

**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 **Baseline Medical History Log 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, genital, or rectal procedure (tubal ligation, dilation and curettage, piercing, hemorrhoidal resection, polyp removal) in the last 60 days?
- Has the participant had a rectal biopsy in the last 7 days?

### Body System Medical History

Assess any significant medical problems involving the following organ/systems.

- |   |  |
|---|--|
| • Head, Eyes, Ears, Nose and Throat (HEENT) | • Neurologic                                     |
| • Lymphatic                                 | • Endocrine/Metabolic                            |
| • Cardiovascular                            | • Hematologic                                    |
| • Liver                                     | • Cancer   |
| • Respiratory                               | • Allergies                                      |
| • Renal (including urinary symptoms)        | • Drug allergies                                 |
| • Musculoskeletal                           | • Mental Illness                                 |
| • Gastrointestinal (GI)                     | • Alcohol / Recreational Drug Use                |
| • Prostrate                                 | • Inflammatory bowel disease                     |
| • Breast                                    | • (Ulcerative colitis or crohns disease)         |
| • Gynecologic                               | • STI/RTI (HPV, HSV, GC/CT, Syphilis,            |
| • Anorectal                                 | Trichomoniasis, Candidiasis, BV, chancroid, PID) |
| • Skin                                      | • Any other health issues                        |

### Anogenital Symptoms/Diagnoses

Assess any previous or current experience of any anogenital symptoms/diagnoses.

- |                                   |                           |
|-----------------------------------|---------------------------|
| • Anal or genital sores or ulcers | • Anal or genital warts   |
| • Dysuria or urethral burning     | • Anal fissures           |
| • Anal pain                       | • Hemorrhoids             |
| • Anorectal Bleeding              | • Urinary tract infection |
| • Anal or rectal abscesses        | • Excessive anal itching  |
| • Urethral or anal discharge      | • Excessive flatulence    |

(Genital Symptoms/Diagnoses - FEMALE ONLY, on next page)

<b>FEMALE ONLY – Genital Symptoms/Diagnoses</b> <input type="checkbox"/> N/A	
Assess experiences of any significant medical problems involving the following organ system/disease.	
<ul style="list-style-type: none"> <li>• Pelvic inflammatory disease</li> <li>• Genital/vaginal warts</li> <li>• Abnormal pap smear</li> </ul>	
In the <u>past 3 months</u> ask if the participant has experienced any of the following genital symptoms.	
<ul style="list-style-type: none"> <li>• Genital/vaginal burning</li> <li>• Genital/vaginal itching</li> <li>• Genital/vaginal pain during sex</li> <li>• Genital/vaginal burning</li> <li>• Genital/vaginal itching</li> <li>• Genital/vaginal pain during sex</li> </ul>	<ul style="list-style-type: none"> <li>• Post-coital bleeding (bleeding after sex)</li> <li>• Genital/vaginal pain not during sex</li> <li>• Abnormal genital/vaginal discharge</li> <li>• Unusual genital/vaginal odor</li> <li>• Dysuria</li> </ul>
Assess menstruation patterns. Document in chart notes and, as applicable, on the Baseline Medical History CRF.	
<ul style="list-style-type: none"> <li>• First and last day of last menstrual period</li> <li>• Any additional details as needed to describe the participant's baseline menstrual bleeding pattern</li> </ul>	
<p><i>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, menses should coincide with the 2 to 6 week washout period follow each dosing visit (V 3, 5 and 7), therefore participant's menstrual cycle must be considered when scheduling the Enrollment Visit (Visit 2).</i></p>	