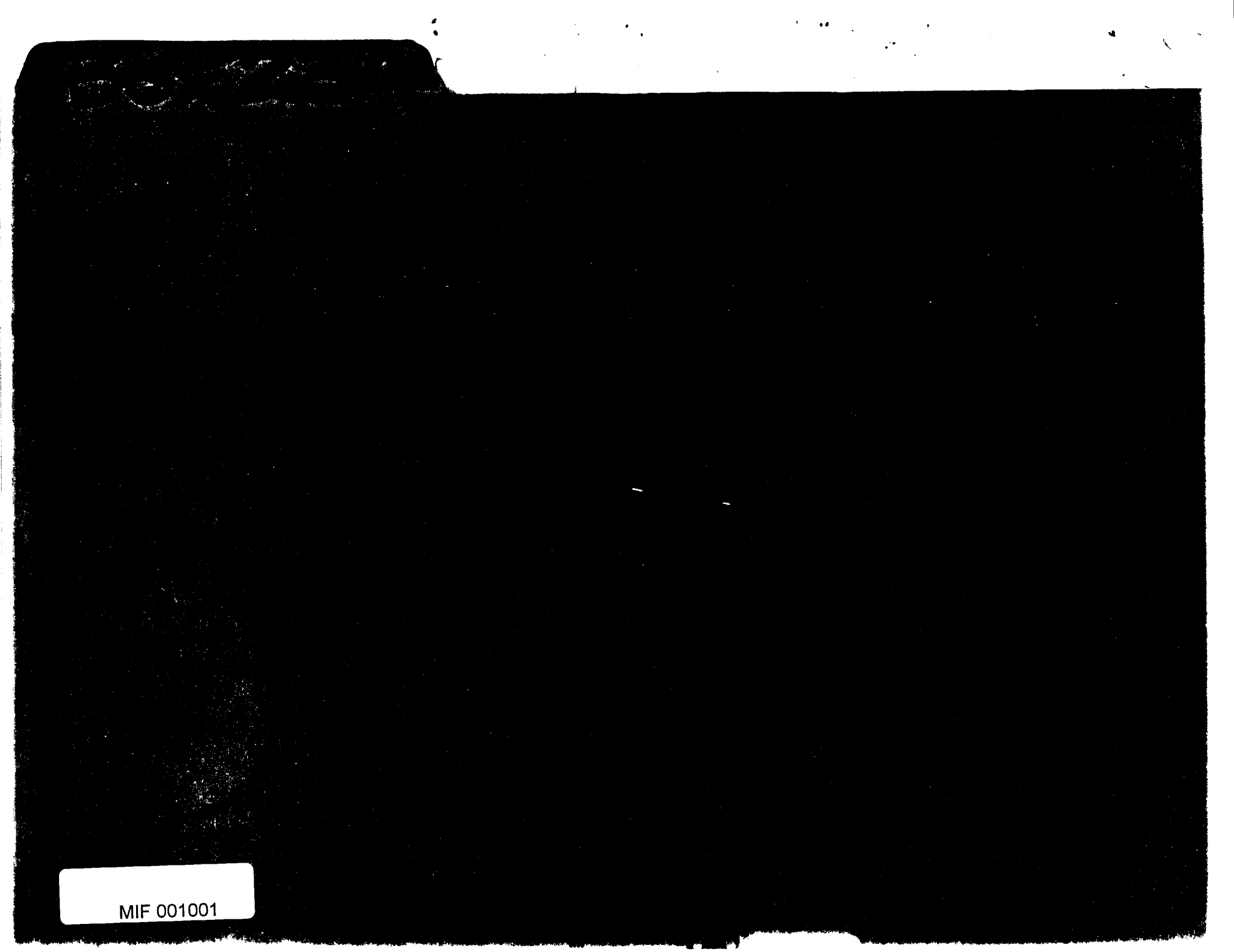
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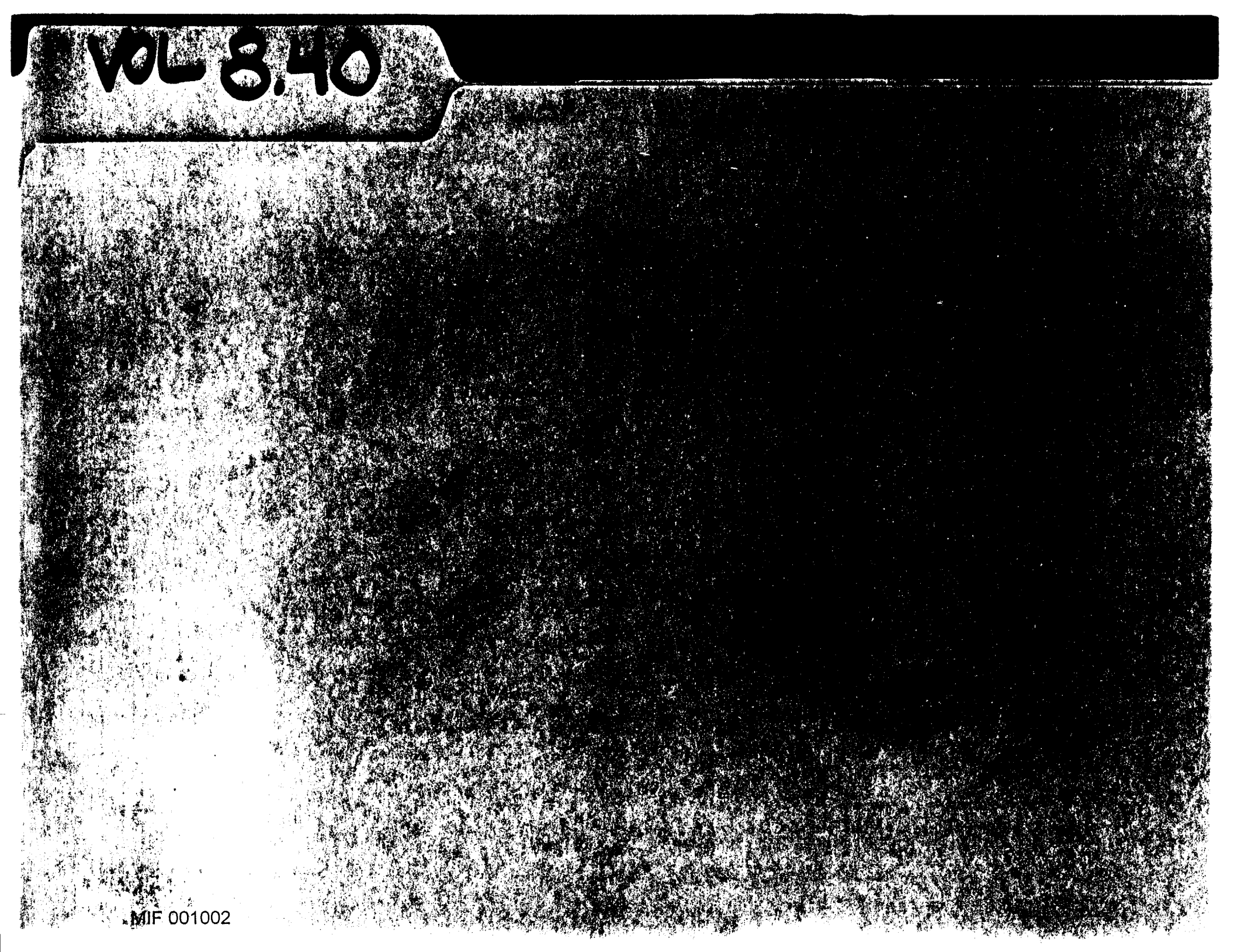
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Appendix D, Table 5a
Adverse Events [1] By Center
[Safety Evaluable Patients]

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	Moderate	Severe	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

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

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	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.)									
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	Moderate	Severe	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	Severity: Moderate	Severity: Severe	Severity: 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	Severity: Moderate	Severity: Severe	Severity: 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	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS (cont.)									
TINNITUS	≤63 Days (All)	151	1 (<1%)	0.2517	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	70	0		0	0	0	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	Moderate	Severe	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 [4]	≤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 [4]	≤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 [4]	≤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

MIF 001025

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
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

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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: [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
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	Moderate	Severe	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	Moderate	Severe	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[4]	≤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

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
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:

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

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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 [4]	≤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	Moderate	Severe	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

MIF 001040

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
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[4]	≤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

MIF 001042

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[4]	≤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	Moderate	Severe	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	Moderate	Severe	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	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA [4]	≤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	Moderate	Severe	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	Moderate	Severe	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[4]	≤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

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

Center: NICHOLS (#25)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number 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	Moderate	Severe	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

MIF 001061

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

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MIF 001062

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 [4]	≤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

MIF 001064

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

MIF 001065

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 [4]	≤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

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

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational 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)	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	Severity: Moderate	Severity: Severe	Severity: 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	Moderate	Severe	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	449	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

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

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational 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

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

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational 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 [4]	≤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	Moderate	Severe	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

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

Center: SHEEHAN (#26)

Body System/Event [2]	Gestational 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

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

Center: DEAN (#27)

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)	191	190 (>99%)	0.5340	1456	498 (34%)	578 (40%)	343 (24%)	37 (3%)
	≤49 Days (Group 1)	29	29 (100%)		203	65 (32%)	99 (49%)	39 (19%)	0
	50 56 Days (Group 2)	73	72 (99%)		541	201 (37%)	215 (40%)	110 (20%)	15 (3%)
	57-63 Days (Group 3)	89	89 (100%)		712	232 (33%)	264 (37%)	194 (27%)	22 (3%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	191	4 (2%)	0.8085	4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50 56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	2 (2%)		2	1 (50%)	0	1 (50%)	0
PRURITUS	≤63 Days (All)	191	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
RASH	≤63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		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: DEAN (#27)

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)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	2 (1%)	0.4261	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	191	1 (<1%)	0.5340	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SKELETAL PAIN	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	65 (34%)	0.9565	119	29 (24%)	69 (58%)	18 (15%)	3 (3%)
	≤49 Days (Group 1)	29	9 (31%)		17	3 (18%)	13 (76%)	1 (6%)	0
	50-56 Days (Group 2)	73	25 (34%)		41	12 (29%)	23 (56%)	4 (10%)	2 (5%)
	57-63 Days (Group 3)	89	31 (35%)		61	14 (23%)	33 (54%)	13 (21%)	1 (2%)

[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: DEAN (#27)

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)	191	16 (8%)	0.2497	20	3 (15%)	11 (55%)	6 (30%)	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	4 (5%)		5	1 (20%)	3 (60%)	1 (20%)	0
	57-63 Days (Group 3)	89	11 (12%)		14	2 (14%)	7 (50%)	5 (36%)	0
HEADACHE	≤63 Days (All)	191	58 (30%)	0.9766	97	25 (26%)	58 (60%)	11 (11%)	3 (3%)
	≤49 Days (Group 1)	29	9 (31%)		16	3 (19%)	12 (75%)	1 (6%)	0
	50-56 Days (Group 2)	73	23 (32%)		35	10 (29%)	20 (57%)	3 (9%)	2 (6%)
	57-63 Days (Group 3)	89	26 (29%)		46	12 (26%)	26 (57%)	7 (15%)	1 (2%)
MENINGITIS	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
MUSCLE CONTRACTIONS INVOLUNTARY	≤63 Days (All)	191	1 (<1%)	0.5340	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
VISION DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	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: DEAN (#27)

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
VISION DISORDERS (cont.)									
MYDRIASIS	≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SPECIAL SENSES OTHER, DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
TASTE PERVERSION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	191	4 (2%)	0.8085	6	0	3 (50%)	3 (50%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		3	0	1 (33%)	2 (67%)	0
	57-63 Days (Group 3)	89	3 (3%)		3	0	2 (67%)	1 (33%)	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

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

Center: DEAN (#27)

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)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
DEPRESSION	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
INSOMNIA	≤63 Days (All)	191	3 (2%)	1.0000	4	0	2 (50%)	2 (50%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	141 (74%)	0.1370	454	159 (35%)	180 (40%)	113 (25%)	2 (<1%)
	≤49 Days (Group 1)	29	17 (59%)		55	20 (36%)	23 (42%)	12 (22%)	0
	50-56 Days (Group 2)	73	55 (75%)		159	60 (38%)	71 (45%)	28 (18%)	0
	57-63 Days (Group 3)	89	69 (78%)		240	79 (33%)	86 (36%)	73 (30%)	2 (<1%)
DIARRHEA	≤63 Days (All)	191	56 (29%)	0.3786	72	37 (51%)	26 (36%)	9 (13%)	0
	≤49 Days (Group 1)	29	6 (21%)		7	5 (71%)	1 (14%)	1 (14%)	0
	50-56 Days (Group 2)	73	20 (27%)		27	16 (59%)	8 (30%)	3 (11%)	0
	57-63 Days (Group 3)	89	30 (34%)		38	16 (42%)	17 (45%)	5 (13%)	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: DEAN (#27)

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)	191	3 (2%)	0.7499	3	0	0	2 (67%)	1 (33%)
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	0	2 (100%)	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	0	1 (100%)
FLATULENCE	≤63 Days (All)	191	3 (2%)	0.3805	4	0	2 (50%)	1 (25%)	1 (25%)
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50 56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	3 (3%)		4	0	2 (50%)	1 (25%)	1 (25%)
NAUSEA	≤63 Days (All)	191	122 (64%)	0.1784	259	101 (39%)	99 (38%)	59 (23%)	0
	≤49 Days (Group 1)	29	14 (48%)		37	13 (35%)	18 (49%)	6 (16%)	0
	50-56 Days (Group 2)	73	48 (66%)		90	38 (42%)	40 (44%)	12 (13%)	0
	57-63 Days (Group 3)	89	60 (67%)		132	50 (38%)	41 (31%)	41 (31%)	0
TOOTH ACHE	≤63 Days (All)	191	1 (<1%)	0.1518	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
VOMITING	≤63 Days (All)	191	66 (35%)	0.3144	115	21 (18%)	52 (45%)	42 (37%)	0
	≤49 Days (Group 1)	29	7 (24%)		10	2 (20%)	3 (30%)	5 (50%)	0
	50-56 Days (Group 2)	73	24 (33%)		40	6 (15%)	23 (58%)	11 (28%)	0
	57-63 Days (Group 3)	89	35 (39%)		65	13 (20%)	26 (40%)	26 (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

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

Center: DEAN (#27)

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									
ANY EVENT	≤63 Days (All)	191	7 (4%)	0.8756	9	3 (33%)	3 (33%)	1 (11%)	2 (22%)
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		4	0	1 (25%)	1 (25%)	2 (50%)
	57-63 Days (Group 3)	89	4 (4%)		4	2 (50%)	2 (50%)	0	0
COUGHING	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	0	1 (100%)
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	0	0	1 (100%)
	57-63 Days (Group 3)	89	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
HYPERVENTILATION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
PHARYNGITIS	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		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: DEAN (#27)

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.)									
RHINITIS*	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	0	1 (100%)
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	0	0	1 (100%)
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	191	3 (2%)	1.0000	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		2	2 (100%)	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
ANAEMIA	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		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: DEAN (#27)

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.)									
URINARY TRACT INFECTION	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	191	16 (8%)	0.0115	22	2 (9%)	10 (45%)	10 (45%)	0
	≤49 Days (Group 1)	29	3 (10%)		5	1 (20%)	1 (20%)	3 (60%)	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	89	12 (13%)		15	1 (7%)	7 (47%)	7 (47%)	0
LEUKORRHOEA	≤63 Days (All)	191	3 (2%)	0.5453	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	191	11 (6%)	0.0088	15	0	7 (47%)	8 (53%)	0
	≤49 Days (Group 1)	29	2 (7%)		4	0	1 (25%)	3 (75%)	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	9 (10%)		11	0	6 (55%)	5 (45%)	0
VAGINAL DISCOMFORT	≤63 Days (All)	191	1 (<1%)	1.0000	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		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: DEAN (#27)

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)	191	2 (1%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	1 (100%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	191	190 (>99%)	0.5340	830	300 (36%)	304 (37%)	196 (24%)	30 (4%)
	≤49 Days (Group 1)	29	29 (100%)		121	38 (31%)	60 (50%)	23 (19%)	0
	50-56 Days (Group 2)	73	72 (99%)		325	127 (39%)	113 (35%)	74 (23%)	11 (3%)
	57-63 Days (Group 3)	89	89 (100%)		384	135 (35%)	131 (34%)	99 (26%)	19 (5%)
ABDOMINAL PAIN	≤63 Days (All)	191	190 (>99%)	0.5340	772	281 (36%)	280 (36%)	186 (24%)	25 (3%)
	≤49 Days (Group 1)	29	29 (100%)		112	34 (30%)	55 (49%)	23 (21%)	0
	50-56 Days (Group 2)	73	72 (99%)		298	118 (40%)	99 (33%)	70 (23%)	11 (4%)
	57-63 Days (Group 3)	89	89 (100%)		362	129 (36%)	126 (35%)	93 (26%)	14 (4%)
ALLERGY	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	0	1 (100%)
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	0	1 (100%)
ASTHENIA	≤63 Days (All)	191	5 (3%)	0.4621	6	2 (33%)	4 (67%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	89	4 (4%)		4	2 (50%)	2 (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: DEAN (#27)

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)	191	17 (9%)	0.8336	31	9 (29%)	13 (42%)	5 (16%)	4 (13%)
	≤49 Days (Group 1)	29	3 (10%)		5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	73	7 (10%)		16	5 (31%)	9 (56%)	2 (13%)	0
	57-63 Days (Group 3)	89	7 (8%)		10	1 (10%)	2 (20%)	3 (30%)	4 (40%)
FATIGUE	≤63 Days (All)	191	7 (4%)	0.1139	7	2 (29%)	5 (71%)	0	0
	≤49 Days (Group 1)	29	3 (10%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	89	2 (2%)		2	1 (50%)	1 (50%)	0	0
FEVER	≤63 Days (All)	191	4 (2%)	0.3736	5	4 (80%)	1 (20%)	0	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	3 (4%)		4	3 (75%)	1 (25%)	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
HOT FLUSHES	≤63 Days (All)	191	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	1 (1%)		1	0	0	1 (100%)	0
MALAISE	≤63 Days (All)	191	1 (<1%)	0.5340	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	89	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: DEAN (#27)

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.)									
PAIN	≤63 Days (All)	191	1 (<1%)	0.1518	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	0		0	0	0	0	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	191	4 (2%)	1.0000	5	1 (20%)	1 (20%)	3 (60%)	0
	≤49 Days (Group 1)	29	0		0	0	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	2 (2%)		3	1 (33%)	0	2 (67%)	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	191	5 (3%)	0.0457	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	191	5 (3%)	0.0457	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

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

Center: CREININ (#28)

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)	115	115 (100%)		953	397 (42%)	335 (35%)	221 (23%)	0
	≤49 Days (Group 1)	23	23 (100%)		154	64 (42%)	56 (36%)	34 (22%)	0
	50-56 Days (Group 2)	50	50 (100%)		432	163 (38%)	160 (37%)	109 (25%)	0
	57-63 Days (Group 3)	42	42 (100%)		367	170 (46%)	119 (32%)	78 (21%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	115	4 (3%)	0.1059	4	0	3 (75%)	1 (25%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	4 (8%)		4	0	3 (75%)	1 (25%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
RASH	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SKIN DISORDER	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	115	2 (2%)	0.6796	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0

[1] Includes all adverse events reported at any point in the study, regardless of causality.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
[4] Events in this body system occurred during the study blood sampling.

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

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

Center: CREININ (#28)

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)	115	3 (3%)	0.7916	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
BONE DISORDER	≤63 Days (All)	115	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SKELETAL PAIN	≤63 Days (All)	115	2 (2%)	0.3173	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	54 (47%)	0.4374	86	37 (43%)	40 (47%)	9 (10%)	0
	≤49 Days (Group 1)	23	9 (39%)		12	7 (58%)	5 (42%)	0	0
	50-56 Days (Group 2)	50	22 (44%)		43	15 (35%)	21 (49%)	7 (16%)	0
	57-63 Days (Group 3)	42	23 (55%)		31	15 (48%)	14 (45%)	2 (6%)	0
DIZZINESS	≤63 Days (All)	115	19 (17%)	0.4389	21	16 (76%)	4 (19%)	1 (5%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	50	8 (16%)		10	8 (80%)	2 (20%)	0	0
	57-63 Days (Group 3)	42	9 (21%)		9	6 (67%)	2 (22%)	1 (11%)	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