISPOSITION – ENROLLED SUBJECTS

(fDisp, <fDisp>)

25 FINAL SUBJECT DISPOSITION – ENROLLED SUBJECTS

Date of Final Disposition

(fDispDt, <fDispDt>)

(Date, Text)

(dd-MMM-yyyy)

Interviewer: Select a final disposition for the subject.

Check only one

(fDispo, <fDispo>)

(Integer, RadioCheckbox)

☐ Completed subject (all data collected) (1)

☐ Completed subject subject with partial missing data: (2)

☐ Lost to follow-up (3)

☐ Subject withdrew consent (do not contact) (4)

☐ Subject withdrew due to an AE (5)

☐ Subject withdrew for other reasons. (6)

☐ Other: (7)

☐ Subject death (8)

If Other, please specify:

(fDispoO, <fDispoO>)

(String, Text)

.

(fDispoW, <fDispoW>)

(Integer, RadioCheckbox)

☐ Investigator decision (1)

☐ Subject Physician decision (2)

☐ Protocol violation (3)

.

(fDispoM2, <fDispoM2>)

(String, MultiCheckbox)

☐ PG test results unknown (1)

☐ PG test results known, but test was taken prior to EOS window; further subject data unable to be collected via follow-up (5)

☐ Missing Week 2 interview (2)

☐ Missing Week 6 interview (3)

☐ Missing EOS interview (4)

Liver Follow-up

(livF, <livF>)

Sub Forms

LIVER-SPECIFIC ADVERSE EVENT NURSE INTERVIEW

LIVER TEST

LIVER TEST 2

LIVER-SPECIFIC ADVERSE EVENT NURSE INTERVIEW

(livFU, <livFU>)

SECTION 2: LIVER-SPECIFIC ADVERSE EVENT NURSE INTERVIEW

S2:Q1 Interviewer: Please indicate if this is a current subject or a completed/withdrawn subject?

(subType, <subType>)

(Integer, RadioCheckbox)

☐ Current as of 1/18/2018 (1)

☐ Completed/Withdrawn as of 1/18/2018 (2)

S2:Q2 If Box 1 to S2:Q1 Interviewer: Please indicate if this is being conducted as part of a regularly scheduled interview or an extra interview?

(subTypeA, <subTypeA>)

(Integer, RadioCheckbox)

☐ Extra: Before Week 2 (1)

☐ Regular: Week 2 (2)

☐ Extra: Between Week 2 and Week 6 (3)

☐ Regular: Week 6/EOS (4)

☐ Extra: After Week 6/EOS (5)

If Box 1 to S2:Q1 and Box 1,3 or 5 to S2:Q2 Read: **Hello, my name is _____.** I am a nurse from PEGUS Research calling about the study that you enrolled in at (study site) on (date of enrollment). This is not one of the previously scheduled follow-up interviews as part of the study, but I have a few questions for you and some information about the study. This usually takes about 10 minutes and you will be paid an additional \$25 for your time. May I go ahead now? (If no, ask when would be a good time to call back)

(IAEint1, <IAEint1>)

(String, PlainText)

If Box 2 to S2:Q1 Read: **Hello, my name is _____.** I am a nurse from PEGUS Research calling about the study that you participated in beginning on (date of enrollment). I know that you have finished your participation, however the US Food and Drug Administration asked us to recontact subjects who were in the study to ask a few additional questions. This usually takes about 10 minutes and you will be paid an additional \$25 for your time. May I go ahead now? (If no, ask when would be a good time to call back)

(IAEint2, <IAEint2>)

(String, PlainText)

Subject Number:

(IAESub, <IAESub>)

(String, Text)

Date of interview:

(IAEDT, <IAEDT>)

(dd-MMM-yyyy)

(Date, Text)

Adverse Event Trigger Questions

These questions should be asked of everybody to determine if any adverse events need to be recorded. Do not repeat these questions if being conducted as part of a regularly scheduled interview.

Read: **First, I'm going to ask you some questions about any health problems you may have had since you enrolled in the study.**

Since you enrolled in the ella study, have you been to the doctor for any reason you haven't previously told us about?

Since you enrolled in the ella study, have you developed any new medical problems you haven't previously told us about?

Since you enrolled in the ella study, have you been to a hospital as a patient for any reason that you haven't previously told us about?

Based on the responses to all questions, go to the Adverse Events Form and complete as necessary.

S2:Q3 Interviewer: Did the subject, during this interview or any previous interview, specifically report liver-related adverse events or report any of the following non-specific symptoms: fatigue, weakness, nausea, vomiting, poor appetite, abdominal pain (right upper quadrant pain or tenderness), jaundice, dark urine, fever, rash, or itching that is not adequately explained by another reported adverse event?

(IAErep, <IAErep>)

(Integer, RadioCheckbox)

☐ Yes If Yes to S2:Q3 , go to the Adverse Events Form and complete as necessary. (1)

☐ No (2)

If Yes to S2:Q3 , go to the Adverse Events Form and complete as necessary.

S2:Q4 Since you enrolled in the ella study, have you had any of the following symptoms?

☐ Yes (1)

☐ No (2)

Read answer options and check Yes or No for each A

Unusual fatigue

(IAEsA, <IAEsA>)

(Integer, RadioCheckbox)

If yes, select AE

(IAEsAref, <IAEsAref>)
(Reference, Select)

Sample reference 1 ()
Sample reference 2 ()
Sample reference 3 ()
(/use/aesum/ae[n])

B Weakness

(IAEsB, <IAEsB>)
(Integer, RadioCheckbox)

☐ Yes (1)
☐ No (2)

If yes, select AE

(IAEsBref, <IAEsBref>)
(Reference, Select)

Sample reference 1 ()
Sample reference 2 ()
Sample reference 3 ()
(/use/aesum/ae[n])

C Nausea

(IAEsC, <IAEsC>)
(Integer, RadioCheckbox)

☐ Yes (1)
☐ No (2)

If yes, select AE

(IAEsCref, <IAEsCref>)
(Reference, Select)

Sample reference 1 ()
Sample reference 2 ()
Sample reference 3 ()
(/use/aesum/ae[n])

D Vomiting

(IAEsD, <IAEsD>)
(Integer, RadioCheckbox)

☐ Yes (1)
☐ No (2)

If yes, select AE

(IAEsDref, <IAEsDref>)
(Reference, Select)

Sample reference 1 ()
Sample reference 2 ()
Sample reference 3 ()
(/use/aesum/ae[n])

E Loss of appetite

(IAEsE, <IAEsE>)
(Integer, RadioCheckbox)

☐ Yes (1)
☐ No (2)

If yes, select AE

(IAEsEref, <IAEsEref>)
(Reference, Select)

Sample reference 1 ()
Sample reference 2 ()
Sample reference 3 ()
(/use/aesum/ae[n])

F Abdominal pain below your ribs on the right side

☐ Yes (1)

(IAEsF, <IAEsF>)
(Integer, RadioCheckbox)

If yes, select AE

(IAEsFref, <IAEsFref>)
(Reference, Select)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

G Jaundice, or yellowing of the skin or eyes

(IAEsG, <IAEsG>)
(Integer, RadioCheckbox)

If yes, select AE

(IAEsGref, <IAEsGref>)
(Reference, Select)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

H Dark urine

(IAEsH, <IAEsH>)
(Integer, RadioCheckbox)

If yes, select AE

(IAEsHref, <IAEsHref>)
(Reference, Select)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

I Fever

(IAEsI, <IAEsI>)
(Integer, RadioCheckbox)

If yes, select AE

(IAEsIref, <IAEsIref>)
(Reference, Select)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

J Rash

(IAEsJ, <IAEsJ>)
(Integer, RadioCheckbox)

If yes, select AE

(IAEsJref, <IAEsJref>)
(Reference, Select)

☐ Yes (1)

☐ No (2)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

K Itching

(IAEsK, <IAEsK>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

If yes, select AE

(IAEsKref, <IAEsKref>)

(Reference, Select)

Sample reference 1 ()

Sample reference 2 ()

Sample reference 3 ()

(/use/aesum/ae[n])

If Yes to any of S2:Q4 , go to the Adverse Events Form and complete as necessary.

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

S2:Q5 If yes to any of S2:Q4: Interviewer: Are any of the above ongoing?

Do not read answer options

Check only one

(IAEong, <IAEong>)

(Integer, RadioCheckbox)

S2:Q6 If yes to any of S2:Q4: **Have you spoken to a healthcare provider about those symptoms?**

Do not read answer options

Check only one

(IAEspk, <IAEspk>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

S2:Q6a If S2:Q6 =Yes: **What did your healthcare provider tell you about it?**

Probe: Probe to get as much information as possible with neutral questions such as “did they give you a diagnosis?” or “anything else?”

Record verbatim response

(IAEtel, <IAEtel>)

(String, MultiLineText)

If Yes to S2:Q5 and No to S2:Q6 Read: **Since you are continuing to have those symptoms, we recommend you see a healthcare provider about them.**

(IAEhc, <IAEhc>)

(String, PlainText)

S2:Q7 Do you have any tablets of the study drug ella left, or any packaging from the study product?

Do not read answer options

Check only one

(IAEtab, <IAEtab>)

(Integer, RadioCheckbox)

☐ Yes, drug (1)

☐ Yes, packaging only (2)

☐ No (3)

☐ Don't know (4)

If Box 1 to S2:Q7 Read: **Please do not take any more tablets of the study drug that you still have. Also, please return any unused tablets and packaging to PEGUS Research right away using the envelope provided to you when you enrolled. You will be reimbursed for your unused study drug.**

(tabTx1, <tabTx1>)

(String, PlainText)

If Box 2 to S2:Q7 Read: **Please return any packaging to PEGUS Research right away using the envelope provided to you when you enrolled.**

(tabTx2, <tabTx2>)

(String, PlainText)

If Box 2 to S2:Q1 Read: **The reason that the FDA asked us to recontact you to answer these questions is because of four reports of serious liver injury in Europe among women taking Esmya, which is ulipristal acetate 5 mg every day to treat uterine fibroids. It is unknown at this time whether that liver damage is related to that medicine or not. No cases of serious liver injury have been reported with ella, which is ulipristal acetate 30 mg, when used for emergency contraception. Thank you for your time today. Your compensation for this interview will come to you in the (mail in the next 2 weeks) or (as an e-card in your email in the next week). End of call.**

(tabTx3, <tabTx3>)

(String, PlainText)

If Box 1 to S2:Q1 Read: **FDA asked us to contact you to answer these questions because of four reports of serious liver injury in Europe among women taking Esmya, which is ulipristal acetate 5 mg every day to treat uterine fibroids. It is unknown at this time whether that liver damage is related to that medicine or not. No cases of serious liver**

☐ Yes (1)

☐ No (2)

☐ Don't know / Refused (3)

injury have been reported with ella, which is ulipristal acetate 30 mg, when used for emergency contraception. However, because of this concern, FDA also asked us to conduct a blood test to check the liver function of all subjects who are still participating or recently finished participating in the study. This would involve another visit to the clinic where you enrolled in the study to have some blood drawn. The visit would be brief, and you would be compensated \$150 for your time to do this.

S2:Q8 If Box 1 to S2:Q1 **Are you willing to return to the site for a blood test to check your liver function?**

Do not read answer options

Check only one

(IAErtn, <IAErtn>)

(Integer, RadioCheckbox)

If No to S2:Q8 skip to the end of the interview, just after

S2:Q12

(IAErtnN, <IAErtnN>)

(String, PlainText)

If Yes to S2:Q8 Read: **Great, thank you. I have just a few additional questions for you and then I will give you instructions about how to schedule an appointment to go back to the site for the blood draw.**

(IAErtnY, <IAErtnY>)

(String, PlainText)

S2:Q9 Have you ever had any kind of liver disease?

☐ Yes (1)

Do not read answer options

☐ No (2)

Check only one

☐ Don't know (3)

(IAEId, <IAEId>)

(Integer, RadioCheckbox)

S2:Q9a If S2:Q9 =Yes: **Please tell me about that.**

Probe: Probe to get as much information as possible with neutral questions such as “what was your diagnosis?” “when were you diagnosed”, “do you still have it?”, etc.

Record verbatim response

(IAEIdA, <IAEIdA>)

(String, MultiLineText)

S2:Q10 Do you currently have or have you been

☐ Yes (1)

diagnosed with any of the following:

☐ No (2)

Read answer options and check Yes or No for each

A Hepatitis A

(IAEdA, <IAEdA>)

(Integer, RadioCheckbox)

start date

(IAEdAsD, <IAEdAsD>)

(Date, Text)

end date

(IAEdAeD, <IAEdAeD>)

(Date, Text)

severity, other specifics

(IAEdAos, <IAEdAos>)

(String, MultiLineText)

(dd-MMM-yyyy)

(dd-MMM-yyyy)

B Hepatitis B

(IAEdB, <IAEdB>)

(Integer, RadioCheckbox)

start date

(IAEdBsD, <IAEdBsD>)

(Date, Text)

end date

(IAEdBeD, <IAEdBeD>)

(Date, Text)

severity, other specifics

(IAEdBos, <IAEdBos>)

(String, MultiLineText)

☐ Yes (1)

☐ No (2)

(dd-MMM-yyyy)

(dd-MMM-yyyy)

C Hepatitis C

(IAEdC, <IAEdC>)

(Integer, RadioCheckbox)

start date

(IAEdCsD, <IAEdCsD>)

(Date, Text)

end date

(IAEdCeD, <IAEdCeD>)

(Date, Text)

severity, other specifics

☐ Yes (1)

☐ No (2)

(dd-MMM-yyyy)

(dd-MMM-yyyy)

(IAEdCos, <IAEdCos>)
(String, MultiLineText)

D Fatty liver disease

(IAEdD, <IAEdD>)
(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

start date

(IAEdDsD, <IAEdDsD>)
(Date, Text)

(dd-MMM-yyyy)

end date

(IAEdDeD, <IAEdDeD>)
(Date, Text)

(dd-MMM-yyyy)

severity, other specifics

(IAEdDos, <IAEdDos>)
(String, MultiLineText)

E Diabetes

(IAEdE, <IAEdE>)
(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

start date

(IAEdEsD, <IAEdEsD>)
(Date, Text)

(dd-MMM-yyyy)

end date

(IAEdEeD, <IAEdEeD>)
(Date, Text)

(dd-MMM-yyyy)

severity, other specifics

(IAEdEos, <IAEdEos>)
(String, MultiLineText)

F High cholesterol

(IAEdF, <IAEdF>)
(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

start date

(IAEdFsD, <IAEdFsD>)
(Date, Text)

(dd-MMM-yyyy)

end date

(IAEdFeD, <IAEdFeD>)

(dd-MMM-yyyy)

(Date, Text)

severity, other specifics

(IAEdFos, <IAEdFos>)

(String, MultiLineText)

G Heart attack

(IAEdG, <IAEdG>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

start date

(IAEdGsD, <IAEdGsD>)

(Date, Text)

(dd-MMM-yyyy)

end date

(IAEdGeD, <IAEdGeD>)

(Date, Text)

(dd-MMM-yyyy)

severity, other specifics

(IAEdGos, <IAEdGos>)

(String, MultiLineText)

H Other heart disease

(IAEdH, <IAEdH>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

start date

(IAEdHsD, <IAEdHsD>)

(Date, Text)

(dd-MMM-yyyy)

end date

(IAEdHeD, <IAEdHeD>)

(Date, Text)

(dd-MMM-yyyy)

severity, other specifics

(IAEdHos, <IAEdHos>)

(String, MultiLineText)

I Any autoimmune disease

(IAEdI, <IAEdI>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

start date

(IAEdIsD, <IAEdIsD>)

(Date, Text)

(dd-MMM-yyyy)

end date

(IAEdleD, <IAEdleD>)

(Date, Text)

(dd-MMM-yyyy)

severity, other specifics

(IAEdlos, <IAEdlos>)

(String, MultiLineText)

S2:Q11 Do you drink alcohol?

Do not read answer options

Check only one

(IAEalc, <IAEalc>)

(Integer, RadioCheckbox)

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

S2:Q11a If S2:Q11 =Yes: How much and how often do you drink alcohol?

Probe: Probe to get as much information as possible, including how many days of the week do they drink, how much do they typically drink when they do drink, and how often they drink to the point that they would consider themselves drunk, etc.

Record verbatim response

(IAEalcA, <IAEalcA>)

(String, MultiLineText)

S2:Q12 If Box 1, Box 2, or Box 3 to S2:Q2: Since you enrolled in this study on (date of enrollment), have you started taking any new medications?

Do not read answer options

Check only one

☐ Yes (1)

☐ No (2)

☐ Don't know (3)

Complete Concomitant Medication Form

Consider new medications or changes in medications reported, and based on the responses to all questions, go to the Adverse Events Form and complete as necessary.

(IAEnew, <IAEnew>)

(Integer, RadioCheckbox)

If Yes to S2:Q8 and Site Number IN (1002, 1004, 1005, 1006, 1007, 1008, 1015, 1016, 1017, 1018, 1037, 1038)
Read: **A member of the study staff at the clinic where you enrolled in the study will call you to schedule your appointment to have your blood drawn. This will be done**

free of charge, and you will be compensated \$150 for your time.

(IAEeTx1, <IAEeTx1>)

(String, PlainText)

If Yes to S2:Q8 and Site Number IN (1003, 1010, 1011, 1012, 1013, 1019, 1020, 1021, 1022, 1023, 1028, 1029, 1030, 1034, 1035, 1036, 1039, 1040) Read: **At the end of this call, I will transfer you over to the clinic where you enrolled in the study so you can schedule your appointment to have your blood drawn. This will be done free of charge, and you will be compensated \$150 for your time. If no one answers the phone when I transfer you, please leave a voicemail and a study staff member will call you back as soon as possible.**

(IAEeTx2, <IAEeTx2>)

(String, PlainText)

If Box 2 or 4 to S2:Q2 , finish regularly scheduled interview

(IAEeTx3, <IAEeTx3>)

(String, PlainText)

If Box 1 to S2:Q2 Read: **That concludes our telephone interview for today. Your compensation for this interview will come to you in the (mail in the next 2 weeks) or (as an e-card in your email in the next week). A nurse from PEGUS Research will contact you when it is time for your 2-week interview. Thank you for your time and have a nice day.**

(IAEeTx4, <IAEeTx4>)

(String, PlainText)

If Box 3 to S2:Q2 Read: **That concludes our telephone interview for today. Your compensation for this interview will come to you in the (mail in the next 2 weeks) or (as an e-card in your email in the next week). A nurse from PEGUS Research will contact you when it is time for your 6-week interview. Remember that the pregnancy test that you were given at the site will need to be taken just before that interview, on the date indicated on the reminder card you received when you enrolled. Thank you for your time and have a nice day.**

(IAEeTx5, <IAEeTx5>)

(String, PlainText)

If Box 5 to S2:Q2 Read: **That concludes our telephone interview for today. Your compensation for this interview will come to you in the (mail in the next 2 weeks) or (as an e-card in your email in the next week). Thank you for your time and have a nice day.**

(IAEeTx6, <IAEeTx6>)

(String, PlainText)

.

(IAENC, <IAENC>)

(Integer, RadioCheckbox)

☐ Not contacted (1)

☐ Refused Interview (2)

LIVER TEST

(livTest, <livTest>)

SECTION 2: LIVER TESTING INFORMED CONSENT

Read: Thank you for coming in today. I first want to give you some information about why you are here today. The United States Food and Drug Agency, or FDA, asked us to conduct a blood test to check the liver function of all subjects who are still participating or recently finished participating in the LIBRella emergency contraception study. The FDA's concern comes from four reports of serious liver injury in Europe among women taking Esmya, which is ulipristal acetate 5 mg taken every day to treat uterine fibroids. It is unknown at this time whether that liver damage is related to that medicine or not. No cases of serious liver injury have been reported with ella, which is ulipristal acetate 30 mg, when used for emergency contraception. You are here today to have your blood drawn for a blood liver function panel test.

Read: I would like you to read this Informed Consent Document that explains all about your participation in this study procedure today. Please read it very carefully; take as much time as you need. If you have any questions, please ask me. Also, please don't sign anything until we have a chance to talk after you've read it.

S2:Q1 Interviewer: Was the subject allowed to ask questions about the study and were questions addressed and answered to the subject's satisfaction prior to obtaining written informed consent?

(t1ask, <t1ask>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

S2:Q2 Interviewer: Did the subject (or parent/guardian of an adolescent subject) sign the informed consent document

(t1ic, <t1ic>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

S2:Q2a If Yes to S2:Q2: Record the date of consent signature.

(DD/MMM/YYYY)

(t1icDt, <t1icDt>)

(Date, Text)

(dd-MMM-yyyy)

S2:Q2b If Yes to S2:Q2: Record first initial and last name of study staff member conducting consent as qualified per the Site Signature and Responsibility Log.

(t1icInt, <t1icInt>)

(String, Text)

S2:Q3 Interviewer, if subject is \leq XX years old or enrolls

☐ Yes: Continue (1)

with a parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(t1ass, <t1ass>)
(Integer, RadioCheckbox)

S2:Q3a If Yes to S2:Q3: Record the date of consent signature.

(DD/MMM/YYYY)
(t1assDt, <t1assDt>)
(Date, Text)

☐ No: STOP here. Subject does not qualify to continue.

Compensate subject for the visit and thank them for participating. (2)

(dd-MMM-yyyy)

SECTION 3: BLOOD COLLECTION

☐ Yes (1)

☐ No (2)

Read: I have a few questions for you before we collect your blood sample.

S3:Q1 Have you used alcohol in the past week?

(t1alc, <t1alc>)
(Integer, RadioCheckbox)

S3:Q1a If Yes to S3:Q1 : How many days in the last week did you use alcohol?

days

(t1alcA, <t1alcA>)
(String, Text)

S3:Q1b If Yes to S3:Q1 : How many drinks have you had in the past week?

Interviewer: please quantify intake in "standard" drinks (where 1 standard drink=12 fl oz of regular beer/8 fl oz of malt liquor/5 fl oz of table wine/1.5 fl oz of distilled spirits)

alcohol units (standard drinks)

(t1alcB, <t1alcB>)
(String, Text)

S3:Q2 Have you used any products containing acetaminophen, which is the medicine in Tylenol and a number of other painkillers and cold preparations, in the past week?

(t1ace, <t1ace>)
(Integer, RadioCheckbox)

☐ Yes: (1)

☐ No (2)

S3:Q2a If Yes to S3:Q2: How many times in the last week did you use acetaminophen?

times

(t1aceA, <t1aceA>)

(String, Text)

Read: **As we just talked about while going over the study procedure information, I (or another member of the study staff) will now collect a sample of your blood.**

☐ Yes: Continue (1)

☐ No: Specify: (2)

S3:Q3 Interviewer: was the blood sample collected?

(t1bld, <t1bld>)

(Integer, RadioCheckbox)

Specify:

(t1bldS, <t1bldS>)

(Integer, RadioCheckbox)

☐ Study staff was unable to collect the blood sample.

STOP here. Subject does not qualify to continue.

Compensate subject. (1)

☐ Subject declined to provide a blood sample. STOP here.

Subject does not qualify to continue. (2)

S3:Q3a If Yes to S3:Q3: Record the date the blood sample was collected.

(DD/MMM/YYYY)

(t1bldDt, <t1bldDt>)

(Date, Text)

(dd-MMM-yyyy)

Read: **Thank you. Your blood sample will be sent to a laboratory for testing. It will take several days for us to obtain the results. If your results are outside of the normal ranges, a study staff member will contact you via phone and you may be asked to return for another blood liver function panel test in several weeks and to answer some additional questions related to your liver function test results.**

☐ Yes (1)

Read: **Your compensation for participating in this study procedure is a \$150 prepaid Visa card. Please note that it expires in a few months.**

Verify that script was read and compensate subject

(t1intScr, <t1intScr>)

(Integer, RadioCheckbox)

Please record the last 5 digits from the card used to compensate the subject, complete the compensation acknowledgment form with subject signature to document receipt:

(t1Cver, <t1Cver>)

(Integer, Text)

Please re-enter the last 5 digits from the card used to compensate the subject:

(t1CverV, <t1CverV>)

(Integer, Text)

SECTION 4: BLOOD LIVER FUNCTION PANEL RESULTS

(dd-MMM-yyyy)

Date of testing:

(t1bldDtT, <t1bldDtT>)

(Date, Text)

Date results entered:

(t1bldDtE, <t1bldDtE>)

(Date, Text)

Blood Liver Function Panel Results

Test

ALT

Result

(t1altR, <t1altR>)

(String, Text)

Normal Range: Lower Limit

(t1altL, <t1altL>)

(String, Text)

Normal Range: Upper Limit

(t1altU, <t1altU>)

(String, Text)

AST

Result

(t1astR, <t1astR>)

(String, Text)

Normal Range: Lower Limit

(t1astL, <t1astL>)

(String, Text)

Normal Range: Upper Limit

(t1astU, <t1astU>)

(String, Text)

Alkaline Phosphatase

Result

(t1alkR, <t1alkR>)

(String, Text)

Normal Range: Lower Limit

(t1alkL, <t1alkL>)

(String, Text)

Normal Range: Upper Limit

(t1alkU, <t1alkU>)

(String, Text)

Total bilirubin

Result

(t1bilR, <t1bilR>)

(String, Text)

Normal Range: Lower Limit

(t1bilL, <t1bilL>)

(String, Text)

Normal Range: Upper Limit

(t1bilU, <t1bilU>)

(String, Text)

S4:Q1 Blood Liver Function Panel Results Disposition

(t1livF, <t1livF>)

(Integer, RadioCheckbox)

☐ Testing completed: no follow-up testing needed (1)

☐ Testing completed: request follow-up testing (2)

☐ Testing not completed, explain: (3)

explain:

(t1livFe, <t1livFe>)

(String, Text)

SECTION 5: SUBJECT NOTIFICATION OF RESULTS

☐ Yes (1)

☐ No, explain: (2)

S5:Q1 Box 1 checked in S4:Q1 : Was subject notified that her results were normal?

(t1not, <t1not>)

(Integer, RadioCheckbox)

explain:

(t1note, <t1note>)

(String, Text)

S5:Q1a If Yes to S5:Q1 : Record the date subject was informed.

(dd-MMM-yyyy)

(DD/MMM/YYYY)

(t1notA, <t1notA>)

(Date, Text)

If results are outside of normal ranges (Box 2 checked in S4:Q1), the following script will be used to contact the subject by phone. ☐ Yes (1)

Read: **Hello, this is _____ calling with the results of your blood liver function panel testing. Your results were higher than the normal range. It is seen in about 1 out of every 10 women who are tested. On its own, that is generally not a cause for concern and can be caused by a number of things, including certain medications and alcohol use. .**

Verify that subject was notified of out of range results.

(t1rtnScr, <t1rtnScr>)

(Integer, RadioCheckbox)

Read: **We would like you to return to the research site to have your blood drawn for repeat liver function testing. This is free of charge to you, and you will be compensated \$150 for your time to do this.** ☐ Yes (1) ☐ No (2) ☐ Don't know / Refused (3)

S5:Q2 If Box 2 checked in S4:Q1: **Are you willing to return for a follow-up liver function test?**

Do not read answer options

Check only one

(t1rtn, <t1rtn>)

(Integer, RadioCheckbox)

If Yes to S5:Q2 AND Site Number IN (1003, 1004, 1005, 1006, 1007, 1008, 1010, 1011, 1012, 1013, 1015, 1016, 1017, 1018, 1019, 1020, 1021, 1022, 1023, 1034, 1035, 1037, 1038, 1039, or 1040), read: **Thank you, I can now schedule an appointment for you.**

(t1eTxt1, <t1eTxt1>)

(String, PlainText)

If Yes to S5:Q2 AND Site Number IN (1002, 1028, 1029, 1030, or 1036), read: **A member of the research staff at the site will be calling you to schedule your appointment.**

(t1eTxt2, <t1eTxt2>)

(String, PlainText)

LIVER TEST 2

(livTest2, <livTest2>)

SECTION 2: LIVER TESTING INFORMED CONSENT

Read: Thank you for coming in today. I first want to give you some information about why you are here today. The United States Food and Drug Agency, or FDA, asked us to conduct a blood test to check the liver function of all subjects who are still participating or recently finished participating in the LIBRella emergency contraception study. The FDA's concern comes from four reports of serious liver injury in Europe among women taking Esmya, which is ulipristal acetate 5 mg taken every day to treat uterine fibroids. It is unknown at this time whether that liver damage is related to that medicine or not. No cases of serious liver injury have been reported with ella, which is ulipristal acetate 30 mg, when used for emergency contraception. You are here today to have your blood drawn for a blood liver function panel test.

Read: I would like you to read this Informed Consent Document that explains all about your participation in this study procedure today. Please read it very carefully; take as much time as you need. If you have any questions, please ask me. Also, please don't sign anything until we have a chance to talk after you've read it.

S2:Q1 Interviewer: Was the subject allowed to ask questions about the study and were questions addressed and answered to the subject's satisfaction prior to obtaining written informed consent?

(t2ask, <t2ask>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

S2:Q2 Interviewer: Did the subject (or parent/guardian of an adolescent subject) sign the informed consent document

(t2ic, <t2ic>)

(Integer, RadioCheckbox)

☐ Yes: Continue (1)

☐ No: STOP here. Subject does not qualify to continue. Compensate subject for the visit and thank them for participating. (2)

S2:Q2a If Yes to S2:Q2: Record the date of consent signature.

(DD/MMM/YYYY)

(t2icDt, <t2icDt>)

(Date, Text)

(dd-MMM-yyyy)

S2:Q2b If Yes to S2:Q2: Record first initial and last name of study staff member conducting consent as qualified per the Site Signature and Responsibility Log.

(t2icInt, <t2icInt>)

(String, Text)

S2:Q3 Interviewer, if subject is \leq XX years old or enrolls

☐ Yes: Continue (1)

with a parent/guardian present: Did the adolescent subject sign assent on the informed consent document?

(t2ass, <t2ass>)
(Integer, RadioCheckbox)

S2:Q3a If Yes to S2:Q3: Record the date of consent signature.

(DD/MMM/YYYY)
(t2assDt, <t2assDt>)
(Date, Text)

☐ No: STOP here. Subject does not qualify to continue.

Compensate subject for the visit and thank them for participating. (2)

(dd-MMM-yyyy)

SECTION 3: BLOOD COLLECTION

☐ Yes: (1)

☐ No (2)

Read: I have a few questions for you before we collect your blood sample.

S3:Q1 Have you used alcohol in the past week?

(t2alc, <t2alc>)
(Integer, RadioCheckbox)

S3:Q1a If Yes to S3:Q1 : How many days in the last week did you use alcohol?

days

(t2alcA, <t2alcA>)
(String, Text)

S3:Q1b If Yes to S3:Q1 : How many drinks have you had in the past week?

Interviewer: please quantify intake in "standard" drinks (where 1 standard drink=12 fl oz of regular beer/8 fl oz of malt liquor/5 fl oz of table wine/1.5 fl oz of distilled spirits)

alcohol units (standard drinks)

(t2alcB, <t2alcB>)
(String, Text)

S3:Q2 Have you used any products containing acetaminophen, which is the medicine in Tylenol and a number of other painkillers and cold preparations, in the past week?

(t2ace, <t2ace>)
(Integer, RadioCheckbox)

☐ Yes: (1)

☐ No (2)

S3:Q2a If Yes to S3:Q2: How many times in the last week did you use acetaminophen?

times

(t2aceA, <t2aceA>)

(String, Text)

Read: **As we just talked about while going over the study procedure information, I (or another member of the study staff) will now collect a sample of your blood.**

☐ Yes: (1)

☐ No: Specify: (2)

S3:Q3 Interviewer: was the blood sample collected?

(t2bld, <t2bld>)

(Integer, RadioCheckbox)

Specify:

(t2bldS, <t2bldS>)

(Integer, RadioCheckbox)

☐ Study staff was unable to collect the blood sample.

STOP here. Subject does not qualify to continue.

Compensate subject. (1)

☐ Subject declined to provide a blood sample. STOP here.

Subject does not qualify to continue. (2)

S3:Q3a If Yes to S3:Q3: Record the date the blood sample was collected.

(DD/MMM/YYYY)

(t2bldDt, <t2bldDt>)

(Date, Text)

(dd-MMM-yyyy)

Read: **Thank you. Your blood sample will be sent to a laboratory for testing. It will take several days for us to obtain the results. If your results are outside of the normal ranges, a study staff member will contact you via phone and you may be asked to return for another blood liver function panel test in several weeks and to answer some additional questions related to your liver function test results.**

☐ Yes (1)

Read: **Your compensation for participating in this study procedure is a \$150 prepaid Visa card. Please note that it expires in a few months.**

Verify that script was read and compensate subject

(t2intScr, <t2intScr>)

(Integer, RadioCheckbox)

Please record the last 5 digits from the card used to compensate the subject, complete the compensation acknowledgment form with subject signature to document receipt:

(t2Cver, <t2Cver>)

(Integer, Text)

Please re-enter the last 5 digits from the card used to
compensate the subject:

(t2CverV, <t2CverV>)

(Integer, Text)

SECTION 4: BLOOD LIVER FUNCTION PANEL RESULTS

(dd-MMM-yyyy)

Date of testing:

(t2bldDtT, <t2bldDtT>)

(Date, Text)

Date results entered:

(t2bldDtE, <t2bldDtE>)

(Date, Text)

Blood Liver Function Panel Results

Test

ALT

Result

(t2altR, <t2altR>)

(String, Text)

Normal Range: Lower Limit

(t2altL, <t2altL>)

(String, Text)

Normal Range: Upper Limit

(t2altU, <t2altU>)

(String, Text)

AST

Result

(t2astR, <t2astR>)

(String, Text)

Normal Range: Lower Limit

(t2astL, <t2astL>)

(String, Text)

Normal Range: Upper Limit

(t2astU, <t2astU>)

(String, Text)

Alkaline Phosphatase

Result

(t2alkR, <t2alkR>)

(String, Text)

Normal Range: Lower Limit

(t2alkL, <t2alkL>)

(String, Text)

Normal Range: Upper Limit

(t2alkU, <t2alkU>)

(String, Text)

Total bilirubin

Result

(t2bilR, <t2bilR>)

(String, Text)

Normal Range: Lower Limit

(t2bilL, <t2bilL>)

(String, Text)

Normal Range: Upper Limit

(t2bilU, <t2bilU>)

(String, Text)

S4:Q1 Blood Liver Function Panel Results Disposition

(t2livF, <t2livF>)

(Integer, RadioCheckbox)

☐ Testing completed: no follow-up testing needed (1)

☐ Testing completed: request follow-up testing (2)

☐ Testing not completed, explain: (3)

explain:

(t2livFe, <t2livFe>)

(String, Text)

Form Architecture

Record

(1) SUBJECT NUMBER

(2) Programming Vars (DON'T MAKE VISIBLE)

(3) *Enrollment*

(1) *3 SCREENING*

(2) *4 PURCHASE QUESTION / 5 REASON FOR PURCHASE / 6 DEMO*

(3) *7 CURRENT / REGULAR RELEVANT MEDICATIONS AND ASSOCIATED CONDITIONS*

(4) *8 REALM TEST*

(5) *9 REALM TEEN TEST*

(6) *11 INFORMED CONSENT*

(7) *12 ENROLLMENT PREGNANCY TEST*

(8) *13 MEDICATIONS AT ENROLLMENT*

(9) *14 CONTACT INFORMATION AND PURCHASE TRANSACTION*

(10) *15 DRUG PURCHASE LOG*

(11) *16 DRUG RETURN LOG*

(12) *17 ENROLLMENT END-OF-STUDY QUESTIONS*

(13) *18 FINAL SUBJECT ENROLLMENT DISPOSITION*

(4) *Use*

(1) *19 NURSE FOLLOW-UP INTERVIEW (WEEK 2)*

(2) *20 CONCOMITANT MEDICATIONS*

(3) *21 NURSE FOLLOW-UP INTERVIEW (WEEK 6)*

(4) *22 END-OF-STUDY OR EARLY TERMINATION INTERVIEW*

(5) *23 END OF STUDY PREGNANCY TEST RESULTS*

(6) *24 AE / SAE / EIU FORMS*

[*24 AE / SAE / EIU FORMS*]

(7) *Pregnancy Collection Form (emergency contraception)*

(8) *25 FINAL SUBJECT DISPOSITION – ENROLLED SUBJECTS*

(5) *Liver Follow-up*

(1) *LIVER-SPECIFIC ADVERSE EVENT NURSE INTERVIEW*

(2) *LIVER TEST*

(3) *LIVER TEST 2*