

**Kawasaki Data Codebook**  
**KD\_FM01: Screen**  
**(raw data)**

**DATA SET: k001      DATE CREATED: 26DEC2017**

**Number of Observations: 589**

**Number of Variables: 40**

**Organization of file: Up to 3 Records per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
A1. Subject ID	SUBJECT_ID						
<created var> Age when randomized (in years)	ENROLL_AGE			199(390)	3.27(2.25)	2.90(1.40,4.70)	0.20-12.30
A4. Patient Gender	GENDER	1:MALE	358(60.8)				
		2:FEMALE	231(39.2)				
A6.<created var> Age at K001 completion date (in years)	SCREEN_AGE			589(0)	3.55(2.91)	2.80(1.40,4.90)	0.00-19.00
A6.<created var>Time from screening to drug/placebo started (day)	SCREEN_DRUG			196(393)	0.21(0.42)	0.00(0.00,0.00)	0.00-2.00
B1. Patient race	RACE	-8:UNKNOWN	4(0.7)				
		1:WHITE	331(56.2)				
		2:BLACK	99(16.8)				
		3:ASIAN	115(19.5)				
		4:Mixed/Other	40(6.8)				
B2. Is patient of Hispanic or Latino origin	HISPANIC	-8:UNKNOWN	29(4.9)				
		1:YES	93(15.8)				
		2:NO	467(79.3)				
B4.<created var> Age at onset of fever	FEVER_AGE			585(4)	3.53(2.93)	2.80(1.30,4.90)	0.00-19.00

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B4.<created var> Time from onset of fever to drug/placebo started (day)	FEVER_DRUG			196(393)	5.83(1.58)	6.00(5.00,7.00)	3.00-11.00
<created var> Days from fever onset until date of screening	K1FEVERDAYS			586(3)	8.02(3.96)	7.00(6.00,9.00)	0.00-35.00
C1. Fever for at least four days	FOURDAYS	1:YES	569(96.6)				
		2:NO	20(3.4)				
C2. Any extremity changes	EXTREMTY	1:YES	456(77.4)				
		2:NO	133(22.6)				
C3. Rash	RASH	1:YES	509(86.4)				
		2:NO	80(13.6)				
C4. Bilateral, conjunctival injection	BCINFECT	1:YES	515(87.4)				
		2:NO	74(12.6)				
C5. Any oral changes	ORALCHNG	1:YES	504(85.6)				
		2:NO	85(14.4)				
C6. Cervical lymphadenopathy	CERVLIMP	1:YES	253(43.0)				
		2:NO	336(57.0)				
C7. Echocardiographic evidence of coronary abnormalities	ECHOEVID	-9:MISSING	1(0.2)				

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		1:YES	61(10.4)				
		2:NO	163(27.7)				
		3:NOT DONE	364(61.8)				
C7a. RCA /LAD body surface area adjusted dimension (z-score) >2.5	RCAORLAD	-2:SKIPPED	528(89.6)				
		1:YES	58(9.8)				
		2:NO	3(0.5)				
C7b. Japanese Ministry of Health Aneurysm criteria met	JMHCRT	-2:SKIPPED	528(89.6)				
		1:YES	30(5.1)				
		2:NO	31(5.3)				
D1. Patient past the 10th day of illness	PASTTEN	1:YES	102(17.3)				
		2:NO	487(82.7)				
D2. Treatment with gamma globulin (IVIG) prior to enrollment	GAMAGLOB	1:YES	27(4.6)				
		2:NO	562(95.4)				
D3. Treatment with steroids,other than inhaled form, within 2 wk	STERIODS	1:YES	16(2.7)				

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		2:NO	573(97.3)				
D4. Believed to have another disease known to mimic	MIMICKAW	1:YES	44(7.5)				
		2:NO	545(92.5)				
D5. Previous diagnosis of Kawasaki disease	KAWASAKI	1:YES	10(1.7)				
		2:NO	579(98.3)				
D6. Suspected infection that would contraindicate steroid use	S_INFECT	1:YES	13(2.2)				
		2:NO	576(97.8)				
D7. Known hypersensitivity to IVMP or its components	IVMPSENS	2:NO	589(100.0)				
D8. Other contraindications to steroid therapy	CONTRAIN	1:YES	2(0.3)				
		2:NO	587(99.7)				
D9. Unable to take aspirin	UNABLE	1:YES	5(0.8)				
		2:NO	584(99.2)				
E1. Eligible	ELIGIBLE	1:AT LEAST 4 OF 5 PRINCIPAL FEATURES	401(68.1)				
		2:AT LEAST 2 OF 5 FEATURES AND Z-SCORE >2.5 IN <6 MO.	5(0.8)				

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		3:AT LEAST 3 OF 5 FEATURES AND Z-SCORE >2.6 IN >6 MO.	12(2.0)				
		4:AT LEAST 1 OF 5 FEATURES AND JAPANESE MINISTRY OF HE	6(1.0)				
		5:PATIENT DOES NOT MEET ABOVE KAWASAKI DISEASE CRITERI	165(28.0)				
E2. Does patient meet all inclusion and no exclusion criteria?	CRITERIA	1:YES	313(53.1)				
		2:NO	276(46.9)				
F1. Parent/Caregiver signed informed consent form	CONSENT	-2:SKIPPED	276(46.9)				
		1:YES	199(33.8)				
		2:NO	114(19.4)				
F1a.<created var> Age when enrolled/signed consent	CONSENT_AGE			199(390)	3.27(2.25)	2.90(1.40,4.70)	0.20-12.30
F1a.<created var> Time from consent to drug/placebo started (day)	CONSENT_DRUG			196(393)	0.20(0.40)	0.00(0.00,0.00)	0.00-1.00
F2. Reason for not signing informed consent	NOREASON	-2:SKIPPED	475(80.6)				
		1:SHORT NOTICE	8(1.4)				
		2:REFUSAL BY FAMILY	87(14.8)				

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		3:PEDIATRICIAN/REFERRING PHYSICIAN DID NOT WANT PATIEN	5(0.8)				
		4:LANGUAGE BARRIER	11(1.9)				
		99:OTHER	3(0.5)				
F2a. If short notice, specify reason	SHORT_RE	-2:SKIPPED	581(98.6)				
		1:INVESTIGATOR NOT NOTIFIED	2(0.3)				
		2:INVESTIGATOR NOT AVAILABLE	2(0.3)				
		3:FAMILY NOT AVAILABLE	1(0.2)				
		4:OTHER REASON FOR SHORT NOTICE	3(0.5)				
TREATMENT	TREATMENT	-9:MISSING	390(66.2)				
		Placebo	98(16.6)				
		Steroid	101(17.1)				
G4.<created var> Age at randomization	RAND_AGE			199(390)	3.27(2.25)	2.90(1.40,4.70)	0.20-12.30
G4.<created var>Time from randomization to drug/placebo started (min)	RAND_DRUG			196(393)	210.09(112.08)	195.00(126.50,265.00)	0.00-600.00
Blinded site ID	SITE_BLIND_ID	1	10(1.7)				
		2	24(4.1)				

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		3	27(4.6)				
		4	17(2.9)				
		5	32(5.4)				
		6	27(4.6)				
		7	10(1.7)				
		8	52(8.8)				
		<i>Missing</i>	390(66.2)				
Form Version	VER_ID	A	589(100.0)				