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Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Lennox JL, DeJesus E, Lazzarin A, et al, for the STARTMRK investigators. Safety and efficacy of raltegravir-based versus efavirenz-based combination therapy in treatment-naive patients with HIV-1 infection: a multicentre, double-blind randomised controlled trial. *Lancet* 2009; published online August 3, 2009. DOI:10.1016/S0140-6736(09)60918-1.

**Number (%) of Patients with Specific Serious Clinical Adverse Experiences of Any Cause
by Organ System Category***

	Raltegravir Group		Efavirenz Group		Total	
	N = 281		N = 282		N = 563	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Serious Clinical Adverse Experiences	28	(10.0)	27	(9.6)	55	(9.8)
Patients With No Serious Clinical Adverse Experiences	253	(90.0)	255	(90.4)	508	(90.2)
Blood And Lymphatic System Disorders	1	(0.4)	1	(0.4)	2	(0.4)
Anaemia					1	(0.2)
Iron Deficiency Anaemia					1	(0.2)
Congenital, Familial, and Genetic Disorders					1	(0.2)
Branchial Cleft Cyst					1	(0.2)
Eye Disorders					1	(0.2)
Conjunctivitis					1	(0.2)
Uveitis					1	(0.2)
Gastrointestinal Disorders	3	(1.1)	3	(1.1)	6	(1.1)
Duodenal Ulcer					1	(0.2)
Gastrointestinal Disorder					1	(0.2)
Nausea					1	(0.2)
Oesophagitis					1	(0.2)
Pancreatitis					1	(0.2)
Peptic Ulcer					1	(0.2)
Proctalgia					1	(0.2)
Vomiting					1	(0.2)
General Disorders and Administration Site Conditions	1	(0.4)	1	(0.4)	2	(0.4)
Chest Pain	1	(0.4)	1	(0.4)	2	(0.4)
Hepatobiliary Disorders					1	(0.2)
Cholecystitis Chronic					1	(0.2)
Immune System Disorders	5	(1.8)	2	(0.7)	7	(1.2)
Immune Reconstitution Syndrome	5	(1.8)	2	(0.7)	7	(1.2)
Infections and Infestations	13	(4.6)	10	(3.5)	23	(4.1)
Anogenital Warts					1	(0.2)
Appendicitis					2	(0.4)
Bacteraemia					1	(0.2)
Cytomegalovirus Colitis					1	(0.2)
Diarrhoea Infectious					1	(0.2)
Enterocolitis Infectious					1	(0.2)
Extrapulmonary Tuberculosis					1	(0.2)
Hepatitis B					1	(0.2)
Hepatitis C					1	(0.2)
Herpes Zoster	1	(0.4)	1	(0.4)	2	(0.4)
Lymphangitis					1	(0.2)
Meningitis					1	(0.2)
Neurosyphilis					1	(0.2)
Oesophageal Candidiasis					1	(0.2)

<i>Pneumocystis jiroveci</i> Pneumonia				1	(0.2)	
Pneumonia	1	(0.4)	3	(1.1)	4	(0.7)
Pyelonephritis Acute				1	(0.2)	
Secondary Syphilis				1	(0.2)	
Sepsis				1	(0.2)	
Subcutaneous Abscess				1	(0.2)	
Viral Upper Respiratory Tract Infection				1	(0.2)	
Injury, Poisoning, and Procedural Complications				2	(0.4)	
Accidental Overdose				1	(0.2)	
Limb Injury				1	(0.2)	
Neoplasms Benign, Malignant and Unspecified (Including Cysts and Polyps)	1	(0.4)	7	(2.5)	8	(1.4)
Anal Cancer				1	(0.2)	
Bone Neoplasm Malignant				1	(0.2)	
Kaposi's Sarcoma AIDS-related	1	(0.4)	5	(1.8)	6	(1.1)
Nervous System Disorders	2	(0.7)	2	(0.7)	4	(0.7)
Cerebral Haemorrhage				1	(0.2)	
Dizziness				1	(0.2)	
Hypoaesthesia				1	(0.2)	
Nervous System Disorder				1	(0.2)	
Psychiatric Disorders	2	(0.7)	4	(1.4)	6	(1.1)
Conversion Disorder				1	(0.2)	
Depression	1	(0.4)	1	(0.4)	2	(0.4)
Drug Abuse				1	(0.2)	
Mental Disorder	1	(0.4)	1	(0.4)	2	(0.4)
Psychotic Disorder				1	(0.2)	
Schizoaffective Disorder				1	(0.2)	
Reproductive System and Breast Disorders				1	(0.2)	
Menorrhagia				1	(0.2)	
Respiratory, Thoracic and Mediastinal Disorders	1	(0.4)	1	(0.4)	2	(0.4)
Bronchial Hyperreactivity				1	(0.2)	
Pleural Effusion				1	(0.2)	
Vascular Disorders				1	(0.2)	
Deep Vein Thrombosis				1	(0.2)	

*To prevent unblinding in the ongoing study, the table only shows the frequency of serious clinical adverse experiences by treatment arm for those adverse events that occurred in at least one patient in each treatment group.

Adverse event terms from MedDRA Version 11.0.

Although a patient may have had two or more specific serious clinical adverse experiences in a given organ system category, the patient is counted only once within a category. The same patient may appear in more than one subcategory associated with a given organ system category and in different categories.