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

Center: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: 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.
[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)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: 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	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
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.
[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)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	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 (33%)	0
	≤49 Days (Group 1)	36	3 (8%)		5	2 (40%)	1 (20%)	2 (40%)	0
	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
	≤49 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
	≤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
	≤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

[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.
[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)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY 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
	≤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

[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.
[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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	52	52 (100%)		259	100 (39%)	92 (36%)	67 (26%)	0
	≤49 Days (Group 1)	19	19 (100%)		84	31 (37%)	28 (33%)	25 (30%)	0
	50-56 Days (Group 2)	11	11 (100%)		58	27 (47%)	21 (36%)	10 (17%)	0
	57-63 Days (Group 3)	22	22 (100%)		117	42 (36%)	43 (37%)	32 (27%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	11 (21%)	0.7522	26	11 (42%)	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
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	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
	≤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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	35 (67%)	1.0000	76	30 (39%)	22 (29%)	24 (32%)	0
	≤49 Days (Group 1)	19	13 (68%)		23	8 (35%)	6 (26%)	9 (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%)	10 (29%)	13 (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.
[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

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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	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
	≤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		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	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.
[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

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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA	≤63 Days (All)	52	2 (4%)	0.0415	2	1 (50%)	1 (50%)	0	0
	≤49 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	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
	≤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
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%)	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

[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.
[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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	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
	≤49 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	0
	50-56 Days (Group 2)	11	0		0	0	0	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.
[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

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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
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.
[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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	21	17 (81%)	0.2919	51	20 (39%)	19 (37%)	12 (24%)	0
	≤49 Days (Group 1)	13	9 (69%)		23	13 (57%)	7 (30%)	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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤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	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	0	1 (100%)	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	12 (57%)	0.3140	21	12 (57%)	6 (29%)	3 (14%)	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.
[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/Event	Fisher's exact p-value	Number of Events	Severity: 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
	≤49 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
	≤49 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.
[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

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/Event	Fisher's exact p-value	Number of Events	Severity: 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
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	5	1 (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.
[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 ≤ 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 (≤ 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

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 [redacted] 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.

Appendix D, Table 5a
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/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	71	71 (100%)	------	357	151 (42%)	160 (45%)	46 (13%)	0
	≤49 Days (Group 1)	28	28 (100%)		112	50 (45%)	57 (51%)	5 (4%)	0
	50-56 Days (Group 2)	26	26 (100%)		128	52 (41%)	52 (41%)	24 (19%)	0
	57-63 Days (Group 3)	17	17 (100%)		117	49 (42%)	51 (44%)	17 (15%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 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
SWEATING INCREASED	≤63 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									
ANY EVENT	≤63 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] 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

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	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (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
	≤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
	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
PSYCHIATRIC 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%)		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.
[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: POINDEXTER (#21)

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	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)									
INSOMNIA	≤63 Days (All)	71	3 (4%)	0.4523	4	1 (25%)	2 (50%)	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 (6%)		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%)	2 (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 (3%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 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	≤63 Days (All)	71	8 (11%)	0.6427	10	6 (60%)	3 (30%)	1 (10%)	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.
[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: POINDEXTER (#21)

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	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	71	3 (4%)	0.6115	3	2 (67%)	1 (33%)	0	0
	≤49 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 (15%)	0
	≤49 Days (Group 1)	28	14 (50%)		17	7 (41%)	9 (53%)	1 (6%)	0
	50-56 Days (Group 2)	26	16 (62%)		24	9 (38%)	10 (42%)	5 (21%)	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
	≤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	≤63 Days (All)	71	1 (1%)	0.6056	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
FLUSHING	≤63 Days (All)	71	1 (1%)	0.6056	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	0	1 (100%)	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.
[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: POINDEXTER (#21)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	71	5 (7%)	0.2784	8	6 (75%)	2 (25%)	0	0
	≤49 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	≤63 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	0	0	0
PULMONARY CONGESTION	≤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
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
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤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

[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

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	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PLATELET,BLEEDING & CLOTTING DISORDERS (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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	71	4 (6%)	0.8280	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	26	2 (8%)		2	1 (50%)	0	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	≤63 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	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.
[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: POINDEXTER (#21)

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINITIS	≤63 Days (All)	71	1 (1%)	0.2394	1	1 (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%)		1	1 (100%)	0	0	0
BODY AS A WHOLE - GENERAL 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
	≤49 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
	≤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	1 (100%)	0	0	0
ASTHENIA	≤63 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.
[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: POINDEXTER (#21)

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	Severity: Mild	Moderate	Severe	Unknown
BODY 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 (8%)		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%)	0	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	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	0	1 (100%)	0	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
	57-63 Days (Group 3)	17	1 (6%)		1	0	0	1 (100%)	0
PAIN	≤63 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	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.
[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: POINDEXTER (#21)

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
RIGORS	≤63 Days (All)	71	2 (3%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	28	1 (4%)		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	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
	57-63 Days (Group 3)	17	1 (6%)		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%)	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
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	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

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	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE 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.
[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: 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 of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	151	150 (>99%)	0.2517	841	291 (35%)	361 (43%)	189 (22%)	0
	≤49 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
SKIN AND APPENDAGES DISORDERS									
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 (50%)	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
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	2 (1%)	0.2861	2	0	2 (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	1 (3%)		1	0	1 (100%)	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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-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		0	0	0	0	0
MYALGIA	≤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
CENTR & 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
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
	≤49 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.
[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: 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 of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (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
	≤49 Days (Group 1)	70	1 (1%)		1	0	0	1 (100%)	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
VISION DISORDERS									
ANY EVENT	≤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
VISION ABNORMAL	≤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
HEARING AND VESTIBULAR DISORDERS									
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.
[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: 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 of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: 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	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
PSYCHIATRIC 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%)	0
	57-63 Days (Group 3)	38	1 (3%)		1	0	0	1 (100%)	0
ANOREXIA	≤63 Days (All)	151	2 (1%)	0.2861	2	0	1 (50%)	1 (50%)	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	0	0	1 (100%)	0
DEPRESSION	≤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
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	0
	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.
[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: 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 of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
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
GASTRO-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 (39%)	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
	≤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		0	0	0	0	0
DIARRHEA	≤63 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	≤63 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.
[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: 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 of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
NAUSEA	≤63 Days (All)	151	104 (69%)	0.3257	166	71 (43%)	67 (40%)	28 (17%)	0
	≤49 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	0	2 (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	1 (3%)		1	0	1 (100%)	0	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 (52%)	5 (22%)	0
METABOLIC 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	≤63 Days (All)	151	1 (<1%)	0.2517	1	1 (100%)	0	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	1 (100%)	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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS (cont.)									
THIRST	≤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		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	3 (2%)	0.7966	6	4 (67%)	1 (17%)	1 (17%)	0
	≤49 Days (Group 1)	70	2 (3%)		5	4 (80%)	0	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
BRONCHITIS	≤63 Days (All)	151	1 (<1%)	1.0000	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	70	1 (1%)		3	2 (67%)	0	1 (33%)	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
PHARYNGITIS	≤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
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%)		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.
[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: 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 of Events	Severity: 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 (1%)		1	0	0	1 (100%)	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
EPISTAXIS	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	70	1 (1%)		1	0	0	1 (100%)	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
URINARY 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%)	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
DYSURIA	≤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
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.
[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: 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 of Events	Severity: Mild	Moderate	Severe	Unknown
URINARY 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
REPRODUCTIVE 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%)	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
LEUKORRHOEA	≤63 Days (All)	151	2 (1%)	0.4993	2	1 (50%)	1 (50%)	0	0
	≤49 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
	≤49 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.
[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: 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 of Events	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINITIS	≤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		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	151	150 (>99%)	0.2517	382	114 (30%)	156 (41%)	112 (29%)	0
	≤49 Days (Group 1)	70	70 (100%)		164	53 (32%)	73 (45%)	38 (23%)	0
	50-56 Days (Group 2)	43	43 (100%)		118	33 (28%)	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
	≤49 Days (Group 1)	70	70 (100%)		146	42 (29%)	66 (45%)	38 (26%)	0
	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 (24%)	32 (36%)	36 (40%)	0
ALLERGY	≤63 Days (All)	151	2 (1%)	0.0621	2	2 (100%)	0	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	2 (5%)		2	2 (100%)	0	0	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%)	2 (29%)	0	0
	50-56 Days (Group 2)	43	6 (14%)		8	5 (63%)	3 (38%)	0	0
	57-63 Days (Group 3)	38	3 (8%)		3	1 (33%)	2 (67%)	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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (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
	≤49 Days (Group 1)	70	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	43	2 (5%)		2	2 (100%)	0	0	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%)	0	0
	≤49 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	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	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
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%)	0	0
	50-56 Days (Group 2)	43	2 (5%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	38	1 (3%)		1	1 (100%)	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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
BODY 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%)	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
RESISTANCE 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%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	43	2 (5%)		3	1 (33%)	1 (33%)	1 (33%)	0
	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	0	0	0
	50-56 Days (Group 2)	43	1 (2%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
INFECTION	≤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
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%)	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	0	1 (100%)	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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
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%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	89	3 (3%)	0.7904	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 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	0
SKIN DISORDER	≤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
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%)	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
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	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.
[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-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%)	0.2247	1	1 (100%)	0	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	1 (100%)	0	0	0
MYALGIA	≤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
SKELETAL PAIN	≤63 Days (All)	89	1 (1%)	0.2247	2	2 (100%)	0	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%)		2	2 (100%)	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	51 (57%)	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.
[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (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
	≤49 Days (Group 1)	35	12 (34%)		19	7 (37%)	11 (58%)	1 (5%)	0
	50-56 Days (Group 2)	34	15 (44%)		28	8 (29%)	14 (50%)	6 (21%)	0
	57-63 Days (Group 3)	20	11 (55%)		25	6 (24%)	15 (60%)	4 (16%)	0
VISION 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
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤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

[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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS (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	≤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
	≤49 Days (Group 1)	35	3 (9%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
DEPRESSION	≤63 Days (All)	89	4 (4%)	0.6735	5	1 (20%)	2 (40%)	2 (40%)	0
	≤49 Days (Group 1)	35	2 (6%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	34	2 (6%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
INSOMNIA	≤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

[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

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	Severity: Mild	Moderate	Severe	Unknown
GASTRO-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 (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	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
	≤49 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.
[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: [redacted]

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	89	3 (3%)	0.1772	3	1 (33%)	0	2 (67%)	0
	≤49 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 (69%)	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 (33%)	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 (60%)	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									
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	1 (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.
[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: [redacted]

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
CARDIOVASCULAR DISORDERS, GENERAL (cont.)									
HYPOTENSION	≤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	1 (100%)	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	1 (100%)	0	0
HEART RATE AND RHYTHM DISORDERS									
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		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
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.
[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY 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	≤63 Days (All)	89	3 (3%)	0.4394	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	35	2 (6%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	34	0		0	0	0	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	89	2 (2%)	0.6961	2	1 (50%)	1 (50%)	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	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.
[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	2 (2%)	1.0000	4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	35	1 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	34	1 (3%)		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%)	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
MICTURITION URGENCY	≤63 Days (All)	89	1 (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 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
URINARY RETENTION	≤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
URINARY TRACT INFECTION	≤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

[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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE, DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	89	14 (16%)	0.1194	17	6 (35%)	0	11 (65%)	0
	≤49 Days (Group 1)	35	3 (9%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	34	9 (26%)		12	3 (25%)	0	9 (75%)	0
	57-63 Days (Group 3)	20	2 (10%)		2	1 (50%)	0	1 (50%)	0
BREAST DISCHARGE	≤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
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	0		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.
[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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FINAL

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE 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
NEOPLASM									
ANY EVENT	≤63 Days (All)	89	2 (2%)	0.6961	2	1 (50%)	0	0	1 (50%)
	≤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	1 (5%)		1	0	0	0	1 (100%)
CERVICAL SMEAR TEST POSITIVE	≤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	0
	57-63 Days (Group 3)	20	1 (5%)		1	0	0	0	1 (100%)
OVARIAN CYST	≤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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	89	88 (99%)	0.6067	392	161 (41%)	142 (36%)	88 (22%)	1 (<1%)
	≤49 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%)	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

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

Center: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	89	88 (99%)	0.6067	333	138 (41%)	118 (35%)	76 (23%)	1 (<1%)
	≤49 Days (Group 1)	35	35 (100%)		130	57 (44%)	41 (32%)	31 (24%)	1 (<1%)
	50-56 Days (Group 2)	34	33 (97%)		128	48 (38%)	54 (42%)	26 (20%)	0
	57-63 Days (Group 3)	20	20 (100%)		75	33 (44%)	23 (31%)	19 (25%)	0
ALLERGY	≤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
ASTHENIA	≤63 Days (All)	89	3 (3%)	0.6123	5	1 (20%)	2 (40%)	2 (40%)	0
	≤49 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 (67%)	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
BACK PAIN	≤63 Days (All)	89	10 (11%)	0.5711	12	4 (33%)	4 (33%)	4 (33%)	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 (1%)	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.
[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: [redacted]

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - 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
	≤49 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%)	0	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		0	0	0	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
PAIN	≤63 Days (All)	89	1 (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 (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.
[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: [redacted]

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	89	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤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
RESISTANCE MECHANISM DISORDERS									
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 (50%)	1 (50%)	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
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.
[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)

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	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	175	171 (98%)	0.6779	983	433 (44%)	401 (41%)	147 (15%)	2 (<1%)
	≤49 Days (Group 1)	71	69 (97%)		359	147 (41%)	152 (42%)	60 (17%)	0
	50-56 Days (Group 2)	72	71 (99%)		398	199 (50%)	152 (38%)	46 (12%)	1 (<1%)
	57-63 Days (Group 3)	32	31 (97%)		226	87 (38%)	97 (43%)	41 (18%)	1 (<1%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	175	6 (3%)	0.7426	7	4 (57%)	3 (43%)	0	0
	≤49 Days (Group 1)	71	3 (4%)		4	3 (75%)	1 (25%)	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	≤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
PRURITUS	≤63 Days (All)	175	1 (<1%)	0.5886	2	2 (100%)	0	0	0
	≤49 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	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

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

Center: WESTHOFF (#24)

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	Severity			
						Mild	Moderate	Severe	Unknown
SKIN AND 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
	≤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
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	3 (2%)	0.7933	3	1 (33%)	2 (67%)	0	0
	≤49 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 (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
SKELETAL PAIN	≤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

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
CENTR & PERIPH NERVOUS 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	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
DIZZINESS	≤63 Days (All)	175	16 (9%)	0.7410	25	10 (40%)	9 (36%)	6 (24%)	0
	≤49 Days (Group 1)	71	6 (8%)		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	≤63 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
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	175	18 (10%)	0.2758	26	8 (31%)	13 (50%)	5 (19%)	0
	≤49 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 (57%)	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.
[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)

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	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)									
ANOREXIA	≤63 Days (All)	175	2 (1%)	0.6642	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	2 (3%)		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
	≤49 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	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
	≤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
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%)	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.
[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)

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	Severity: Mild	Moderate	Severe	Unknown
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 (4%)		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)	≤63 Days (All)	175	4 (2%)	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 (2%)	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.
[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)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
DIARRHEA	≤63 Days (All)	175	32 (18%)	0.1747	33	19 (58%)	13 (39%)	1 (3%)	0
	≤49 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	≤63 Days (All)	175	12 (7%)	0.1428	13	6 (46%)	7 (54%)	0	0
	≤49 Days (Group 1)	71	2 (3%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	72	6 (8%)		6	4 (67%)	2 (33%)	0	0
	57-63 Days (Group 3)	32	4 (13%)		4	2 (50%)	2 (50%)	0	0
FLATULENCE	≤63 Days (All)	175	3 (2%)	0.5895	5	4 (80%)	1 (20%)	0	0
	≤49 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	≤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
NAUSEA	≤63 Days (All)	175	88 (50%)	0.4871	133	60 (45%)	53 (40%)	20 (15%)	0
	≤49 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.
[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)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-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
	≤49 Days (Group 1)	71	15 (21%)		18	4 (22%)	8 (44%)	6 (33%)	0
	50-56 Days (Group 2)	72	33 (46%)		44	24 (55%)	18 (41%)	2 (5%)	0
	57-63 Days (Group 3)	32	11 (34%)		11	6 (55%)	4 (36%)	1 (9%)	0
METABOLIC 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	1 (100%)	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	1 (100%)	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	175	2 (1%)	0.6642	2	1 (50%)	1 (50%)	0	0
	≤49 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.
[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)

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	Severity: Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS (cont.)									
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
	≤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
VASCULAR (EXTRACARDIAC) DISORDERS									
ANY EVENT	≤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
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
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	10 (6%)	0.0017	11	4 (36%)	6 (55%)	1 (9%)	0
	≤49 Days (Group 1)	71	5 (7%)		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%)		6	2 (33%)	4 (67%)	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

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

Center: WESTHOFF (#24)

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	Severity: 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 (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
	≤49 Days (Group 1)	71	2 (3%)		2	0	1 (50%)	1 (50%)	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
RHINITIS	≤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
SINUSITIS	≤63 Days (All)	175	5 (3%)	0.0021	6	1 (17%)	5 (83%)	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	4 (13%)		5	1 (20%)	4 (80%)	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤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

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA	≤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
URINARY SYSTEM DISORDERS									
ANY EVENT	≤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
DYSURIA	≤63 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
URINARY TRACT INFECTION	≤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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤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

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
BREAST PAIN FEMALE	≤63 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	≤63 Days (All)	175	1 (<1%)	0.1829	1	0	0	1 (100%)	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	0	1 (100%)	0
LEUKORRHOEA	≤63 Days (All)	175	5 (3%)	0.4077	5	5 (100%)	0	0	0
	≤49 Days (Group 1)	71	1 (1%)		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
	≤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

[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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
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 (3%)		1	1 (100%)	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	175	167 (95%)	0.5126	513	229 (45%)	209 (41%)	73 (14%)	2 (<1%)
	≤49 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.
[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)

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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
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
	≤49 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 (6%)		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.
[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)

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
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 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	72	4 (6%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	32	3 (9%)		5	1 (20%)	3 (60%)	1 (20%)	0
LEG PAIN	≤63 Days (All)	175	2 (1%)	0.6642	2	2 (100%)	0	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	0		0	0	0	0	0
MALAISE	≤63 Days (All)	175	5 (3%)	0.0641	5	1 (20%)	4 (80%)	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	3 (9%)		3	0	3 (100%)	0	0
PALLOR	≤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
RIGORS	≤63 Days (All)	175	2 (1%)	0.3331	2	0	1 (50%)	1 (50%)	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	0	1 (100%)	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

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

Center: WESTHOFF (#24)

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	175	3 (2%)	0.0864	3	1 (33%)	0	2 (67%)	0
	≤49 Days (Group 1)	71	0		0	0	0	0	0
	50-56 Days (Group 2)	72	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	32	2 (6%)		2	1 (50%)	0	1 (50%)	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	175	3 (2%)	0.4032	3	1 (33%)	2 (67%)	0	0
	≤49 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	1 (3%)		1	0	1 (100%)	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤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
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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	178	175 (98%)	0.6319	1506	578 (38%)	550 (37%)	377 (25%)	1 (<1%)
	≤49 Days (Group 1)	72	70 (97%)		534	215 (40%)	186 (35%)	133 (25%)	0
	50-56 Days (Group 2)	54	54 (100%)		494	203 (41%)	179 (36%)	111 (22%)	1 (<1%)
	57-63 Days (Group 3)	52	51 (98%)		478	160 (33%)	185 (39%)	133 (28%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	178	6 (3%)	0.5845	6	1 (17%)	2 (33%)	3 (50%)	0
	≤49 Days (Group 1)	72	2 (3%)		2	0	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	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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	178	3 (2%)	0.4881	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 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
SKELETAL PAIN	≤63 Days (All)	178	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 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		0	0	0	0	0
CENTR & 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	6 (12%)		10	4 (40%)	2 (20%)	4 (40%)	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

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 of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (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
	≤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	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

[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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS 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 (2%)		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		0	0	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
SPECIAL 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									
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%)		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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS (cont.)									
ANOREXIA	≤63 Days (All)	178	4 (2%)	1.0000	4	2 (50%)	2 (50%)	0	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	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
	≤49 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	5 (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
GASTRO-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%)		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.
[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: 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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤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
CONSTIPATION	≤63 Days (All)	178	2 (1%)	0.5155	2	1 (50%)	0	1 (50%)	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	1 (2%)		1	0	0	1 (100%)	0
DIARRHEA	≤63 Days (All)	178	40 (22%)	0.6344	46	19 (41%)	22 (48%)	5 (11%)	0
	≤49 Days (Group 1)	72	14 (19%)		15	7 (47%)	5 (33%)	3 (20%)	0
	50-56 Days (Group 2)	54	12 (22%)		17	7 (41%)	9 (53%)	1 (6%)	0
	57-63 Days (Group 3)	52	14 (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
	≤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	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
	≤49 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.
[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: 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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
IRRITABLE BOWEL SYNDROME	≤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
MOUTH DRY	≤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
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
	≤49 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 NUTRITIONAL DISORDERS									
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	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

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 of Events	Severity: 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
	≤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
	≤49 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.
[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: 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	Severity: 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	≤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
PHARYNGITIS	≤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
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
	≤49 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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
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		0	0	0	0	0
	57-63 Days (Group 3)	52	0		0	0	0	0	0
PLATELET,BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤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
EPISTAXIS	≤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
URINARY SYSTEM DISORDERS									
ANY EVENT	≤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

[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

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 of Events	Severity: 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	≤63 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 (13%)	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
	≤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	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	0	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	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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
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	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
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 (25%)	3 (75%)	0
	50-56 Days (Group 2)	54	4 (7%)		5	0	0	5 (100%)	0
	57-63 Days (Group 3)	52	6 (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
NEOPLASM									
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.
[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: 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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
NEOPLASM (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
BODY 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 (27%)	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	3 (100%)	0	0
	50-56 Days (Group 2)	54	3 (6%)		4	2 (50%)	1 (25%)	1 (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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	178	11 (6%)	0.2234	17	7 (41%)	6 (35%)	4 (24%)	0
	≤49 Days (Group 1)	72	5 (7%)		8	5 (63%)	1 (13%)	2 (25%)	0
	50-56 Days (Group 2)	54	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	52	5 (10%)		8	2 (25%)	4 (50%)	2 (25%)	0
CHEST PAIN	≤63 Days (All)	178	2 (1%)	0.1750	2	0	2 (100%)	0	0
	≤49 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		0	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%)		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	0
	50-56 Days (Group 2)	54	3 (6%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	52	4 (8%)		4	1 (25%)	2 (50%)	1 (25%)	0
HOT FLUSHES	≤63 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	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

[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

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 of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - 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
	≤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 (2%)		1	0	0	1 (100%)	0
OEDEMA	≤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
PAIN	≤63 Days (All)	178	3 (2%)	0.6319	3	3 (100%)	0	0	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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
BODY 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
	≤49 Days (Group 1)	72	2 (3%)		2	0	1 (50%)	1 (50%)	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
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 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 (11%)		7	5 (71%)	2 (29%)	0	0
	57-63 Days (Group 3)	52	6 (12%)		7	2 (29%)	2 (29%)	3 (43%)	0
INFECTION VIRAL	≤63 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 (11%)		7	5 (71%)	2 (29%)	0	0
	57-63 Days (Group 3)	52	6 (12%)		7	2 (29%)	2 (29%)	3 (43%)	0
SECONDARY TERMS									
ANY EVENT	≤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	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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
SECONDARY TERMS (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	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.
[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: 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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	179	179 (100%)	------	1294	518 (40%)	579 (45%)	193 (15%)	4 (<1%)
	≤49 Days (Group 1)	63	63 (100%)		422	175 (41%)	193 (46%)	52 (12%)	2 (<1%)
	50-56 Days (Group 2)	59	59 (100%)		433	164 (38%)	197 (45%)	71 (16%)	1 (<1%)
	57-63 Days (Group 3)	57	57 (100%)		439	179 (41%)	189 (43%)	70 (16%)	1 (<1%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	179	5 (3%)	0.0822	5	3 (60%)	1 (20%)	1 (20%)	0
	≤49 Days (Group 1)	63	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	59	4 (7%)		4	3 (75%)	0	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
	≤49 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.
[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: 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	Severity: 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%)	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
MYALGIA	≤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
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 NERVOUS SYSTEM DISORDERS									
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] 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

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	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (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 (29%)	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%)	0	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
	≤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	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	≤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

[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

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	Severity: Mild	Moderate	Severe	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	≤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
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	0	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.
[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: 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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
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 (43%)	12 (9%)	0
	50-56 Days (Group 2)	59	54 (92%)		163	69 (42%)	70 (43%)	23 (14%)	1 (<1%)
	57-63 Days (Group 3)	57	52 (91%)		148	76 (51%)	51 (34%)	21 (14%)	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%)	0	0
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
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	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	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%)	8 (67%)	0	0
	50-56 Days (Group 2)	59	7 (12%)		8	4 (50%)	4 (50%)	0	0
	57-63 Days (Group 3)	57	9 (16%)		10	6 (60%)	4 (40%)	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

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	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
DYSPEPSIA	≤63 Days (All)	179	6 (3%)	0.1224	7	3 (43%)	3 (43%)	1 (14%)	0
	≤49 Days (Group 1)	63	2 (3%)		3	2 (67%)	1 (33%)	0	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 (<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		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	179	149 (83%)	0.3284	319	166 (52%)	111 (35%)	41 (13%)	1 (<1%)
	≤49 Days (Group 1)	63	49 (78%)		100	56 (56%)	34 (34%)	10 (10%)	0
	50-56 Days (Group 2)	59	52 (88%)		118	54 (46%)	47 (40%)	16 (14%)	1 (<1%)
	57-63 Days (Group 3)	57	48 (84%)		101	56 (55%)	30 (30%)	15 (15%)	0
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%)		19	3 (16%)	14 (74%)	2 (11%)	0
	50-56 Days (Group 2)	59	24 (41%)		33	10 (30%)	17 (52%)	6 (18%)	0
	57-63 Days (Group 3)	57	27 (47%)		34	13 (38%)	16 (47%)	5 (15%)	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

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	Severity: Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL 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
	≤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
CARDIOVASCULAR 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
HEART 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

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	Severity: 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	≤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
VEIN 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
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS (cont.)									
COUGHING	≤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
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
DYSPNOEA	≤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
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		0	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 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	59	2 (3%)		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 (15%)	0.0320	26	17 (65%)	7 (27%)	2 (8%)	0
	≤49 Days (Group 1)	63	4 (6%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	59	9 (15%)		9	6 (67%)	2 (22%)	1 (11%)	0
	57-63 Days (Group 3)	57	13 (23%)		13	8 (62%)	4 (31%)	1 (8%)	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

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	Severity: Mild	Moderate	Severe	Unknown
RED 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	0
	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	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
URINARY 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%)	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
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	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
REPRODUCTIVE DISORDERS, FEMALE									
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 (10%)		7	2 (29%)	2 (29%)	3 (43%)	0
	57-63 Days (Group 3)	57	7 (12%)		8	0	3 (38%)	5 (63%)	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

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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE 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	≤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
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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE 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%)		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 (7%)		4	0	0	4 (100%)	0
VAGINAL DISCOMFORT	≤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
VAGINITIS	≤63 Days (All)	179	3 (2%)	0.4189	3	1 (33%)	2 (67%)	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	2 (4%)		2	0	2 (100%)	0	0
VULVITIS	≤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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	179	177 (99%)	1.0000	645	237 (37%)	295 (46%)	111 (17%)	2 (<1%)
	≤49 Days (Group 1)	63	62 (98%)		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%)		226	84 (37%)	100 (44%)	42 (19%)	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

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	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	179	177 (99%)	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	≤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
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
	≤49 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
	≤49 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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
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%)		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%)		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
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
LEG PAIN	≤63 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	≤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
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.
[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: 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	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
PAIN	≤63 Days (All)	179	2 (1%)	0.7667	2	1 (50%)	0	1 (50%)	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	1 (2%)		1	0	0	1 (100%)	0
RIGORS	≤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
SYNCOPE	≤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
	50-56 Days (Group 2)	59	0		0	0	0	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	0	1 (100%)	0
RESISTANCE 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	≤63 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.
[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: 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	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS (cont.)									
MONILIASIS GENITAL	≤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
SECONDARY TERMS									
ANY EVENT	≤63 Days (All)	179	2 (1%)	0.5413	2	0	2 (100%)	0	0
	≤49 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	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	0	1 (100%)	0	0
	≤49 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.
[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