

MTN-035 AE Text Guidance

Condition	Recommended AE Text	Notes
Abdominal Pain		
Gastrointestinal in nature with no other unifying diagnosis	“abdominal pain”	
Genitourinary in nature and a specific anatomic location is known	Use term that describes the anatomic location, for example, “bladder pain”	
Pelvic or reproductive in nature and a specific anatomic location is known	Use term that describes the anatomic location, for example, “adnexal pain” or “uterine pain”	
Pain associated with menstruation	“dysmenorrhea”	
Pain that cannot be localized to a specific organ, but is believed to be gynecologic in origin	Use term that identify a reproductive or genitourinary anatomical location, for example, “pelvic pain” or “urinary tract pain”	
Anorectal in nature and a specific anatomic location is known	Use term that describes the anatomic location, for example, “anal pain,” “proctalgia” or “rectal pain”	
Discharge		Grade all per appropriate row in the FGGT or MGGT.
Vaginal/urethral discharge, participant report only	“vaginal discharge- participant reported” or “urethral discharge- participant reported”	
Vaginal/urethral discharge, clinician observed only	“vaginal discharge- clinician observed” or “urethral discharge- clinician observed”	
Vaginal/urethral discharge present both by participant report and on examination	Only report the one with the most severe grade. If they are the same grade, report “vaginal discharge- participant report” or “urethral discharge- participant report.”	
Vaginal/urethral discharge as a symptom of an overall diagnosis	Report the diagnosis as the AE	Discharge (and any other associated signs and symptoms) should be documented in the comments section

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STIs/RTIs		
Chlamydia	For genital infection, report “genitourinary chlamydia infection.” For rectal infection, report “rectal chlamydia.”	
Gonorrhea	For genital infection, report “genitourinary gonorrhea infection.” For rectal infection, report “rectal gonorrhea.”	
Genital herpes (confirmed by laboratory testing)	“genital herpes”	Laboratory testing is required in order to use the term “genital herpes” for AE reporting. This testing is not required per protocol and should only be done if clinically indicated. Any new lesion/ulcer observed during the study should be reported as an AE even if thought to be due to prior herpes diagnosis/infection
Suspected genital herpes outbreak	Use the term marked on the Anorectal Exam CRF or the Pelvic Exam CRF (as applicable) describing the lesion together with the anatomical location, for example, “anal ulcer” or “vaginal blister”	
Genital warts	Use the term “external” or “internal” and “condyloma” and include the anatomical location of the warts, for example, cervical, vaginal or perianal.	Report all outbreaks of genital warts as AE, regardless of whether infection with HPV was known to be pre-existing before enrollment/randomization
Syphilis (confirmed by laboratory testing)	“syphilis infection”	Contact the MTN-035 PSRT in the event a participant has a positive treponemal test and a negative non-treponemal test, as this could represent late latent syphilis

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Bacterial Vaginosis (symptomatic)	"symptomatic bacterial vaginosis"	Only report symptomatic infections that are confirmed with saline wet mount testing and fulfilling Amsel's criteria as AEs Asymptomatic BV will not be a reportable AE, but a diagnosis will be captured on the STI Test Results CRF
Candidiasis (symptomatic)	"vulvovaginal candidiasis"	Only report symptomatic infections that are confirmed with KOH wet prep and/or culture as AEs. Asymptomatic candida will not be a reportable AE, but a diagnosis will be captured on the STI Test Results CRF
Absence of a laboratory-confirmed STI/RTI diagnosis. Two or more of the genital/vaginal signs or symptoms listed below are present <ul style="list-style-type: none"> • pain • itching • erythema • edema • rash • tenderness • discharge 	"vulvovaginitis"	Comment on the individual signs/symptoms in the comments field of the AE log CRF
Absence of a laboratory-confirmed STI/RTI diagnosis. Two or more of the genital/vaginal signs or symptoms listed below are present <ul style="list-style-type: none"> • dyspareunia • erythema • edema • tenderness • discharge 	"cervicitis"	Comment on the individual signs/symptoms in the comments field of the AE log CRF

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Other AEs		
Sexual assault with physical sequelae	Each physical sequela resulting from a sexual assault should be reported as its own AE, with sexual assault (and additional details, if applicable), referenced in the comments section	Do not complete a separate AE log form with “sexual assault” as the AE term
Sexual assault without any physical sequelae	Report the event as “sexual assault”	Consult the PSRT if there are any questions about classification or documentation of a sexual assault