Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total	Num		Fisher's			0		
Body System/Event	Age Group [2]	Number of Pts	of w/E	Pts vent	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)						···			
VOMITING	≤63 Days (All)	64	13	(20%)	0.3300	16	6 (38%)	5 (31%)	5 (31%)	0
	≤49 Days (Group 1)	36	10	(28%)		13	5 (38%)	4 (31%)	4 (31%)	0
	50-56 Days (Group 2)	16	2	(13%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	12	1	(8%)		1	0	1 (100%)	0	0
RESPIRATORY SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
· ·	≤49 Days (Group 1)	36	1	(3%)	,	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0			0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
SINUSITIS	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0			0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
RED BLOOD CELL DISORDERS										
ANY EVENT	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0			0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number		Sever	itv	
Body System/Event	Age Group [2]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	1 (3%)	•	1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	64	1 (2%)	1.0000	1	o	0	1 (100%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	64	57 (89%)	0.3526	148	62 (42%)	55 (37 ♦)	31 (21%)	0
	≤49 Days (Group 1)	36	30 (83%)		82	41 (50%)	26 (32%)	15 (18%)	0
	50-56 Days (Group 2)	16	15 (94%)		36	10 (28%)	16 (44%)	10 (28%)	0
	57-63 Days (Group 3)	12	12 (100%)		30	11 (37%)	13 (43%)	6 (20%)	0
	•				•				

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total	Number of Pts	Fisher's exact	Number				Severi	tv		
Body System/Event		Number of Pts	w/Event		of Events		ld		rate	Sev		Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)												
ABDOMINAL PAIN	≤63 Days (All)	64	57 (89%)	0.3526	131	53	(40%)	50	(38%)	28	(21%)	0
	≤49 Days (Group 1)	36	30 (83%)		70	35	(50%)	22	(31%)	13	(19%)	0
	50-56 Days (Group 2)	16	15 (94%)		32	8	(25%)	15	(47%)	9	(28%)	0
	57-63 Days (Group 3)	12	12 (100%)		29	10	(34%)	13	(45%)	6	(21%)	0
BACK PAIN	≤63 Days (All)	64	4 (6%)	0.8096	6	3	(50%)	1	(17%)	2	(331)	0
BACK FAIN	≤49 Days (Group 1)	36	3 (8%)		5	2	(40%)	1	(20%)	2	(40%)	0
. 1	50-56 Days (Group 2)	16	1 (6%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	12	0	,	0	0		0		0		0
FATIGUE	≤63 Days (All)	64	5 (8%)	1.0000	6	2	(33%)	4	(67%)	0		0
FRIIGUE	s49 Days (Group 1)	36	3 (8%)		3	0		3	(100%)	0		0
	50-56 Days (Group 2)	16	1 (6%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	12	1 (8%)		1	1	(100%)	0		0		0
HOT FLUSHES	≤63 Days (All)	64	1 (2%)	1.0000	1	1	(100%)	0		0		0
NOT PROSIECO	≤49 Days (Group 1)	36	1 (3%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	16	0		0	0		0		0		0
	57-63 Days (Group 3)	12	0		0	0		0		0		0
LEG PAIN	≤63 Days (All)	64	2 (3%)	0.6875	2	1	(50%)	0		1	(50%)	0
DEG FAIR	≤49 Days (Group 1)	36	1 (3%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	16	1 (6%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	12	0		. 0	0		0		0		0
	•				•				ļ.			

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table Sc (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: BORGATTA (#6)

	Gestational	Total	Numbe		Fisher's			Sever:	l Fra	
Body System/Event	Age Group [2]	Number of Pts	of Pt w/Eve		exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
SODY AS A WHOLE - GENERAL DISORDERS (cont.)									
MALAISE	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0			0	0	0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
RIGORS	≤63 Days (All)	64	1	(2%)	1.0000	1	1 (100%)	0	0	0
ı	≤49 Days (Group 1)	36	1	(3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0			0	0	. 0	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
RESISTANCE MECHANISM DISORDERS										
ANY EVENT	≤63 Days (All)	64	1	(2%)	0.4375	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0			0	0	0	0	0
	50-56 Days (Group 2)	16	1	(6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	64	1	(2%)	0.4375	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0			0	0	0	0	0
	50-56 Days (Group 2)	16	1	(6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0			0	0	0	0	0
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^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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⁽²⁾ Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Number	Fisher's exact	Mountage				Severi	tv		
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	p-value	Number of Events		1d		rate	Sev		Unknow
	42.2		53 (100 \$)		259	100	(39%)	92	(36%)	67	(26%)	0
ANY EVENT	s63 Days (All)	52	52 (100%)		259 84	31	(37%)	28	(33%)	25	(30%)	0
	≤49 Days (Group 1)	19	19 (100%)		58	27	(47%)	21	(36%)	10	(17%)	0
	50-56 Days (Group 2) 57-63 Days (Group 3)	11 22	11 (100%) 22 (100%)		117	42	(36%)	43	(37%)	32	(27%)	ō
	37-03 Days (Group 3)	22	22 (1004)		•••		(00)		, , , , ,			
ENTR & PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	52	11 (21%)	0.7522	26	11		11	(42%)	4	(15%)	0
	≤49 Days (Group 1)	19	3 (16%)		5	1	(20%)	4	(80%)	0		0
	50-56 Days (Group 2)	11	3 (27%)		6	5	(83∜)	0		1	(17%)	0
	57-63 Days (Group 3)	22	5 (23%)		15	5	(33%)	7	(47%)	3	(20%)	0
DIZZINESS	≤63 Days (All)	52	4 (8%)	1.0000	7	4	(57%)	2	(29%)	1	(14%)	0
2130111000	≤49 Days (Group 1)	19	1 (5%)		1	0		1	(100%)	0		0
The state of the s	50-56 Days (Group 2)	11	1 (9%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	22	2 (9%)		5	3	(60%)	1	(20%)	1	(20%)	0
HEADACHE	≤63 Days (All)	52	9 (17%)	0.5764	19	7	(37%)	9	(47%)	3	(16%)	0
HERDACIS	≤49 Days (Group 1)	19	3 (16%)		4	1	(25%)	3	(75%)	0		0
	50-56 Days (Group 2)	11	3 (27%)		5	4	(80%)	0		1	(20%)	0
	57-63 Days (Group 3)	22	3 (14%)		10	2	(20%)	6	(60%)	2	(20%)	0
ASTRO-INTESTINAL SYSTEM DISORDERS	•											
ANY EVENT	≤63 Days (All)	52	35 (67%)	1.0000	76	30	(39%)	22	(29%)	24	(32%)	0
MII BYENI	s49 Days (Group 1)	19	13 (68%)	1.0000	23	8	(35%)	6	(26%)		(39%)	0
	50-56 Days (Group 2)	11	7 (64%)		18	10	(56%)	6	(33%)	2	(11%)	0
	57-63 Days (Group 3)	22	15 (68%)		35	12	(34%)		(29%)		(37%)	0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography. Appendix A.1, Tables 16 and 25

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Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Numi		Fisher's					_			
Body System/Event	Age Group (2)	Number of Pts	of w/E	Pts vent	exact p-value	Number of Events	Mi	ld	Mode	Sever rate	-	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)						··- · · · · · · · · · · · · · · · · · ·							
CONSTIPATION	≤63 Days (All)	52	1	(2%)	1.0000	1	0		0		1	(100%)	0
•	≤49 Days (Group 1)	19	0			0	0		0		0		0
	50-56 Days (Group 2)	11	0			0	0		0		0		0
	57-63 Days (Group 3)	22	1	(5%)		1	0		0		1	(100%)	0
DIARRHEA	≰63 Days (All)	52	10	(19%)	0.7388	11	5	(45%)	3	(27%)	3	(27%)	0
ı	≤49 Days (Group 1)	19	4	(21%)		4	2	(50%)	2	(50%)	0		0
	50-56 Days (Group 2)	11	1	(9%)	•	1	1	(100%)	0		0		0
	57 63 Days (Group 3)	22	5	(23%)		6	2	(33%)	1	(17%)	3	(50%)	0
NAUSEA	≤63 Days (All)	52	33	(63%)	0.8720	43	17	(40%)	11	(26%)	15	(35%)	0
	≤49 Days (Group 1)	19	11	(58%)		14	5	(36%)	1	(7%)	8	(57%)	0
	50-56 Days (Group 2)	11	7	(64%)		11	6	(55%)	4	(36%)	. 1	(9%)	0
	57-63 Days (Group 3)	22	15	(68%)		18	6	(33%)	6	(33%)	6	(33%)	0
VOMITING	≤63 Days (All)	52	15	(29%)	0.9255	21	8	(38%)	8	(38%)	5	(24%)	0
	≤49 Days (Group 1)	19	5	(26%)		5	1	(20%)	3	(60%)	1	(20%)	0
	50-56 Days (Group 2)	11	3	(27%)		6	3	(50%)	2	(33%)	1	(17%)	0
	57-63 Days (Group 3)	22	7	(32%)		10	4	(40%)	3	(30%)	3	(30%)	0
RED BLOOD CELL DISORDERS													
ANY EVENT	≤63 Days (All)	52	2	(4%)	0.0415	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	19	0			, o	0		0		0		0
	50-56 Days (Group 2)	11	2	(18%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	22	0			0	0		0	•	0		0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number			Se	everity		
Body System/Event	Group (2)	of Pts	w/Even		p-value	of Events	Mi	ld	Moderate	Se	vere	Unknown
RED BLOOD CELL DISORDERS (cont.)												
ANAEMIA	≤63 Days (All)	52	2 ((4%)	0.0415	2	1	(50%)	1 (50	b) 0		0
	≤49 Days (Group 1)	19	0			0	0		0	0		0
	50-56 Days (Group 2)	11	2 (1	18%)		2	1	(50%)	1 (50	b) 0		0
	57-63 Days (Group 3)	22	0			0	0		0	0		0
URINARY SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	52	1 ((2%)	1.0000	2	1	(50%)	0	1	(50%)	0
,	s49 Days (Group 1)	19	0			0	0		0	0		0
	50-56 Days (Group 2)	11	0			0	0		0	0		0
	57-63 Days (Group 3)	22	1 ((5%)		2	1	(50%)	0	1	(50%)	0
URINARY TRACT INFECTION	≤63 Days (All)	52	1 ((2%)	1.0000	2	1	(50%)	0	1	(50%)	0
	≤49 Days (Group 1)	19	0			0	0		0	0		0
	50-56 Days (Group 2)	11	0			0	0		0	0		0
	57-63 Days (Group 3)	22	1 ((5%)		2	1	(50%)	0	1	(50%)	0
REPRODUCTIVE DISORDERS, FEMALE												
ANY EVENT	≤63 Days (All)	52	1 ((2%)	0.2115	1	0		1 (100	b) 0		0
	≤49 Days (Group 1)	19	0			0	0		0	0		0
	50-56 Days (Group 2)	11	1 ((9%)		1	0		1 (100	b) 0		0
	57-63 Days (Group 3)	22	0			0	0		0	0		0
	1											

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

	Gestational	Total	Number	Fisher's					Severi	i +		
Body System/Event		Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mil			rate	-	ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)												
VAGINITIS	≤63 Days (All)	52	1 (2%)	0.2115	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	19	0		0	0		0		0		0
	50-56 Days (Group 2)	11	1 (9%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	22	0		0	0		0		0		0
BODY AS A WHOLE - GENERAL DISORDERS												
ANY EVENT	≤63 Days (All)	52	51 (98%)	1.0000	152	57	(38%)	57	(38%)	38	(25%)	0
	≤49 Days (Group 1)	19	19 (100%)		56	22	(39%)	18	(32%)	16	(29%)	0
	50-56 Days (Group 2)	11	11 (100%)		31	11	(35%)	13	(42%)	7	(23%)	0
	57-63 Days (Group 3)	22	21 (95%)		65	24	(37%)	26	(40%)	15	(23%)	0
ABDOMINAL PAIN	≤63 Days (All)	52	50 (96%)	0.5023	142	55	(39%)	50	(35%)	37	(26%)	0
	≤49 Days (Group 1)	19	19 (100%)		54	22	(41%)	16	(30%)	16	(30%)	0
	50-56 Days (Group 2)	11	11 (100%)		28	10	(36%)	12	(43%)	6	(21%)	0
	57-63 Days (Group 3)	22	20 (91%)		60	23	(38%)	22	(37%)	15	(25%)	0
BACK PAIN	≤63 Days (All)	52	7 (13%)	0.0838	7	2	(29%)	5	(71%)	0		0
	s49 Days (Group 1)	19	0		0	0		0		0		0
	50-56 Days (Group 2)	11	2 (18%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	22	5 (23%)		5	1	(20%)	4	(80%)	0		0
LEG PAIN	≤63 Days (All)	52	1 (2%)	0.5769	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	19	1 (5%)		2	0		2	(100%)	0	1	0
	50-56 Days (Group 2)	11	0		. 0	0		0	1	0	•	0
	57-63 Days (Group 3)	22	0		0	0		0	Įı	0		0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: MALLOY (#7)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Ever	9	Fisher's exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont.)									. (2004)	
RIGORS	≤63 Days (All)	52	1	(2%)	0.2115	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	19	0			0	0	0	0	0
	50-56 Days (Group 2)	11	1	(9%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	22	0			0	0	0	0	0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table Sc (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: ROTHENBERG (#8)

	Gestational	Total Number	Number of Pts	Fisher's exact					·Sever	itv		
Body System/Event	Age Group [2]	of Pts	w/Event	p-value	of Events	Mi			rate	•	ere	Unknown
ANY EVENT	≤63 Days (All)	21	17 (81%)	0.2919	51	20	(39%)	19	(37%)	12	(24%)	0
MAI EVENI	s49 Days (Group 1)	13	9 (69%)	0.2313	23	13	(57%)	7		3	(13%)	0
	50-56 Days (Group 2)	5	5 (100%)		18	4	(22%)	8	(44%)	6	(33%)	0
	57-63 Days (Group 3)	3	3 (100%)		10	3	(30%)	4	(40%)	3	(30%)	0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS												
ANY EVENT	s63 Days (All)	21	4 (19%)	0.1724	4	0		3	(75%)	1	(25%)	0
	≤49 Days (Group 1)	13	1 (8%)		. 1	O		1	(100%)	0		0
	50-56 Days (Group 2)	5	2 (40%)		2	0		1	(50%)	1	(50%)	0
	57-63 Days (Group 3)	3	1 (33%)		1	0		1	(100%)	0		0
HEADACHE	≤63 Days (All)	21	4 (19%)	0.1724	4	0		3	(75%)	1	(25%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	5	2 (40%)		2	0		1	(50%)	1	(50%)	0
	57-63 Days (Group 3)	3	1 (33%)		1	О		1	(100%)	0		0
JASTRO-INTESTINAL SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	21	12 (57%)	0.3140	21	12	(57%)	6	(29%)	3		0
	≤49 Days (Group 1)	13	6 (46%)		13	8	(62%)	3	(23%)	2	(15%)	0
	50-56 Days (Group 2)	5	3 (60%)		4	1	(25%)	2	(50%)	1	(25%)	0
	57-63 Days (Group 3)	3	3 (100%)		4	3	(75%)	1	(25%)	0		0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: ROTHENBERG (#8)

	Gestational	Total	Number	Fisher's				tv	
Body System/Event	Age Group [2]	Number of Pts	of Pts w/Event	exact p-value	Number - of Events	Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
DIARRHEA	≤63 Days (All)	21	5 (24%)	0.7892	6	4 (67%)	2 (33%)	0	0
	≤49 Days (Group 1)	13	4 (31%)		5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	21	8 (38%)	0.0394	11	7 (64%)	2 (18%)	2 (18%)	0
HAUGUA	s49 Days (Group 1)	13	3 (23%)		6	4 (67%)	1 (17%)	1 (17%)	0
•	50 56 Days (Group 2)	5	2 (40%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	3	3 (100%)		3	3 (100%)	0	0	0
VOMITING	≤63 Days (All)	21	4 (19%)	0.7611	4	1 (25%)	2 (50%)	1 (25%)	0
VOMITING	s49 Days (Group 1)	13	2 (15%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
: !	57-63 Days (Group 3)	3	1 (33%)		1	0	1 (100%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									_
ANY EVENT	≤63 Days (All)	21	15 (71%)	0.0652	26	8 (31%)	10 (38%)	8 (31%)	0
	≤49 Days (Group 1)	13	7 (54%)		9	5 (56%)	3 (33%)	1 (11%)	0
	50-56 Days (Group 2)	5	5 (100%)		12	3 (25%)	5 (42%)	4 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		5	0	2 (40%)	3 (60%)	0
ABDOMINAL PAIN	≤63 Days (All)	21	15 (71%)	0.0652	25	8 (32%)	9 (36%)	8 (32%)	0
	≰49 Days (Group 1)	13	7 (54%)		9	5 (56%)	3 (33%)	1 , (11%)	0
	50-56 Days (Group 2)	5	5 (100%)		[11	3 (27%)	4 (36%)	4 (36%)	0
	57-63 Days (Group 3)	3	3 (100%)		. 5	0	2 (40%)	3 (60%)	0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix D, Table 5c (Continued) Adverse Events Possibly or Probably Related to Misoprostol [1] By Center [Safety Evaluable Patients]

Center: ROTHENBERG (#8)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Ever	\$	Fisher's exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)										_
BACK PAIN	≤63 Days (All)	21	1	(5%)	0.3810	1	0	1 (100%)	0	0
	s49 Days (Group 1)	13	0			0	0	0	0	0
	50-56 Days (Group 2)	5	1 (2	20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0			0	0	0	0	0

^[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.

Appendix A.1, Tables 16 and 25

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^[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Continuation of Protocol 166B

Appendix C

Part B. Protocol Cover Sheet

APPENDIX C THE POPULATION COUNCIL PROTOCOL 166B

B. PROTOCOL COVER SHEET

Study Phase: III

Name of Drug:

Active Ingredient: Mifepristone

Dosage: 600 mg

Route of Administration: oral Duration of Treatment: single dose

Objective: the study was conducted to evaluate the effectiveness, safety, acceptability, feasibility of using mifepristone and misoprostol in a setting within the United States health care system for the induction of abortion in women whose duration of amenorrhea was no more than 63 days.

Patient Population: women at least 18 years of age who were \leq 63 days from onset of their last menstrual period and who requested a voluntary termination of pregnancy.

Structure: open-label, single treatment group with patients stratified by gestational age ($\leq 49, 50 - 56, 57 - 63$ days).

Multicenter: yes

Number of Centers: 9 Common Training: yes

Blinding: none

Method of Patient Assignment: all patients were assigned to treatment with 600 mg mifepristone and 400 µg misoprostol.

Concurrent Control: none

Estimated Total Sample Size: 1050

Statistical Rationale Provided: no

Primary Efficacy Variable: proportion of patients with complete expulsion of the

products of conception.

Adverse Reactions: observed/volunteered

Plan for Data Analysis: yes

The Population Council Protocol 166B

Continuation of Protocol 166B

Appendix C

Part C. Protocol and Informed Consent, Protocol Amendments, Case Record Forms

APPEARS THIS WAY ON ORIGINAL

APPENDIX C THE POPULATION COUNCIL PROTOCOL 166B STUDY PROTOCOL AND AMENDMENTS AND GENERAL INFORMATION

A. Date Protocol Filed to and Dates Amended:

Date Filed: August 3, 1994

Dates Amended:

November 2, 1994

May 5, 1995

- B. Protocol Cover Sheet
- C. Protocol, Protocol Amendments, Sample Informed Consent Form, and Case Report Forms
- D. Mifepristone and Misoprostol Drug Lot Numbers

Mifepristone: JMP25524-109 (all centers)

Misoprostol:

Center 21: 4P456, 4P457

Center 22: 04H437, 4H438, 4H438A, 4N451

Center 23: 4F434, 4N454, 5B468

Center 24: 4F434, 4S459, 4S462, 5B468

Center 25: 4N453

Center 26: 4F434, 4F435, 4K446, 4S462

Center 27: 3P411, 4P456, 4S459, 5C476, 5D479

Center 28: 4P455, 4P456, 4S459, 5D479

Center 29: 4H438A

E. Publications Based on the Study

Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. New Engl J Med 1998;338:1241-7.

Winikoff B, Ellertson C, Elul B, Sivin I for the mifepristone clinical trials group. Acceptability and feasibility of early pregnancy termination by mifepristone - misoprostol: results of a large multicenter trial in the United States. Arch Fam Med 1998;7:360-6.

The Population Council Protocol 166B

> Appendix D, Table 5a Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher' exact	s Number				·Severit	ty		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value		Mi	.1d	Mode	rate	Sev	ere	Unknown
•												
ANY EVENT	≤63 Days (All)	71	71 (100	k)	357	151	(42%)	160		46		0
	≤49 Days (Group 1)	28	28 (100	b)	112	50	(45%)	57		5	(4%)	0
	50-56 Days (Group 2)	26	26 (100	F)	128	52	(41%)	52	(41%)	24	(19%)	0
	57-63 Days (Group 3)	17	17 (100	b)	117	49	(42%)	51	(44%)	17	(15%)	0
IKIN AND APPENDAGES DISORDERS												
ANY EVENT	≤63 Days (All)	71	1 (1	k) 0.2394	1	0		1	(100%)	0		0
•	s49 Days (Group 1)	28	0		i o	0		0	!	0.		0
ì	50-56 Days (Group 2)	26	0		0	0		0	•	0		0
	57-63 Days (Group 3)	17	1 (6	b)	1	0		1	(100%)	0		0
SWEATING INCREASED	s63 Days (All)	71	1 (1	0.2394	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	28	0		0	0		0		0		0
	50-56 Days (Group 2)	; 26	0		0	0		0		0		0
	57-63 Days (Group 3)	17	1 (6	₩)	1	0		1	(100%)	0		0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS		ļ										
ANY EVENT	s63 Days (All)	71	28 (39	0.0057	42	15	(36%)	19	(45%)	8	(19%)	0
	£49 Days (Group 1)	28	15 (54		16	7	(44%)	7	(44%)	2	(13%)	0
	50-56 Days (Group 2)	26	4 (15		7	1	(14%)	3	(43%)	3	(43%)	0
	57-63 Days (Group 3)	17	9 (53		19	7	(37%)	9	(47%)	3	(16%)	0
	•	1										

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number				Severit	v		
Body System/Event [2]	Group (3)	of Pts	w/Ev		p-value	of Events		1 d	Mode		•	(25%) (17%) (7%) (7%) (43%) (14%) (50%) (100%)	Unknow
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)												
DIZZINESS	≤63 Days (All)	71	3	(4%)	0.0119	4	1	(25%)	. 2	(50%)	1	(25%)	· 0
	≤49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	26	0			0	0		' 0		0		0
	57-63 Days (Group 3)	17	3	(18%)		4	1	(25%)	2	(50%)	1	(25%)	0
HEADACHE	≤63 Days (All)	71	26	(37%)	0.0145	36	14	(39%)	16	(44%)	6	(17%)	0
1	≰49 Days (Group 1)	28	14	(50%)		15	7	(47%)	7	(47%)	1	(7%)	0
	50-56 Days (Group 2)	26	4	(15%)		7	1	(14%)	3	(43%)	3 -	(43%)	0
	57-63 Days (Group 3)	17	8	(47%)		14	6	(43%)	6	(43%)	2	(14%)	0
MIGRAINE	≤63 Days (All)	71	2	(3%)	0.7070	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	28	1	(4%)		1	0		0		1	(100%)	0
4	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	1	(6%)		1	0		1	(100%)	0		0
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	71	5	(7%)	0.7284	10	6	(60%)	3	(30%)	1	(10%)	0
	≤49 Days (Group 1)	28	2	(7%)		3	2	(67%)	1	(33%)	0		0
	50-56 Days (Group 2)	26	1	(4%)		4	4	(100%)	, 0		0		0
	57-63 Days (Group 3)	17	2	(12%)		3	0		2	(67%)	1	(33%)	0
ANXIETY	∌63 Days (All)	71	3	(4%)	1 0000	6	5	(83%)	1	(17%)	0		0
	£49 Days (Group 1)	28	1	(4%)	!	1	1	(100%)	0		0		0
	50-56 Days (Group 2)	26	1	(4%)	ļ	. 4	4	(100%)	0		0		0
	57-63 Days (Group 3)	17	1	(6%)		· 1	0		1	(100%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational	Total	Numb		Fisher's	M				- Coveri			
Body System/Event [2]	Age Group (3)	Number of Pts	of I		exact p-value	Number of Events	Mi		Mode		Sev		Unknown
PSYCHIATRIC DISORDERS (cont.)													
INSOMNIA	≤63 Days (All)	71	3	(4%)	0.4523	4	1	(25%)	2		1	(25%)	0
	#49 Days (Group 1)	28	2	(7%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	26	0			0	0		0		0		0
	57-63 Days (Group 3)	17	1	(61)		2	0		1	(50%)	1	(50%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	71	52	(73%)	0.1254	123	51	(41%)	53	(43%) _[19	(15%)	0
•	≤49 Days (Group 1)	28	17	(61%)		30	14	(47%)	14	(47,4)	7.	(7%)	0
	50-56 Days (Group 2)	26	20	(77%)		50	18	(36%)	21	(42%)	11	(22%)	0
	57-63 Days (Group 3)	17	15	(#88)		43	19	(44%)	18	(42%)	6	(14%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	71	2	(31)	1.0000	2	1	(50%)	0		1	(50%)	0
	s49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	26	1	(4%)		1	0		0		1	(100%)	0
	57-63 Days (Group 3)	17	0			0	0		0		0		0
DIARRHEA	s63 Days (All)	71	8	(11%)	0.6427	10	6	(60%)	3	(30%)	1		0
	≤49 Days (Group 1)	28	2	(7%)		3	2	(67%)	0		1	(33%)	0
	50-56 Days (Group 2)	26	4	(15%)		5	3	(60%)	2	(40%)	0		0
	57-63 Days (Group 3)	17	2	(12%)		2	1	(50%)	1	(50%)	0		0
DYSPEPSIA	≤63 Days (All)	71	2	(3%)	0.5155	2	1	(50%)	0		1	(50%)	0
	≤49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	26	1	(4%)		. 1	0		0		1	(100%)	0
	57-63 Days (Group 3)	17	1	(6%)		• 1	1	(100%)	0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Num of w/E		Fisher's exact p-value	Number of Events		1d	Mode		-	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
FLATULENCE	≤63 Days (All)	71	3	(4%)	0.6115	3	2	(67%)	1	(33%)	0		0
FLATOBENCE	s49 Days (Group 1)	28	1	(4%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	26	2	(8%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	17	0	,		0	0		0		0		0
NAUSEA	≤63 Days (All)	71	42	(59%)	0.3779	67	27	(40%)	30	(45%)	10		0
1	≤49 Days (Group 1)	28	14	(50%)		17	7	(41%)	9	(531)	1	(6%)	0
•	50-56 Days (Group 2)	26	16	(62%)		24	9	(38%)	10	(421)	5		0
	57-63 Days (Group 3)	17	12	(71%)		26	11	(42%)	11	(42%)	4	(15%)	0
VOMITING	≤63 Days (All)	71	25	(35%)	0.1310	39	14	(36%)	19	(49%)	6	(15%)	0
701122110	≤49 Days (Group 1)	28	6	(21%)		8	3	(38%)	5	(63%)	0		0
	50-56 Days (Group 2)	26	11	(42%)		17	5	(29%)	8	(47%)	4	(24%)	0
	57-63 Days (Group 3)	17	8	(47%)		14	6	(43%)	6	(43%)	2	(14%)	• 0
VASCULAR (EXTRACARDIAC) DISORDERS													
ANY EVENT	s63 Days (All)	71	1	(1%)	0.6056	1	0			(100%)	0		0
	s49 Days (Group 1)	28	0			0	0		0		0		0
	50-56 Days (Group 2)	26	1	(4%)		1	0			(100%)	0		0
	57-63 Days (Group 3)	17	0	•		0	0		0		. 0		0
FLUSHING	s63 Days (All)	71	1	(1%)	0.6056	1	0		1	(100%)	0		0
	s49 Days (Group 1)	28	0			0	0		0		P		0
	50-56 Days (Group 2)	26	1	(4%)		. 1	0		1	(100%)	þ		0
	57-63 Days (Group 3)	17	0			0	0		0		Ö		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number ·		Severit	·V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value		Mild	Moderate	Severe	Unknow
ESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	71	5 (7%)	0.2784	8	6 (75%)	2 (25%)	0	0
	s49 Days (Group 1)	28	4 (14%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	26	1 (4%)		4	4 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
PHARYNGITIS	s63 Days (All)	71	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
•	50,56 Days (Group 2)	26	0		0	0	0 '	0 ·	0
	57 63 Days (Group 3)	17	0		0	0	ο '	0	0
PULMONARY CONGESTION	≤63 Days (All)	71	1 (1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	28	1 (4%)		1,	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0		O	0	0	0	0
	57-63 Days (Group 3)	17	0		o	0	0	0	0
SINUSITIS	≤63 Days (All)	71	3 (4%)	0.7835	6	5 (83%)	1 (17%)	0	0
	≤49 Days (Group 1)	28	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	26	1 (4%)		4	4 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
LATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	71	1 (1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0		. 0	0	0	0	0
	57-63 Days (Group 3)	17	0		• 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
(Safety Evaluable Patients)

Center: POINDEXTER (#21)

	Gestational	Total	Number	Fisher's	Number -		·Severit	·V	
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	of Events	Mild	Moderate	Severe	Unknow
LATELET, BLEEDING & CLOTTING DISC	ORDERS (cont.)								_
EPISTAXIS	≤63 Days (All)	71	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0		0	0	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
EPRODUCTIVE DISORDERS, FEMALE		4							
ANY EVENT	≤63 Days (All)	71	4 (6%)	0.8280	4	2 (50%)	1 (25%)	1 (25%)	0
,	s49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	O ·	0
	50-56 Days (Group 2)	26	2 (8%)		2	1 (50%)	О,	1 (50%)	0
	57-63 Days (Group 3)	17	1 (6%)		1	1 (100%)	0	0	0
LEUKORRHOEA	≤63 Days (All)	71	1 (1%)	0.6056	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	71	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	0		0	0	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
UTERINE HAEMORRHAGE	s€3 Days (All)	71	1 (1%)	0.6056	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4%)		1 1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	0			0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		·Severit	V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknowr
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINITIS	≤63 Days (All)	71	1 (1%)	0.2394	1	1 (100%)	0	0	0
	s49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	0		0	0	0	0	0
	57-63 Days (Group 3)	17	1 (6%)		1	1 (100%)	0	0	0
BODY AS A WHOLE - GEMERAL DISORDERS									
ANY EVENT	≤63 Days (All)	71	69 (97%)	1.0000	165	69 (42%)	79 (48%)	17 (10%)	0
'	≤49 Days (Group 1)	28	27 (96%)		57	25 (44%)	31 (54%)	1. (2%)	0
	50-56 Days (Group 2)	26	25 (96%)		58	22 (38%)	27 (47%)	9 (16%)	0
	57-63 Days (Group 3)	17	17 (100%)		50	22 (44%)	21 (42%)	7 (14%)	0
ABDOMINAL PAIN	≤63 Days (All)	71	65 (92%)	0.8736	147	60 (41%)	75 (51%)	12 (8%)	0
	s49 Days (Group 1)	28	26 (93%)		52	22 (42%)	29 (56%)	1 (2%)	0
	50-56 Days (Group 2)	26	24 (92%)		53	21 (40%)	25 (47%)	7 (13%)	0
	57-63 Days (Group 3)	17	15 (88%)		42	17 (40%)	21 (50%)	4 (10%)	0
ALLERGY	≤63 Days (All)	71	1 (1%)	0.2394	1	1 (100%)	0	0	0
	s49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	0		0	0	0	0	0
	57-63 Days (Group 3)	17	1 (6%)		1	1 (100%)	0	0	0
ASTHENIA	s63 Days (All)	71	2 (3%)	0.0547	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	' 28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	0		. 0	0	0	0	0
	57-63 Days (Group 3)	17	2 (12%)		• 2	2 (100%)	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: POINDEXTER (#21)

Body System/Event (2)	Gestational Age Group [3]	Total Number of Pts	Number of Ptr w/Ever	s	Fisher's exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)							· · · · · · · · · · · · · · · · · · ·		
BACK PAIN	≤63 Days (All)	71	7 (10%)	0.6817	7	4 (57%)	2 (29%)	1 (14%)	0
	≤49 Days (Group 1)	28	4 (14%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	26	2	(B%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	17	1	(6%)		1	0	0	1 (100%)	0
FATIGUE	≤63 Days (All)	71	1	(1%)	0.2394	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	28	0			0	0	0	0	0
•	50-56 Days (Group 2)	26	0			0	0	0 !	0 .	0
	57-63 Days (Group 3)	17	1	(6%)		2	2 (100%)	о '	0	0
FEVER	≤63 Days (All)	71	1	(1%)	0.6056	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0			0	0	0	ò	0
1	50-56 Days (Group 2)	26	1	(4%)		1	0	1 (100%)	O	0
	57-63 Days (Group 3)	17	0			0	0	0	0	0
LEG PAIN	≤63 Days (All)	71	1	(1%)	0.2394	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0			0	0	0	0	0
	50-56 Days (Group 2)	26	0			0	0	0	0	0
ļ.	57-63 Days (Group 3)	17	1	(6%)		1	0	o i	1 (100%)	0
PAIN	≤63 Days (All)	71	1	(1%)	0.6056	1	·O	i o	1 (100%)	0
	≤#9 Days (Group 1)	28	0			0	0	0	0	0
	50-56 Days (Group 2)	26	1	(4%)	j	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	0		\	. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

⁽²⁾ NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: POINDEXTER (#21)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		·Severi	ty	
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (CO	ont.)								
RIGORS	≤63 Days (All)	71	2 (3	1.0000	2	0	1 (50%)	1 (50%)	0
·	s49 Days (Group 1)	28	1 (4	1)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	1 (4	:)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	71	1 (1	0.2394	1	0 .	O	1 (100%)	0
,	≤49 Days (Group 1)	28	0		0	0	0	0	0
,	50 56 Days (Group 2)	26	0		0	0	o !	D .	0
	57-63 Days (Group 3)	17	1 (6	1)	1	0	0 '	1 (100%)	0
APPLICATION SITE DISORDERS [4]									
ANY EVENT	≤63 Days (All)	71	1 (1	0.6056	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4	:)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
INJECTION SITE BRUISING	≤63 Days (All)	71	1 (1	0.6056	1	1 (100%)	O	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4	1)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	71	1 (1	0.6056	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		. 0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4	;)	• 1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0 (,	•	0	0	0	0	Ö

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Even	Fisher's exact p-value	Number	Mild	Moderate	Severe	Unknown
ESISTANCE MECHANISM DISORDERS (cont.)									
INFECTION PARASITIC	≤63 Days (All)	71	1 ((1) 0.6056	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4	*)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's								
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events		ild		Severi rate	•	ere	Unknown
4											•	
ANY EVENT	≤63 Days (All)	151	150 (>99%)	0.2517	841	291	(35%)	361	(43%)	189	(22%)	0
	s49 Days (Group 1)	70	70 (100%)		347	121	(35%)	164	(47%)	62	(18%)	0
	50-56 Days (Group 2)	43	43 (100%)		268	93	(35%)	110	(41%)	65	(24%)	0
	57-63 Days (Group 3)	38	37 (97%)		226	77	(34%)	87	(38%)	62	(27%)	0
KIN AMD APPENDAGES DISORDERS	1											
ANY EVENT	≤63 Days (All)	151	3 (2%)	0.7966	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	70	2 (3%)		2	1	(50%)	1	(5ģ¥)	0 .		0
	50 56 Days (Group 2)	43	1 (2%)		1	1	(100%)	0	•	0		0
	57-63 Days (Group 3)	38	0		0	0		0		0		0
RASH	≤63 Days (All)	151	2 (1%)	1.0000	2;	2	(100%)	0		0		0
	≤49 Days (Group 1)	70	1 (1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	43	1 (2%)		1 !	1	(100%)	0		0		0
	57-63 Days (Group 3)	38	0		0	0		0		0		0
URTICARIA	≤63 Days (All)	151	1 (<1%)	1.0000	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	1 (1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	43	0		0	0		0		0		0
	57-63 Days (Group 3)	38	0		0	0		0		0		0
USCULO-SKELETAL SYSTEM DISORDERS	•											
ANY EVENT	s63 Days (All)	151	2 (1%)	0.2861	2	0		2	(100%)	0		0
	s49 Days (Group 1)	70	0		. 0	0		0		0		0
	50-56 Days (Group 2)	43	1 (2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	1 (3%)		1	0		1	(100%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

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^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Center: VARGAS (#22)

	Gestational	Total	Numb		Fisher's								
Body System/Event [2]	Age Group [3]	Number of Pts	of F w/Ev		exact p-value	Number of Events		1d	Mode	Severi rate	•	ere	Unknow
USCULO-SKELETAL SYSTEM DISORDERS (cont.)													
ARTHRALGIA	≤63 Days (All)	151	1	(<1%)	0.5364	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	70	0			. 0	0		0		0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	0			´ O	0		0		0		0
HYALGIA	≤63 Days (All)	151	1	(<1%)	0.2517	1	0		1	(100%)	0		0
1	s49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	0	į		0	0		0	!	0 .		0
	57 63 Days (Group 3)	38	1	(3%)		1	0		1	(10Ó %)	0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	151	65	(43%)	0.7381	97	36	(37%)	51	(53%)	10	(10%)	0
	≤49 Days (Group 1)	70	28	(40%)		41	16	(39%)	21	(51%)	4	(10%)	0
	50-56 Days (Group 2)	43	19	(44%)		29	13	(45%)	15	(52%)	1	(3%)	0
	57-63 Days (Group 3)	38	18	(47%)		27	7	(26%)	15	(56%)	5	(19%)	0
							1						
DIZZINESS	≤63 Days (All)	151	22	(15%)	0.7975	27	10	(37%)	16	(59%)	1	(4%)	0
	≤49 Days (Group 1)	70	11	(16%)		13	6	(46%)	7	(54%)	0		0
	50-56 Days (Group 2)	43	7	(16%)		8	3	(38%)	5	(63%)	0		0
	57-63 Days (Group 3)	38	4	(11%)		6	1	(17%)	4	(67%)	1	(17%)	0
HEADACHE	≤63 Days (All)	151	54	(36%)	0.4003	68	25	(37%)	35	(51%)	8	(12%)	0
	s49 Days (Group 1)	70	22	(31%)		26	9	(35%)	14	(54%)	3	(12%)	0
	50-56 Days (Group 2)	43	15	(35%)		21	10	(48%)	10	(48%)	1	(5%)	0
	57-63 Days (Group 3)	38	17	(45%)		21	6	(29%)	11	(52%)	4	(19%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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> Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	NumberSeverity							
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow			
ENTR & PEREPH NERVOUS SYSTEM DISORDE	RS (cont.)											
HYPOAESTHESIA	≤63 Days (All)	151	1 (<1%)	1.0000	1	1 (100%)	0	0	0			
	≤49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0			
	50-56 Days (Group 2)	43	0		0	0	0	0	0			
	57-63 Days (Group 3)	38	0		0	0	0	0	0			
MIGRAINE	≤63 Days (All)	151	1 (<1%)	1.0000	1	0	0	1 (100%)	0			
1	s49 Days (Group 1)	70	1 (1%)		1	0	0 .	1 (100%)	0			
	50-56 Days (Group 2)	43	0		O	0	0 .	0.	0			
	50-56 Days (Group 2) 43 0 0 0 0	0	0	0	0							
ISION DISORDERS												
ANY EVENT	s63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0			
	s49 Days (Group 1)	70	0		0	0	0	0	0			
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0			
	57-63 Days (Group 3)	38	0		0	0	0	0	0			
VISION ABNORMAL	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0			
	<pre>s49 Days (Group 1)</pre>	70	0		0	0	0	0	0			
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0			
	57-63 Days (Group 3)	38	0		0	0	0	0	0			
MARING AND VESTIBULAR DISORDERS	•	1										
ANY EVENT	≤63 Days (All)	151	1 (<1%)	0.2517	1	0	1 (100%)	0	0			
	≤49 Days (Group 1)	70	0		. 0	0	0	0	0			
	50-56 Days (Group 2)	43	0		0	0	0	0	0			
	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	0			

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's									
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p·value	Number of Events	Mild	Moderate	Severe	Unknown				
HEARING AND VESTIBULAR DISORDERS (cont.)													
TINNITUS	≤63 Days (All)	151	1 (<1%)	0.2517	1	0	1 (100%)	0	0				
	≤49 Days (Group 1)	70	0		0	0	0	Ö	ō				
	50-56 Days (Group 2)	43	0		0	0	0	0	ō				
	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	0				
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	151	9 (6%)	0.6789	9	2 (22%)	5 (56%)	2 (22%)	0				
,	≤49 Days (Group 1)	70	5 (7%)		5	2 (40%)	3 (60%)	0.	0				
	50 56 Days (Group 2)	43	3 (7%)		3	0	2 (67%)	1 (33%)	Ô				
	57-63 Days (Group 3)	38	1 (3%)		1	o	0	1 (100%)	ŏ				
ANOREXIA	s63 Days (All)	151	2 (1%)	0.2861	2	0	1 (50%)	1 (50%)	0				
	≤49 Days (Group 1)	70	0 (10)	0.2001	0	0	1 (304)	0	0				
	50-56 Days (Group 2)	43	1 (2%)		1	0	1 (100%)	0	n				
	57-63 Days (Group 3)	38	1 (3%)		1	ō	0	1 (100%)	ō				
DEPRESSION	≤63 Days (All)	151	1 (<1%)	1.0000	1	1 (100%)	0	0	0				
	s49 Days (Group 1)	70	1 (1%)	2.000	1	1 (100%)	Ŏ	Ö	0				
1	50-56 Days (Group 2)	43	0 (21)		0	0 ;	0	o	0				
	57-63 Days (Group 3)	38	ō		0	, 0	o	ō	ō				
EMOTIONAL LABILITY	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0				
	±49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	n				
	50-56 Days (Group 2)	43	1 (2%)	\	1	0	0	1 (100%)	0				
	57-63 Days (Group 3)	38	0		• 0	0	0	0	0				

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: VARGAS (#22)

	Gestational Age	Total Number	Num of	ber Pts	Fisher's exact	Number				Severit	y		
Body System/Event (2)	Group (3)	of Pts	W/E	vent	p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unknowr
PSYCHIATRIC DISORDERS (cont.)					•								
INSOMNIA	≤63 Days (All)	151	4	(3%)	0.6950	4	0		4	(100%)	0		0
	≤49 Days (Group 1)	70	3	(4%)		3	0		3	(100%)	0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
lastro-intestinal system disorders													
ANY EVENT	≤63 Days (All)	151	119	(79%)	0.1176	316	125	(40%)	134	(42%)	57	(18%)	0
	≤49 Days (Group 1)	70	50	(71%)		119	43	(36%)	59	(50%)	17	(14%)	0
	50-56 Days (Group 2)	43	36	(84%)		105	41	(39%)	41	(394)	23	(22%)	0
	57-63 Days (Group 3)	38	33	(87%)		92	41	(45%)	34	(37%)	17	(18%)	0
CONSTIPATION	≤63 Days (All)	151	1	(<1%)	0.5364	1	0		1	(100%)	0		0
	s49 Days (Group 1)	70	0			0	0		0		0	1	0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	0			0	0		0		0		0
DIARRHEA	s63 Days (All)	151	50	(33%)	0.1287	68	34	(50%)	25	(37%)	9	(13%)	0
	≤49 Days (Group 1)	70	18	(26%)		24	11	(46%)	10	(42%)	3	(13%)	0
	50-56 Days (Group 2)	43	19	(44%)		24	11	(46%)	10	(42%)	3	(13%)	0
	57-63 Days (Group 3)	38	13	(34%)		20	12	(60%)	5	(25%)	3	(15%)	0
DYSPEPSIA	s63 Days (All)	151	2	(1%)	0.4993	2	0		1	(50%)	1	(50%)	0
	≤49 Days (Group 1)	70	2	(3%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	43	0			. 0	0		0		0		0
	57-63 Days (Group 3)	38	0			• 0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

Body System/Event (2)	Gestational Age	Total Number	of	ber Pts	Fisher's exact								
BOOY SYBCEM/EVERIC (2)	Group [3]	of Pts	W/E	Event	p-value	of Events	M1	.1d	Mode	erate	Sev	ere	Unknowr
ASTRO-INTEGTINAL SYSTEM DISORDERS (cont.)													
NAUSEA	≤63 Days (All)	151	104	(69%)	0.3257	166	71	(43%)	67	(40%)	28	(17%)	0
	s49 Days (Group 1)	70	44	(63%)		65	27	(42%)	29	(45%)	9	(14%)	0
	50-56 Days (Group 2)	43	31	(72%)		53	21	(40%)	22	(42%)	10	(19%)	0
	57-63 Days (Group 3)	38	29	(76%)		48	23	(48%)	16	(33%)	9	(19%)	0
TOOTH ACHE	≤63 Days (All)	151	2	(1%)	0.7342	2	o		2	(100%)	0		0
	≤49 Days (Group 1)	70	1	(1%)		1	0			(100%)	0		0
'	50-56 Days (Group 2)	43	0	, ,		0	0		0	1	0.		0
	57-63 Days (Group 3)	38	1	(3%)		1	o		1	(100%)	ō		0
VOMITING	≤63 Days (All)	151	51	(34%)	0.1493	77	20	(26%)	38	(49%)	19	(25%)	0
	≤49 Days (Group 1)	70	18	(26%)		27	5	(19%)	18	(67%)	4	(15%)	0
	50-56 Days (Group 2)	43	18	(42%)		27	9	(33%)	8	(30%)	10	(37%)	0
	57-63 Days (Group 3)	38	15	(39%)		23	6	(26%)	12	• •	5	(22%)	. 0
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	151	2	(1%)	0.2861	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	70	0			0	0		0		0		0
	50-56 Days (Group 2)	43	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	38	1	(3%)		1	1	(100%)	0		. 0		0
DEHYDRATION	s63 Days (All)	151	1	(<1%)	0.2517	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	70	0			0	0		0		į 0		0
	50-56 Days (Group 2)	43	0			0	0		0		o		ō
	57 63 Days (Group 3)	38	1	(3%)		1 1	1	(100%)	0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's	Number -	- ·····Severity · · · · · · · · · · · · · · · · · · ·							
Body System/Event [2]	Group [3]	of Pts	w/Event	exact p-value	of Events	Mild	Moderate	Severe	Unknown				
GTABOLIC AND NUTRITIONAL DISORDERS (cont.)	*	, , , ,	 	, , , , , , , , , , , , , , , , , , , 	· · · · · · · · · · · · · · · · · · ·	**************************************		-,, -				
THIRST	≤63 Days (All)	151	1 (<1%)	0.5364	1	0	1 (100%)	0	0				
	s49 Days (Group 1)	70	0 -		0	0	0	0	0				
	50-56 Days (Group 2)	43	1 (2%)		1	0	1 (100%)	0	0				
	57-63 Days (Group 3)	38	0		0	0	0	0	0				
RESPIRATORY SYSTEM DISORDERS	1												
ANY EVENT	≤63 Days (All)	151	3 (2%)	0.7966	6	4 (67%)	1 (17%)	1 (17%)	0				
	s49 Days (Group 1)	70	2 (3%)		5	4 (80%)	o .'	1 (20%)	0				
	50-56 Days (Group 2)	43	1 (2%)		1	0	1 (100%)	0	0				
	57-63 Days (Group 3)	38	0		0	0	0	0 0	0				
BRONCHITIS	s63 Days (All)	151	1 (<1%)	1.0000	3	2 (67%)	o	1 (33%)	0				
	≤49 Days (Group 1)	70	1 (1%)		3	2 (67%)	0	1 (33%)	0				
	50-56 Days (Group 2)	43	0		o [†]	0	0	0	0				
	57-63 Days (Group 3)	38	0		0	0	0	0	0				
PHARYNGITIS	≤63 Days (All)	151	1 (<1%)	1.0000	1	1 (100%)	o	0	0				
	s49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0				
	50-56 Days (Group 2)	43	0		0	0	0	0	0				
	57-63 Days (Group 3)	38	0		0	0	0	0	0				
SINUSITIS	±63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0				
	≤49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0				
	50-56 Days (Group 2)	43	1 (2%)		i 1	0	1 (100%)	0	0				
	57-63 Days (Group 3)	38	0		0	0	0	0	0				

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: VARGAS (#22)

	Gestational	Total	Number	Fisher's		Severity						
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown			
PLATELET, BLEEDING & CLOTTING DISORDERS				•								
ANY EVENT	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0			
	≰49 Days (Group 1)	70	1 (11)		. 1	0	0	1 (100%)	ō			
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	o			
	57-63 Days (Group 3)	38	0		0	0	0	0	o			
EPISTAXIS	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0			
	s49 Days (Group 1)	70	1 (1%)		1	0	Ō	1 (100%)	ō			
•	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0,	ō			
	57-63 Days (Group 3)	38	0		0	0	0	0	o			
RIMARY SYSTEM DISORDERS												
ANY EVENT	≤63 Days (All)	151	2 (1%)	1.0000	3	1 (33%)	2 (67%)	0	0			
	≤49 Days (Group 1)	70	1 (1%)		2	0	2 (100%)	o	ō			
	50-96 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	ō	o			
	57-63 Days (Group 3)	38	0		0	0	0	0	0			
DYSURIA	≤63 Days (All)	151	1 (<1%)	1.0000	1	, o	1 (100%)	0	0			
	≤49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	0			
	50-56 Days (Group 2)	43	0		0	0	0	0	0			
	57-63 Days (Group 3)	38	0		0	0	0	0	0			
MICTURITION DISORDER	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	0	0	0			
	≤49 Days (Group 1)	70	0		0	0	0	0	0			
	50-56 Days (Group 2)	43	1 (2%)		. 1	1 (100%)	0	0	0			
	57-63 Days (Group 3)	38	0		. 0	0	0	0	0			

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: VARGAS (#22)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number -	Mild	····Severity Moderate	Severe	Unknow
BODY SYSTEM/EVENT (2)	Group (3)	OI PCS	w/Event	p-varue	Of Evence	MIIG	Moderace	Gevere	
FRINARY SYSTEM DISORDERS (cont.)									
MICTURITION FREQUENCY	£63 Days (All)	151	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≰49 Days (Group 1)	70	1 (1%)		1	0 .	1 (100%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
EPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	. ≤63 Days (All)	151	9 (6%)	1.0000	9	2 (22%)	3 (33%)	4 (44%)	0
	≤49 Days (Group 1)	70	4 (6%)		4	1 (25%)	2 (50)	1 (25%)	0
	50-56 Days (Group 2)	43	3 (7%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	38	2 (5%)		2	0	0	2 (100%)	0
BREAST PAIN FEMALE	≤63 Days (All)	151	1 (<1%)	0.5364	1	1 (100%)	O	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	151	2 (1%)	0.4993	2	1 (50%)	1 (50%)	0	0
	s49 Days (Group 1)	70	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	43	0		0	0	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	151	5 (3%)	0.7184	5	0	1 (20%)	4 (80%)	0
	s49 Days (Group 1)	70	2 (3%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	43	1 (2%)		. 1	0	0	1 (100%)	0
	57-63 Days (Group 3)	38	2 (5%)		2	0	0	2 (100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: VARGAS (#22)

	Gestational	Total		Fisher's exact p-value								
Body System/Event [2]	Age Group (3)	Number of Pts			Number of Events	Mi	1 d	Mode	Severi erate	-	ere	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									·			
VAGINITIS	≤63 Days (All)	151	1 (<1%)	0.5364	3	0		. 1	(100%)	0		0
	≤49 Days (Group 1)	70	0		Ô	ō		0	(1004)	o		0
	50-56 Days (Group 2)	43	1 (2%)		1	0			(100%)	0		0
	57-63 Days (Group 3)	38	0		ō	ō		ō	(1000)	0		0
SODY AS A WHOLE - GENERAL DISORDERS												
ANY EVENT	s63 Days (All)	151	150 (>99%)	0.2517	382	114	(30%)	156	(41%)	112	(29%)	0
·	≤49 Days (Group 1)	70	70 (100%)		164	53	(321)	73	(45%)	38		0
	50-56 Days (Group 2)	43	43 (100%)		118	33	(281)	47	(40%)	38	(32%)	0
	57-63 Days (Group 3)	38	37 (97%)		100	28	(28%)	36	(36%)	36	(36%)	0
ABDOMINAL PAIN	≤63 Days (All)	151	150 (>99%)	0.2517	337	88	(26%)	137	(41%)	112	(33%)	0
1	≤49 Days (Group 1)	70	70 (100%)	0.232.	146	42	(29%)	66	(45%)	38	(26%)	
1	50-56 Days (Group 2)	43	43 (100%)		101	24	(24%)	39	(39%)	38	(38%)	0
	57-63 Days (Group 3)	38	37 (97%)		90	22	(241)	32	(36%)	36	(40%)	0
ALLERGY	s63 Days (All)	151	2 (1%)	0.0621	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	70	0		ō	_	(1001)	0		0		0
i	50-56 Days (Group 2)	43	0		ō	0		, 0		0		0
i i	57-63 Days (Group 3)	38	2 (5%)		2	2	(100%)	0		o		0
BACK PAIN	≤63 Days (All)	151	15 (10%)	0.6078	18	11	(61%)	7	(39%)	0		0
	≤49 Days (Group 1)	70	6 (9%)		7	5	(71%)	,	(29%)	0		0
	50-56 Days (Group 2)	43	6 (14%)	l l	8	5	(63%)	1	(38%)	0		0
	57-63 Days (Group 3)	38	3 (8%)	•	٠ 3	ī	(33%)	2	(67%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: VARGAS (#22)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Saveri		
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDER	s (cont.)					·			
FATIGUE	≤63 Days (All)	151	8 (5%)	0.8096	9	2 (22%)	7 (78%)	0	0
	≤49 Days (Group 1)	70	4 (6%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	43	3 (7%)		4	0	4 (100%)	0	0
	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	0
FEVER	≤63 Days (All)	151	4 (3%)	0.8104	4	4 (100%)	0	0	0
6	≤49 Days (Group 1)	70	1 (1%)		1	1 (100%)	o , l	0	o
	50-56 Days (Group 2)	43	2 (5%)		2	2 (100%)	0	j ·	0
	57-63 Days (Group 3)	38	1 (3%)		1	1 (100%)	0	0	0
HOT FLUSHES	≤63 Days (All)	151	3 (2%)	0.6120	3	2 (67%)	1 (33%)	a	0
	≤49 Days (Group 1)	70	2 (3%)		2	1 (50%)	1 (50%)	o	ō
	50-56 Days (Group 2)	43	0		0	0	0	0	. 0
	57-63 Days (Group 3)	38	1 (3%)		1	1 (100%)	0	0	0
LEG PAIN	≤63 Days (All)	151	1 (<1%)	0.2517	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	Ô
	50-56 Days (Group 2)	43	0		Ö	0	Ō	0	ò
	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	Ō
RIGORS	≤63 Days (All)	151	6 (4%)	1.0000	6	4 (67%)	2 (33%)	0	0
	≤49 Days (Group 1)	70	3 (4%)		3	2 (67%)	1 (33%)	ō	0
	50-56 Days (Group 2)	43	2 (5%)		2	1 (50%)	1 (50%)	0	Ö
	57-63 Days (Group 3)	38	1 (3%)		• ī	1 (100%)	0	o	ō

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: VARGAS (#22)

	Ges tational A ge	Total Number	Number of Pts	Fisher's exact	Number	• • • • • • • • • • • • • • • • • • • •	Severit	y	· • • • •
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknow
SODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
SYNCOPE	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	o o	0
	50-56 Days (Group 2)	4.3	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	Ö	ō	ō
ESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	151	7 (5%)	0.8873	8	2 (25%)	4 (50%)	2 (25%)	0
•	\$49 Days (Group 1)	70	4 (6%)	0.0073	4	1 (25%)	3 (75%)	0 ·	0
	50-56 Days (Group 2)	43	2 (5%)		3	1 (33%)	1 (331)	1 (33%)	ō
	57-63 Days (Group 3)	38	1 (3%)		1	0	0	1 (100%)	0
HERPES SIMPLEX	≤63 Days (All)	151	1 (<1%)	0.5364	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	70	0		0	0	Ö	0	0
	50-56 Days (Group 2)	43	1 (2%)		2	1 (50%)	Ö	1 (50%)	0
	57-63 Days (Group 3)	38	0		0	0	ō	0	ō
INFECTION	≤63 Days (All)	151	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	70	1 (1%)		i	n	1 (1001)	0	0
	50-56 Days (Group 2)	43	0		0	Ŏ	0	0	0
	57-63 Days (Group 3)	38	0		0	0	Ö	. 0	0
	• • •			i	•	•	•	. •	•
INFECTION VIRAL	≤63 Days (All)	151	5 (3%)	1.0000	5	1 (20%)	3 (60%)	1 (20%)	0
	≤49 Days (Group 1)	70	3 (4%)		3	1 (33%)	2 (67%)	D (200)	0
	50-56 Days (Group 2)	43	1 (2%)		. 1	0	1 (100%)	6	0
	57-63 Days (Group 3)	38	1 (3%)		• <u>-</u>	0	0	1 (100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center:

	Gestational	Total	Number	Fisher's	M				
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Severi Moderate	Severe	Unknown
<u> </u>				· · · · · · · · · · · · · · · · · · ·					
ANY EVENT	≤63 Days (All)	89	89 (100%)		770	307 (40%)	303 (39%)	157 (20%)	3 (<1%
	≤49 Days (Group 1)	35	35 (100%)		288	123 (43%)	105 (36%)	59 (20%)	1 (<1%
	50-56 Days (Group 2)	34	34 (100%)		304	107 (35%)	133 (44%)	64 (21%)	0
	57-63 Days (Group 3)	20	20 (100%)		178	77 (43%)	65 (37%)	34 (19%)	2 (1%
KIN AND APPENDAGES DISORDERS	1								
ANY EVENT	≤63 Days (All)	89	3 (3%)	0.7904	3	1 (33%)	1 (33%)	1 (33%)	0
	s49 Days (Group 1)	35	2 (6%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	1 (100%)	0	0
	57 · 63 Days (Group 3)	20	0		0	0	0	0	Ō
SKIN DISORDER	≤63 Days (All)	89	1 (1%)	0.6067	1!	0	1 (100%)	0	0
	≤49 Days (Group 1)	35	0		o	ō	0	0	o
	50-56 Days (Group 2)	34	1 (3%)		1	ō	1 (100%)	Ö	ō
	57-63 Days (Group 3)	20	0		0	0	0	0	Ŏ
SWEATING INCREASED	≤63 Days (All)	89	1 (1%)	1.0000	1	0	0	1 (100%)	0
	#49 Days (Group 1)	35	1 (3%)		1	0	0	1 (100%)	o
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
VERRUCA	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0			0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center:

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher' exact p-value	Number	Mild	Severity Moderate	Severe	Unknown
	occup (5)		-, 5. 6.1.0	P					
rusculo-skeletal system disorders									
ANY EVENT	≤63 Days (All)	89	2 (2	%) 0.5174	. 4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3	*)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1 (5	*)	3	3 (100%)	0	0	0
ARTHRALGIA	≤63 Days (All)	89	1 (1	1 0.2247	1	1 (100%)	0	0	0
ı	s49 Days (Group 1)	35	0		0	0	0	0	0
•	50-56 Days (Group 2)	34	0		0	0	0 1	0 -	0
	57-63 Days (Group 3)	20	1 (5	\$)	1	1 (100%)	о '	0	0
MYALGIA	≤63 Days (All)	89	1 . (1	1 0.6067	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3	1)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
SKELETAL PAIN	≤63 Days (All)	89	1 (1	1 0.2247	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	35	0		0	b	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5	\$)	2	2 (100%)	0	0	0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	51 (57	1) 0.5776	101	34 (34%)	48 (48%)	19 (19%)	0
	≤49 Days (Group 1)	35	22 (63	*)	36	16 (44%)	15 (42%)	5 (14%)	0
	50-56 Days (Group 2)	34	17 (50	%)	: 35	10 (29%)	18 (51%)	7 (20%)	0
	57-63 Days (Group 3)	20	12 (60	•)	30	8 (27%)	15 (50%)	7 (23%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center:

	Gestational Age	Total Number	Number of Pt	-	Fisher's exact	Number				Severit	. v	- 	
Body System/Event [2]	Group [3]	of Pts	w/Eve		p-value	of Events		ld		rate	Sev		Unknow
ENTR & PERIPH NERVOUS SYSTEM DISORDER	S (cont.)												
DIZZINESS	≰63 Days (All)	89	18 (20%)	0.1305	29	13	(45%)	8	(28%)	8	(28%)	0
	≤49 Days (Group 1)	35	11 (31*)		17	9	(53%)	4	(24%)	4	(24%)	0
	50-56 Days (Group 2)	34	4 (12%)		7	2	(29%)	4	(57%)	1	(14%)	0
	57-63 Days (Group 3)	20	3 (15%)		5	2	(40%)	0		3	(60%)	0
HEADACHE	≤63 Days (All)	89	38 (-	43%)	0.3337	72	21	(29%)	40	(56%)	11	(15%)	0
•	. s49 Days (Group 1)	35	12 (34%)		19	7	(37%)	11	(58%)	1	(5%)	0
	50-56 Days (Group 2)	34	15 (44%)		28	8	(291)	14	(50 %)	6	(21%)	0
	57-63 Days (Group 3)	20	11 (55%)		25	6	(24%)	15	(60%)	4	(16%)	0
ISION DISORDERS													
ANY EVENT	≤63 Days (All)	89	1	(1%)	0.6067	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
BLEPHARITIS	≤63 Days (All)	89	1	(1%)	0.6067	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
EARING AND VESTIBULAR DISORDERS	+	1											
ANY EVENT	≤63 Days (All)	89	2	(2%)	0.3437	3	1	(33%)	1	(33%)	1	(33%)	0
	s49 Days (Group 1)	35		(6%)		3	1	(33%)	1	(33%)	1	-	ō
	50-56 Days (Group 2)	34	0			0	b		0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Center:

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

		Gestational Age	Total Number	Numi of		Fisher's exact		· · · · · · · · · · · · · · · · · · ·		-Severii		,	
Body System/Event [2]		Group [3]	of Pts		vent	p-value	of Events	Mild	Moder		Sev		Unknown
HEARING AND + VESTIBULAR D	ISORDERS (cont.)					· · · · · · · · · · · · · · · · · · ·							
EAR ACHE		≤63 Days (All)	89	2	(2%)	0.3437	3	1 (33%)	1	(33%)	1	(33%)	0
		≤49 Days (Group 1)	35	2	(6%)		3	1 (33%)	1	(33%)	1	(33%)	0
		50-56 Days (Group 2)	34	0			0	0	0		0		0
		57-63 Days (Group 3)	20	0			0	0	0		0		0
PSYCHIATRIC DISORDERS													
ANY EVENT	1	≤63 Days (All)	89	7	(8%)	0.6869	11	5 (45%)	3	(27%)	3	(27%)	0
	•	≤49 Days (Group 1)	35	4	(11%)		7	3 (43%)	2	(29%)	2 -	(29%)	0
		50 56 Days (Group 2)	34	2	(6%)		3	1 (33%)	1	(33%)	1	(33%)	0
		57-63 Days (Group 3)	20	1	(5%)		1	1 (100%)	0		0		0
ANOREXIA		≤63 Days (All)	89	4	(4%)	0.2672	. 5	4 (80%)	1	(20%)	0		0

(9%)

(5%)

(4%)

(6%)

(6%)

(11)

(3%)

0.6735

1.0000

3

1

0

1

2

1

0

0

(75%)

(20%)

(33%)

1 (100%)

1

0

1 (25%)

(40%)

1 (50%)

1 (33%)

0

0

2 (40%)

1 (50%)

1 (100%)

1 (100%)

0

(33%)

0

0

0

0

0

0

≤49 Days (Group 1)

≤49 Days (Group 1)

≤49 Days (Group 1)

50-56 Days (Group 2)

57-63 Days (Group 3)

50-56 Days (Group 2)

57-63 Days (Group 3)

≤63 Days (All)

±63 Days (All)

50-56 Days (Group 2)

57-63 Days (Group, 3)

35

34

20

89

35

34

20

89

35

34

20

Source Data: Appendix A.1, Tables 16 and 25

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DEPRESSION

INSOMNIA

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center:

	Gestational ; Age	Total Number	Numbe of Pt		Fisher's exact	Number				Severit	y			
Body System/Event [2]	Group [3]	of Pts	w/Eve	ent	p-value	of Events	M	ild	Mode	rate	Sev	ere	Unk	nown
ASTRO-INTESTINAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	89	69 (78%)	0.3563	212	86	(41%)	99	(47%)	26	(12%)	1	(<1%
	≰49 Days (Group 1)	35	28 (80%)		69	27	(39%)	28	(41%)	14	(20%)	. 0	
	50-56 Days (Group 2)	34	28 (82%)		94	34	(36%)	52	(55%)	8	(9%)	0	
	57-63 Days (Group 3)	20	13 (65%)		49	25	(51%)	19	(39%)	4	(8%)	1	(2%
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	89	2	(2%)	0.5174	2	1	(50%)	0	1	1	(50%)	0	
	≤49 Days (Group 1)	35	0			0	0		0	. '	, 0		0	
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0	:	0		0	
	57-63 Days (Group 3)	20	1	(5%)		1	0		0		1	(100%)	0	
CONSTIPATION	≤63 Days (All)	89	1	(1%)	0.2247	1	0		0		0		1	(100%
	≤49 Days (Group 1)	35	0			0	0		0		0		0	
	50-56 Days (Group 2)	34	0			0	0		0		0	1	0	
	57-63 Days (Group 3)	20	1	(5%)		1	0		0		0		1	(100%
DIARRHEA	≤63 Days (All)	89	27 (30%)	0.8750	33	15	(45%)	14	(42%)	4	(12%)	0	
	≤49 Days (Group 1)	35	11 (31%)		13	8	(62%)	4	(31%)	1	(8%)	0	
	50-56 Days (Group 2)	34	11 (32%)		14	6	(43%)	7	(50%)	1	(7%)	0	
	57-63 Days (Group 3)	20	5 (25%)		6	1	(17%)	3	(50%)	2	(33%)	0	
DYSPEPSIA	≤63 Days (All)	89	3	(3%)	1.0000	5	2	(40%)	3	(60%)	0		0	
	449 Days (Group 1)	35	1	(3%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	20	1	(5%)		. 3	1	(33%)	2	(67%)	0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center:

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numb of P w/Ev	ts	Fisher's exact p value	Number of Events	Mi	 1d	Mode	Severity		ere	Unknow
MASTRO-INTESTINAL SYSTEM DISORDERS (cont.)	· · · · · · · · · · · · · · · · · · ·					3.5.*****							
FLATULENCE	≤63 Days (All)	89	3	(3%)	0.1772	3	1	(33%)	0		2	(67%)	0
	s49 Days (Group 1)	35	3	(9%)		3	1	(33%)	0		2	(67%)	0
	50-56 Days (Group 2)	34	0	• • • • •		0	0		0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	89	61	(691)	0.4707	117	52	(44%)	51	(44%)	14	(12%)	0
	≤49 Days (Group 1)	35	22	(63%)		37	13	(35%)	16	(43%)	8	(22%)	0
•	50-56 Days (Group 2)	34	26	(76%)		53	22	(42%)	26	(49%)	5.	(9%)	0
	57-63 Days (Group 3)	20	13	(65%)		27	17	(63%)	9	(334)	1	(4%)	0
SALIVA INCREASED	≤63 Days (All)	89	1	(1%)	0.2247	1	0		1	(100%)	0		0
	≰49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	0			0	0		0		0		0
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0		0
VOMITING	≤63 Days (All)	89	33	(37%)	0.2789	50	15	(30%)	30		5	(10%)	0
	≤49 Days (Group 1)	35	10	(29%)		15	5	(33%)	7	(47%)	3	(20%)	0
	50-56 Days (Group 2)	34	16	(47%)		25	4	(16%)	19	(76%)	2	(8%)	0
	57-63 Days (Group 3)	20	7	(35%)		10	6	(60%)	4	(40%)	0		0
CARDIOVASCULAR DISORDERS, GENERAL										į			
ANY EVENT	≤63 Days (All)	89	2	(2%)	0.5174	2	0		1	(50%)	. 1	(50%)	0
	≤49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	0		0			(100%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center:

	Gestational	Total	Numbe		Fisher's	N					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pt w/Eve		exact p-value	Number - of Events	Mild	Mode		Severe	Unknown
CARDIOVASCULAR DISORDERS, GEMERAL (CO	mt.)										
HYPOTENSION	s63 Days (All)	89	2	(2%)	0.5174	2	0	1	(50%)	1 (50%)	0
	≤49 Days (Group 1)	35	0			0	0	0		0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0		1 (100%)	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	1	(100%)	0	0
HEART RATE AND RHYTHM DISORDERS	ı										
ANY EVENT	. ≤63 Days (All)	89	1	(1%)	0.2247	1	0	0		1 (100%)	0
	≤49 Days (Group 1)	35	0			0	0	0	· ·	0.	0
	50 56 Days (Group 2)	34	0			0	0	0		0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0		1 (100%)	0
PALPITATION	≤63 Days (All)	89	1	(1%)	0.2247	1	0	0		1 (100%)	0
	≤49 Days (Group 1)	35	0			o	0	0		0	0
	50-56 Days (Group 2)	34	0			o [']	0	0		0	0
	57-63 Days (Group 3)	20	1	(5%)		1	0	0		1 (100%)	0
RESPIRATORY SYSTEM DISORDERS											
ANY EVENT	≤63 Days (All)	89	6	(7%)	0.6419	11	5 (45%)	5	(45%)	1 (9%)	0
	≤49 Days (Group 1)	35	3	(9%)		5	2 (40%)	3	(60%)	0	0
	50-56 Days (Group 2)	34	1	(3%)		1	0	0		1 (100%)	0
	57-63 Days (Group 3)	20	2	(10%)		5	3 (60%)	2	(40%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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⁽²⁾ NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center:

	Gestational	Total	Number of Pts	Fisher's	Wb.s.		g!		
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknow
ESPIRATORY SYSTEM DISORDERS (cont.)								·	
COUGHING	≤63 Days (All)	89	1 (1%)	0.6067	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
PHARYNGITIS	s63 Days (All)	89	3 (3%)	0.4394	3	2 (67%)	1 (33%)	0	0
1	≤49 Days (Group 1)	35	2 (6%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	34	0		0	0	o '	0 .	0
	57-63 Days (Group 3)	20	1 (\$*)		1	1 (100%)	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	89	2 (2%)	0.6961	2	1 (50%)	1 (50%)	0	0
	s49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	0
RHINITIS	≤63 Days (All)	89	1 (1%)	0.2247	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		3	2 (67%)	1 (33%)	0	0
SINUSITIS	≤63 Days (All)	89	1 (1%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	35	1 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center:

,	Gestational	Total	Number	Fisher			0		
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Even	exact p-valu	Number e of Events	Mild	Moderate	Severe	Unknow
RINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	2 (1.0000	4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	35	1 (1%)	2	2 (100%)	0	0	0
	50-56 Days (Group 2)	34	1 (14)	2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
MICTURITION FREQUENCY	≤63 Days (All)	89	1 (:	.*) 1.0000	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	35	1 ((%)	1	1 (100%)	0 .	0	0
	50-56 Days (Group 2)	34	0		0	0	ο .	0.	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
MICTURITION URGENCY	≤63 Days (All)	89	1 (:	.*) 0.6067	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 (11)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	•	0	0	0
URINARY RETENTION	≤63 Days (All)	89	1 (1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (11)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	89	1 ((*) 0.6067	1	0	0	1 (100%)	0
	#49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	1 ((%)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	0		. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center:

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Mild	Severi	ty Severe	Unknowr
REPRODUCTIVE DISORDERS, PENALE		· · · · · · · · · · · · · · · · · · ·	*******				· · · · · · · · · · · · · · · · · · ·		
ANY EVENT	≤63 Days (All)	89	14 (16%)	0.1194	17	6 (35%)	0	11 (65%)	o
	≤49 Days (Group 1)	35	3 (9%)	0.1154	3	2 (67%)	Ö	1 (33%)	0
	50-56 Days (Group 2)	34	9 (26%)		12	3 (25%)	0	9 (75%)	ő
	57-63 Days (Group 3)	20	2 (10%)		2	1 (50%)	Ö	1 (50%)	ō
BREAST DISCHARGE	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	o	o	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
'	50 56 Days (Group 2)	34	0		0	0	о ,	O .	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	89	3 (3%)	1.0000	3	1 (33%)	0	2 (67%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0	0	1 (100%)	0
!	50-56 Days (Group 2)	34	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
LEUKORRHOEA	≤63 Days (All)	89	2 (2%)	0.1918	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	35	σ		0	0	0	0	0
	50-56 Days (Group 2)	34	2 (6%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
OVARIAN DISORDER	≤63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0	\	. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

⁽³⁾ Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)						· · · · · · · · · · · · · · · · · · ·			
UTERINE HAEMORRHAGE	≤63 Days (All)	89	7 (8%)	0.0113	10	1 (10%)	0	9 (90%)	0
!	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	6 (18%)		9	1 (11%)	0	8 (89%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	1 (100%)	0
ROPLASM									
ANY EVENT	≤63 Days (All)	89	2 (2%)	0.6961	2	1 (50%)	0	0	1 (501
•	s49 Days (Group 1)	35	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0 '	Ö	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	0	1 (100)
CERVICAL SMEAR TEST POSITIVE	s63 Days (All)	89	1 (1%)	0.2247	1	0	0	0	1 (100%
	≤49 Days (Group 1)	35	0		0	0	0	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	0	1 (100%
OVARIAN CYST	s63 Days (All)	89	1 (1%)	1.0000	1	1 (100%)	0	0	0
	s49 Days (Group 1)	35	1 (3%)		1	1 (100%)	o	Ō	Ö
	50-56 Days (Group 2)	34	0		0	0	Ö	Ŏ	ō
	57-63 Days (Group 3)	20	o		0	0	0	o	0
ODY AS A WHOLE - GENERAL DISORDERS	1								
ANY EVENT	≤63 Days (All)	89	88 (99%)	0.6067	392	161 (41%)	142 (36%)	88 (22%)	1 (<1%
	s49 Days (Group 1)	35	35 (100%)		158	68 (43%)	55 (35%)	34 (22%)	1 (<1%
	50-56 Days (Group 2)	34	33 (97%)		149	57 (38%)	59 (40%)	33 (22%)	0
	57-63 Days (Group 3)	20	20 (100%)		85	36 (42%)	28 (33%)	21 (25%)	ŏ

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center:

•	Gestational Age	Total Number	Numbe of Pt		Fisher's exact	Number			-	Severit	.y			
Body System/Event [2]	Group [3]	of Pts	s w/Event		p-value	of Events	Mi	ld	Mode	rate	Sev	ere	Unk	nown
ODY AS A WHOLE - GENERAL DISORDERS (cont.))													
ABDOMINAL PAIN	s63 Days (All)	89	86 (991)	0.6067	333	138	(41%)	118	(35%)	76	(231)	1	(<11
	≤49 Days (Group 1)	35	35 (1	.001)		130	57	(44%)	41	(32%)	31	(24%)	1	(<11
	50-56 Days (Group 2)	34	33 (97%)		128	48	(38%)	54	(42%)	26	(201)	0	
	57-63 Days (Group 3)	20	20 (1	00%)		75	33	(44%)	23	(31%)	19	(251)	0	
ALLERGY	≤63 Days (All)	89	1	(1%)	0.2247	1	0		1	(100%)	0		0	
1	≤49 Days (Group 1)	35	0			0	0		0		0		0	
•	50-56 Days (Group 2)	34	0			0	0		0	!	0		0	
	57-63 Days (Group 3)	20	1	(5%)		1	0		1	(100%)	0		0	
ASTHENIA	≤63 Days (All)	89	3	(3%)	0.6123	5	1	(20%)	2	(40%)	2	(40%)	0	
	s49 Days (Group 1)	35	1	(3%)		2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	34	2	(6%)		3	0		1	(33%)	2	(671)	0	
	57-63 Days (Group 3)	20	0			0	0		0		0		0	
BACK PAIN	≤63 Days (All)	89	10 ((114)	0.5711	12	4	(33%)	4	(33%)	4	(331)	0	
	≤49 Days (Group 1)	35	4 ((11%)		5	1	(20%)	3	(60%)	1	(20%)	0	
	50-56 Days (Group 2)	34	5 ((15%)		6	3	(50%)	1	(17%)	2	(33%)	0	
	57-63 Days (Group 3)	20	1	(5%)		1	0		0		. 1	(100%)	0	
CHEST PAIN	≤63 Days (All)	89	1	(11)	0.6067	2	1	(50%)	1	(50%)	. 0		0	
	≤49 Days (Group 1)	35	0			0	0		0		0		0	
	50-56 Days (Group 2)	34	1	(3%)		2	1	(50%)	1	(50%)	, 0		0	
	57-63 Days (Group 3)	20	0			0	0		0		0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center:

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number -		· • · • · · · · · · · · ·	. .	Severit	.y		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events		ild		rate	Sev		Unknown
ODY AS A WROLE - GENERAL DISORDERS (cont.)											,,	· · · · · · · ·
FATIGUE	≤63 Days (All)	89	20	(22*)	0.3933	25	9	(36%)	11	(44%)	5	(20%)	0
	≤49 Days (Group 1)	35	9	(26%)		12	4	(33%)	6	(50%)	2	(17%)	0
	50-56 Days (Group 2)	34	5	(15%)		6	3	(50%)	1	(17%)	2	(33%)	0
	57-63 Days (Group 3)	20	6	(30%)		7	2	(29%)	4	(57%)	1	(14%)	0
FEVER	≤63 Days (All)	89	6	(7%)	1.0000	6	5	(83%)	1	(17%)	0		0
· ·	s49 Days (Group 1)	35	3	(9%)		3	3	(100%)	0		0.		0
	50-56 Days (Group 2)	34	2	(6%)		2	1	(50%)	1	(50%)	o		0
	57 63 Days (Group 3)	20	1	(5%)		1	1	(100%)	0		0		0
LEG PAIN	≤63 Days (All)	89	1	(1%)	1.0000	3	0		3	(100%)	0		0
	≤49 Days (Group 1)	35	1	(3%)		3!	0		3	(100%)	0		0
	50-56 Days (Group 2)	34	0			o	0		0		0		0
	57-63 Days (Group 3)	20	0			o [']	0		0		0		0
PAIN	s63 Days (All)	89	1	(1%)	0.6067	1	1	(100%)	0		0		0
	s49 Days (Group 1)	35	0			0	0		0		0		0
	50-56 Days (Group 2)	34	1	(3%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	20	0			0	0		0		0		0
RIGORS	≤63 Days (All)	89	3	(3%)	0.7904	3	2	(67%)	0		1	(33%)	0
	±49 Days (Group 1)	35	2	(6%)		2	2	(100%)	0		0		0
	50-56 Days (Group 2)	34	1	(3%)		. 1	0		0		1	(100%)	0
	57-63 Days (Group 3)	20	0			• 0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

<u>[61</u>

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center:	

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severit	y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
ODY AS A WHOLE - GENERAL DISORDS	R\$ (cont.)								
SYNCOPE	≤63 Days (All)	89	1 (1%)	1.0000	1	0	1 (100%)	0	0
٠	≤49 Days (Group 1)	35	1 (3%)		1	0	1 (100%)	0	0
	50.56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
ESISTANCE NECHANISM DISORDERS		ı							
ANY EVENT	≤63 Days (All)	89	4 (4%)	0.6735	6	1 (17%)	2 (33%)	3 (50%)	0
	≤49 Days (Group 1)	35	2 (6%)		2	0	1 (5b%)	1. (50%)	0
	50-56 Days (Group 2)	34	2 (6%)		4	1 (25%)	1 (251)	2 (50%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
HERPES SIMPLEX	≰63 Days (All)	89	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	89	3 (3%)	0.6123	5	1 (20%)	2 (40%)	2 (40%)	0
	≤49 Days (Group 1)	35	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	34	2 (6%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number				Severi	ty		- · · · •	
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	14	Mode	rate	Sev	ere	Unk	nown
•										(4.5.6.)		(154)	•	1.11
ANY EVENT	≤63 Days (All)	175	171	(98%)	0.6779	983	433	(44%)	401	(41%) (42%)	147 60	(15%) (17%)	2	(<11
	s49 Days (Group 1)	71	69	(97%)		359	147	(41%)	152 152	(38%)	46	(12%)	1	(<11
	50-56 Days (Group 2)	72	71	(99%)		398	199	(50%)		(43%)	41	(18%)	1	
	57-63 Days (Group 3)	32	31	(97%)		226	87	(38%)	97	(434)	41	(104)	•	(<14
KIN AND APPENDAGES DISORDERS														
ANY EVENT	, ≤63 Days (All)	175	6	(3%)	0.7426	,7	4	(57%)	3	,	0		0	
	≤49 Days (Group 1)	71	3	(4%)		4	3	(75%)	1		0 .		0	
	50-56 Days (Group 2)	72	3	(4%)		3	1	(33%)	2	(67%)	0		0	
	57-63 Days (Group 3)	32	0			0	0		0		0		0	
ACNE	s63 Days (All)	175	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	71	0			0	0		0		0		0	
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	32	0			0	0		0		0		0	
PRURITUS	≤63 Days (All)	175	1	(<1%)	0.5886	2	2	(100%)	0		0		0	
	s49 Days (Group 1)	71	1	(1%)		2	2	(100%)	0		0		0	
	50-56 Days (Group 2)	72	0			0	0		0		0		0	
	57-63 Days (Group 3)	32	0			0	0		0		0		0	
RASH	≤63 Days (All)	175	2	(1%)	1.0000	2	0		2	(100%)	0		0	
	≤49 Days (Group 1)	71	1	(1%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	72	1	(1%)		. 1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	32	0			0	G		0		0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: WESTHOFF (#24)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe 0	Unknow
KIN AMD APPENDAGES DISORDERS (cont.)	**************************************								
SWEATING INCREASED	≤63 Days (All)	175	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
VERRUCA	≤63 Days (All)	175	1 (<1%)	0.5886	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	71	1 (1%)		1	1 (100%)	0	0	0
•	50-56 Days (Group 2)	72	0		0	0	o :	0 ·	0
	57-63 Days (Group 3)	32	0		0	0	О ,	0	0
SCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	3 (2%)	0.7933	3	1 (33%)	2 (67%)	0	0
1	s49 Days (Group 1)	71	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	0
!	57-63 Days (Group 3)	32	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	175	2 (11)	1.0000	2	1 (50%)	1 (50%)	0	. 0
	≤49 Days (Group 1)	71	1 (1%)		1	0	1 (100%)	Ō	0
	50-56 Days (Group 2)	72	1 (1%)		1	1 (100%)	0	0	Ō
!	57.63 Days (Group 3)	32	0		0	0	0	0	0
SKELETAL PAIN	963 Days (All)	175	1 (<1%)	0.5886,	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	1 (1%)	į.	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	72	0	ļ	. 0	0	0	0	0
	57-63 Days (Group 3)	32	0		• 0	0	O	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational	Total		ber	Fisher's	Number				Severit			
Body System/Event [2]	Age Group [3]	Number of Pts		Pts vent	exact p-value	of Events	Mi			rate	Sev		Unknown
CENTR & PERIPH MERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	175	64	(37%)	0.2349	110	40	(36%)	49	(45%)	21	(19%)	0
	£49 Days (Group 1)	71	30	(42%)		48	17	(35%)	24	(50%)	7	(15%)	0
	50-56 Days (Group 2)	72	21	(29%)		39	16	(41%)	16	(41%)	7	(18%)	0
	57-63 Days (Group 3)	32	13	(41%)		23	7	(30%)	9	(39%)	7	(30%)	0
CONVULSIONS	≤63 Days (All)	175	1	(<1%)	0.5886	1	1	(100%)	0	1	0		0
· · · · · · · · · · · · · · · · · · ·	£49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0	. 1	0		0
	50-56 Days (Group 2)	72	0			0	0		0		ю.		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
DIZZINESS	≤63 Days (All)	175	16	(9%)	0.7410	25	10	(40%)	9	(36%)	6	(24%)	0
	≤49 Days (Group 1)	71	6	(B%)		8	2	(25%)	5	(63%)	1	(13%)	0
	50-56 Days (Group 2)	72	6	(8%)		10	5	(50%)	3	(30%)	2	(20%)	0
	57-63 Days (Group 3)	32	4	(13%)		7	3	(43%)	1	(14%)	3	(43%)	0
HEADACHE	s63 Days (All)	175	58	(33%)	0.2714	84	29	(35%)	40	(48%)	15	(18%)	0
	≤49 Days (Group 1)	71	27	(38%)		39	14	(36%)	19	(49%)	6	(15%)	0
	50-56 Days (Group 2)	72	19	(26%)		29	11	(38%)	13	(45%)	5	(17%)	0
	57-63 Days (Group 3)	32	12	(38%)		16	4	(25%)	8	(50%)	4	(25%)	0
SYCHIATRIC DISORDERS													
ANY EVENT	≤63 Days (All)	175	18	(10%)	0.2758	26	8	(31%)	13	(50%)	5	(19%)	0
	s49 Days (Group 1)	71	10	(14%)		17	6	(35%)	9	(53%)	2	(12%)	0
	50-56 Days (Group 2)	72	7	(10%)		. 7	2	(29%)	4	(571)	1	(14%)	0
	57-63 Days (Group 3)	32	1	(3%)		2	0		0		2	(100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mild	Moderate	Severe	Unknowr
PSYCHIATRIC DISORDERS (cont.)									
ANOREXIA	≤63 Days (All)	175	2 (1%	0.6642	2	0	2 (100%)	0	0
	<pre>s49 Days (Group 1)</pre>	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	2 (3%	1	2	0	2 (100%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	175	6 (3%	0.0462	8	3 (38%)	2 (25%)	3 (38%)	0
l ·	s49 Days (Group 1)	71	5 (7%)	6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	72	0		0	0	0	0 '	0
	57-63 Days (Group 3)	32	1 (3%)	2	0	•	2 (100%)	0
DEPRESSION	≤63 Days (All)	175	3 (2%	0.7933	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	71	2 (3%)	2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	72	1 (1%)	1	0	0	1 (100%)	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
DYSPAREUNIA	≤63 Days (All)	175	1 (<1%	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	32	0		0	0	0	. 0	0
EMOTIONAL LABILITY	≤63 Days (All)	175	2 (1%	0.4964	4	2 (50%)	2 (50%)	, 0	0
	≥49 Days (Group 1)	71	2 (3%)	4	2 (50%)	2 (50%)	' o	0
	50-56 Days (Group 2)	72	0		0	0	0	į O	0
	57-63 Days (Group 3)	32	0		; 0	0	0	ю	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational	Total Number	Numi of		Fisher's exact	Number				- Severit	· V	 .	
PSYCHOSIS STRO-INTESTINAL SYSTEM DISORDERS	Age Group (3)	of Pts		vent	p value	of Events		1 d		rate	-	ere	Unknow
PSYCHIATRIC DISORDERS (cont.)													
INSOMNIA	≤63 Days (All)	175	7	(4%)	0.4620	7	2	(29%)	4	(57%)	1	(14%)	0
	≤49 Days (Group 1)	71	4	(6%)		4	0		3	(75%)	1	(25%)	0
	50-56 Days (Group 2)	72	3	(41)		3	2	(67%)	1	(33%)	0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0
PSYCHOSIS	≤63 Days (All)	175	1	(<1%)	0.5886	1	0		1	(100%)	0		0
	≤49 Days (Group 1)	71	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57 63 Days (Group 3)	32	0			0	0		0		0		0
GASTRO-INTESTINAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	175	113	(65%)	0.0989	270;	129	(48%)	107	(40%)	34	(13%)	0
	≤49 Days (Group 1)	71	39	(55%)		85	30	(35%)	37	(44%)	18	(21%)	0
	50-56 Days (Group 2)	72	51	(71%)		123	69	(56%)	46	(37%)	8	(7%)	0
	57-63 Days (Group 3)	32	23	(72%)		62	30	(48%)	24	(39%)	8	(13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	s63 Days (All)	175	4	(21)	0.6779	4	1	(25%)	2	(50%)	1	(25%)	0
	≤49 Days (Group 1)	71	2	(3%)		2	0		1	(50%)	1	(50%)	0
	50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0
CONSTIPATION	≤63 Days (All)	175	4	(21)	0.8318	4	3	(75%)	0		1	(25%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	72	2	(3%)		. 2	2	(100%)	0		0		0
	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severit	. y		
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mi	.ld	Mode	rate	Sev	ere	Unknow
ASTRO-INTESTIMAL SYSTEM DISORDERS (cont.)												
DIARRHEA	≤63 Days (All)	175	32 (18%)	0.1747	33	19	(58%)	13	(39%)	1	(3%)	0
	s49 Days (Group 1)	71	9 (13%)		9	4	(44%)	4	(44%)	1	(11%)	0
	50-56 Days (Group 2)	72	14 (19%)		14	10	(71%)	4	(29%)	0		0
	57-63 Days (Group 3)	32	9 (28%)		10	5	(50%)	5	(50%)	0		0
DYSPEPSIA	s63 Days (All)	175	12 (7%)	0.1428	13	6	(46%)	7	(54%)	0		0
1	≤49 Days (Group 1)	71	2 (3%)		3	0		3	(100%)	0		0
•	50-56 Days (Group 2)	72	6 (\$%)		6	4	(67%)	2	(334)	0.		0
	57-63 Days (Group 3)	32	4 (134)		4	2	(50%)	2	(5 0 %)	0		0
FLATULENCE	≤63 Days (All)	175	3 (2%)	0.5895	5	4	(80%)	1	(20%)	0		0
	s49 Days (Group 1)	71	1 (1%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	72	1 (1%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	32	1 (3%)		2	2	(100%)	0		0		0
HAEMORRHOIDS	x63 Days (All)	175	1 (<1%)	1.0000	1	ρ		1	(100%)	0		0
	<pre>s49 Days (Group 1)</pre>	71	0		0	0		0		0		0
	50-56 Days (Group 2)	72	1 (1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	32	0		0	0		0		0		0
NAUSEA	≤63 Days (All)	175	88 (50%)	0.4871	133	60	(45%)	53	(40%)	20	(15%)	0
	s49 Days (Group 1)	71	33 (46%)		49	20	(41%)	20	(41%)	9	(18%)	0
	50-56 Days (Group 2)	72	36 (50%)		54	27	(50%)	21	(39%)	6	(11%)	0
	57-63 Days (Group 3)	32	19 (59%)		30	13	(43%)	12	(40%)	5	(17%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Num of		Fisher's exact	Number	. .			Severit	.y		
Body System/Event [2]	Group [3]	of Pts		vent	p-value	of Events	Mi	.1d	Mode	rate	Sev	ere	Unknow
MASTRO-INTESTINAL SYSTEM DISORDERS (cont.)													
TOOTH ACHE	≤63 Days (All)	175	4	(2%)	0.0103	4	2	(50%)	0		2	(50%)	0
	≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	72	0			0	0		0		0		0
	57-63 Days (Group 3)	32	3	(9%)		3	1	(33*)	0		2	(67%)	0
VOMITING	≤63 Days (All)	175	59	(34%)	0.0066	73	34	(47%)	30	(41%)	9	(12%)	0
1	≤49 Days (Group 1)	71	15	(21%)		18	4	(221)	8	(44%)	6	(33%)	0
•	50-56 Days (Group 2)	72	33	(461)		44	24	(55%)	18	(41%)	2.	(5%)	0
i	57-63 Days (Group 3)	32	11	(34%)		11	6	(55%)	4	(364)	1	(9%)	0
ETABOLIC AND NUTRITIONAL DISORDERS													
ANY EVENT	≤63 Days (All)	175	2	(1%)	0.3331	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	71	0			0	0		0		0		0
	50-56 Days (Group 2)	72	1	(1%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	32	1	(3%)		1	0	•	1	(100%)	0		0
DEHYDRATION	≤63 Days (All)	175	2	(1%)	0.3331	2	0		2	(100%)	0		0
	≤49 Days (Group 1)	71	0			0	0		0		0		0
	50-56 Days (Group 2)	72	1	(1%)		1	0			(100%)	0		0
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0
EART RATE AND RHYTHM DISORDERS	•	1											
ANY EVENT	≤63 Days (All)	175	2	(1%)	0.6642	2	1	(50%)	1	(50%)	0		0
	s49 Days (Group 1)	71	0			, 0	0		0		0		0
	50-56 Days (Group 2)	72	2	(3%)		2	1	(50%)	1	(50%)	0		0
	57-63 Days (Group 3)	32	0			0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D. Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severit	·v	
Body System/Event {2}	Group (3)	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS (cont.)					<u> </u>				
PALPITATION	≤63 Days (All)	175	1 (<1	1.0000	1	1 (100%)	. 0	0	0
	≰49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1	;)	1	1 (100%)	· 0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
TACHYCARDIA	≤63 Days (All)	175	1 (<1	1.0000	1	0	1 (100%)	0	0
ı .	≤49 Days (Group 1)	71	0		0	0	0	0	0
·	50-56 Days (Group 2)	72	1 (1	;)	1	0	1 (1001)	0.	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
ASCULAR (EXTRACARDIAC) DISORDERS									
ANY EVENT	≤63 Days (All)	175	1 (<1	0.1829	1	1 (100%)	0	0	0
į	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
İ	57-63 Days (Group 3)	32	1 (3	;)	1	1 (100%)	0	0	0
VEIN PAIN	≤63 Days (All)	175	1 (<1	0.1829	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
:	57-63 Days (Group 3)	32	1 (3	;)	1	1 (100%)	0	0	0
ESPIRATORY SYSTEM DISORDERS	,								
ANY EVENT	≤63 Days (All)	175	10 (6	0.0017	11	4 (36%)	6 (55%)	1 (9%)	0
	s49 Days (Group 1)	71	5 (7	1)	5	2 (40%)	2 (40%)	1 (20%)	0
	50-56 Days (Group 2)	72	0	•	. 0	0	0	0	0
	57-63 Days (Group 3)	32	5 (16	1)	6	2 (33%)	4 (67%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		· · · · · · Severit	. y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
COUGHING	≤63 Days (All)	175	1 (<1	0.5886	1	1 (100%)	0	0	0
· ·	≤49 Days (Group 1)	71	1 (1	1)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
PHARYNGITIS	≤63 Days (All)	175	3 (2	0.3100	3	1 (33%)	1 (33%)	1 (33%)	0
ı	≤49 Days (Group 1)	71	2 (3	1)	2	o '	1 (50%)	1 (50%)	0
•	50-56 Days (Group 2)	72	0		0	0	0	lo ·	0
	57-63 Days (Group 3)	32	1 (3	1)	1	1 (100%)	0	0	0
RHINITIS	≤63 Days (All)	175	1 (<1	0.5886	1	1 (100%)	0	0	0
	s49 Days (Group 1)	71	1 (1	1)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	175	5 (3	0.0021	6	1 (17%)	5 (83%)	0	0
	s49 Days (Group 1)	71	1 (1	1)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	4 (13	1)	5	1 (20%)	4 (80%)	0	0
ED BLOOD CELL DISORDERS									
ANY EVENT	463 Days (All)	175	3 (2	0.7933	3	1 (33%)	0	2 (67%)	0
	s49 Days (Group 1)	71	2 (3	1)	2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	72	1 (1		. 1	0	0	1 (100%)	0
	57-63 Days (Group 3)	32	0		. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

Gestational Age	Total Number	Number of Pt		Fisher's exact	Number	 -			Severit	.y		
Group [3]	of Pts	w/Eve	ent	p value	of Events	Mi	.1d	Mode	rate	Sev	ere	Unknow
												
≤63 Days (All)	175	3	(2%)	0.7933	3	1	(33%)	0		2	(67%)	0
≤49 Days (Group 1)	71	2	(3%)		2	1	(50%)	0		1	(50%)	0
50-56 Days (Group 2)	72	1	(1%)		1	0		0		1	(100%)	0
57-63 Days (Group 3)	32	0			0	0		0		0		0
≤63 Days (All)	175	4	(2%)	0.5263	4	2	(50%)	2	(50%)	0		0
≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0	•	0		0
50-56 Days (Group 2)	72	3	(4%)		3	1	(33%)	2	(67 %)	0		0
57-63 Days (Group 3)	32	0			0	0		0		0		0
s63 Days (All)	175	3	(2%)	0.2195	3	1	(33%)	2	(67%)	0		0
≤49 Days (Group 1)	71	0			0	0		0		0		0
50-56 Days (Group 2)	72	3	(4%)		3	1	(33%)	2	(67%)	0		0
57-63 Days (Group 3)	32	0			0	0		0		0		0
£63 Days (All)	175	1 ((<1%)	0.5886	1	1	(100%)	0		0		0
≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0		0		0
50-56 Days (Group 2)	72	0			0	0		0		0		0
57 63 Days (Group 3)	32	0	,		0	0		0		. 0		0
•										ı		
≤63 Days (All)	175	21 ((12%)	0.7869	25	11	(44%)	3	(12%)	11	(44%)	0
≤49 Days (Group 1)	71	8 ((11%)		. 9	3	(33%)	1	(11%)	5	(56%)	0
50-56 Days (Group 2)	72	8 ((11%)		• 9	5	(56%)	0		4	(44%)	0
57-63 Days (Group 3)	32	5 ((16%)		7	3	(43%)	2	(29%)	2	(29%)	0
	### ##################################	Group {3} of Pts #63 Days (All) 175 #49 Days (Group 1) 71 50-56 Days (Group 2) 72 57-63 Days (Group 3) 32 #63 Days (All) 175 #49 Days (Group 1) 71 50-56 Days (Group 2) 72 57-63 Days (Group 3) 32 #63 Days (All) 175 #49 Days (Group 1) 71 50-56 Days (Group 2) 72 57-63 Days (Group 3) 32 #63 Days (All) 175 #49 Days (Group 3) 32 #63 Days (All) 175 #49 Days (Group 1) 71 50-56 Days (Group 2) 72 57-63 Days (Group 3) 32	### Group {3} ### Group {3} ### Group {3} ### Group 1) ### Group 1) ### Group 1) ### Group 1) ### Group 2) ### Group 3) Group [3] of Pts w/Event #63 Days (All) 175 3 (2%) #49 Days (Group 1) 71 2 (3%) 50-56 Days (Group 2) 72 1 (1%) 57-63 Days (Group 3) 32 0 #63 Days (All) 175 4 (2%) #49 Days (Group 1) 71 1 (1%) 50-56 Days (Group 2) 72 3 (4%) 57-63 Days (Group 3) 32 0 #63 Days (All) 175 3 (2%) #49 Days (Group 1) 71 0 50-56 Days (Group 2) 72 3 (4%) 57-63 Days (Group 3) 32 0 #63 Days (Group 3) 32 0 #63 Days (Group 3) 32 0 #64 Days (Group 3) 32 0 #65 Days (Group 3) 32 0 #65 Days (Group 3) 32 0 #66 Days (Group 3) 32 0 #67 Days (Group 3) 32 0 #68 Days (Group 1) 71 1 (1%) #69 Days (Group 3) 32 0 #68 Days (Group 3) 32 0	Group {3} of Pts w/Event p value *63 Days (All) 175 3 (2%) 0.7933 *49 Days (Group 1) 71 2 (3%) 50-56 Days (Group 2) 72 1 (1%) 57-63 Days (Group 3) 32 0 *63 Days (All) 175 4 (2%) 0.5263 *49 Days (Group 1) 71 1 (1%) 50-56 Days (Group 2) 72 3 (4%) 57-63 Days (Group 3) 32 0 *63 Days (All) 175 3 (2%) 0.2195 *49 Days (Group 1) 71 0 50-56 Days (Group 2) 72 3 (4%) 57-63 Days (Group 2) 72 3 (4%) 57-63 Days (Group 3) 32 0 *63 Days (All) 175 1 (<1%) 0.5886 *49 Days (Group 1) 71 1 (1%) 50-56 Days (Group 2) 72 0 57-63 Days (Group 3) 32 0 *63 Days (All) 175 1 (1%) 50-56 Days (Group 3) 32 0 *63 Days (Group 1) 71 1 (1%) 50-56 Days (Group 3) 32 0	Group [3] of Pts w/Event p value of Events #63 Days (All) 175 3 (2%) 0.7933 3 #49 Days (Group 1) 71 2 (3%) 2 50-56 Days (Group 2) 72 1 (1%) 1 57-63 Days (Group 3) 32 0 0 #63 Days (All) 175 4 (2%) 0.5263 4 #49 Days (Group 1) 71 1 (1%) 1 50-56 Days (Group 2) 72 3 (4%) 3 57-63 Days (Group 3) 32 0 0 #63 Days (All) 175 3 (2%) 0.2195 3 #49 Days (Group 1) 71 0 0 50-56 Days (Group 2) 72 3 (4%) 3 57-63 Days (Group 3) 32 0 0 #63 Days (Group 1) 71 0 0 50-56 Days (Group 2) 72 3 (4%) 3 57-63 Days (Group 3) 32 0 0 #63 Days (Group 3) 32 0 0 #63 Days (Group 3) 32 0 0 #63 Days (Group 3) 32 0 0 #64 Days (Group 1) 71 1 (1%) 1 50-56 Days (Group 2) 72 0 0 57-63 Days (Group 3) 32 0 0 #65 Days (Group 3) 32 0 0 #66 Days (Group 3) 32 0 0 #67 Days (Group 3) 32 0 0 #68 Days (Group 3) 32 0 0 #68 Days (Group 3) 32 0 0 #69 Days (Group 3) 32 0 0 #60 Days (Group 3) 32 0 #	Group {3} of Pts w/Event p value of Events Mi s63 Days (All) 175 3 (2%) 0.7933 3 1 s49 Days (Group 1) 71 2 (3%) 2 1 50-56 Days (Group 2) 72 1 (1%) 1 0 57-63 Days (Group 3) 32 0 0 0 0 s63 Days (All) 175 4 (2%) 0.5263 4 2 s49 Days (Group 1) 71 1 (1%) 1 1 50-56 Days (Group 2) 72 3 (4%) 3 1 57-63 Days (Group 3) 32 0 0 0 0 s63 Days (All) 175 3 (2%) 0.2195 3 1 s49 Days (Group 1) 71 0 0 0 0 50-56 Days (Group 2) 72 3 (4%) 3 1 57-63 Days (Group 3) 32 0 0 0 s63 Days (All) 175 3 (2%) 0.2195 3 1 s49 Days (Group 3) 32 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 s63 Days (Group 1) 71 1 (1%) 1 1 s49 Days (Group 3) 32 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 0 s63 Days (Group 3) 32 0 0 0 0 0	Group [3] of Pts w/Event p value of Events Mild *63 Days (All) 175 3 (2%) 0.7933 3 1 (33%) *49 Days (Group 1) 71 2 (3%) 2 1 (50%) 50-56 Days (Group 2) 72 1 (1%) 1 0 57-63 Days (Group 3) 32 0 0 0 0 *63 Days (All) 175 4 (2%) 0.5263 4 2 (50%) *49 Days (Group 1) 71 1 (1%) 1 1 (100%) 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 57-63 Days (Group 3) 32 0 0 0 0 *63 Days (All) 175 3 (2%) 0.2195 3 1 (33%) *49 Days (Group 1) 71 0 0 0 0 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 57-63 Days (Group 3) 32 0 0 0 0 *63 Days (All) 175 3 (2%) 0.2195 3 1 (33%) 57-63 Days (Group 3) 32 0 0 0 0 *63 Days (Group 1) 71 0 0 0 0 50-56 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 *64 Days (Group 3) 32 0 0 0 0 0 0 *65 Days (Group 3) 32 0 0 0 0 0 0 *66 Days (Group 3) 32 0 0 0 0 0 0 *67 68 Days (Group 3) 32 0 0 0 0 0 0 0 0 *68 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Group [3] of Pts w/Event p value of Events Mild Mode *63 Days (All) 175 3 (2%) 0.7933 3 1 (33%) 0 *49 Days (Group 1) 71 2 (3%) 2 1 (50%) 0 50-56 Days (Group 2) 72 1 (1%) 1 0 0 57-63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 1) 71 1 (1%) 1 1 (100%) 0 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 2 57-63 Days (Group 3) 32 0 0 0 0 0 *63 Days (All) 175 3 (2%) 0.2195 3 1 (33%) 2 *49 Days (Group 1) 71 0 0 0 0 0 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 2 57-63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 1) 71 0 0 0 0 0 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 2 57-63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 *63 Days (Group 2) 72 3 (4%) 3 1 (33%) 2 57-63 Days (Group 3) 32 0 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 0 0 *63 Days (Group 3) 32 0 0 0 0 0 0 0 *64 Days (Group 3) 32 0 0 0 0 0 0 0 0 *65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 *65 Days (Group 1) 71 1 (1%) 1 1 (100%) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	### Group [3] ### Of Pts w/Event p value of Events Mild Moderate ### ### ### ### ### ### ### ### ###	Group [3] of Pts w/Event p value of Events Mild Moderate Sev #63 Days (All) 175 3 (2%) 0.7933 3 1 (33%) 0 2 #49 Days (Group 1) 71 2 (3%) 2 1 (50%) 0 1 50-56 Days (Group 2) 72 1 (1%) 1 0 0 0 1 57-63 Days (Group 3) 32 0 0 0 0 0 0 0 #63 Days (All) 175 4 (2%) 0.5263 4 2 (50%) 2 (50%) 0 #49 Days (Group 1) 71 1 (1%) 1 1 (100%) 0 0 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 2 (67%) 0 #63 Days (Group 3) 32 0 0 0 0 0 0 0 #63 Days (All) 175 3 (2%) 0.2195 3 1 (33%) 2 (67%) 0 #63 Days (Group 1) 71 0 0 0 0 0 #63 Days (Group 1) 71 0 0 0 0 0 50-56 Days (Group 2) 72 3 (4%) 3 1 (33%) 2 (67%) 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 0 0 0 #65 Days (Group 3) 32 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Group [3] of Pts w/Event p-value of Events Mild Moderate Severe	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

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^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational	Total	Number of Pts	Fisher's	Mumbaa		Severit		
Body System/Event [2]	Age Group [3]	Number of Pts	w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknow
EPRODUCTIVE DISORDERS, PENALE (cont.)									
BREAST PAIN FEMALE	s63 Days (All)	175	2 (1	1.0000	2	1 (50%)	1 (50%)	0	0
•	≤49 Days (Group 1)	71	1 (1%)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	72	1 (1%)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0
ENDOMETRITIS	s63 Days (All)	175	1 (<1%	0.1829	1	0	0	1 (100%)	0
1	#49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0.	0
	57-63 Days (Group 3)	32	1 (31)	1	0	0	1 (100%)	0
EUKORRHOEA	≤63 Days (All)	175	5 (3%	0.4077	5	5 (100%)	0	o	0
	≤49 Days (Group 1)	71	1 (19)	1:	1 (100%)	0	0	0
	50-56 Days (Group 2)	72	2 (3%)	2	2 (100%)	0	0	0
	57-63 Days (Group 3)	32	2 (6%)	2	2 (100%)	0	0	0
OVARIAN DISORDER	≤63 Days (All)	175	1 (<1%	0.1829	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	1 (3%)	1	0	1 (100%)	0	0
PREMENSTRUAL TENSION	≤63 Days (All)	175	1 (<1%	0.5886	1	1 (100%)	0	0	0
	k49 Days (Group 1)	71	1 (1%)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	72	0		0	0	0	0	0
	57-63 Days (Group 3)	32	0		. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Numl of		Fisher's exact	Number				Severit	. v			
Body System/Event [2]	Group (3)	of Pts		vent	p value	of Events	Mi	ld		rate	•	ere		nown
REPRODUCTIVE DISORDERS, FEMALE (cont.)														
UTERINE DISORDER NOS	≤63 Days (All)	175	3	(2%)	0.4032	3	2	(67%)	1	(33%)	0		0	
•	≤49 Days (Group 1)	71	0			0	0		0		0		0	
	50-56 Days (Group 2)	72	2	(3%)		2	2	(100%)	0		0		0	
	57-63 Days (Group 3)	32	1	(3%)		1	0		1	(100%)	0		0	
UTERINE HAEMORRHAGE	≤63 Days (All)	175	9	(5%)	1.0000	10	0		0		10	(100%)	0	
	≤49 Days (Group 1)	71	4	(6%)		5	0		0		5	(100%)	0	
•	50-56 Days (Group 2)	72	4	(6%)		4	0		0	!	4 -	(100%)	0	
	57-63 Days (Group 3)	32	1	(3∜)		1	0		0	•	1	(100%)	0	
VAGINITIS	≤63 Days (All)	175	2	(1%)	0.1818	2	2	(100%)	0		0		0	
·	≤49 Days (Group 1)	71	1	(1%)		1	1	(100%)	0		0		0	
	50-56 Days (Group 2)	72	0			0	0		0		0		0	
	57-63 Days (Group 3)	32	1	(31)		1	1	(100%)	0		0		0	
ODY AS A WHOLE - GENERAL DISORDERS							r							
ANY EVENT	≤63 Days (All)	175	167	(95%)	0.5126	513	229	(45%)	209	(41%)	73	(14%)	2	(<1%
	s49 Days (Group 1)	71	66	(93%)		182	82	(45%)	74	(41%)	26	(14%)	0	
	50-56 Days (Group 2)	72	70	(97%)		209	103	(49%)	80	(38%)	25	(12%)	1	(<1%
	57-63 Days (Group 3)	32	31	(97%)		122	44	(36%)	55	(45%)	22	(18%)	1	(<1%
ABDOMINAL PAIN	≤63 Days (All)	175	162	(93%)	0.5159	437	200	(46%)	176	(40%)	59	(14%)	2	(<1%
	≤49 Days (Group 1)	71	64	(90%)		157	72	(46%)	64	(41%)	21	(13%)	0	
	50-56 Days (Group 2)	72	67	(93%)		182	89	(49%)	69	(38%)	23	(13%)	1	(<1%
	57-63 Days (Group 3)	32	31	(97%)		98	39	(40%)	43	(44%)	15	(15%)	1	(1%

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Numi of		Fisher's exact	Number	· • · · · · · • • • • • • • • • • • • •		. Severit	· V		
Body System/Event [2]	Group (3)	of Pts		vent	p-value	of Events	Mild		rate	•	ere	Unknown
BODY AS A MROLE - GENERAL DISORDERS (co	at.)											
ALLERGY	≤63 Days (All)	175	2	(1%)	1.0000	3	1 (33%)	2	(67%)	0		0
	≤49 Days (Group 1)	71	1	(1%)		2	0	2	(100%)	0		0
	50-56 Days (Group 2)	72	1	(1%)		1	1 (100%)	0		0		0
	57-63 Days (Group 3)	32	0			0	0	0		0		0
ASTHENIA	≤63 Days (All)	175	8	(5%)	0.7986	10	2 (20%)	6	(60%)	2	(20%)	0
I .	s49 Days (Group 1)	71	3	(4%)		! 3	1 (33%)	2	(67%)	0		0
	50-56 Days (Group 2)	72	3	(4%)		3	1 (33%)	2	(67%)	0.		0
	57-63 Days (Group 3)	32	2	(61)		4	0	2	(50%)	2	(50%)	0
BACK PAIN	≤63 Days (All)	175	18	(10%)	0.8483	26	9 (35%)	12	(46%)	5	(19%)	0
	≤49 Days (Group 1)	71	8	(11%)		9	3 (33%)	4	(44%)	2	(22%)	0
	50-56 Days (Group 2)	72	8	(11%)		11	5 (45%)	5	(45%)	1	(9%)	0
	57-63 Days (Group 3)	32	2	(6%)		6	1 (17%)	3	(50%)	2	(33%)	0
CHEST PAIN	≤63 Days (All)	175	1	(<1%)	0.5886	. 1	1 (100%)	0		0		0
	≤49 Days (Group 1)	71	1	(1%)		1	1 (100%)	0		0		0
	50-56 Days (Group 2)	72	0			0	0	0		0		0
	57-63 Days (Group 3)	32	0			0	0	0		0		0
FATIGUE	≤63 Days (All)	175	8	(5%)	0.0880	8	5 (63%)	0		3	(38%)	0
	#49 Days (Group 1)	71	6	(8%)		6	3 (50%)	0		3	(50%)	0
	50-56 Days (Group 2)	72	1	(1%)		1	1 (100%)	0		0		0
	57-63 Days (Group 3)	32	1	(3%)		. 1	1 (100%)	0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: WESTHOFF (#24)

Body System/Eve	ent [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pi w/Eve	ts	Fisher's exact p-value	Number of Events		ild		···-Severity- derate	Severe	Unknow
ODY AS A MHOLE -	- GENERAL DISORDERS (cont	.1		···								· · · · · · · · · · · · · · · · · · ·	
FEVER		≤63 Days (All)	175	10	(6%)	0.6252	12	5	(42%)		6 (50%)	1 (8%)	0
		≤49 Days (Group 1)	71	3	(4%)		3	2			1 (33%)	0	ō
		50-56 Days (Group 2)	72	4	(6%)		4	2	(50%)	,	2 (50%)	o	ō
		57-63 Days (Group 3)	32	3	(9%)		5	1			3 (60%)	1 (20%)	Ō
LEG PAIN		≤63 Days (All)	175	2	(1%)	0.6642	2	2	(100%)		0	0	0
	1	≤49 Days (Group 1)	71	0			0	0			0	0	0
	•	50-56 Days (Group 2)	72	2	(3%)		2	2	(100%)		o :	0-	0
		57-63 Days (Group 3)	32	0			0	0			0	0	0
MALAISE		≰63 Days (All)	175	5	(3%)	0.0641	5	1	(20%)		£ (80%)	0	0
		≤49 Days (Group 1)	71	1	(1%)		1	0		;	1 (100%)	0	Ó
Į.		50-56 Days (Group 2)	72	1	(1%)		1	1	(100%)		0	0	0
į	· :	57-63 Days (Group 3)	32	3	(9%)		3	0		:	3 (100%)	0	0
PALLOR		≤63 Days (All)	175	· 1	(<1%)	0.1829	1	1	(100%)	()	0	0
		≤49 Days (Group 1)	71	0			0	0			ס	0	0
		50-56 Days (Group 2)	72	0			0	0		()	0	0
	1	57-63 Days (Group 3)	32	1	(3%)		1	1	(100%)	")	0	0
RIGORS		≤63 Days (All)	175	2	(1%)	0.3331	2	. 0	,	' :	L (50%)	1 (50%)	0
		≤49 Days (Group 1)	71	0		1	0	0		()	0	0
		50-56 Days (Group 2)	72	1	(1%)	1	1	0		1	l (100%)	0	0
		57-63 Days (Group 3)	32	1	(3%)	/	1	0		()	1 (100%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: WESTHOFF (#24)

	Gestational Age	Total Number	Numbe of Pt	. 8	Fisher's exact					•		
Body System/Event (2)	Group [3]	of Pts	w/Eve	ent	p value	of Events	Mil	ld	Mode	rate	Severe	Unknowr
BODY AS A WHOLE - GENERAL DISORDERS (co	nt.)									· · · · · · · · · · · · · · · · · · ·		
SYNCOPE	≤63 Days (All)	175	3	(2%)	0.0864	3	1	(33%)	0		2 (67) 0
	£49 Days (Group 1)	71	0	,,		Ō	0	•	ō		0	0
	50-56 Days (Group 2)	72		(1%)		1	o		0		1 (100) 0
	57-63 Days (Group 3)	32	2	(6%)		2	1	(50%)	o		1 (50	•
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	175	3	(2%)	0.4032	3	1	(33%)	2	(67%)	0	0
1	s49 Days (Group 1)	71	Ō			0	o '		0	1.	: 0	0
1	50-56 Days (Group 2)	72		(3%)		2	1	(50%)	1	(50%)	l o	Ö
	57-63 Days (Group 3)	32		(3%)		1	Ō	,,,,,	1	(1004)	0	0
RESISTANCE NECHANISM DISORDERS												
ANY EVENT	≤63 Days (All)	175	6	(3%)	0.0716	6	2	(33%)	4	(67%)	0	0
	≤49 Days (Group 1)	71		(6%)		4	2	(50%)		(50%)	0	0
	50-56 Days (Group 2)	72	0			0	0		0	,	Ö	0
	57-63 Days (Group 3)	32	2	(6%)		2	0		2	(100%)	0	0
INFECTION VIRAL	≤63 Days (All)	175	6	(3%)	0.0716	6	2	(33%)	4	(67%)	0	0
	≤49 Days (Group 1)	71	4	(6%)		4	2	(50%)	2	(50%)	0	0
	50-56 Days (Group 2)	72	0			0	0		0		0	0
	57-63 Days (Group 3)	32	2	(6%)		2	0		2 ((100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational Age	Total Number		nber Pts	Fisher's exact	Number				Severit	•			
Body System/Event [2]	Group [3]	of Pts	w/E	Event	p-value	of Events	Mi	1d	Mode	rate ———	Sev	ere	Unk	nown
	44.5			(000)		1506		(205)		(37%)	377	(25%)	1	(<15
ANY EVENT	≰63 Days (All)	178	175		0.6319	1506	578 215	(38%) (40%)	550 186	(35%)	133	(25%)	0	(<1)
	≤49 Days (Group 1)	72	70			534 494	203	(41%)	179	(36%)	111	(22%)	1	(<11
	50-56 Days (Group 2)	54		(100%)		478	160	(33%)	185	(39%)	133	(28%)	0	(\ 1 \
•	57-63 Days (Group 3)	52	51	(98%)		4 / 0	160	(334)	103	(398)	133	(204)	U	
KIN AND APPENDAGES DISORDERS														
ANY EVENT	≰63 Days (All)	178	6	(3%)	0.5845	6	1	(17%)	2		3	(50%)	0	
	≤49 Days (Group 1)	72	2	(3%)		2	Ö		1	(50%)	1 -	(50¥)	0	
	50-56 Days (Group 2)	54	1	(2%)		1	0		0	.•	1	(100%)	0	
	57-63 Days (Group 3)	52	3	(6%)		3	1	(33%)	1	(33%)	1	(33%)	0	
ACNE	≤63 Days (All)	178	1	(<1%)	0.2921	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	72	0			0	0		0		0		0	
	50-56 Days (Group 2)	54	0			0	0		0		0		0	
	57-63 Days (Group 3)	52	1	(2%)		1	1	(100%)	0		0		0	
SWEATING INCREASED	≤63 Days (All)	178	3	(2%)	1.0000	3	0		0		3	(100%)	0	
	≤49 Days (Group 1)	72	1	(1%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	54	1	(2%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	52	1	(2%)		1	0		0		. 1	(100%)	0	
URTICARIA	≤63 Days (All)	178	2	(1%)	0.7532	2	0		2	(100%)	0		0	
	≤49 Days (Group 1)	72	1	(1%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	54	0			· 0	0		0		lo		0	
	57-63 Days (Group 3)	52	1	(2%)		1	0		1	(100%)	0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational	Total	Numbe		Fisher's	M. mban				Pavarit			
Body System/Event [2]	Age Group [3]	Number of Pts	of Pi w/Eve		exact p-value	Number of Events	Mi	1d	Mode	Severit rate	Sev	ere	Unknow
RUSCULO-SKEŽETAL SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	178	3	(2%)	0.4881	4	2	(50¥)	1	(25%)	1	(25%)	0
	s49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	2	(4%)		3	1	(33%)	1	(33%)	1	(33%)	0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
ARTHRALGIA	≤63 Days (All)	178	2	(1%)	0.1750	2	1	(50%)	0		1	(50%)	0
•	≤49 Days (Group 1)	72	0			0	0		0		0		0
	50 56 Days (Group 2)	54	2	(4%)		2	1	(50%)	0		1	(50%)	0
	57 63 Days (Group 3)	52	0			0	0		0	·	0		0
KELETAL PAIN	≤63 Days (All)	178	2	(1%)	1.0000	2	1	(50%)	1	(50%)	0		0
	s49 Days (Group 1)	72	1	(1%)		1;	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	52	0			o¹	0		0		0		0
ENTR & PERIPH NERVOUS SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	178	73	(41%)	0.1182	138	52	(38%)	63	(46%)	23	(17%)	0
	≤49 Days (Group 1)	72	24	(33%)		36	10	(28%)	19	(53%)	7	(19%)	0
	50-56 Days (Group 2)	54	22	(41%)		50	23	(46%)	19	(38%)	8	(16%)	0
	57-63 Days (Group 3)	52	27	(52%)		52	19	(37%)	25	(48%)	8	(15%)	0 .
DIZZINESS	±63 Days (All)	178	23	(13%)	0.3425	33	12	(36%)	9	(27%)	12	(36%)	0
	≤49 Days (Group 1)	72	7	(10%)		8	2	(25%)	1	(13%)	5	(63%)	0
	50-56 Days (Group 2)	54	10	(19%)		. 15	6	(40%)	6	(40%)	3	(20%)	0
	57-63 Days (Group 3)	52		(12%)		10	4	(40%)	2	(20%)	4	(40%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: NICHOLS (#25)

	Gestational Age	Total Number		ber Pts	Fisher's exact	Number	. .			Severit	y		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p value	of Events		11d		rate	•	ere	Unknown
ENTR & PERIPH NERVOUS SYSTEM DISC	ORDERS (cont.)												
HEADACHE	≤63 Days (All)	178	59	(33%)	0.1795	98	35	(36%)	53	(54%)	10	(10%)	0
	≤49 Days (Group 1)	72	19	(26%)		26	6	(23%)	18	(69%)	2	(8%)	0
	50-56 Days (Group 2)	54	18	(33%)		34	17	(50%)	13	(38%)	4	(12%)	0
	57-63 Days (Group 3)	52	22	(42%)		38	12	(32%)	22	(58%)	4	(11%)	0
HYPOAESTHESIA	≤63 Days (All)	178	1	(<1%)	0.5955	1	0		0		1	(100%)	0
1	. ≤49 Days (Group 1)	72	0			0	0		0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	0		0		1 .	(100%)	0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
MIGRAINE	≤63 Days (All)	178	1	(<1%)	0.2921	1	0		1	(100 %)	0		0
	≤49 Days (Group 1)	72	0			0	0		0		0		0
	50-56 Days (Group 2)	54	0			0	0		0		0		0
	57-63 Days (Group 3)	52	1	(2%)		1	0		1	(100%)	0		0
NEURALGIA	≤63 Days (All)	178	1	(<1%)	0.2921	2	-2	(100%)	0		0		0
	≤49 Days (Group 1)	72	0			0	0		0		0		0
	50-56 Days (Group 2)	54	0			0	0		0		0		0
	57-63 Days (Group 3)	52	1	(2%)		2	2	(100%)	0		0		0
PARAESTHESIA	≤63 Days (All)	178	1	(<1%)	1.0000	1	1	(100%)	0		o		0
	449 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	0			0	0		0		0		0
	57-63 Days (Group 3)	52	0			. 0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational Age	Total Number	Numb of f		Fisher's exact	Number -		Sever	i tv	
Body System/Event [2]	Group [3]	of Pts	w/E		p-value	of Events	Mild	Moderate	Severe	Unknowr
ENTR & PERIPH MERVOUS SYSTEM DISORDERS	(cont.)									
SPEECH DISORDER	≤63 Days (All)	178	1	(<1%)	0.2921	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	0			0	0	0	0	0
	50-56 Days (Group 2)	54	0			0	0	0	0	0
	57-63 Days (Group 3)	52	1	(21)		1	1 (100%)	0	0	0
TREMOR	≤63 Days (All)	178	1	(<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	1	(1%)		1	1 (100%)	0	0	0
•	50-56 Days (Group 2)	54	0			io	0	0 :	Ο.	0
	57-63 Days (Group 3)	52	0			0	0	0 ,	0	0
PECIAL SENSES OTHER, DISORDERS										
ANY EVENT	≤63 Days (All)	178	1	(<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	72	1	(1%)		1	0 .	0	1 (100%)	0
	50-56 Days (Group 2)	54	0			0	0	0	0	0
	57-63 Days (Group 3)	52	0			0	0 '	0	0	0
TASTE PERVERSION	≤63 Days (All)	178	1	(<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	72	. 1	(1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	54	0			0	0	0	0	0
	57-63 Days (Group 3)	52	0			0	0	0	0	0
PSYCHIATRIC DISORDERS	,	1								
ANY EVENT	≤63 Days (All)	178	15	(8%)	0.2858	17	5 (29%)	6 (35%)	6 (35%)	0
	≤49 Days (Group 1)	72	4	(6%)		6	2 (33%)	3 (50%)	1 (17%)	0
	50-56 Days (Group 2)	54	4	(7%)		٠ 4	0	2 (50%)	2 (50%)	0
	57-63 Days (Group 3)	52	7	(13%)		7	3 (43%)	1 (14%)	3 (43%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

%

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event		Fisher's exact p-value	Number	.			Severit	everity			
						of Events	Mi		Mode		Sev		Unknown	
SYCHIATRIC DISORDERS (cont.)														
ANOREXIA	≤63 Days (All)	178	4	(2%)	1.0000	4	2	(50%)	2	(50%)	0		0	
	s49 Days (Group 1)	72	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	54	1	(2%)		1	0		1	(100%)	0		0	
	57-63 Days (Group 3)	52	1	(2%)		1	1	(100%)	0		0		0	
ANXIETY	≤63 Days (All)	178	6	(3%)	1.0000	6	3	(50%)	2	(33%)	1	(17%)	0	
	, s49 Days (Group 1)	72	2	(3%)		2	1	(50%)	1	(50%)	0		0	
	50-56 Days (Group 2)	54	2	(4%)		2	0		1	(50%)	1	(50%)	0	
	57-63 Days (Group 3)	52	2	(4%)		2	2	(100%)	0		0		0	
EMOTIONAL LABILITY	≤63 Days (All)	178	2	(1%)	0.5155	2	0		0		2	(100%)	0	
	≤49 Days (Group 1)	72	0			0	0		0		0		0	
	50-56 Days (Group 2)	54	1	(2%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	52	1	(2%)		1	0		0		1	(100%)	0	
INSOMNIA	≤63 Days (All)	178	15	(3%)	0.2297	5	0		2	(40%)	3	(60%)	0	
	≤49 Days (Group 1)	72	2	(3%)		2	0		1	(50%)	1	(50%)	0	
	50-56 Days (Group 2)	54	0			0	0		0		0		0	
!	57-63 Days (Group 3)	52	3	(6%)		3	0		1	(33*)	2	(67%)	0	
NASTRO-INTESTINAL SYSTEM DISORDERS									•					
ANY EVENT	≰63 Days (All)	178	148	(83%)	0.5143	456	189	(41%)	172	(38%)	95	(21%)	0	
	≤49 Days (Group 1)	72	57	(79%)	1	155	71	(46%)	49	(32%)	35	(23%)	0	
	50-56 Days (Group 2)	54	47	(87%)	,	158	70	(44%)	60	(38%)	28	(18%)	0	
	57-63 Days (Group 3)	52	44	(85%)		143	48	(34%)	63	(44%)	32	(22%)	0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational	Total Number	Number of Pi		Fisher's exact	Number				Severit	v		
Body System/Event [2]	Age Group [3]	of Pts	w/Ev		p-value	of Events	Mí		Mode		Sev	ere	Unknow
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)				_									
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	±63 Days (All)	178	1	(<1%)	0.2921	1	0		1	(100%)	0		0
	s49 Days (Group 1)	72	0			0	0		0		0		0
	50-56 Days (Group 2)	54	0			0	0		0		0		0
	57-63 Days (Group 3)	52	1	(2%)		1	0		1	(100%)	0		0
CONSTIPATION	≤63 Days (All)	178	2	(11)	0.5155	2	1	(50%)	0		1	(50%)	0
	±49 Days (Group 1)	72	0			0	0	1	0	1	0		0
,	50-56 Days (Group 2)	54	1	(21)		1	1	(100%)	0	1	Ю.		0
	57-63 Days (Group 3)	52	1	(2%)		1	0		0	А	1	(100%)	0
DIARRHEA	s63 Days (All)	178	40	(22%)	0.6344	46	19	(41%)	22	(48%)	5	(11%)	0
	s49 Days (Group 1)	72	14	(19%)		15	7	(47%)	5	(33%)	3	(20%)	0
	50-56 Days (Group 2)	54		(22%)		17	7	(41%)	9	(53%)	1	(6%)	0
	57-63 Days (Group 3)	52		(27%)		14	5	(36%)	8	(57%)	1	(7%)	0
DYSPEPSIA	≤63 Days (All)	178	5	(3%)	0.4526	5	4	(80%)	1	(20%)	0		0
	s49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	52	3	(6%)		3	2	(67%)	1	(33%)	0		0
FLATULENCE	≤63 Days (All)	178	2	(1%)	0.3373	2	1	(50%)	1	(50%)	0		0
•	s49 Days (Group 1)	72	2	(3%)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	54	0			0	0		0		0		0
	57-63 Days (Group 3)	52	0			. 0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational Age	Total Number	Numi of i		Fisher's exact	Number				Severi	ty		
Body System/Event [2]	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	1d	Mode	rate	Sev	ere	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)												
IRRITABLE BOWEL SYNDROME	s63 Days (All)	178	2	(1%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	1	(100%)	0		0		0
•	57-63 Days (Group 3)	52	0			0	0		0		0		0
MOUTH DRY	≤63 Days (All)	178	1	(<1%)	1.0000	1	0		0		1	(100%)	0
	s49 Days (Group 1)	72	1	(1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	54	0			0	0		0		oʻ		0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
NAUSEA	≤63 Days (All)	178	141	(79%)	0.8440	301	126	(42%)	108	(36%)	67	(22%)	0
	≤49 Days (Group 1)	72	57	(79%)		103	49	(48%)	34	(33%)	20	(19%)	0
	50-56 Days (Group 2)	54	44	(81%)		107	49	(46%)	34	(32%)	24	(22%)	0
	57-63 Days (Group 3)	52	40	(77%)		91	28	(31%)	40	(44%)	23	(25%)	0
VOMITING	≤63 Days (All)	178	71	(40%)	0.1756	96	36	(38%)	39	(41%)	21	(22%)	0
	s49 Days (Group 1)	72	23	(32%)		32	12	(38%)	9	(28%)	11	(34%)	0
	50-56 Days (Group 2)	54	23	(43%)		31	11	(35%)	17	(55%)	3	(10%)	0
	57-63 Days (Group 3)	52	25	(48%)		33	13	(39%)	13	(39%)	. 7	(21%)	0
METABOLIC AND MUTRITIONAL DISORDERS											i		
ANY EVENT	£63 Days (All)	178	1	(<1%)	1.0000	1	0		1	(100%)	. 0		0
	£49 Days (Group 1)	72	1	(1%)		1	0		1	(100%)	0		0
	50-56 Days (Group 2)	54	0			• 0	0		0		10		0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
	i												

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number -			y	
Body System/Event [2]	Group [3]	of Pts	w/Ev		p value	of Events	Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS (cont.)									
OEDEMA GENERALISED	≤63 Days (All)	178	1	(<1%)	1.0000	1	0 .	1 (100%)	0	0
	≤49 Days (Group 1)	72	1	(1∜)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	54	0	:		0	0	0	0	0
	57-63 Days (Group 3)	52	0			0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS										
ANY EVENT	≤63 Days (All)	178	4	(2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
1 ,	≤49 Days (Group 1)	72	2	(3%)		2	1 (50%)	1 (50%)	0.	0
	50,56 Days (Group 2)	54	1	(2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	1	(2%)		1	1 (100%)	0	0	0
TACHYCARDIA	≤63 Days (All)	178	4	(2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	72	2	(3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	54	1	(2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	52	1	(2%)		1	1 (100%)	0	0	0
RESPIRATORY SYSTEM DISORDERS										
ANY EVENT	≤63 Days (All)	178	7	(4%)	0.8021	13	5 (38%)	7 (54%)	1 (8%)	0
	s49 Days (Group 1)	72	2	(3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	54	2	(4%)		6	3 (50%)	3 (50%)	0	0
	57-63 Days (Group 3)	52	3	(6%)		5	2 (40%)	2 (40%)	1 (20%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number -		Severit	·v	
Body System/Event [2]	Age Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
COUGHING	≤63 Days (All)	178	3 (2%)	0.1928	8	4 (50%)	3 (38%)	1 (13%)	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		5	3 (60%)	2 (40%)	0	0
	57-63 Days (Group 3)	52	2 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
DYSPNOEA	s63 Days (All)	178	1 (<1%)	0.5955	1	0	1 (100%)	0	0
T.	≤49 Days (Group 1)	72	0		0	0	0 ,	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	1 (100%)	o ·	0
	57-63 Days (Group 3)	52	o !		0	0	0	0	0
PHARYNGITIS	s63 Days (All)	178	1 (<1%)	0.2921	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	1 (2%)		1	0	1 (100%)	0	0
RHINITIS	≤63 Days (All)	178	1 (<1%)	0.2921	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	0	0
SINUSITIS	≤63 Days (All)	178	2 (1%)	0.3373	2	0	2 (100%)	0	0
	449 Days (Group 1)	72	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	54	0		. 0	0	0	0	0
	57-63 Days (Group 3)	52	0		• 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational	Total Number	Number of Pts	Fisher's exact	Number -		Severi	t y	· • • • • · · · · · · ·
Body System/Event [2]	Group (3)	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
ANAEMIA	≤63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	1 (1%)		; 1	1 (100%)	0	0	0
·.	50-56 Days (Group 2)	54	0		i o	0	0 !	O .	0
i	57-63 Days (Group 3)	52	0		0	0	о .	0	0
LATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	178	1 (<1%)	0.5955	1	1 (100%)	0	0	0
	s49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
EPISTAXIS	≤63 Days (All)	178	1 (<1%)	0.5955	1	1 (100%)	0	0	0
	s49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
RIMARY SYSTEM DISORDERS									
ANY EVENT	s63 Days (All)	178	1 (<1%)	0.5955	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	72	0		. 0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1 1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Center: NICHOLS (#25)

	Gestational	Total Number	Number of Pts	Fisher's	Atombo er		Cavenia		
Body System/Event [2]	Age Group (3)	of Pts	w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS (CONt.)						··			
DYSURIA	≤63 Days (All)	178	1 (<1%)	0.5955	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	. s63 Days (All)	178	21 (12%)	0.9155	25	8 (32%)	2 (8%)	15 (60%)	0
	≤49 Days (Group 1)	72	8 (11%)		8	4 (50%)	1 (134)	3 (38%)	0
	50-56 Days (Group 2)	54	6 (11%)		8	3 (38%)	0	5 (63%)	0
	57-63 Days (Group 3)	52	7 (13%)		9	1 (11%)	1 (11%)	7 (78%)	0
BREAST PAIN FEMALE	≤63 Days (All)	178	2 (1%)	0.7532	2	1 (50%)	1 (50%)	0	0
1	≤49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	ō
1 1	50-56 Days (Group 2)	54	0		0	0	0	0	0
į	57-63 Days (Group 3)	52	1 (2%)		1	0	1 (100%)	0	0
ENDOMETRITIS	≤63 Days (All)	178	2 (1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	0
!	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	52	0		0	. 0	i o	0	0
PREMENSTRUAL TENSION	≟63 Days (All)	178	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	72	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	54	0	,	. 0	0	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	ō

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational	Total	Number		Fisher's						
Body System/Event [2]	Age Group (3)	Number of Pts	of Pts w/Even		exact p-value	Number of Events	Mild	Moderat	-	Severe	Unknow
REPRODUCTIVE DISORDERS, FEMALE (cont.)											
SALPINGITIS	≤63 Days (All)	178	1 (<	:1%)	0.5955	1	1 (100%)	0		0	0
	≤49 Days (Group 1)	72	0			0	0	0		0	0
	50-56 Days (Group 2)	54	1 ((2%)		1	1 (100%)	0		0	0
	57-63 Days (Group 3)	52	0			0	0	0		0	0
UTERINE DISORDER NOS	≤63 Days (All)	178	1 (<	(1%)	0.2921	1	1 (100%)	0		0	, о
	≤49 Days (Group 1)	72	0			0	0 '	0	1	0	0
·	50-56 Days (Group 2)	54	0			0	0	0	1	Ď.	0
	57-63 Days (Group 3)	52	1 ((2%)		1	1 (100%)	0	.•	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	178	14 ((8%)	0.5002	16	0	1	(6%)	15 (94%)	0
	≤49 Days (Group 1)	72	4 ((6%)		4	0	1 (2	251)	3 (75%)	0
	50-56 Days (Group 2)	54	4 ((7%)		5	0	0		5 (100%)	0
	57-63 Days (Group 3)	52	6 (1	12%)		7	0	0		7 (100%)	0
VAGINITIS	≤63 Days (All)	178	2 ((1%)	1.0000	2	2 (100%)	0		0	0
	≤49 Days (Group 1)	72	1 ((1%)		1	1 (100%)	0		0	0
	50-56 Days (Group 2)	54	1 ((2%)		1	1 (100%)	0		0	0
	57-63 Days (Group 3)	52	0			0	0	0		0	0
ROPLASM											
ANY EVENT	≤63 Days (All)	178	2 ((1%)	1.0000	2	2 (100%)	0		0	0
	≤49 Days (Group 1)	72	1 ((1%)		1	1 (100%)	0		0	0
	50-56 Days (Group 2)	54	1 ((2%)		1	1 (100%)	0		0	0
	57-63 Days (Group 3)	52	0			• 0	0	0		0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table Sa (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Numb of F w/Ev	Pts .	Fisher's exact p value	Number of Events		1d	Mode		ty Sev	ere	Unknow
MOPLASM (cont.)													
OVARIAN CYST	≤63 Days (All)	178	2	(1%)	1.0000	2	2	(100%)	0		0		0
	≤49 Days (Group 1)	72	1	(1%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	54	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	52	0			0	0		0		0		0
ODY AS A WHOLE - GENERAL DISORDERS													
ANY EVENT	. ≤63 Days (All)	178	175	(98%)	0.6319	818	300	(37%)	290	(35%)	228	(28%)	0
	≤49 Days (Group 1)	72	70	(97%)		315	121	(38%)	109	(35%)	85		0
	50-56 Days (Group 2)	54	54 ((100%)		252	96	(38%)	91	(36%)	65	(26%)	0
	57-63 Days (Group 3)	52	51	(98%)		251	83	(33%)	90	(36%)	78	(31%)	0
ABDOMINAL PAIN	≤63 Days (All)	178	174	(98%)	0.3085	730	272	(37%)	252	(35%)	206	(28%)	0
	≤49 Days (Group 1)	72	69	(96%)		279	109	(39%)	95	(34%)	75	(27%)	0
	50-56 Days (Group 2)	54	54	(100%)		229	87	(38%)	80	(35%)	62	(27%)	0
	57-63 Days (Group 3)	52	51	(98%)		222	76	(34%)	77	(35%)	69	(31%)	0
ALLERGY	≤63 Days (All)	178	1	(<1%)	0.2921	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	72	0			0	0		0		0		0
	50-56 Days (Group 2)	54	0			0	0		0		. 0		0
	57-63 Days (Group 3)	52	1	(2%)		1	1	(100%)	0		0		0
ASTHENIA	≤63 Days (All)	178	5	(3%)	0.5186	8	2	(25%)	5	(63%)	1	(13%)	0
	≤49 Days (Group 1)	72	1	(1%)		3	0			(100%)	þ		0
	50-56 Days (Group 2)	54	3	(6%)		• 4	2	(50%)	1	(25%)	ì	(25%)	0
	57-63 Days (Group 3)	52	1	(2%)		1	0		1	(100%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: NICHOLS (#25)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	V	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
PODY AS A WHOLE - GENERAL DISORDERS	(cont.)						······································		
BACK PAIN	≤63 Days (All)	178	11 (6	b) 0.2234	17	7 (41%)	6 (35%)	4 (24%)	0
	≤49 Days (Group 1)	72	5 (7	1.)	8	5 (63%)	1 (13%)	2 (25%)	0
	50-56 Days (Group 2)	54	1 (2	r)	1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	5 (10	1)	8	2 (25%)	4 (50%)	2 (25%)	0
CHEST PAIN	≤63 Days (All)	178	2 (1) 0.1750	2	0	2 (100%)	0	0
f	. s49 Days (Group 1)	72	0		0	0	0	0	0
	50+56 Days (Group 2)	54	2 (4	:)	2	0	2 (100%)	0.	0
	57 63 Days (Group 3)	52	0		O	0	0	0	0
FATIGUE	≤63 Days (All)	178	17 (10	0.3777	23	7 (30%)	11 (48%)	5 (22%)	0
	≤49 Days (Group 1)	72	7 (10	:)	10:	3 (30%)	4 (40%)	3 (30%)	0
	50-56 Days (Group 2)	54	3 (6	:)	4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	52	7 (13	1)	9	2 (22%)	5 (56%)	2 (22%)	0
FEVER	≤63 Days (All)	178	8 (4) 0.2389	8	3 (38%)	4 (50%)	1 (13%)	0
	≤49 Days (Group 1)	72	1 (1	:)	1	1 (100%)	0	0	Ō
	50-56 Days (Group 2)	54	3 (6	:)	3	1 (33%)	2 (67%)	0	o
	57-63 Days (Group 3)	52	4 (8	;)	4	1 (25%)	2 (50%)	1 (25%)	0
HOT FLUSHES	s63 Days (All)	178	3 (2)) 0.7812	3	0	2 (67%)	1 (33%)	0
	#49 Days (Group 1)	72	2 (3)	2	0	2 (100%)	0	ō
	50-56 Days (Group 2)	54	1 (2	•	1	0	0	1 (100%)	Ö
	57-63 Days (Group 3)	52	0		Ö	0	Ö	0	Ö

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: NICHOLS (#25)

	Gestational	Total	Number	Fisher's					
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Event	exact p-value	Number of Events	Mild	Moderate	Severe	Unknown
ODY AS A WEOLE - GENERAL DISORDERS	(cont.)								······································
LEG PAIN	≤63 Days (All)	178	3 (2%)	0.7812	3	1 (33%)	2 (67%)	0	0
,	≤49 Days (Group 1)	72	2 (3%)		. 2	0	2 (100%)	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
MALAISE	≤63 Days (All)	178	4 (2%)	0.1014	4	1 (25%)	2 (50%)	1 (25%)	0
1	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	3 (6%)		3	1 (33%)	2 (67%)	0.	0
	57-63 Days (Group 3)	52	1 (21)		1	0	0 "	1 (100%)	0
OEDEMA	≤63 Days (All)	178	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	s49 Days (Group 1)	72	1 (14)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
PAIN	≤63 Days (All)	178	3 (2%)	0.6319	3	·3 (100%)	0	o	0
	≤49 Days (Group 1)	72	2 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	1 (2%)		1	1 (100%)	0	0	0
RIGORS	≤63 Days (All)	178	6 (3%)	0.5094	6	1 (17%)	2 (33%)	3 (50%)	0
	±49 Days (Group 1)	72	4 (6%)		4	1 (25%)	0	3 (75%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	1 (2%)		. 1	0	1 (100%)	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table Sa (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: NICHOLS (#25)

	Gestational Age	Total Number	Number of Pts		Fisher's exact	Number				- Severit	V		
Body System/Event [2]	Group (3)	of Pts	w/Ever	-	p.value	of Events		1 d	Mode		•	vere	Unknown
ODY AS A WHOLE - GENERAL DISORDERS (cont	:.)												
SYNCOPE	≤63 Days (All)	178	6 ((3%)	0.3798	6	1	(17%)	0		5	(83%)	0
	≤49 Days (Group 1)	72	1 ((1%)		1	0		0		1	(100%)	0
	50-56 Days (Group 2)	54	2 ((4%)		2	1	(50%)	0		1	(50%)	0
	57-63 Days (Group 3)	52	3 ((6%)		3	0		0		3	(100%)	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	178	3 ((2%)	0.7812	3	1	(33%)	1	(33%)	1	(33%)	0
ı	≤49 Days (Group 1)	72	2 ((3%)		2	0		1	(50%)	1	(50%)	0
•	50-56 Days (Group 2)	54	1 ((2%)		ⁱ 1	1	(100%)	0		0		0
;	57-63 Days (Group 3)	52	0			ა	0		0	.0	0		0
ESISTANCE NECHANISM DISORDERS													
ANY EVENT	≤63 Days (All)	178	15 ((B%)	0.2052	17	10	(59%)	4	(24%)	3	(18%)	0
	≤49 Days (Group 1)	72	3 ((4%)		3	3	(100%)	0		0		0
	50-56 Days (Group 2)	i 54	6 (1	11%)		7	5	(71%)	2	(29%)	0		0
	57-63 Days (Group 3)	52	6 (1	12%)		7	2	(29%)	2	(29%)	3	(43%)	0
INFECTION VIRAL	s63 Days (All)	178	15 ((8%)	0.2052	17	10	(59∜)	4	(24%)	3	(18%)	0
	≤49 Days (Group 1)	72	3 ((4%)		3	3	(100%)	0		0		0
	50-56 Days (Group 2)	54	6 (1	114)		7	5	(71%)	2	(29%)	0		0
	57-63 Days (Group 3)	52	6 (1	12%)		7	2	(29%)	2	(29%)	3	(43%)	0
ECONDARY TERMS	•	1											
ANY EVENT	≤63 Days (All)	178	1 (<	<1%)	0.5955	1	0		0		0		1 (100
	s49 Days (Group 1)	72	0			. 0	0		0		0		0
	50-56 Days (Group 2)	54	1 ((2%)		1	0		0		0		1 (100
	57-63 Days (Group 3)	52	0			0	0		0		0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Mild	Severit	y	Unknown
SECONDARY DERMS (cont.)									
INFLICTED INJURY	≤63 Days (All)	178	1 (<1%)	0.5955	1	0	. 0	0	1 (100%
	≤49 Days (Group 1)	72	0		0	0	0	0	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	; o	0	1 (100%
	57-63 Days (Group 3)	52	0		0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number				Severity	•			
Body System/Event [2]	Group [3]	of Pts	w/Event	p·value	of Events	Mi	1d	Mode	rate	Sev	ere	Unk	nown
•													
ANY EVENT	≤63 Days (All)	179	179 (100%)	• • • • • •	1294	518	(40¥)	57 9	(45%)	193	(15%)		(<1%
	<pre>s49 Days (Group 1)</pre>	63	63 (100%)		422	175	(41%)	193	(46%)	52	(12%)		(<1%
	50-56 Days (Group 2)	59	59 (100%)		433	164	(381)	197	(45%)	71	(16%)		(<1%
	57-63 Days (Group 3)	57	57 (100%)		439	179	(41%)	189	(43%)	70	(16%)	1	(<1%
KIN AND APPENDAGES DISORDERS													
ANY EVENT	≤63 Days (All)	179	5 (3%)	0.0822	5	3	(60%)	1	(20%)	1	(20%)	0	
	s49 Days (Group 1)	63	1 (2%)		1	0		1	(10b%)	0		0	
	50-56 Days (Group 2)	59	4 (7%)		4	3	(75%)	0	3	1	(25%)	0	
57-63 Days (Group 3)	57	0		0	0		0		0		0		
PRURITUS	≤63 Days (All)	179	1 (<1%)	0.6480	1	1	(100%)	0		0		0	
	≤49 Days (Group 1)	63	0		0	0		0		0		0	
	50-56 Days (Group 2)	59	1 (2%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	57	0		0	0		0		0		0	
SKIN DISORDER	≤63 Days (All)	179	1 (<1%)	0.6480	1	1	(100%)	0		0		0	
	≰49 Days (Group 1)	63	0		0	0		0		0		0	
	50-56 Days (Group 2)	59	1 (2%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	57	0		0	0		0		0		0	
SWEATING INCREASED	≤63 Days (All)	179	2 (1%)	1.0000	2	0		1	(50%)	1	(50%)	0	
•	s49 Days (Group 1)	63	1 (2%)		1	0		1	(100 %)	0		0	
	50-56 Days (Group 2)	59	1 (2%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	57	0		• 0	0		0		0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severit	.y	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
SKIN AND APPENDAGES DISORDERS (cont.)									
URTICARIA	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	2 (1%)	0.7667	2	1 (50%)	1 (50%)	0	0
·	#49 Days (Group 1)	63	1 (2%)		1	1 (100%)	ο ΄	0.	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
MYALGIA	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	o	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
SKELETAL PAIN	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
CENTR & PERIPH MERVOUS SYSTEM DISORDERS	•							i	
ANY EVENT	≤63 Days (All)	179	64 (36%)	0.7717	104	27 (26%)	70 (67%)	6 (6%)	1 (<1
	£49 Days (Group 1)	63	23 (37%)		41	12 (29%)	24 (59%)	5 (12%)	0
	50-56 Days (Group 2)	59	19 (32%)		30	7 (23%)	22 (73%)	1 (3%)	0
	57-63 Days (Group 3)	57	22 (39%)		33	8 (24%)	24 (73%)	0	1 (3
•	1							1	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational	Total	Numi		Fisher's									
Body System/Event [2]	Age Group [3]	Number of Pts	of w/E	Pts vent	exact p-value	Number of Events		.ld	Mode	Severit rate	•	ere		nown
ENTR & PEREPH NERVOUS SYSTEM DIS	ORDERS (cont.)													
DIZZINESS	≤63 Days (All)	179	20	(11%)	0.0534	24	11	(46%)	9	(38%)	4	(17%)	0	
	≤49 Days (Group 1)	63	12	(19%)		14	7	(50%)	4		3	(21%)	0	
	50-56 Days (Group 2)	59	5	(8€)		7	2	(29%)	4	(57%)	1	(14%)	0	
	57-63 Days (Group 3)	57	3	(5%)		3	2	(67%)	1	(33%)	0		0	
HEADACHE	≤63 Days (All)	179	53	(30%)	0.3635	79	15	(19%)	61	(77%)	2	(3%)	1	(1)
•	≤49 Days (Group 1)	63	17	(27%)		27	5	(19%)	20	(74%)	2	(7%)	0	
	50-56 Days (Group 2)	59	15	(25%)		23	5	(22%)	18	(78%)	σ		0	
	57-63 Days (Group 3)	57	21	(37%)		29	5	(17%)	23	(79%)	0		1	(3\$
PARAESTHESIA	≤63 Days (All)	179	1	(<1%)	0.3184	1	1	(100%)	0		0		0	
	s49 Days (Group 1)	63	0			Q	0		0		0		0	
	50-56 Days (Group 2)	59	0			ò	0		0		0		0	
	57-63 Days (Group 3)	57	1	(2%)		1	1	(100%)	0		0		0	
VISION DISORDERS														
ANY EVENT	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		0		1	(100%)	0	
	≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
VISION ABNORMAL	x63 Days (All)	179	1	(<1%)	1.0000	1	0		0		1	(100%)	0	
	≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	59	0			. 0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

	Gestational Age	Total Number	Numb of P		Fisher's exact	Number	 .			Severit	·v		
Body System/Event [2]	Group [3]	of Pts	w/Ev		p·value	of Events	M	ild	Mode	rate	Sev	еге	Unknown
PSYCHIATRIC disorders					, .								
ANY EVENT	≤63 Days (All)	179	11	(6%)	0.3620	14	5	(36%)	8	(57%)	1	(7%)	0
	≤49 Days (Group 1)	63	6	(10%)		7	2	(29%)	4	(57%)	1	(14%)	0
	50-56 Days (Group 2)	59	2	(3%)		3	2	(67%)	1	(33%)	0		0
	57-63 Days (Group 3)	57	3	(5%)		4	1	(25%)	3	(75%)	0		0
ANOREXIA	s63 Days (All)	179	1	(<1%)	1.0000	1	1	(100%)	0		0		0
1	≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0		0		0
	50-56 Days (Group 2)	59	0	į		0	0		0	•	0 -		0
	57-63 Days (Group 3)	57	0			0	0		0	•	0		0
ANXIETY	≤63 Days (All)	179	4	(2%)	1.0000	4	0		4	(100%)	0		0
	≤49 Days (Group 1)	63	2	(3%)		2	0		2	(100%)	0		0
	50-56 Days (Group 2)	59	1	(2%)		1	0		1	(100%)	0		0
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	0		0
DEPRESSION	≤63 Days (All)	179	2	(1%)	0.5413	2	1	(50%)	1	(50%)	0		0
	≤49 Days (Group 1)	63	0			0	o		0		0		0
	50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0		0		0
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	0		0
EMOTIONAL LABILITY	≤63 Days (All)	179	4	(2%)	0.4684	5	2	(40%)	2	(40%)	1	(20%)	0
	≤49 Days (Group 1)	63	2	(3%)		3	1	(33%)	1	(33%)	1	(33%)	0
	50-56 Days (Group 2)	59	0			0	0		0		0		0
	57-63 Days (Group 3)	57	2	(4%)		2	1	(50%)	1	(50%)	0		0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age	Total Number	of	ber Pts	Fisher's exact	Number				Severity			**-1	
body byseem/seems (2)	Group [3]	of Pts	W/E	vent	p value	of Events	MI	1 d	Mode	erate	Sev	ere	Unk	cnown
PSYCHIATRIC, DISORDERS (cont.)														
INSOMNIA	≤63 Days (All)	179	2	(1%)	1.0000	2	1	(50%)	1	(50%)	0		0	
	≤49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
GASTRO-INTESTINAL SYSTEM DISORDERS														
ANY EVENT	≤63 Days (All)	179	159	(89%)	0.3485	489	212	(47%)	180	(40%)	56	(12%)	1	(<1%)
•	≤49 Days (Group 1)	63	53	(84%)		138	67	(49%)	59	(45%)	12		0	
1	50-56 Days (Group 2)	59	54	(921)		163	69	(42%)	70	(431)	23	(14%)	1	(<1%)
	57-63 Days (Group 3)	57	52	(91%)		148	76	(51%)	51	(34%)	21		0	,
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	179	3	(2%)	0.6520	4	2	(50%)	1	(25%)	1	(25%)	0	
	≤49 Days (Group 1)	63	2	(3%)		3	2	(67%)	1	(33%)	ō	(,	0	
	50-56 Days (Group 2)	59	0	(0.07)		0	0	1	0	(330)	ň		Ô	
	57-63 Days (Group 3)	57	1	(2%)		1	ō		ŏ		1	(100%)	ō	
CONSTIPATION	≤63 Days (All)	179	1	(<1%)	0.3184	1	0		1	(100%)	0		0	
	≤49 Days (Group 1)	63	0			0	0		0	,	0		0	
	50-56 Days (Group 2)	59	0			0	ō		0		0		0	
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	ō		0	
DIARRHEA	≤63 Days (All)	. 179	27	(15%)	0.7017	30	14	(47%)	16	(53%)	0		0	
	≤49 Days (Group 1)	63	11	(17%)		12	4	(33%)	A	(67%)	ō		n	
	50-56 Days (Group 2)	59	7	(12%)		. 8	4	(50%)	4	(50%)	o		ő	
	57-63 Days (Group 3)	57	9			10	6	(60%)	4	1	Ö		ő	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

	Gestational Age	Total Number	Num of	ber Pts	Fisher's exact	Number				Severi	ty		. ;	. .
Body System/Event (2)	Group [3]	of Pts	w/E	vent	p-value	of Events	Mi	lld	Mode	erate	•	ere	Unk	cnown
ASTRO-INTESTINAL SYSTEM DISORDERS (cont.)														
DYSPEPSIA	≤63 Days (All)	179	6	(3%)	0.1224	7	3	(43%)	1 3	(43%)	1	(14%)	0	
	≰49 Days (Group 1)	63	2	(3%)		3	2	(67%)	1	(33%)	ō	,,	0	
	50-56 Days (Group 2)	59	4	(7%)		4	1	(25%)	2	(50%)	1	(25%)	0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
MELAENA	≤63 Days (All)	179	1	(<11)	0.3184	1	1	(100%)	0		0		0	
,	s49 Days (Group 1)	63	0	,,		0	0	(0000)	ō		0		Ô	
•	50-56 Days (Group 2)	59	0			o			ō	:	0.		ñ	
	57-63 Days (Group 3)	57	1	(2%)		1	1	(100%)	ō	•	0		0	
NAUSEA	≤63 Days (All)	179	149	(83%)	0.3284	319	166	(52%)	111	(35%)	41	(13%)	1	(<19
	≤49 Days (Group 1)	63	49	(78%)		100	56	(56%)	34		10	(10%)	ō	,
1	50-56 Days (Group 2)	59	52	(88%)		118	54	(46%)	47		16	(14%)	1	(<11
	57-63 Days (Group 3)	57	48	(84%)		101	56	(55%)	30		15	(15%)	ō	,
												*		
TOOTH ACHE	≤63 Days (All)	179	1	(<1%)	1.0000	1	0		1	(100%)	0		0	
	≰49 Days (Group 1)	63	1	(2%)		1	0		1	(100%)	0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
!	57-63 Days (Group 3)	57	0			0	0		0		0		0	
VOMITING	≤63 Days (All)	179	68	(38%)	0.0606	86	26	(30%)	47	(55%)	13	(15%)	0	
	≰49 Days (Group 1)	63	17	(27%)	1	19	3	(16%)	14	(74%)	2	(11%)	ō	
	50-56 Days (Group 2)	59	24	(41%)	i	33	10	(30%)	17	(52%)	6	(18%)	ō	
	57-63 Days (Group 3)	57	27	(47%)	ì	34	13	(38%)	16		5		ō	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number -		Severit	· w	
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
METABOLIC AND MUTRITIONAL DISORDERS									- · · · · · · · · · · · · · · · · · · ·
ANY EVENT	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
ı	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0 '	; 0	0
	50-56 Days (Group 2)	59	0		0	0	o :	o.	0
	57-63 Days (Group 3)	57	0		0	0	о .	0	0
ARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	. 0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
HYPOTENSION	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	1 (100%)	0	0
	\$49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
EART RATE AND RHYTHM DISORDERS	•								
ANY EVENT	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		. 0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	. 0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact	Number		Severi	ty	
Body System/Event (2)	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS (cont.)									
TACHYCARDIA	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
VASCULAR (EXTRACARDIAC) DISORDERS									
ANY EVENT	s63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
•	≤49 Days (Group 1)	63	0		0	0	o '	0.	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	o '	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
VEIN DISORDER	≤63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	O	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	s63 Days (All)	179	9 (5%)	0.6995	10	3 (30%)	4 (40%)	3 (30%)	0
	≤49 Days (Group 1)	63	3 (5%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	59	2 (3%)		3	0	1 (33%)	2 (67%)	0
	57-63 Days (Group 3)	57	4 (7%)		4	2 (50%)	1 (25%)	1 (25%)	0
	•								

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational	Total	Number		Fisher's	N				Cauari			
Body System/Event [2]	Age Group [3]	Number of Pts	of Pts w/Even		exact p-value	Number of Events	Mil		Mode	Severit rate	•	ere	Unknowr
RESPIRATORY SYSTEM DISORDERS (cont.)													
COUGHING	s63 Days (All)	179	1 (<	1%)	0.3184	1	0		0		1	(100%)	0
	s49 Days (Group 1)	63	0	1		0	0		0		0		0
	50-56 Days (Group 2)	59	0	4		0	0		0		0		0
	57-63 Days (Group 3)	57	1 (21)		1	0		0		1	(100%)	0
DYSPNOEA	≤63 Days (All)	179	1 (<	1%)	1.0000	1	0		1	(100%)	0		0
1	s49 Days (Group 1)	63	1 (21)		1	0		1	(100%)	0		0
	50-156 Days (Group 2)	59	0			0	0		0	:	0	,	0
	57-63 Days (Group 3)	57	0			0	0		0	•	0		0
PULMONARY CONGESTION	≤63 Days (All)	179	1 (<	1%)	0.3184	1	1	(100%)	0		0		0
	≤49 Days (Group 1)	63	0			0.	0		0		0		0
	50-56 Days (Group 2)	59	0			o	0		0		0		0
	57-63 Days (Group 3)	57	1 (2%)		1 '	1	(100%)	0		0		0
SINUSITIS	≤63 Days (All)	179	6 (3%)	1.0000	7	2	(29%)	3	(43%)	2	(29%)	0
	≤49 Days (Group 1)	63	2 (34)		2	1	(50%)	1	(50%)	0		0
	50-56 Days (Group 2)	59	2 (31)		3	0		1	(33%)	2	(67%)	0
	57-63 Days (Group 3)	57	2 (4%)		2	1	(50%)	1	(50%)	0		0
RED BLOOD CELL DISORDERS													
ANY EVENT	≤63 Days (All)	179	26 (1	51)	0.0320	26	17	(65%)	7	(27%)	2	(8%)	0
	≤49 Days (Group 1)	63	4 (6 %)		4	3	(751)	1	(25%)	0		0
	50-56 Days (Group 2)	59	9 (1	5%)		<u>,</u> 9	6	(67%)	2	(22%)	1	(11%)	0
	57-63 Days (Group 3)	57	13 (2	3%)		13	8	(62%)	4	(31%)	1	(8%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

^[2] NOS - Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Center: SHEEHAN (#26)

	Gestational	Total	Num	-	Fisher's								
Body System/Event (2)	Age Group [3]	Number of Pts	of w/E	Pts vent	exact p value	Number of Events		ld.		Severit rate	•	ere	Unknow
ED BLOOD CELL DISORDERS (cont.)		·											
ANAEMIA	≤63 Days (All)	179	25	(14%)	0.0345	25	16	(64%)	7	(28%)	2	(8%)	0
·	≤49 Days (Group 1)	63	4	(6%)		4	3	(75%)	1	(25%)	0		Ó
	50-56 Days (Group 2)	59	8	(14%)		8	5	(63%)	2	(25%)	1	(13%)	0
	57-63 Days (Group 3)	57	13	(23%)		13	8	(62%)	4	(31%)	1	(8%)	0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	179	1	(<1%)	0.6480	1	1	(100%)	0		0		0
•	≰49 Days (Group 1)	63	ō			0	ō		ō		ō		0
	50-56 Days (Group 2)	59	1	(21)		1	1	(100%)	ō	•	0.		Ö
	57-63 Days (Group 3)	57	0			0	0	, ,	0	•	0		0
RINARY SYSTEM DISORDERS													
ANY EVENT	≤63 Days (All)	179	3	(2%)	0.7746	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	63	2	(3%)		2	1	(50%)	1	(50%)	ō		ō
	50-56 Days (Group 2)	59	1	(2%)		1	1	(100%)	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ō		0
	57-63 Days (Group 3)	57	0	,		0	0	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	ō		ō		0
URINARY TRACT INFECTION	≤63 Days (All)	179	3	(2%)	0.7746	3	2	(67%)	1	(33%)	0		0
	≤49 Days (Group 1)	63	2	(3%)		2	1	(50%)	1	(50%)	0		Ō
	50-56 Days (Group 2)	59	1	(21)		1	1	(100%)	ō		ō		o o
	57-63 Days (Group 3)	57	0			0	0	,	0		ō		0
EPRODUCTIVE DISORDERS, FEMALE	i												
ANY EVENT	≤63 Days (All)	179	19	(11%)	0.9103	23	6	(26%)	6	(26%)	11	(48%)	0
	≤49 Days (Group 1)	63	6	(10%)		. 8	4	(50%)	1	(13%)	3	(38%)	0
	50-56 Days (Group 2)	59	6	(101)		7	2	(29%)	2	(29%)	3	(43%)	0
	57-63 Days (Group 3)	57	7	(12%)		8	0		3	(38%)	5		o

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling. Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational Age	Total Number	Number of Pts	Fisher's exact			Severity	•	· · · · · · · · · · · · · · · · · · ·
Body System/Event [2]	Group [3]	of Pts	w/Event	p-value	of Events	Mild	Moderate	Severe	Unknow
EPRODUCTIVE DISORDERS, FEMALE (cont.)									
BREAST DISCHARGE	≤63 Days (All)	179	2 (1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
BREAST ENLARGEMENT	s63 Days (All)	179	1 (<1%)	0.6480	1	1 (100%)	0	0	0
1	≤49 Days (Group 1)	63	0		; O	0	0	0	0
·	50-56 Days (Group 2)	59	1 (2%)		1	1 (100%)	0 '	0.	0
i	57-63 Days (Group 3)	57	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	179	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≰49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
UTERINE ATONY	≤63 Days (All)	179	2 (1%)	0.1002	2	0	1 (50%)	1 (50%)	0
	±49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	2 (4%)		. 2	0	1 (50%)	1 (50%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

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Appendix D, Table 5a (Continued)
Adverse Events [1] By Center
[Safety Evaluable Patients]

Center: SHEEHAN (#26)

	Gestational	Total Number	Number of Pts	Fisher's	Number		Saw	erity	
Body System/Event [2]	Age Group [3]	of Pts	w/Even	exact p-value	of Events	Mild	Moderate	Severe	Unknown
EPRODUCTIVE DISORDERS, FEMALE (cont.)									·
UTERINE HAEMORRHAGE	≤63 Days (All)	179	10 (6	0.1981	11	0	2 (18%	9 (82%)	0
	≤49 Days (Group 1)	63	- 1 (2	t)	2	0	0	2 (100%)	0
	50-56 Days (Group 2)	59	5 (8	•)	5	0	2 (40%	3 (60%)	0
	57-63 Days (Group 3)	57	4 (•)	4	0	O	4 (100%)	0.
VAGINAL DISCOMFORT	≤63 Days (All)	179	1 (<	1.0000	1	0	o	1 (100%)	0
,	s49 Days (Group 1)	63	1 (2	•)	1	0	0	1 (100%)	0
, ·	50-56 Days (Group 2)	59	0		0	0	o :	0.	0
	57-63 Days (Group 3)	57	0		0	0	О .,	0	0
VAGINITIS	≤63 Days (All)	179	3 (2	0.4189	3	1 (33%)	2 (67%) 0	0
	s49 Days (Group 1)	63	1 (2	b)	1	1 (100%)	0	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	2 (4	•)	2	0	2 (100%) 0	0
VULVITIS	≤63 Days (All)	179	1 (<	1.0000	1	0	1 (100%) 0	0
	≤49 Days (Group 1)	63	1 (2	b)	1	0	1 (100%)) 0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
ODY AS A WHOLE - GENERAL DISORDERS							1		
ANY EVENT	≤63 Days (All)	179	177 (99	1.0000	645	237 (37%)	295 (46%	111 (17%)	2 (<1
	s49 Days (Group 1)	63	62 (9)	()	212	82 (39%)	99 (47%	29 (14%)	2 (<1
	50-56 Days (Group 2)	59	58 (98	•)	207	71 (34%)	96 (46%	40 (19%)	0
	57-63 Days (Group 3)	57	57 (100	6)	1226	84 (37%)	100 (44%)	42 (19%)	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age	Total Number			Fisher's exact p value	Number		Severity						
	Group [3]	of Pts				of Events			Mode		Severe		Unknown	
BODY AS A WHOLE - GENERAL DISORDERS (cont.)													
ABDOMINAL PAIN	≤63 Days (All)	179	177	(991)	1.0000	597	216	(36%)	277	(46%)	102	(17%)	2	(<1%
	≤49 Days (Group 1)	63	62	(98%)		193	75	(39%)	89	(46%)	27	(14%)	2	(1%
	50-56 Days (Group 2)	59	58	(98%)		193	64	(33%)	93	(48%)	36	(19%)	0	
	57-63 Days (Group 3)	57	57	(100%)		211	77	(36%)	95	(45%)	39	(18%)	0	
ALLERGY	s63 Days (All)	179	1	(<1%)	1.0000	1	1	(100%)	0		0		0	
1	≤49 Days (Group 1)	63	1	(2%)		1	1	(100%)	0	.	0		0	
	50-56 Days (Group 2)	59	0			0	0		0		0		0	
	57-63 Days (Group 3)	57	0			0	0		0		0		0	
ASTHENIA	≤63 Days (All)	179	3	(2%)	1.0000	3	0		1	(33%)	2	(67%)	0	
	≤49 Days (Group 1)	63	1	(2%)		1	0		0		1	(100%)	0	
	50-56 Days (Group 2)	59	1	(2%)		1	0		0		1	(100%)	0	
	57-63 Days (Group 3)	57	1	(2%)		1	0		1	(100%)	0		0	
BACK PAIN.	≤63 Days (All)	179	12	(7%)	0.3682	15	7	(47%)	7	(47%)	1	(7%)	0	
	s49 Days (Group 1)	63	4	(6%)		6	1	(17%)	5	(83%)	0		0	
	50-56 Days (Group 2)	59	6	(10%)		7	4	(57%)	2	(29%)	1	(14%)	0	
	57-63 Days (Group 3)	57	2	(4%)		2	2	(100%)	0		0		0	
FATIGUE	≤63 Days (All)	179	14	(8%)	0.5725	14	7	(50%)	5	(36%)	2	(14%)	0	
	k49 Days (Group 1)	63	5	(8%)		5	2	(40%)	2	(40%)	1	(20%)	0	
	50-56 Days (Group 2)	59	3	(5%)		3	2	(67%)	0		1	(33%)	0	
	57-63 Days (Group 3)	57	6	(11%)		. 6	3	(50%)	3	(50%)	0		0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

^[2] NOS = Not otherwise specified

^[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age Group {3}	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Mild	Moderate	y Severe	Unknowr
BODY AS A WHOLE - GENERAL DISORDERS	(cont.)								
FEVER	≤63 Days (All)	179	5 (3%	0.2837	5	3 (60%)	2 (40%)	0	0
	≤49 Days (Group 1)	63	3 (5%	1	3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	2 (4%	1	2	1 (50%)	1 (50%)	0	0
HYPOVOLAEMIA	≤63 Days (All)	179	1 (<1%	0.3184	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
1 .	50-56 Days (Group 2)	59	0		0	0	О '	O .	0
	57-63 Days (Group 3)	57	1 (2%)	1	0	0	1 (100%)	0
LEG PAIN	s63 Days (All)	179	2 (1%	0.7667	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	63	1 (2%)	1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)	1	1 (100%)	0	0	0
MALAISE	s63 Days (All)	179	1 (<1%	0.6480	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	1 (2%)	1	1 (100%)	0	0	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
OEDEMA	≤63 Days (All)	179	2 (1%	0.2076	2	0	1 (50%)	1 (50%)	0
	≰49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	2 (3%)	2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	57	0		. 0	0	0	0	0

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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FINAL

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^[4] Events in this body system occurred during the study blood sampling.

Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational Age	Total Number of Pts	Number of Pts	Fisher's exact	Number -	. .	Severity			
	Group (3)		w/Event	p value	of Events	Mild	Moderate	Severe	Unknow	
ODY AS A WHOLE - GENERAL DISORDERS	(cont.)									
PAIN	s63 Days (All)	179	2 (1%)	0.7667	2	1 (50%)	0	1 (50%)	0	
	s49 Days (Group 1)	63	1 (2%)		1	1 (100%)	0	0	0	
	50-56 Days (Group 2)	59	o '		0	0	0	0	0	
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0	
RIGORS	≰63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0	
i	. s49 Days (Group 1)	63	1 (2%)		1	0	1 (10,0%)	0	0	
	50-56 Days (Group 2)	59	0		0	0	0	oʻ	0	
	57-63 Days (Group 3)	57	0		0	0	0	0	0	
SYNCOPE	≤63 Days (All)	179	1 (<1%)	0.3184	1	0	0	1 (100%)	0	
	≤49 Days (Group 1)	63	0		Q	0	0	0	0	
	50-56 Days (Group 2)	59	0		d	0	0	0	0	
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0	
ESISTANCE MECHANISM DISORDERS										
ANY EVENT	≤63 Days (All)	179	6 (3%)	0.2504	6	2 (33%)	3 (50%)	1 (17%)	0	
	≤49 Days (Group 1)	63	3 (5%)		3	1 (33%)	1 (33%)	1 (33%)	0	
	50-56 Days (Group 2)	59	3 (5%)		3	1 (33%)	2 (67%)	0	0	
	57-63 Days (Group 3)	57	0		0	0	0	0	0	
INFECTION VIRAL	s63 Days (All)	179	5 (3%)	0.3275	5	2 (40%)	2 (40%)	1 (20%)	0	
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	0	1 (50%)	0	
	50-56 Days (Group 2)	59	3 (5%)		• 3	1 (33%)	2 (67%)	0	0	
	57-63 Days (Group 3)	57	0		0	0	0	0	0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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Appendix D, Table 5a (Continued) Adverse Events [1] By Center [Safety Evaluable Patients]

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational	Total Number of Pts	Number of Pts	Fisher's exact p-value	NumberSeverity					
	Age Group [3]		w/Event			Mild	Moderate	Severe	Unknown	
RESISTANCE WECHANISH DISORDERS (cont.)										
MONILIASIS GENITAL	≤63 Days (All)	179	1 (<1%)	1.0000	1	0	1 (100%)	0	0	
4	≤49 Days (Group 1)	63	1 (2%)		. 1	0	1 (100%)	0	0	
	50-56 Days (Group 2)	59	0		0	0	0	0	0	
	57-63 Days (Group 3)	57	0		0	0	0	0	0	
SECONDARY TERMS		1								
ANY EVENT	≤63 Days (All)	179	2 (1%)	0.5413	2	0	2 (100%)	0	0	
•	s49 Days (Group 1)	63	o ;		0	0	0 !	0.	0	
	50-56 Days (Group 2)	59	1 (21)		1	0	1 (100%)	0	0	
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0	
INFLICTED INJURY	≤63 Days (All)	179	1 : (<1%)	0.3184	1	0	1 (100%)	0	0	
	≤49 Days (Group 1)	63	0		0	0	0 -	0	0	
	50-56 Days (Group 2)	59	0		0	0	0	0	0	
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0	
POST-OPERATIVE PAIN	≤63 Days (All)	179	1 (<1%)	0.6480	1	, O	1 (100%)	0	0	
	s49 Days (Group 1)	63	0		0	0	0	0	0	
	50-56 Days (Group 2)	59	1 (2%)		1	0	1 (100%)	0	0	
	57-63 Days (Group 3)	57	0		0	0	0	0	0	

^[1] Includes all adverse events reported at any point in the study, regardless of causality.

Source Data: Appendix A.1, Tables 16 and 25

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^[4] Events in this body system occurred during the study blood sampling.