

Condition	Recommended AE Text	Notes
Abnormal vaginal discharge		
Clinician-observed only Trich neg; BV and candida may be pos or neg	“Vaginal discharge – clinician-observed”	Document discharge on Pelvic Exam Diagrams
Clinician-observed only Trich positive	“Vaginal Trichomoniasis”	Document discharge on Pelvic Exam Diagrams. Note report of discharge in AE Log “Comments” section
Participant-reported only Trich, BV, and candidiasis all neg	“Vaginal discharge – participant reported”	
Participant-reported and clinician-observed with same severity grade, Trich, BV, and candidiasis all neg	“Vaginal discharge – participant reported”	Document discharge on Pelvic Exam Diagrams
Participant-reported and Trich, BV or candidiasis positive Discharge may or may not be observed by a clinician.	“Symptomatic bacterial vaginosis” or “Vulvovaginal candidiasis” or “Vaginal trichomoniasis”	Note report of discharge in AE Log “Comments” section.
Abdominal Pain		
Gastrointestinal in nature with no other unifying diagnosis	“abdominal pain” or “lower abdominal pain”	Record on GAE if Grade 1
Genitourinary	Use text that describes the pain, for example, “bladder pain”	
Reproductive	Use text that describes the pain, for example, “Adnexal pain” or “uterine pain:	
Pain that cannot be localized	Use terms that identify a reproductive or genitourinary anatomical location, such as “pelvic pain”, “urinary tract pain”, or other descriptive text that includes location	
STIs/Genital Infections		
Asymptomatic syphilis (positive screening and confirmatory results) with treatment initiated	“syphilis infection”	If recorded as Baseline Medical Condition, note in comments of condition entry information on treatment.

Symptomatic bacterial vaginosis	“symptomatic bacterial vaginosis”	Only report symptomatic infections that are confirmed with saline wet mount testing and fulfilling Amsels criteria as AEs.
Condition	Recommended AE Text	Notes
Symptomatic vaginal candidiasis	“Vulvovaginal candidiasis”	
Trichomoniasis	“Vaginal trichomoniasis”	Must be Grade 2
Chlamydia	“Genitourinary chlamydia infection”	
Gonorrhea	“Genitourinary gonorrhea infection”	
Dyspareunia, erythema, edema, tenderness, and/or discharge (any two or more) without laboratory testing that the presence of an STI/RTI	“Cervicitis”	
Combinations of vulvar and vaginal pain, itching, erythema, edema, rash, tenderness, (any two or more) without laboratory testing confirming the presence of STI/RTI	“Vulvovaginitis”	
Genital herpes outbreak with laboratory testing of characteristic ulcerative or vesicular lesions confirmed by culture, PCR, Tzanck prep or other diagnostic test of lesion or previous type-specific serology.	“Genital herpes”	
Genital wart outbreaks	“Condyloma” with anatomical location	Grade according to the “Condyloma” row of the FGGT. Report all outbreaks of genital warts as AEs, regardless of whether infection with HPV was known to be pre-existing before enrollment.
Genital ulcer disease (herpes and syphilis testing negative or not performed)	“Ulcer” with anatomical location specified (vulvar, vaginal, etc.)	
Other AEs		
AEs in pregnancy participants, including complications associated with pregnancy or pregnancy outcome/delivery	See SSP Section 11.3.4 for detailed guidance; may use “pre-term labor” as AE text when applicable	
Grade 1 or higher pap test result	Use actual result as AE text (LSIL, for	

	example)	
Assault	Report each physical sequela as a separate AE using the appropriate description of each physical sequela within the AE text item. See section 11.3.9.	
Weight Loss	"Weight loss abnormal"	Weight loss is reportable as an AE only if it is considered potentially deleterious to the participant's health by either the participant or the site clinician. Add a comment to the AE log CRF to document that the weight loss is considered deleterious to the participant's health.