|  |
| --- |
| **Instructions:** Assess the participant’s baseline medical history using this guide. If the participant has any condition that is grade 1 or higher, or if determined relevant by the clinician, document on the **Medical History CRF** including the description, onset/outcome date(s), and severity grade. Add any associated medications the participant is currently taking on the **Concomitant Medications Log CRF.** |
| **General Medical History** |
| * Does the participant have any health problems?
* Has the participant ever been hospitalized for any reason other than giving birth?
* Has the participant ever had surgery, including a hysterectomy?
* In the past year, has the participant been to the emergency room?
* Has the participant had any medical or health problems in the past year?
* Has the participant had a gynecologic or genital procedure (tubal ligation, dilation and curettage, piercing) in the last 45 days?
 |
|
|
|
|
| **Body System Medical History** |
| Assess any significant medical problems involving the following organ/systems.  |
| * Head, Eyes, Ears, Nose and Throat (HEENT)
* Gastrointestinal (GI)
* Lymphatic
* Cardiovascular
* Liver
* Respiratory
* Renal
* Musculoskeletal
* OB/GYN (genital bleeding not associated with menses or childbirth, uterine fibroids, abnormal PAP, genital infection, hysterectomy e.g. uterus, at least one ovary)
 | * Breast
* Skin
* Neurologic
* Endocrine/Metabolic
* Hematologic
* Cancer
* Allergies
* Mental Illness
* Alcohol / Recreational Drug Use
* STI/RTI (HPV, HSV, GC/CT, Syphilis, Trichomoniasis, Candidiasis, PID)
* Any other health issues
 |
| **Female Symptoms/Diagnoses**  |
| Assess experiences of any significant medical problems involving the following organ system/disease. |
| * Pelvic inflammatory disease
* Genital/vaginal warts
* Abnormal pap smear
 |
| In the past 3 months ask if the participant has experienced any of the following genital symptoms. |  |  |
| * Genital/vaginal burning
 | * Post-coital bleeding (bleeding after sex)
 |
| * Genital/vaginal itching
 | * Genital/vaginal pain not during sex
 |
| * Genital/vaginal pain during sex
 | * Abnormal genital/vaginal discharge
 |
| * Genital/vaginal burning
 | * Unusual genital/vaginal odor
 |
| * Genital/vaginal itching
 | * Dysuria
 |
| * Genital/vaginal pain during sex
 |  |
| Assess menstruation patterns. Document in chart notes or other site-specific form and, as applicable, on the **Medical History CRF.** |
| * First and last day of last menstrual period
* Any additional details as needed to describe the participant's baseline menstrual bleeding pattern

*NOTE: For the purposes of scheduling enrollment visit (if otherwise eligible), discuss when the participant anticipates her next menses to start/end, as applicable. Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-4 (Days 0, 1, and 7).* |
|