

**Kawasaki Data Codebook**  
**KD\_FM010: Adverse Event Form**  
**(raw data)**

**DATA SET: k010      DATE CREATED: 26DEC2017**

**Number of Observations: 61**

**Number of Variables: 60**

**Organization of file: One Record per Patient**

Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
A1. Subject ID	SUBJECT_ID						
A3.<created var> Age when adverse event occurs	AEDATE_AGE			61(0)	4.50(2.89)	4.00(2.20,6.00)	0.30-12.30
A3.<created var> Time from drug/placebo started to adverse event occurs(min)	AEDATE_DRUG			55(6)	6485.22(8956.37)	3450.00(540.00,9045.00)	-20.00-39066.00
A5.<created var> Age at form completion	COMP_AGE			61(0)	4.53(2.88)	4.00(2.30,6.00)	0.50-12.30
A5.<created var> Time from drug/placebo started to form completion(day)	COMP_DRUG			61(0)	16.51(28.08)	8.00(3.00,17.00)	1.00-200.00
B1. Adverse event occurrence	AEOCCUR	1:INPATIENT	32(52.5)				
		2:OUTPATIENT	29(47.5)				
B1a. Was patient hospitalized for this event?	EVNTHOSP	-2:SKIPPED	32(52.5)				
		1:YES	3(4.9)				
		2:NO	26(42.6)				
B2a. Kawasaki Disease-related adverse event	KDREL	1:YES	6(9.8)				
		2:NO	55(90.2)				

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B2b. Other cardiac-related adverse event	CARDIAC	2:NO	61(100.0)				
B2c. Infection	INFECT	1:YES	11(18.0)				
		2:NO	50(82.0)				
B2d. Allergic reaction adverse event	ALLERG	1:YES	8(13.1)				
		2:NO	53(86.9)				
B2e. Other adverse event	OTHER	1:YES	36(59.0)				
		2:NO	25(41.0)				
<created var> Adverse Event Code: _ - ____ (see code list E)	AECODE	A-0003: Anaphylaxis	1(1.6)				
		A-0009: Arthritis, ankles	1(1.6)				
		A-0015: Aseptic meningitis (confirmed by Lumbar Punctu	2(3.3)				
		A-0021: Cough	2(3.3)				
		A-0027: Diarrhea	1(1.6)				
		A-0036: Flushing	2(3.3)				
		A-0037: Headache	8(13.1)				
		A-0038: Hearing loss	1(1.6)				

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		A-0039: Hemolytic anemia	1(1.6)				
		A-0040: Hives	1(1.6)				
		A-0044: Hypotension (SBP<5th percentile)	6(9.8)				
		A-0048: Mood changes	1(1.6)				
		A-0062: Rhinorrhea	3(4.9)				
		A-0063: Rigors	6(9.8)				
		A-0066: Shock	1(1.6)				
		A-0071: Strep throat (confirmed by throat culture)	2(3.3)				
		A-0072: Sudden increase in fever	1(1.6)				
		A-0074: Vomiting	2(3.3)				
		A-0075: Weakness	2(3.3)				
		A-9999: Other non-cardiac, specify	14(23.0)				
		B-0023: Syncope	1(1.6)				
		B-9999: Other cardiac, specify	2(3.3)				
B41. Event Code	F10CRDCD	a	7(11.5)				
		A	51(83.6)				

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		B	3(4.9)				
B42. Event code	F10EVTCD	0003	1(1.6)				
		0009	1(1.6)				
		0015	2(3.3)				
		0021	2(3.3)				
		0023	1(1.6)				
		0027	1(1.6)				
		0036	2(3.3)				
		0037	8(13.1)				
		0038	1(1.6)				
		0039	1(1.6)				
		0040	1(1.6)				
		0044	6(9.8)				
		0048	1(1.6)				
		0062	3(4.9)				
		0063	6(9.8)				

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		0066	1(1.6)				
		0071	2(3.3)				
		0072	1(1.6)				
		0074	2(3.3)				
		0075	2(3.3)				
		9999	16(26.2)				
B5. Was this event related to IVMP/Placebo?	IVMPEVNT	1:NOT RELATED	56(91.8)				
		2:POSSIBLY RELATED	5(8.2)				
B6. Was this event related to IVIG?	IVIGEVNT	1:NOT RELATED	40(65.6)				
		2:POSSIBLY RELATED	6(9.8)				
		3:PROBABLY RELATED	15(24.6)				
B7. Was this event related to a study procedure?	STPXEVNT	1:NOT RELATED	59(96.7)				
		2:POSSIBLY RELATED	2(3.3)				
B7a. Specify procedure:	SPECPROC	-2:SKIPPED	59(96.7)				
		Infusion of study drug	1(1.6)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		tubing being flushed	1(1.6)				
B8. Was event resolved?	AERESOLV	1:YES	61(100.0)				
B8a.<created var> Age event resolved	RESOLV_D_AGE			61(0)	4.53(2.92)	4.00(2.20,6.00)	0.30-12.30
B8a.<created var> Time from drug/placebo started to event resolved(day)	RESOLV_D_DRUG			61(0)	16.70(50.51)	4.00(1.00,13.00)	0.00-387.00
B9. Seriousness of the event	SEVERITY	1:NOT SERIOUS	50(82.0)				
		2:MODERATELY SERIOUS	7(11.5)				
		3:SERIOUS	4(6.6)				
B10. Was event expected?	EXPECTED	-9:MISSING	1(1.6)				
		1:YES	57(93.4)				
		2:NO	3(4.9)				
C1. Abnormal laboratory findings related to event?	ABNLAB	1:YES	13(21.3)				
		2:NO	26(42.6)				
		3	22(36.1)				
D1. Number of medications for treatment of adverse event	AEMEDS			61(0)	0.85(1.34)	0.00(0.00,1.00)	0.00-8.00

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
<created var> Medication code for treatment of adverse event: _ _ _ _ (0)	AEMED_0	03.00-03.99: Antibiotics	2(3.3)				
		05.00-05.99: Antiemetics	1(1.6)				
		07.00-07.99: Antithrombotics	2(3.3)				
		10.00-10.99: Bronchodilators	1(1.6)				
		15.00-15.99: Electrolytes	1(1.6)				
		16.00-16.99: Gastrointestinals	1(1.6)				
		18.00-18.99: Hormonal Agents	2(3.3)				
		19.00-19.99: Inotropic Agents	1(1.6)				
		22.00-22.99: Sedatives, hypnotics, anesthetics, analge	14(23.0)				
		99.99: Unclassified	5(8.2)				
		<i>Missing</i>	31(50.8)				
<created var> Medication code for treatment of adverse event: _ _ _ _ (1)	AEMED_1	03.00-03.99: Antibiotics	1(1.6)				
		07.00-07.99: Antithrombotics	1(1.6)				
		09.00-09.99: Biologics	1(1.6)				
		10.00-10.99: Bronchodilators	1(1.6)				

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		19.00-19.99: Inotropic Agents	1(1.6)				
		22.00-22.99: Sedatives, hypnotics, anesthetics, analge	5(8.2)				
		99.99: Unclassified	1(1.6)				
		<i>Missing</i>	50(82.0)				
<created var> Medication code for treatment of adverse event: _ _ _ _ (2)	AEMED_2	03.00-03.99: Antibiotics	1(1.6)				
		15.00-15.99: Electrolytes	1(1.6)				
		19.00-19.99: Inotropic Agents	1(1.6)				
		22.00-22.99: Sedatives, hypnotics, anesthetics, analge	1(1.6)				
		<i>Missing</i>	57(93.4)				
<created var> Medication code for treatment of adverse event: _ _ _ _ (3)	AEMED_3	07.00-07.99: Antithrombotics	1(1.6)				
		19.00-19.99: Inotropic Agents	1(1.6)				
		22.00-22.99: Sedatives, hypnotics, anesthetics, analge	1(1.6)				
		<i>Missing</i>	58(95.1)				



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<created var> Medication code for treatment of adverse event: _ _ _ _ (4)	AEMED_4	19.00-19.99: Inotropic Agents	1(1.6)				
		<i>Missing</i>		60(98.4)			
<created var> Medication code for treatment of adverse event: _ _ _ _ (5)	AEMED_5	03.00-03.99: Antibiotics	1(1.6)				
		<i>Missing</i>		60(98.4)			
<created var> Medication code for treatment of adverse event: _ _ _ _ (6)	AEMED_6	03.00-03.99: Antibiotics	1(1.6)				
		<i>Missing</i>		60(98.4)			
<created var> Medication code for treatment of adverse event: _ _ _ _ (7)	AEMED_7	03.00-03.99: Antibiotics	1(1.6)				
		<i>Missing</i>		60(98.4)			
D1a. Medication code for treatment of adverse event (first 2 digits: _ _ _ _ ) (0)	F10MED1_0	<i>Missing</i>		31(50.8)			
		03		2(3.3)			
		05		1(1.6)			
		07		2(3.3)			
		10		1(1.6)			
		15		1(1.6)			

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			16				1(1.6)
			18				2(3.3)
			19				1(1.6)
			22				14(23.0)
			99				5(8.2)
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (1)	F10MED1_1	<i>Missing</i>					50(82.0)
			03				1(1.6)
			07				1(1.6)
			09				1(1.6)
			10				1(1.6)
			19				1(1.6)
			22				5(8.2)
			99				1(1.6)
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (2)	F10MED1_2	<i>Missing</i>					57(93.4)
			03				1(1.6)

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
			15				
			19				
			22				
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (3)	F10MED1_3	<i>Missing</i>	58(95.1)				
			07				
			19				
			22				
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (4)	F10MED1_4	<i>Missing</i>	60(98.4)				
			19				
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (5)	F10MED1_5	<i>Missing</i>	60(98.4)				
			03				
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (6)	F10MED1_6	<i>Missing</i>	60(98.4)				
			03				
D1a. Medication code for treatment of adverse event (first 2 digits: __. __) (7)	F10MED1_7	<i>Missing</i>	60(98.4)				

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		03	1(1.6)				
D1a1. Medication code for treatment of adverse event (last 2 digits: __ __) (0)	F10MED2_0	<i>Missing</i>	31(50.8)				
		00	1(1.6)				
		01	11(18.0)				
		02	1(1.6)				
		04	3(4.9)				
		06	5(8.2)				
		09	2(3.3)				
		13	1(1.6)				
		99	6(9.8)				
D1a1. Medication code for treatment of adverse event (last 2 digits: __ __) (1)	F10MED2_1	<i>Missing</i>	50(82.0)				
		01	2(3.3)				
		03	1(1.6)				
		04	1(1.6)				
		05	1(1.6)				

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Variable Label (VAR)	Variable Name	Category	N(%)	N(Missing)	Mean(SD)	Median(Q1,Q3)	Range of Values
		06	2(3.3)				
		08	2(3.3)				
		99	2(3.3)				
D1a1. Medication code for treatment of adverse event (last 2 digits: __. __) (2)	F10MED2_2	Missing	57(93.4)				
		04	1(1.6)				
		06	1(1.6)				
		15	1(1.6)				
		99	1(1.6)				
D1a1. Medication code for treatment of adverse event (last 2 digits: __. __) (3)	F10MED2_3	Missing	58(95.1)				
		02	1(1.6)				
		06	1(1.6)				
		99	1(1.6)				
D1a1. Medication code for treatment of adverse event (last 2 digits: __. __) (4)	F10MED2_4	Missing	60(98.4)				
		03	1(1.6)				

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D1a1. Medication code for treatment of adverse event (last 2 digits: __ __) (5)	F10MED2_5	Missing	60(98.4)				
				37	1(1.6)		
D1a1. Medication code for treatment of adverse event (last 2 digits: __ __) (6)	F10MED2_6	Missing	60(98.4)				
				13	1(1.6)		
D1a1. Medication code for treatment of adverse event (last 2 digits: __ __) (7)	F10MED2_7	Missing	60(98.4)				
				20	1(1.6)		
D1a2. Specify other medication for adverse event (0)	F10MED_0	-2:SKIPPED	17(27.9)				
		Missing	38(62.3)				
		ACYCLOVIR	1(1.6)				
		CYCLOGYL	1(1.6)				
		IBUPROFEN	1(1.6)				
		IVFLUIDS	1(1.6)				
		NSSBOLUS	1(1.6)				
		OVERTHECOUNTERCOUGHSUPPRESSANT	1(1.6)				

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D1a2. Specify other medication for adverse event (1)	F10MED_1	-2:SKIPPED	7(11.5)				
		<i>Missing</i>	52(85.2)				
		DEMEROL	1(1.6)				
		PEDFORTE	1(1.6)				
D1a2. Specify other medication for adverse event (2)	F10MED_2	-2:SKIPPED	1(1.6)				
		<i>Missing</i>	59(96.7)				
		ORMALSALINE	1(1.6)				
D1a2. Specify other medication for adverse event (3)	F10MED_3	-2:SKIPPED	2(3.3)				
		<i>Missing</i>	58(95.1)				
		VASOPRESSIN	1(1.6)				
D1a2. Specify other medication for adverse event (4)	F10MED_4	<i>Missing</i>	61(100.0)				
D1a2. Specify other medication for adverse event (5)	F10MED_5	<i>Missing</i>	61(100.0)				
D1a2. Specify other medication for adverse event (6)	F10MED_6	<i>Missing</i>	61(100.0)				

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D1a2. Specify other medication for adverse event (7)	F10MED_7	-2:SKIPPED	1(1.6)				
		<i>Missing</i>	60(98.4)				
D2. Patient received supplemental oxygen for event?	AEO2	1:YES	3(4.9)				
		2:NO	58(95.1)				
Form Version	VER_ID	A	61(100.0)				