

S4 Table. Summary for Adverse Event Occurrence Rates by Sequence Assignment

MedDRA Preferred Term	Reported Severity (DAIDS Grade)	Group A N=87	Group B N=82	Total N=169
Participant with Any Adverse Event		73 (83.9%)	65 (79.3%)	138 (81.7%)
ABDOMINAL MASS	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
ABDOMINAL PAIN	Grade 1,2,3	4 (4.6%)	0 (0.0%)	4 (2.4%)
ABDOMINAL PAIN LOWER	Grade 1,2	6 (6.9%)	2 (2.4%)	8 (4.7%)
ABDOMINAL PAIN UPPER	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
ABDOMINAL TENDERNESS	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
ABSCESS LIMB	Grade 2	2 (2.3%)	0 (0.0%)	2 (1.2%)
ADNEXA UTERI PAIN	Grade 1	0 (0.0%)	2 (2.4%)	2 (1.2%)
ANXIETY	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
APPENDICITIS	Grade 3	1 (1.1%)	0 (0.0%)	1 (0.6%)
ARTHRALGIA	Grade 2	0 (0.0%)	1 (1.2%)	1 (0.6%)
ASCARIASIS	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
ASTHMA	Grade 1	1 (1.1%)	1 (1.2%)	2 (1.2%)
BACK PAIN	Grade 1	2 (2.3%)	1 (1.2%)	3 (1.8%)
BREAST PAIN	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
BRONCHIAL HYPERREACTIVITY	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
BRONCHITIS	Grade 2	5 (5.7%)	3 (3.7%)	8 (4.7%)
CERVICAL DISCHARGE	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
CERVICITIS	Grade 1,2	0 (0.0%)	1 (1.2%)	1 (0.6%)
CERVIX ERYTHEMA	Grade 1	2 (2.3%)	1 (1.2%)	3 (1.8%)
CERVIX HAEMORRHAGE UTERINE	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
CHEST PAIN	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
COITAL BLEEDING	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
CONSTIPATION	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)

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CONTUSION	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
CONVERSION DISORDER	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
COUGH	Grade 1,2	4 (4.6%)	0 (0.0%)	4 (2.4%)
CYSTITIS	Grade 1,2,3	3 (3.4%)	1 (1.2%)	4 (2.4%)
DEAFNESS UNILATERAL	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
DEPRESSION	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
DERMATITIS ALLERGIC	Grade 1,2	1 (1.1%)	1 (1.2%)	2 (1.2%)
DIARRHOEA	Grade 1,2	2 (2.3%)	4 (4.9%)	6 (3.6%)
DIZZINESS	Grade 1	2 (2.3%)	1 (1.2%)	3 (1.8%)
DYSENTERY	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
DYSMENORRHOEA	Grade 1,2	5 (5.7%)	3 (3.7%)	8 (4.7%)
DYSPAREUNIA	Grade 1	1 (1.1%)	1 (1.2%)	2 (1.2%)
DYSURIA	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
EAR PAIN	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
EAR PRURITUS	Grade 2	0 (0.0%)	1 (1.2%)	1 (0.6%)
ECZEMA	Grade 1,2	2 (2.3%)	0 (0.0%)	2 (1.2%)
EPISTAXIS	Grade 1	1 (1.1%)	1 (1.2%)	2 (1.2%)
FATIGUE	Grade 1,2	1 (1.1%)	1 (1.2%)	2 (1.2%)
FIBROADENOMA OF BREAST	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
FOLLICULITIS	Grade 1	2 (2.3%)	1 (1.2%)	3 (1.8%)
FOOT FRACTURE	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
GASTRITIS	Grade 1,2	0 (0.0%)	2 (2.4%)	2 (1.2%)
GASTROENTERITIS	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
GASTROENTERITIS SHIGELLA	Grade 2	1 (1.1%)	1 (1.2%)	2 (1.2%)

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GENITAL BURNING SENSATION	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
GENITAL DISCOMFORT	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
GENITAL EROSION	Grade 1	2 (2.3%)	1 (1.2%)	3 (1.8%)
GENITAL ERYTHEMA	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
GENITAL HERPES	Grade 1,2	4 (4.6%)	0 (0.0%)	4 (2.4%)
GENITAL PAIN	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
GINGIVAL ULCERATION	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
GONORRHOEA	Grade 1,2	3 (3.4%)	3 (3.7%)	6 (3.6%)
GYNAECOLOGICAL CHLAMYDIA INFECTION	Grade 1,2	10 (11.5%)	5 (6.1%)	15 (8.9%)
HAEMORRHOIDS	Grade 1,2	0 (0.0%)	1 (1.2%)	1 (0.6%)
HEAD INJURY	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
HEADACHE	Grade 1,2	15 (17.2%)	6 (7.3%)	21 (12.4%)
HEAT RASH	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
INFLUENZA LIKE ILLNESS	Grade 1,2	11 (12.6%)	15 (18.3%)	26 (15.4%)
INJURY	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
JOINT SPRAIN	Grade 2	1 (1.1%)	1 (1.2%)	2 (1.2%)
LACERATION	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
LARYNGITIS	Grade 2	3 (3.4%)	3 (3.7%)	6 (3.6%)
LARYNGOTRACHEITIS	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
LOWER RESPIRATORY TRACT INFECTION	Grade 2	0 (0.0%)	1 (1.2%)	1 (0.6%)
LYMPHADENOPATHY	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
MALAISE	Grade 1	0 (0.0%)	2 (2.4%)	2 (1.2%)
MALARIA	Grade 2	2 (2.3%)	3 (3.7%)	5 (3.0%)
MENORRHAGIA	Grade 1,2	3 (3.4%)	1 (1.2%)	4 (2.4%)
METRORRHAGIA	Grade 1,2	8 (9.2%)	15 (18.3%)	23 (13.6%)

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MOUTH ULCERATION	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
MUSCLE STRAIN	Grade 1	1 (1.1%)	1 (1.2%)	2 (1.2%)
NAIL TINEA	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
NASOPHARYNGITIS	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
NAUSEA	Grade 1	2 (2.3%)	0 (0.0%)	2 (1.2%)
NECK PAIN	Grade 2	2 (2.3%)	0 (0.0%)	2 (1.2%)
PAIN	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
PALPITATIONS	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
PEPTIC ULCER	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
PERIORBITAL ABSCESS	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
PHARYNGITIS	Grade 1	1 (1.1%)	1 (1.2%)	2 (1.2%)
PHARYNGOLARYNGEAL PAIN	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
PRURITUS GENITAL	Grade 1	0 (0.0%)	3 (3.7%)	3 (1.8%)
PYREXIA	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
RASH	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
RASH GENERALISED	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
RASH PRURITIC	Grade 2	1 (1.1%)	1 (1.2%)	2 (1.2%)
RASH PUSTULAR	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
RASH VESICULAR	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
SINUS HEADACHE	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
SINUSITIS	Grade 1,2	1 (1.1%)	3 (3.7%)	4 (2.4%)
SKIN LACERATION	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
SOFT TISSUE INFECTION	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
SOFT TISSUE INJURY	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
STRESS	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)

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SUBCUTANEOUS ABSCESS	Grade 2	1 (1.1%)	1 (1.2%)	2 (1.2%)
TINEA INFECTION	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
TONSILLITIS	Grade 2	6 (6.9%)	2 (2.4%)	8 (4.7%)
TOOTH INJURY	Grade 2	1 (1.1%)	0 (0.0%)	1 (0.6%)
TOOTHACHE	Grade 1,2	2 (2.3%)	0 (0.0%)	2 (1.2%)
UPPER RESPIRATORY TRACT INFECTION	Grade 1,2	5 (5.7%)	10 (12.2%)	15 (8.9%)
URINARY TRACT INFECTION	Grade 1,2	5 (5.7%)	3 (3.7%)	8 (4.7%)
UTERINE PAIN	Grade 1	1 (1.1%)	1 (1.2%)	2 (1.2%)
UTERINE SPASM	Grade 1,2	2 (2.3%)	0 (0.0%)	2 (1.2%)
VAGINAL CANDIDIASIS	Grade 1,2	18 (20.7%)	14 (17.1%)	32 (18.9%)
VAGINAL DISCHARGE	Grade 1	4 (4.6%)	6 (7.3%)	10 (5.9%)
VAGINAL ERYTHEMA	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
VAGINAL INFECTION	Grade 2	0 (0.0%)	0 (0.0%)	0 (0.0%)
VAGINAL LACERATION	Grade 2	0 (0.0%)	1 (1.2%)	1 (0.6%)
VAGINAL ODOUR	Grade 1	4 (4.6%)	0 (0.0%)	4 (2.4%)
VAGINAL PAIN	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
VAGINITIS BACTERIAL	Grade 1,2	14 (16.1%)	9 (11.0%)	23 (13.6%)
VIRAL RHINITIS	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
VULVAL ERYTHEMA	Grade 1	1 (1.1%)	0 (0.0%)	1 (0.6%)
VULVAR EROSION	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
VULVOVAGINAL DISCOMFORT	Grade 1	0 (0.0%)	3 (3.7%)	3 (1.8%)
VULVOVAGINAL DRYNESS	Grade 1	0 (0.0%)	1 (1.2%)	1 (0.6%)
VULVOVAGINAL PRURITUS	Grade 1	2 (2.3%)	2 (2.4%)	4 (2.4%)
VULVOVAGINITIS TRICHOMONAL	Grade 1,2	4 (4.6%)	0 (0.0%)	4 (2.4%)

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