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

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
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

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	Severity: Moderate	Severity: Severe	Severity: 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	Severity: Moderate	Severity: Severe	Severity: 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

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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
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

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

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

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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS (cont.)									
HEADACHE	≤63 Days (All)	115	44 (38%)	0.9680	64	21 (33%)	35 (55%)	8 (13%)	0
	≤49 Days (Group 1)	23	8 (35%)		10	5 (50%)	5 (50%)	0	0
	50-56 Days (Group 2)	50	20 (40%)		33	7 (21%)	19 (58%)	7 (21%)	0
	57-63 Days (Group 3)	42	16 (38%)		21	9 (43%)	11 (52%)	1 (5%)	0
MIGRAINE	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	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
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
TINNITUS	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	115	7 (6%)	0.2715	12	4 (33%)	6 (50%)	2 (17%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	5 (10%)		8	2 (25%)	4 (50%)	2 (25%)	0
	57-63 Days (Group 3)	42	2 (5%)		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: 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
PSYCHIATRIC DISORDERS (cont.)									
ANOREXIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
ANXIETY	≤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
DEPRESSION	≤63 Days (All)	115	3 (3%)	1.0000	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	42	1 (2%)		3	1 (33%)	2 (67%)	0	0
DYSPAREUNIA	≤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
EMOTIONAL LABILITY	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	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

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
PSYCHIATRIC DISORDERS (cont.)									
INSOMNIA	≤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
PARONIRIA	≤63 Days (All)	115	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	104 (90%)	0.0948	305	149 (49%)	106 (35%)	50 (16%)	0
	≤49 Days (Group 1)	23	18 (78%)		45	18 (40%)	17 (38%)	10 (22%)	0
	50-56 Days (Group 2)	50	46 (92%)		140	61 (44%)	55 (39%)	24 (17%)	0
	57-63 Days (Group 3)	42	40 (95%)		120	70 (58%)	34 (28%)	16 (13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	0	1 (100%)	0
CONSTIPATION	≤63 Days (All)	115	3 (3%)	0.5960	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	2 (5%)		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: 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
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
DIARRHEA	≤63 Days (All)	115	45 (39%)	1.0000	63	37 (59%)	18 (29%)	8 (13%)	0
	≤49 Days (Group 1)	23	9 (39%)		13	7 (54%)	4 (31%)	2 (15%)	0
	50-56 Days (Group 2)	50	20 (40%)		30	14 (47%)	11 (37%)	5 (17%)	0
	57-63 Days (Group 3)	42	16 (38%)		20	16 (80%)	3 (15%)	1 (5%)	0
DYSPEPSIA	≤63 Days (All)	115	3 (3%)	0.0967	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	3 (7%)		3	2 (67%)	0	1 (33%)	0
FLATULENCE	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	115	93 (81%)	0.0320	178	85 (48%)	61 (34%)	32 (18%)	0
	≤49 Days (Group 1)	23	14 (61%)		26	8 (31%)	12 (46%)	6 (23%)	0
	50-56 Days (Group 2)	50	42 (84%)		84	36 (43%)	31 (37%)	17 (20%)	0
	57-63 Days (Group 3)	42	37 (88%)		68	41 (60%)	18 (26%)	9 (13%)	0
TOOTH ACHE	≤63 Days (All)	115	2 (2%)	1.0000	2	0	2 (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	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: 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
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
VOMITING	≤63 Days (All)	115	36 (31%)	0.0905	54	21 (39%)	25 (46%)	8 (15%)	0
	≤49 Days (Group 1)	23	3 (13%)		6	3 (50%)	1 (17%)	2 (33%)	0
	50-56 Days (Group 2)	50	17 (34%)		24	10 (42%)	12 (50%)	2 (8%)	0
	57-63 Days (Group 3)	42	16 (38%)		24	8 (33%)	12 (50%)	4 (17%)	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	3 (3%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
PHARYNGITIS	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	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
RHINITIS	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SINUSITIS	≤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

[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: 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
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	5 (4%)	0.5170	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	3 (7%)		3	1 (33%)	2 (67%)	0	0
DYSURIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
MICTURITION FREQUENCY	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	115	3 (3%)	0.3075	3	0	3 (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	2 (5%)		2	0	2 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	115	27 (23%)	0.8453	30	9 (30%)	12 (40%)	9 (30%)	0
	≤49 Days (Group 1)	23	5 (22%)		6	2 (33%)	2 (33%)	2 (33%)	0
	50-56 Days (Group 2)	50	13 (26%)		13	4 (31%)	6 (46%)	3 (23%)	0
	57-63 Days (Group 3)	42	9 (21%)		11	3 (27%)	4 (36%)	4 (36%)	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: 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
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
BREAST DISCHARGE	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
ENDOMETRITIS	≤63 Days (All)	115	1 (<1%)	0.2000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
LEUKORRHOEA	≤63 Days (All)	115	2 (2%)	0.6796	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	2 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
PELVIC INFLAMMATION	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	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
UTERINE HAEMORRHAGE	≤63 Days (All)	115	8 (7%)	0.8972	9	0	1 (11%)	8 (89%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	50	3 (6%)		3	0	1 (33%)	2 (67%)	0
	57-63 Days (Group 3)	42	3 (7%)		4	0	0	4 (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: 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
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINAL DISCOMFORT	≤63 Days (All)	115	2 (2%)	0.3173	2	1 (50%)	1 (50%)	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	1 (100%)	0	0	0
VAGINITIS	≤63 Days (All)	115	12 (10%)	0.9261	13	4 (31%)	8 (62%)	1 (8%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	50	6 (12%)		6	1 (17%)	4 (67%)	1 (17%)	0
	57-63 Days (Group 3)	42	4 (10%)		5	2 (40%)	3 (60%)	0	0
VULVA DISORDER	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	115	115 (100%)	------	493	191 (39%)	154 (31%)	148 (30%)	0
	≤49 Days (Group 1)	23	23 (100%)		89	37 (42%)	30 (34%)	22 (25%)	0
	50-56 Days (Group 2)	50	50 (100%)		214	78 (36%)	66 (31%)	70 (33%)	0
	57-63 Days (Group 3)	42	42 (100%)		190	76 (40%)	58 (31%)	56 (29%)	0
ABDOMINAL PAIN	≤63 Days (All)	115	114 (>99%)	1.0000	419	144 (34%)	135 (32%)	140 (33%)	0
	≤49 Days (Group 1)	23	23 (100%)		77	30 (39%)	27 (35%)	20 (26%)	0
	50-56 Days (Group 2)	50	49 (98%)		183	59 (32%)	57 (31%)	67 (37%)	0
	57-63 Days (Group 3)	42	42 (100%)		159	55 (35%)	51 (32%)	53 (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

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
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ASTHENIA	≤63 Days (All)	115	1 (<1%)	0.5652	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
BACK PAIN	≤63 Days (All)	115	21 (18%)	0.5438	25	10 (40%)	9 (36%)	6 (24%)	0
	≤49 Days (Group 1)	23	3 (13%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	50	8 (16%)		9	2 (22%)	5 (56%)	2 (22%)	0
	57-63 Days (Group 3)	42	10 (24%)		13	6 (46%)	4 (31%)	3 (23%)	0
CHEST PAIN	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	115	33 (29%)	0.4918	35	29 (83%)	5 (14%)	1 (3%)	0
	≤49 Days (Group 1)	23	6 (26%)		8	5 (63%)	2 (25%)	1 (13%)	0
	50-56 Days (Group 2)	50	12 (24%)		12	11 (92%)	1 (8%)	0	0
	57-63 Days (Group 3)	42	15 (36%)		15	13 (87%)	2 (13%)	0	0
FEVER	≤63 Days (All)	115	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		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: 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
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
LEG PAIN	≤63 Days (All)	115	4 (3%)	1.0000	5	1 (20%)	4 (80%)	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	50	2 (4%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	0	1 (100%)	0	0
MALAISE	≤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
RIGORS	≤63 Days (All)	115	3 (3%)	0.2273	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	3 (6%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	115	9 (8%)	0.3185	10	3 (30%)	7 (70%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	5 (10%)		5	1 (20%)	4 (80%)	0	0
	57-63 Days (Group 3)	42	4 (10%)		5	2 (40%)	3 (60%)	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: 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
RESISTANCE MECHANISM DISORDERS (cont.)									
INFECTION BACTERIAL	≤63 Days (All)	115	1 (<1%)	0.5652	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	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
INFECTION FUNGAL	≤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
INFECTION PARASITIC	≤63 Days (All)	115	2 (2%)	1.0000	2	0	2 (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	1 (2%)		1	0	1 (100%)	0	0
INFECTION VIRAL	≤63 Days (All)	115	6 (5%)	0.6523	6	3 (50%)	3 (50%)	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	3 (6%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	42	3 (7%)		3	2 (67%)	1 (33%)	0	0
SECONDARY TERMS									
ANY EVENT	≤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

[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: 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
SECONDARY TERMS (cont.)									
BITE	≤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

[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: SOGOR (#29)

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)	83	79 (95%)	1.0000	379	85 (22%)	160 (42%)	133 (35%)	1 (<1%)
	≤49 Days (Group 1)	28	27 (96%)		124	25 (20%)	68 (55%)	30 (24%)	1 (<1%)
	50-56 Days (Group 2)	37	35 (95%)		165	34 (21%)	64 (39%)	67 (41%)	0
	57-63 Days (Group 3)	18	17 (94%)		90	26 (29%)	28 (31%)	36 (40%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
URTICARIA	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	22 (27%)	0.6226	31	9 (29%)	15 (48%)	7 (23%)	0
	≤49 Days (Group 1)	28	8 (29%)		11	3 (27%)	7 (64%)	1 (9%)	0
	50-56 Days (Group 2)	37	8 (22%)		8	2 (25%)	5 (63%)	1 (13%)	0
	57-63 Days (Group 3)	18	6 (33%)		12	4 (33%)	3 (25%)	5 (42%)	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: SOGOR (#29)

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.)									
DEPRESSION	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	48 (58%)	0.8080	115	18 (16%)	43 (37%)	54 (47%)	0
	≤49 Days (Group 1)	28	15 (54%)		29	3 (10%)	12 (41%)	14 (48%)	0
	50-56 Days (Group 2)	37	23 (62%)		55	6 (11%)	23 (42%)	26 (47%)	0
	57-63 Days (Group 3)	18	10 (56%)		31	9 (29%)	8 (26%)	14 (45%)	0
DIARRHEA	≤63 Days (All)	83	13 (16%)	0.7334	16	3 (19%)	6 (38%)	7 (44%)	0
	≤49 Days (Group 1)	28	3 (11%)		3	0	1 (33%)	2 (67%)	0
	50-56 Days (Group 2)	37	7 (19%)		9	1 (11%)	5 (56%)	3 (33%)	0
	57-63 Days (Group 3)	18	3 (17%)		4	2 (50%)	0	2 (50%)	0
DYSPEPSIA	≤63 Days (All)	83	2 (2%)	0.0450	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	2 (11%)		2	2 (100%)	0	0	0
NAUSEA	≤63 Days (All)	83	39 (47%)	0.5120	55	10 (18%)	23 (42%)	22 (40%)	0
	≤49 Days (Group 1)	28	12 (43%)		16	3 (19%)	7 (44%)	6 (38%)	0
	50-56 Days (Group 2)	37	20 (54%)		27	5 (19%)	11 (41%)	11 (41%)	0
	57-63 Days (Group 3)	18	7 (39%)		12	2 (17%)	5 (42%)	5 (42%)	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: SOGOR (#29)

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)	83	1 (1%)	0.5542	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
VOMITING	≤63 Days (All)	83	28 (34%)	0.7612	41	3 (7%)	14 (34%)	24 (59%)	0
	≤49 Days (Group 1)	28	8 (29%)		9	0	4 (44%)	5 (56%)	0
	50-56 Days (Group 2)	37	14 (38%)		19	0	7 (37%)	12 (63%)	0
	57-63 Days (Group 3)	18	6 (33%)		13	3 (23%)	3 (23%)	7 (54%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	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: SOGOR (#29)

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)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	2 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
ASTHMA	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
SINUSITIS	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	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: SOGOR (#29)

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)	83	1 (1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	83	4 (5%)	1.0000	4	0	2 (50%)	2 (50%)	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	2 (5%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	18	1 (6%)		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: SOGOR (#29)

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)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	83	2 (2%)	0.6956	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	83	74 (89%)	0.5331	214	58 (27%)	86 (40%)	69 (32%)	1 (<1%)
	≤49 Days (Group 1)	28	26 (93%)		75	19 (25%)	40 (53%)	15 (20%)	1 (1%)
	50-56 Days (Group 2)	37	33 (89%)		94	26 (28%)	30 (32%)	38 (40%)	0
	57-63 Days (Group 3)	18	15 (83%)		45	13 (29%)	16 (36%)	16 (36%)	0
ABDOMINAL PAIN	≤63 Days (All)	83	74 (89%)	0.5331	198	53 (27%)	77 (39%)	67 (34%)	1 (<1%)
	≤49 Days (Group 1)	28	26 (93%)		70	17 (24%)	37 (53%)	15 (21%)	1 (1%)
	50-56 Days (Group 2)	37	33 (89%)		87	25 (29%)	26 (30%)	36 (41%)	0
	57-63 Days (Group 3)	18	15 (83%)		41	11 (27%)	14 (34%)	16 (39%)	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: SOGOR (#29)

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 [4]	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
BACK PAIN	≤63 Days (All)	83	4 (5%)	0.8173	5	1 (20%)	3 (60%)	1 (20%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0
CHEST PAIN	≤63 Days (All)	83	1 (1%)	0.2169	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0
FEVER	≤63 Days (All)	83	4 (5%)	0.8173	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	28	2 (7%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	1 (100%)	0	0	0
MALAISE	≤63 Days (All)	83	2 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	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: SOGOR (#29)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
OEDEMA	≤63 Days (All)	83	1 (1%)	0.2169	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	1 (100%)	0	0	0
PAIN	≤63 Days (All)	83	1 (1%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	83	4 (5%)	1.0000	5	0	5 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	37	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0
INFECTION	≤63 Days (All)	83	1 (1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
INFECTION PARASITIC	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	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: SOGOR (#29)

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 VIRAL	≤63 Days (All)	83	3 (4%)	1.0000	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	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

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Appendix D, Table 5b
Adverse Events Possibly or Probably Related to Mifepristone [1] By Center
[Safety Evaluable Patients]

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	71	48 (68%)	1.0000	103	51 (50%)	44 (43%)	8 (8%)	0
	≤49 Days (Group 1)	28	19 (68%)		38	20 (53%)	18 (47%)	0	0
	50-56 Days (Group 2)	26	18 (69%)		36	18 (50%)	14 (39%)	4 (11%)	0
	57-63 Days (Group 3)	17	11 (65%)		29	13 (45%)	12 (41%)	4 (14%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	71	12 (17%)	0.0639	16	7 (44%)	7 (44%)	2 (13%)	0
	≤49 Days (Group 1)	28	7 (25%)		7	4 (57%)	3 (43%)	0	0
	50-56 Days (Group 2)	26	1 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	17	4 (24%)		6	2 (33%)	3 (50%)	1 (17%)	0
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	10 (14%)	0.0666	12	6 (50%)	5 (42%)	1 (8%)	0
	≤49 Days (Group 1)	28	7 (25%)		7	4 (57%)	3 (43%)	0	0
	50-56 Days (Group 2)	26	1 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	17	2 (12%)		2	1 (50%)	1 (50%)	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	71	2 (3%)	0.7070	3	0	2 (67%)	1 (33%)	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	1 (6%)		2	0	1 (50%)	1 (50%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)								
INSOMNIA	≤63 Days (All)	71	2 (3%)	0.7070	3	0	2 (67%)	1 (33%)	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	1 (6%)		2	0	1 (50%)	1 (50%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	71	32 (45%)	0.3338	44	22 (50%)	19 (43%)	3 (7%)	0
	≤49 Days (Group 1)	28	10 (36%)		14	7 (50%)	7 (50%)	0	0
	50-56 Days (Group 2)	26	12 (46%)		16	10 (63%)	5 (31%)	1 (6%)	0
	57-63 Days (Group 3)	17	10 (59%)		14	5 (36%)	7 (50%)	2 (14%)	0
DIARRHEA	≤63 Days (All)	71	2 (3%)	0.1855	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	26	2 (8%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	17	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	71	2 (3%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	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
NAUSEA	≤63 Days (All)	71	23 (32%)	0.1340	25	11 (44%)	13 (52%)	1 (4%)	0
	≤49 Days (Group 1)	28	7 (25%)		8	4 (50%)	4 (50%)	0	0
	50-56 Days (Group 2)	26	7 (27%)		7	4 (57%)	3 (43%)	0	0
	57-63 Days (Group 3)	17	9 (53%)		10	3 (30%)	6 (60%)	1 (10%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
VOMITING	≤63 Days (All)	71	14 (20%)	0.9300	15	7 (47%)	6 (40%)	2 (13%)	0
	≤49 Days (Group 1)	28	5 (18%)		5	2 (40%)	3 (60%)	0	0
	50-56 Days (Group 2)	26	5 (19%)		6	3 (50%)	2 (33%)	1 (17%)	0
	57-63 Days (Group 3)	17	4 (24%)		4	2 (50%)	1 (25%)	1 (25%)	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
RESPIRATORY SYSTEM 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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESPIRATORY SYSTEM DISORDERS	(cont.)								
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
REPRODUCTIVE DISORDERS, FEMALE									
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
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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	71	33 (46%)	0.2664	37	21 (57%)	14 (38%)	2 (5%)	0
	≤49 Days (Group 1)	28	15 (54%)		15	9 (60%)	6 (40%)	0	0
	50-56 Days (Group 2)	26	13 (50%)		15	6 (40%)	7 (47%)	2 (13%)	0
	57-63 Days (Group 3)	17	5 (29%)		7	6 (86%)	1 (14%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS	**(cont.)**								
ABDOMINAL PAIN	≤63 Days (All)	71	28 (39%)	0.2916	30	17 (57%)	11 (37%)	2 (7%)	0
	≤49 Days (Group 1)	28	13 (46%)		13	8 (62%)	5 (38%)	0	0
	50-56 Days (Group 2)	26	11 (42%)		13	6 (46%)	5 (38%)	2 (15%)	0
	57-63 Days (Group 3)	17	4 (24%)		4	3 (75%)	1 (25%)	0	0
ASTHENIA	≤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
BACK PAIN	≤63 Days (All)	71	2 (3%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	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
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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: POINDEXTER (#21)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
RIGORS [4]	≤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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	151	122 (81%)	0.9300	278	108 (39%)	139 (50%)	31 (11%)	0
	≤49 Days (Group 1)	70	57 (81%)		132	52 (39%)	69 (52%)	11 (8%)	0
	50-56 Days (Group 2)	43	35 (81%)		83	31 (37%)	41 (49%)	11 (13%)	0
	57-63 Days (Group 3)	38	30 (79%)		63	25 (40%)	29 (46%)	9 (14%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤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
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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	43 (28%)	0.8219	50	24 (48%)	21 (42%)	5 (10%)	0
	≤49 Days (Group 1)	70	19 (27%)		22	13 (59%)	8 (36%)	1 (5%)	0
	50-56 Days (Group 2)	43	14 (33%)		16	7 (44%)	8 (50%)	1 (6%)	0
	57-63 Days (Group 3)	38	10 (26%)		12	4 (33%)	5 (42%)	3 (25%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
DIZZINESS	≤63 Days (All)	151	14 (9%)	0.9368	14	6 (43%)	7 (50%)	1 (7%)	0
	≤49 Days (Group 1)	70	6 (9%)		6	4 (67%)	2 (33%)	0	0
	50-56 Days (Group 2)	43	4 (9%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	38	4 (11%)		4	1 (25%)	2 (50%)	1 (25%)	0
HEADACHE	≤63 Days (All)	151	34 (23%)	0.6316	35	17 (49%)	14 (40%)	4 (11%)	0
	≤49 Days (Group 1)	70	14 (20%)		15	8 (53%)	6 (40%)	1 (7%)	0
	50-56 Days (Group 2)	43	12 (28%)		12	6 (50%)	5 (42%)	1 (8%)	0
	57-63 Days (Group 3)	38	8 (21%)		8	3 (38%)	3 (38%)	2 (25%)	0
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
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
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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	151	8 (5%)	0.8096	8	1 (13%)	5 (63%)	2 (25%)	0
	≤49 Days (Group 1)	70	4 (6%)		4	1 (25%)	3 (75%)	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
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
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	75 (50%)	0.8332	95	30 (32%)	52 (55%)	13 (14%)	0
	≤49 Days (Group 1)	70	34 (49%)		40	12 (30%)	24 (60%)	4 (10%)	0
	50-56 Days (Group 2)	43	23 (53%)		31	8 (26%)	17 (55%)	6 (19%)	0
	57-63 Days (Group 3)	38	18 (47%)		24	10 (42%)	11 (46%)	3 (13%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
DIARRHEA [4]	≤63 Days (All)	151	3 (2%)	0.4489	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	2 (5%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
DYSPEPSIA	≤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
NAUSEA	≤63 Days (All)	151	65 (43%)	0.7560	65	25 (38%)	30 (46%)	10 (15%)	0
	≤49 Days (Group 1)	70	28 (40%)		28	11 (39%)	13 (46%)	4 (14%)	0
	50-56 Days (Group 2)	43	20 (47%)		20	5 (25%)	11 (55%)	4 (20%)	0
	57-63 Days (Group 3)	38	17 (45%)		17	9 (53%)	6 (35%)	2 (12%)	0
VOMITING	≤63 Days (All)	151	26 (17%)	0.6197	26	4 (15%)	19 (73%)	3 (12%)	0
	≤49 Days (Group 1)	70	10 (14%)		10	1 (10%)	9 (90%)	0	0
	50-56 Days (Group 2)	43	9 (21%)		9	2 (22%)	5 (56%)	2 (22%)	0
	57-63 Days (Group 3)	38	7 (18%)		7	1 (14%)	5 (71%)	1 (14%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS (cont.)									
THIRST	≤63 Days (All)	151	1 (<1%)	0.5364	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
PLATELET,BLEEDING & CLOTTING 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
EPISTAXIS	≤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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE	(cont.)								
LEUKORRHOEA	≤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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	151	98 (65%)	0.5619	120	52 (43%)	57 (48%)	11 (9%)	0
	≤49 Days (Group 1)	70	48 (69%)		65	26 (40%)	33 (51%)	6 (9%)	0
	50-56 Days (Group 2)	43	28 (65%)		30	15 (50%)	12 (40%)	3 (10%)	0
	57-63 Days (Group 3)	38	22 (58%)		25	11 (44%)	12 (48%)	2 (8%)	0
ABDOMINAL PAIN	≤63 Days (All)	151	94 (62%)	0.4483	98	39 (40%)	48 (49%)	11 (11%)	0
	≤49 Days (Group 1)	70	47 (67%)		51	17 (33%)	28 (55%)	6 (12%)	0
	50-56 Days (Group 2)	43	26 (60%)		26	13 (50%)	10 (38%)	3 (12%)	0
	57-63 Days (Group 3)	38	21 (55%)		21	9 (43%)	10 (48%)	2 (10%)	0
BACK PAIN	≤63 Days (All)	151	8 (5%)	1.0000	8	6 (75%)	2 (25%)	0	0
	≤49 Days (Group 1)	70	4 (6%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	43	2 (5%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	38	2 (5%)		2	1 (50%)	1 (50%)	0	0
FATIGUE	≤63 Days (All)	151	7 (5%)	0.8873	7	2 (29%)	5 (71%)	0	0
	≤49 Days (Group 1)	70	4 (6%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	43	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: VARGAS (#22)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FEVER	≤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
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
RIGORS	≤63 Days (All)	151	3 (2%)	0.3365	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	70	3 (4%)		3	2 (67%)	1 (33%)	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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: [redacted]

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	89	75 (84%)	0.7079	210	114 (54%)	82 (39%)	14 (7%)	0
	≤49 Days (Group 1)	35	28 (80%)		80	45 (56%)	29 (36%)	6 (8%)	0
	50-56 Days (Group 2)	34	30 (88%)		83	38 (46%)	37 (45%)	8 (10%)	0
	57-63 Days (Group 3)	20	17 (85%)		47	31 (66%)	16 (34%)	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	1 (1%)	0.2247	3	3 (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%)		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
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	25 (28%)	0.8682	31	14 (45%)	16 (52%)	1 (3%)	0
	≤49 Days (Group 1)	35	11 (31%)		12	8 (67%)	4 (33%)	0	0
	50-56 Days (Group 2)	34	9 (26%)		14	3 (21%)	10 (71%)	1 (7%)	0
	57-63 Days (Group 3)	20	5 (25%)		5	3 (60%)	2 (40%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: [redacted]

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
DIZZINESS	≤63 Days (All)	89	10 (11%)	0.0281	12	8 (67%)	4 (33%)	0	0
	≤49 Days (Group 1)	35	8 (23%)		9	7 (78%)	2 (22%)	0	0
	50-56 Days (Group 2)	34	1 (3%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	20	1 (5%)		1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	89	15 (17%)	0.2145	19	6 (32%)	12 (63%)	1 (5%)	0
	≤49 Days (Group 1)	35	3 (9%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	34	8 (24%)		12	3 (25%)	8 (67%)	1 (8%)	0
	57-63 Days (Group 3)	20	4 (20%)		4	2 (50%)	2 (50%)	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	89	3 (3%)	0.1772	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	35	3 (9%)		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
ANOREXIA	≤63 Days (All)	89	2 (2%)	0.3437	2	1 (50%)	1 (50%)	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	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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: [redacted]

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	89	42 (47%)	0.4325	77	39 (51%)	36 (47%)	2 (3%)	0
	≤49 Days (Group 1)	35	14 (40%)		23	12 (52%)	11 (48%)	0	0
	50-56 Days (Group 2)	34	19 (56%)		37	16 (43%)	19 (51%)	2 (5%)	0
	57-63 Days (Group 3)	20	9 (45%)		17	11 (65%)	6 (35%)	0	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤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
DIARRHEA	≤63 Days (All)	89	3 (3%)	1.0000	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	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	1 (100%)	0	0
DYSPEPSIA	≤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
NAUSEA	≤63 Days (All)	89	35 (39%)	0.1987	47	23 (49%)	24 (51%)	0	0
	≤49 Days (Group 1)	35	10 (29%)		13	6 (46%)	7 (54%)	0	0
	50-56 Days (Group 2)	34	17 (50%)		23	10 (43%)	13 (57%)	0	0
	57-63 Days (Group 3)	20	8 (40%)		11	7 (64%)	4 (36%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: [redacted]

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
VOMITING	≤63 Days (All)	89	18 (20%)	0.4694	25	12 (48%)	11 (44%)	2 (8%)	0
	≤49 Days (Group 1)	35	5 (14%)		9	5 (56%)	4 (44%)	0	0
	50-56 Days (Group 2)	34	9 (26%)		11	3 (27%)	6 (55%)	2 (18%)	0
	57-63 Days (Group 3)	20	4 (20%)		5	4 (80%)	1 (20%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤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
BREAST PAIN FEMALE	≤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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	89	61 (69%)	0.9566	94	57 (61%)	29 (31%)	8 (9%)	0
	≤49 Days (Group 1)	35	23 (66%)		40	24 (60%)	13 (33%)	3 (8%)	0
	50-56 Days (Group 2)	34	24 (71%)		32	19 (59%)	8 (25%)	5 (16%)	0
	57-63 Days (Group 3)	20	14 (70%)		22	14 (64%)	8 (36%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: [redacted]

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	89	55 (62%)	0.8865	70	47 (67%)	18 (26%)	5 (7%)	0
	≤49 Days (Group 1)	35	22 (63%)		27	18 (67%)	7 (26%)	2 (7%)	0
	50-56 Days (Group 2)	34	20 (59%)		25	16 (64%)	6 (24%)	3 (12%)	0
	57-63 Days (Group 3)	20	13 (65%)		18	13 (72%)	5 (28%)	0	0
BACK PAIN	≤63 Days (All)	89	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	35	1 (3%)		1	1 (100%)	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
FATIGUE	≤63 Days (All)	89	14 (16%)	0.7079	18	6 (33%)	9 (50%)	3 (17%)	0
	≤49 Days (Group 1)	35	7 (20%)		9	3 (33%)	5 (56%)	1 (11%)	0
	50-56 Days (Group 2)	34	4 (12%)		5	2 (40%)	1 (20%)	2 (40%)	0
	57-63 Days (Group 3)	20	3 (15%)		4	1 (25%)	3 (75%)	0	0
FEVER	≤63 Days (All)	89	2 (2%)	1.0000	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	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	20	0		0	0	0	0	0
LEG PAIN	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: [redacted]

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
RIGORS	≤63 Days (All)	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
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤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
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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: WESTHOFF (#24)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	175	112 (64%)	0.2663	182	91 (50%)	69 (38%)	22 (12%)	0
	≤49 Days (Group 1)	71	46 (65%)		72	33 (46%)	28 (39%)	11 (15%)	0
	50-56 Days (Group 2)	72	42 (58%)		73	43 (59%)	22 (30%)	8 (11%)	0
	57-63 Days (Group 3)	32	24 (75%)		37	15 (41%)	19 (51%)	3 (8%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	5 (3%)	0.6146	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	72	3 (4%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	32	1 (3%)		1	0	1 (100%)	0	0
DIZZINESS	≤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
HEADACHE	≤63 Days (All)	175	4 (2%)	0.8318	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	1 (100%)	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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	175	41 (23%)	0.7746	65	24 (37%)	27 (42%)	14 (22%)	0
	≤49 Days (Group 1)	71	16 (23%)		26	10 (38%)	9 (35%)	7 (27%)	0
	50-56 Days (Group 2)	72	16 (22%)		28	12 (43%)	11 (39%)	5 (18%)	0
	57-63 Days (Group 3)	32	9 (28%)		11	2 (18%)	7 (64%)	2 (18%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: WESTHOFF (#24)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤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
DIARRHEA	≤63 Days (All)	175	4 (2%)	0.6779	4	1 (25%)	3 (75%)	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	1 (3%)		1	0	1 (100%)	0	0
DYSPEPSIA	≤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
NAUSEA	≤63 Days (All)	175	32 (18%)	0.9035	36	15 (42%)	13 (36%)	8 (22%)	0
	≤49 Days (Group 1)	71	14 (20%)		17	9 (53%)	5 (29%)	3 (18%)	0
	50-56 Days (Group 2)	72	13 (18%)		14	6 (43%)	5 (36%)	3 (21%)	0
	57-63 Days (Group 3)	32	5 (16%)		5	0	3 (60%)	2 (40%)	0
VOMITING	≤63 Days (All)	175	20 (11%)	0.7771	21	7 (33%)	8 (38%)	6 (29%)	0
	≤49 Days (Group 1)	71	7 (10%)		7	1 (14%)	2 (29%)	4 (57%)	0
	50-56 Days (Group 2)	72	10 (14%)		11	4 (36%)	5 (45%)	2 (18%)	0
	57-63 Days (Group 3)	32	3 (9%)		3	2 (67%)	1 (33%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: WESTHOFF (#24)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	175	1 (<1%)	0.5886	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	0	1 (100%)	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
UTERINE HAEMORRHAGE	≤63 Days (All)	175	1 (<1%)	0.5886	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	71	1 (1%)		1	0	0	1 (100%)	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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	175	96 (55%)	0.0655	111	65 (59%)	39 (35%)	7 (6%)	0
	≤49 Days (Group 1)	71	39 (55%)		44	23 (52%)	18 (41%)	3 (7%)	0
	50-56 Days (Group 2)	72	34 (47%)		42	29 (69%)	10 (24%)	3 (7%)	0
	57-63 Days (Group 3)	32	23 (72%)		25	13 (52%)	11 (44%)	1 (4%)	0
ABDOMINAL PAIN	≤63 Days (All)	175	93 (53%)	0.0947	102	61 (60%)	35 (34%)	6 (6%)	0
	≤49 Days (Group 1)	71	38 (54%)		41	22 (54%)	16 (39%)	3 (7%)	0
	50-56 Days (Group 2)	72	33 (46%)		38	27 (71%)	9 (24%)	2 (5%)	0
	57-63 Days (Group 3)	32	22 (69%)		23	12 (52%)	10 (43%)	1 (4%)	0
BACK PAIN	≤63 Days (All)	175	5 (3%)	0.7278	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	71	3 (4%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	72	2 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	32	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: WESTHOFF (#24)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FEVER	≤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
MALAISE	≤63 Days (All)	175	2 (1%)	0.3331	2	1 (50%)	1 (50%)	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	1 (3%)		1	0	1 (100%)	0	0
TEMPERATURE CHANGED SENSATION	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: NICHOLS (#25)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	178	52 (29%)	0.0176	72	40 (56%)	21 (29%)	11 (15%)	0
	≤49 Days (Group 1)	72	13 (18%)		19	9 (47%)	5 (26%)	5 (26%)	0
	50-56 Days (Group 2)	54	18 (33%)		23	15 (65%)	5 (22%)	3 (13%)	0
	57-63 Days (Group 3)	52	21 (40%)		30	16 (53%)	11 (37%)	3 (10%)	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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	178	27 (15%)	0.4218	36	16 (44%)	13 (36%)	7 (19%)	0
	≤49 Days (Group 1)	72	8 (11%)		12	6 (50%)	3 (25%)	3 (25%)	0
	50-56 Days (Group 2)	54	9 (17%)		10	6 (60%)	2 (20%)	2 (20%)	0
	57-63 Days (Group 3)	52	10 (19%)		14	4 (29%)	8 (57%)	2 (14%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: NICHOLS (#25)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
NAUSEA	≤63 Days (All)	178	25 (14%)	0.1595	30	14 (47%)	11 (37%)	5 (17%)	0
	≤49 Days (Group 1)	72	6 (8%)		8	4 (50%)	2 (25%)	2 (25%)	0
	50-56 Days (Group 2)	54	9 (17%)		10	6 (60%)	2 (20%)	2 (20%)	0
	57-63 Days (Group 3)	52	10 (19%)		12	4 (33%)	7 (58%)	1 (8%)	0
VOMITING	≤63 Days (All)	178	5 (3%)	0.3309	6	2 (33%)	2 (33%)	2 (33%)	0
	≤49 Days (Group 1)	72	3 (4%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	54	0		0	0	0	0	0
	57-63 Days (Group 3)	52	2 (4%)		2	0	1 (50%)	1 (50%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	178	32 (18%)	0.0007	35	24 (69%)	8 (23%)	3 (9%)	0
	≤49 Days (Group 1)	72	4 (6%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	54	13 (24%)		13	9 (69%)	3 (23%)	1 (8%)	0
	57-63 Days (Group 3)	52	15 (29%)		16	12 (75%)	3 (19%)	1 (6%)	0
ABDOMINAL PAIN	≤63 Days (All)	178	32 (18%)	0.0007	35	24 (69%)	8 (23%)	3 (9%)	0
	≤49 Days (Group 1)	72	4 (6%)		6	3 (50%)	2 (33%)	1 (17%)	0
	50-56 Days (Group 2)	54	13 (24%)		13	9 (69%)	3 (23%)	1 (8%)	0
	57-63 Days (Group 3)	52	15 (29%)		16	12 (75%)	3 (19%)	1 (6%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
ANY EVENT	≤63 Days (All)	179	164 (92%)	0.1663	359	161 (45%)	149 (42%)	47 (13%)	2 (<1%)
	≤49 Days (Group 1)	63	55 (87%)		120	59 (49%)	45 (38%)	15 (13%)	1 (<1%)
	50-56 Days (Group 2)	59	57 (97%)		126	51 (40%)	57 (45%)	17 (13%)	1 (<1%)
	57-63 Days (Group 3)	57	52 (91%)		113	51 (45%)	47 (42%)	15 (13%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤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
SWEATING INCREASED	≤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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	26 (15%)	0.1804	29	9 (31%)	17 (59%)	3 (10%)	0
	≤49 Days (Group 1)	63	13 (21%)		16	6 (38%)	7 (44%)	3 (19%)	0
	50-56 Days (Group 2)	59	5 (8%)		5	1 (20%)	4 (80%)	0	0
	57-63 Days (Group 3)	57	8 (14%)		8	2 (25%)	6 (75%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
DIZZINESS	≤63 Days (All)	179	10 (6%)	0.0008	11	5 (45%)	3 (27%)	3 (27%)	0
	≤49 Days (Group 1)	63	9 (14%)		10	4 (40%)	3 (30%)	3 (30%)	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
HEADACHE	≤63 Days (All)	179	17 (9%)	0.4097	18	4 (22%)	14 (78%)	0	0
	≤49 Days (Group 1)	63	5 (8%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	59	4 (7%)		4	0	4 (100%)	0	0
	57-63 Days (Group 3)	57	8 (14%)		8	2 (25%)	6 (75%)	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
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	179	3 (2%)	0.7746	3	2 (67%)	0	1 (33%)	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	0	1 (50%)	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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)								
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
DEPRESSION	≤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
EMOTIONAL LABILITY	≤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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	179	123 (69%)	0.0422	192	86 (45%)	78 (41%)	27 (14%)	1 (<1%)
	≤49 Days (Group 1)	63	36 (57%)		54	28 (52%)	22 (41%)	4 (7%)	0
	50-56 Days (Group 2)	59	46 (78%)		75	30 (40%)	31 (41%)	13 (17%)	1 (1%)
	57-63 Days (Group 3)	57	41 (72%)		63	28 (44%)	25 (40%)	10 (16%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	**(cont.)**								
DIARRHEA *	≤63 Days (All)	179	4 (2%)	1.0000	5	1 (20%)	4 (80%)	0	0
	≤49 Days (Group 1)	63	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	59	1 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	0	1 (100%)	0	0
DYSPEPSIA	≤63 Days (All)	179	3 (2%)	0.5336	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	63	1 (2%)		1	1 (100%)	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
NAUSEA	≤63 Days (All)	179	114 (64%)	0.0393	141	68 (48%)	55 (39%)	17 (12%)	1 (<1%)
	≤49 Days (Group 1)	63	33 (52%)		42	24 (57%)	16 (38%)	2 (5%)	0
	50-56 Days (Group 2)	59	44 (75%)		56	24 (43%)	23 (41%)	8 (14%)	1 (2%)
	57-63 Days (Group 3)	57	37 (65%)		43	20 (47%)	16 (37%)	7 (16%)	0
VOMITING	≤63 Days (All)	179	36 (20%)	0.1848	41	15 (37%)	18 (44%)	8 (20%)	0
	≤49 Days (Group 1)	63	8 (13%)		8	1 (13%)	5 (63%)	2 (25%)	0
	50-56 Days (Group 2)	59	14 (24%)		15	6 (40%)	5 (33%)	4 (27%)	0
	57-63 Days (Group 3)	57	14 (25%)		18	8 (44%)	8 (44%)	2 (11%)	0
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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS (cont.)									
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
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
RED BLOOD CELL DISORDERS									
ANY EVENT	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS	(cont.)								
ANAEMIA [4]	≤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
REPRODUCTIVE DISORDERS, FEMALE									
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
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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	179	117 (65%)	0.9040	128	60 (47%)	52 (41%)	15 (12%)	1 (<1%)
	≤49 Days (Group 1)	63	40 (63%)		44	22 (50%)	15 (34%)	6 (14%)	1 (2%)
	50-56 Days (Group 2)	59	40 (68%)		43	18 (42%)	21 (49%)	4 (9%)	0
	57-63 Days (Group 3)	57	37 (65%)		41	20 (49%)	16 (39%)	5 (12%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	179	116 (65%)	0.9800	122	58 (48%)	51 (42%)	12 (10%)	1 (<1%)
	≤49 Days (Group 1)	63	40 (63%)		43	22 (51%)	15 (35%)	5 (12%)	1 (2%)
	50-56 Days (Group 2)	59	39 (66%)		39	17 (44%)	20 (51%)	2 (5%)	0
	57-63 Days (Group 3)	57	37 (65%)		40	19 (48%)	16 (40%)	5 (13%)	0
ASTHENIA	≤63 Days (All)	179	2 (1%)	1.0000	2	0	0	2 (100%)	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	0		0	0	0	0	0
BACK PAIN	≤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	0	1 (100%)	0	0
	57-63 Days (Group 3)	57	1 (2%)		1	1 (100%)	0	0	0
FATIGUE	≤63 Days (All)	179	2 (1%)	0.2076	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	63	0		0	0	0	0	0
	50-56 Days (Group 2)	59	2 (3%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	57	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SHEEHAN (#26)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RESISTANCE MECHANISM DISORDERS	(cont.)								
INFECTION VIRAL	≤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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	191	138 (72%)	0.2852	385	136 (35%)	170 (44%)	71 (18%)	8 (2%)
	≤49 Days (Group 1)	29	24 (83%)		68	24 (35%)	37 (54%)	7 (10%)	0
	50-56 Days (Group 2)	73	49 (67%)		142	47 (33%)	68 (48%)	25 (18%)	2 (1%)
	57-63 Days (Group 3)	89	65 (73%)		175	65 (37%)	65 (37%)	39 (22%)	6 (3%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤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
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
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
MYALGIA [4]	≤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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	33 (17%)	0.9010	49	14 (29%)	29 (59%)	5 (10%)	1 (2%)
	≤49 Days (Group 1)	29	5 (17%)		7	1 (14%)	6 (86%)	0	0
	50-56 Days (Group 2)	73	14 (19%)		18	7 (39%)	9 (50%)	1 (6%)	1 (6%)
	57-63 Days (Group 3)	89	14 (16%)		24	6 (25%)	14 (58%)	4 (17%)	0
DIZZINESS	≤63 Days (All)	191	10 (5%)	0.7536	11	2 (18%)	8 (73%)	1 (9%)	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	73	3 (4%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	89	6 (7%)		7	1 (14%)	5 (71%)	1 (14%)	0
HEADACHE	≤63 Days (All)	191	29 (15%)	0.8248	37	11 (30%)	21 (57%)	4 (11%)	1 (3%)
	≤49 Days (Group 1)	29	5 (17%)		6	1 (17%)	5 (83%)	0	0
	50-56 Days (Group 2)	73	12 (16%)		14	5 (36%)	7 (50%)	1 (7%)	1 (7%)
	57-63 Days (Group 3)	89	12 (13%)		17	5 (29%)	9 (53%)	3 (18%)	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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
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
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	2 (1%)	0.6419	2	0	2 (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	2 (2%)		2	0	2 (100%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
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
INSOMNIA	≤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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	191	80 (42%)	0.9796	161	42 (26%)	74 (46%)	44 (27%)	1 (<1%)
	≤49 Days (Group 1)	29	12 (41%)		30	11 (37%)	15 (50%)	4 (13%)	0
	50-56 Days (Group 2)	73	30 (41%)		57	12 (21%)	31 (54%)	14 (25%)	0
	57-63 Days (Group 3)	89	38 (43%)		74	19 (26%)	28 (38%)	26 (35%)	1 (1%)
DIARRHEA	≤63 Days (All)	191	3 (2%)	0.1818	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	29	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	73	2 (3%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	89	0		0	0	0	0	0
DYSPEPSIA	≤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 events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	191	2 (1%)	0.6419	2	0	1 (50%)	0	1 (50%)
	≤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	2 (2%)		2	0	1 (50%)	0	1 (50%)
NAUSEA	≤63 Days (All)	191	66 (35%)	0.9566	99	33 (33%)	46 (46%)	20 (20%)	0
	≤49 Days (Group 1)	29	10 (34%)		22	8 (36%)	12 (55%)	2 (9%)	0
	50-56 Days (Group 2)	73	24 (33%)		33	9 (27%)	18 (55%)	6 (18%)	0
	57-63 Days (Group 3)	89	32 (36%)		44	16 (36%)	16 (36%)	12 (27%)	0
VOMITING	≤63 Days (All)	191	38 (20%)	0.9103	56	8 (14%)	26 (46%)	22 (39%)	0
	≤49 Days (Group 1)	29	5 (17%)		7	2 (29%)	3 (43%)	2 (29%)	0
	50-56 Days (Group 2)	73	14 (19%)		21	3 (14%)	12 (57%)	6 (29%)	0
	57-63 Days (Group 3)	89	19 (21%)		28	3 (11%)	11 (39%)	14 (50%)	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤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
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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	191	3 (2%)	0.0607	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	29	2 (7%)		2	1 (50%)	1 (50%)	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
LEUKORRHOEA	≤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
UTERINE HAEMORRHAGE	≤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
VAGINAL DISCOMFORT	≤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
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	191	105 (55%)	0.7532	164	77 (47%)	60 (37%)	21 (13%)	6 (4%)
	≤49 Days (Group 1)	29	18 (62%)		27	10 (37%)	14 (52%)	3 (11%)	0
	50-56 Days (Group 2)	73	39 (53%)		65	28 (43%)	26 (40%)	10 (15%)	1 (2%)
	57-63 Days (Group 3)	89	48 (54%)		72	39 (54%)	20 (28%)	8 (11%)	5 (7%)

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: DEAN (#27)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	191	103 (54%)	0.6419	147	71 (48%)	50 (34%)	20 (14%)	6 (4%)
	≤49 Days (Group 1)	29	18 (62%)		23	8 (35%)	12 (52%)	3 (13%)	0
	50-56 Days (Group 2)	73	38 (52%)		58	27 (47%)	21 (36%)	9 (16%)	1 (2%)
	57-63 Days (Group 3)	89	47 (53%)		66	36 (55%)	17 (26%)	8 (12%)	5 (8%)
ASTHENIA	≤63 Days (All)	191	4 (2%)	0.8085	4	1 (25%)	3 (75%)	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	3 (3%)		3	1 (33%)	2 (67%)	0	0
BACK PAIN	≤63 Days (All)	191	8 (4%)	0.0551	9	4 (44%)	4 (44%)	1 (11%)	0
	≤49 Days (Group 1)	29	3 (10%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	73	4 (5%)		5	1 (20%)	3 (60%)	1 (20%)	0
	57-63 Days (Group 3)	89	1 (1%)		1	1 (100%)	0	0	0
FATIGUE	≤63 Days (All)	191	3 (2%)	0.5453	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	29	1 (3%)		1	0	1 (100%)	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
FEVER	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: CREININ (#28)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	115	94 (82%)	0.4921	216	110 (51%)	68 (31%)	38 (18%)	0
	≤49 Days (Group 1)	23	19 (83%)		46	24 (52%)	16 (35%)	6 (13%)	0
	50-56 Days (Group 2)	50	43 (86%)		97	42 (43%)	34 (35%)	21 (22%)	0
	57-63 Days (Group 3)	42	32 (76%)		73	44 (60%)	18 (25%)	11 (15%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤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	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
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	21 (18%)	0.7389	25	15 (60%)	7 (28%)	3 (12%)	0
	≤49 Days (Group 1)	23	3 (13%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	50	9 (18%)		12	5 (42%)	5 (42%)	2 (17%)	0
	57-63 Days (Group 3)	42	9 (21%)		10	7 (70%)	2 (20%)	1 (10%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: CREININ (#28)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
DIZZINESS	≤63 Days (All)	115	7 (6%)	1.0000	7	6 (86%)	1 (14%)	0	0
	≤49 Days (Group 1)	23	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	50	3 (6%)		3	3 (100%)	0	0	0
	57-63 Days (Group 3)	42	3 (7%)		3	2 (67%)	1 (33%)	0	0
HEADACHE	≤63 Days (All)	115	15 (13%)	0.8756	18	9 (50%)	6 (33%)	3 (17%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	50	7 (14%)		9	2 (22%)	5 (56%)	2 (22%)	0
	57-63 Days (Group 3)	42	6 (14%)		7	5 (71%)	1 (14%)	1 (14%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	115	49 (43%)	0.6670	72	31 (43%)	25 (35%)	16 (22%)	0
	≤49 Days (Group 1)	23	11 (48%)		19	7 (37%)	8 (42%)	4 (21%)	0
	50-56 Days (Group 2)	50	19 (38%)		28	11 (39%)	8 (29%)	9 (32%)	0
	57-63 Days (Group 3)	42	19 (45%)		25	13 (52%)	9 (36%)	3 (12%)	0
CONSTIPATION	≤63 Days (All)	115	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	1 (2%)		1	1 (100%)	0	0	0
DIARRHEA	≤63 Days (All)	115	7 (6%)	0.3142	10	6 (60%)	3 (30%)	1 (10%)	0
	≤49 Days (Group 1)	23	3 (13%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	50	2 (4%)		4	2 (50%)	1 (25%)	1 (25%)	0
	57-63 Days (Group 3)	42	2 (5%)		2	1 (50%)	1 (50%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: CREININ (#28)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS	(cont.)								
DYSPEPSIA	≤63 Days (All)	115	2 (2%)	0.1699	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50-56 Days (Group 2)	50	0		0	0	0	0	0
	57-63 Days (Group 3)	42	2 (5%)		2	2 (100%)	0	0	0
NAUSEA	≤63 Days (All)	115	30 (26%)	0.7897	39	13 (33%)	15 (38%)	11 (28%)	0
	≤49 Days (Group 1)	23	7 (30%)		12	3 (25%)	6 (50%)	3 (25%)	0
	50-56 Days (Group 2)	50	12 (24%)		14	4 (29%)	4 (29%)	6 (43%)	0
	57-63 Days (Group 3)	42	11 (26%)		13	6 (46%)	5 (38%)	2 (15%)	0
VOMITING	≤63 Days (All)	115	17 (15%)	0.7018	19	8 (42%)	7 (37%)	4 (21%)	0
	≤49 Days (Group 1)	23	2 (9%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	50	8 (16%)		9	4 (44%)	3 (33%)	2 (22%)	0
	57-63 Days (Group 3)	42	7 (17%)		7	3 (43%)	3 (43%)	1 (14%)	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤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
UTERINE HAEMORRHAGE	≤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

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: CREININ (#28)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	115	85 (74%)	0.4191	117	64 (55%)	35 (30%)	18 (15%)	0
	≤49 Days (Group 1)	23	16 (70%)		24	14 (58%)	8 (33%)	2 (8%)	0
	50-56 Days (Group 2)	50	40 (80%)		55	26 (47%)	20 (36%)	9 (16%)	0
	57-63 Days (Group 3)	42	29 (69%)		38	24 (63%)	7 (18%)	7 (18%)	0
ABDOMINAL PAIN	≤63 Days (All)	115	83 (72%)	0.4705	102	57 (56%)	29 (28%)	16 (16%)	0
	≤49 Days (Group 1)	23	16 (70%)		19	10 (53%)	7 (37%)	2 (11%)	0
	50-56 Days (Group 2)	50	39 (78%)		47	24 (51%)	15 (32%)	8 (17%)	0
	57-63 Days (Group 3)	42	28 (67%)		36	23 (64%)	7 (19%)	6 (17%)	0
BACK PAIN	≤63 Days (All)	115	9 (8%)	0.6621	9	4 (44%)	3 (33%)	2 (22%)	0
	≤49 Days (Group 1)	23	2 (9%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	50	5 (10%)		5	1 (20%)	3 (60%)	1 (20%)	0
	57-63 Days (Group 3)	42	2 (5%)		2	1 (50%)	0	1 (50%)	0
FATIGUE	≤63 Days (All)	115	3 (3%)	0.1479	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	23	2 (9%)		2	2 (100%)	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
LEG PAIN	≤63 Days (All)	115	2 (2%)	0.4928	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	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: CREININ (#28)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	115	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	23	0		0	0	0	0	0
	50 56 Days (Group 2)	50	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	42	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SOGOR (#29)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	83	55 (66%)	0.9552	107	28 (26%)	50 (47%)	28 (26%)	1 (<1%)
	≤49 Days (Group 1)	28	18 (64%)		35	10 (29%)	18 (51%)	6 (17%)	1 (3%)
	50-56 Days (Group 2)	37	25 (68%)		42	10 (24%)	16 (38%)	16 (38%)	0
	57-63 Days (Group 3)	18	12 (67%)		30	8 (27%)	16 (53%)	6 (20%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	9 (11%)	1.0000	9	3 (33%)	4 (44%)	2 (22%)	0
	≤49 Days (Group 1)	28	3 (11%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	37	4 (11%)		4	2 (50%)	1 (25%)	1 (25%)	0
	57-63 Days (Group 3)	18	2 (11%)		2	0	1 (50%)	1 (50%)	0
DIZZINESS	≤63 Days (All)	83	5 (6%)	0.7091	5	2 (40%)	2 (40%)	1 (20%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	37	3 (8%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	83	3 (4%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0
MIGRAINE	≤63 Days (All)	83	1 (1%)	0.2169	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	0	1 (100%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SOGOR (#29)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	83	30 (36%)	0.8737	48	11 (23%)	22 (46%)	15 (31%)	0
	≤49 Days (Group 1)	28	9 (32%)		13	3 (23%)	7 (54%)	3 (23%)	0
	50-56 Days (Group 2)	37	14 (38%)		20	3 (15%)	8 (40%)	9 (45%)	0
	57-63 Days (Group 3)	18	7 (39%)		15	5 (33%)	7 (47%)	3 (20%)	0
DIARRHEA	≤63 Days (All)	83	3 (4%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	1 (100%)	0	0	0
NAUSEA	≤63 Days (All)	83	24 (29%)	0.9503	28	8 (29%)	13 (46%)	7 (25%)	0
	≤49 Days (Group 1)	28	9 (32%)		10	3 (30%)	5 (50%)	2 (20%)	0
	50-56 Days (Group 2)	37	10 (27%)		11	3 (27%)	4 (36%)	4 (36%)	0
	57-63 Days (Group 3)	18	5 (28%)		7	2 (29%)	4 (57%)	1 (14%)	0
VOMITING	≤63 Days (All)	83	14 (17%)	0.2069	17	2 (12%)	7 (41%)	8 (47%)	0
	≤49 Days (Group 1)	28	2 (7%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	37	8 (22%)		8	0	3 (38%)	5 (63%)	0
	57-63 Days (Group 3)	18	4 (22%)		7	2 (29%)	3 (43%)	2 (29%)	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SOGOR (#29)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
HEART RATE AND RHYTHM DISORDERS	(cont.)								
TACHYCARDIA	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	83	42 (51%)	0.7469	49	14 (29%)	23 (47%)	11 (22%)	1 (2%)
	≤49 Days (Group 1)	28	15 (54%)		18	6 (33%)	8 (44%)	3 (17%)	1 (6%)
	50-56 Days (Group 2)	37	17 (46%)		18	5 (28%)	7 (39%)	6 (33%)	0
	57-63 Days (Group 3)	18	10 (56%)		13	3 (23%)	8 (62%)	2 (15%)	0
ABDOMINAL PAIN	≤63 Days (All)	83	42 (51%)	0.7469	46	14 (30%)	20 (43%)	11 (24%)	1 (2%)
	≤49 Days (Group 1)	28	15 (54%)		17	6 (35%)	7 (41%)	3 (18%)	1 (6%)
	50-56 Days (Group 2)	37	17 (46%)		18	5 (28%)	7 (39%)	6 (33%)	0
	57-63 Days (Group 3)	18	10 (56%)		11	3 (27%)	6 (55%)	2 (18%)	0
BACK PAIN	≤63 Days (All)	83	1 (1%)	0.2169	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0
CHEST PAIN	≤63 Days (All)	83	1 (1%)	0.2169	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	0		0	0	0	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	1 (6%)		1	0	1 (100%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

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

Center: SOGOR (#29)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FEVER	≤63 Days (All)	83	1 (1%)	0.5542	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	37	0		0	0	0	0	0
	57-63 Days (Group 3)	18	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Source Data: Appendix A.1, Table 25

Appendix D, Table 5c
Adverse Events Possibly or Probably Related to Misoprostol [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	61 (86%)	0.5665	213	76 (36%)	109 (51%)	28 (13%)	0
	≤49 Days (Group 1)	28	24 (86%)		64	24 (38%)	38 (59%)	2 (3%)	0
	50-56 Days (Group 2)	26	21 (81%)		73	22 (30%)	34 (47%)	17 (23%)	0
	57-63 Days (Group 3)	17	16 (94%)		76	30 (39%)	37 (49%)	9 (12%)	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	14 (20%)	0.3532	21	7 (33%)	11 (52%)	3 (14%)	0
	≤49 Days (Group 1)	28	6 (21%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	26	3 (12%)		4	0	2 (50%)	2 (50%)	0
	57-63 Days (Group 3)	17	5 (29%)		11	5 (45%)	5 (45%)	1 (9%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: POINDEXTER (#21)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
CENTR & PERIPH NERVOUS SYSTEM DISORDERS(cont.)									
HEADACHE	≤63 Days (All)	71	14 (20%)	0.3532	20	7 (35%)	10 (50%)	3 (15%)	0
	≤49 Days (Group 1)	28	6 (21%)		6	2 (33%)	4 (67%)	0	0
	50-56 Days (Group 2)	26	3 (12%)		4	0	2 (50%)	2 (50%)	0
	57-63 Days (Group 3)	17	5 (29%)		10	5 (50%)	4 (40%)	1 (10%)	0
MIGRAINE	≤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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	71	35 (49%)	0.7211	66	23 (35%)	31 (47%)	12 (18%)	0
	≤49 Days (Group 1)	28	12 (43%)		14	6 (43%)	7 (50%)	1 (7%)	0
	50-56 Days (Group 2)	26	14 (54%)		28	7 (25%)	13 (46%)	8 (29%)	0
	57-63 Days (Group 3)	17	9 (53%)		24	10 (42%)	11 (46%)	3 (13%)	0
ABDOMINAL PAIN (STOMACH AND INTESTINAL)	≤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

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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.)								
DIARRHEA	≤63 Days (All)	71	6 (8%)	0.5594	6	3 (50%)	3 (50%)	0	0
	≤49 Days (Group 1)	28	1 (4%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	26	3 (12%)		3	1 (33%)	2 (67%)	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
NAUSEA	≤63 Days (All)	71	27 (38%)	0.7787	34	11 (32%)	15 (44%)	8 (24%)	0
	≤49 Days (Group 1)	28	9 (32%)		9	3 (33%)	5 (56%)	1 (11%)	0
	50-56 Days (Group 2)	26	11 (42%)		14	4 (29%)	5 (36%)	5 (36%)	0
	57-63 Days (Group 3)	17	7 (41%)		11	4 (36%)	5 (45%)	2 (18%)	0
VOMITING	≤63 Days (All)	71	16 (23%)	0.1143	23	7 (30%)	13 (57%)	3 (13%)	0
	≤49 Days (Group 1)	28	3 (11%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	26	7 (27%)		10	2 (20%)	6 (60%)	2 (20%)	0
	57-63 Days (Group 3)	17	6 (35%)		10	4 (40%)	5 (50%)	1 (10%)	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 nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Source Data: Appendix A.1, Tables 16 and 25

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

Center: 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	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
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 nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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									
ANY EVENT	≤63 Days (All)	71	59 (83%)	0.6130	122	46 (38%)	64 (52%)	12 (10%)	0
	≤49 Days (Group 1)	28	24 (86%)		42	16 (38%)	25 (60%)	1 (2%)	0
	50-56 Days (Group 2)	26	20 (77%)		40	15 (38%)	19 (48%)	6 (15%)	0
	57-63 Days (Group 3)	17	15 (88%)		40	15 (38%)	20 (50%)	5 (13%)	0
ABDOMINAL PAIN	≤63 Days (All)	71	59 (83%)	0.6130	115	42 (37%)	63 (55%)	10 (9%)	0
	≤49 Days (Group 1)	28	24 (86%)		39	14 (36%)	24 (62%)	1 (3%)	0
	50-56 Days (Group 2)	26	20 (77%)		38	14 (37%)	19 (50%)	5 (13%)	0
	57-63 Days (Group 3)	17	15 (88%)		38	14 (37%)	20 (53%)	4 (11%)	0
ASTHENIA	≤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
BACK PAIN	≤63 Days (All)	71	5 (7%)	0.8396	5	3 (60%)	1 (20%)	1 (20%)	0
	≤49 Days (Group 1)	28	3 (11%)		3	2 (67%)	1 (33%)	0	0
	50-56 Days (Group 2)	26	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	17	1 (6%)		1	0	0	1 (100%)	0
RIGORS	≤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 nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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
ANY EVENT	≤63 Days (All)	151	137 (91%)	0.1814	513	162 (32%)	201 (39%)	150 (29%)	0
	≤49 Days (Group 1)	70	60 (86%)		187	59 (32%)	82 (44%)	46 (25%)	0
	50-56 Days (Group 2)	43	41 (95%)		174	58 (33%)	64 (37%)	52 (30%)	0
	57-63 Days (Group 3)	38	36 (95%)		152	45 (30%)	55 (36%)	52 (34%)	0
SKIN AND APPENDAGES 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
RASH	≤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
MUSCULO-SKELETAL SYSTEM 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 nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: VARGAS (#22)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
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	29 (19%)	0.0650	37	9 (24%)	25 (68%)	3 (8%)	0
	≤49 Days (Group 1)	70	8 (11%)		11	2 (18%)	8 (73%)	1 (9%)	0
	50-56 Days (Group 2)	43	11 (26%)		13	6 (46%)	7 (54%)	0	0
	57-63 Days (Group 3)	38	10 (26%)		13	1 (8%)	10 (77%)	2 (15%)	0
DIZZINESS	≤63 Days (All)	151	11 (7%)	0.8507	13	4 (31%)	9 (69%)	0	0
	≤49 Days (Group 1)	70	5 (7%)		7	2 (29%)	5 (71%)	0	0
	50-56 Days (Group 2)	43	4 (9%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	38	2 (5%)		2	0	2 (100%)	0	0
HEADACHE	≤63 Days (All)	151	20 (13%)	0.0182	24	5 (21%)	16 (67%)	3 (13%)	0
	≤49 Days (Group 1)	70	4 (6%)		4	0	3 (75%)	1 (25%)	0
	50-56 Days (Group 2)	43	7 (16%)		9	4 (44%)	5 (56%)	0	0
	57-63 Days (Group 3)	38	9 (24%)		11	1 (9%)	8 (73%)	2 (18%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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
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
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	151	99 (66%)	0.0669	211	93 (44%)	76 (36%)	42 (20%)	0
	≤49 Days (Group 1)	70	39 (56%)		76	31 (41%)	33 (43%)	12 (16%)	0
	50-56 Days (Group 2)	43	32 (74%)		72	33 (46%)	23 (32%)	16 (22%)	0
	57-63 Days (Group 3)	38	28 (74%)		63	29 (46%)	20 (32%)	14 (22%)	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

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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.)									
DIARRHEA*	≤63 Days (All)	151	47 (31%)	0.2075	65	33 (51%)	23 (35%)	9 (14%)	0
	≤49 Days (Group 1)	70	17 (24%)		23	11 (48%)	9 (39%)	3 (13%)	0
	50-56 Days (Group 2)	43	17 (40%)		22	10 (45%)	9 (41%)	3 (14%)	0
	57-63 Days (Group 3)	38	13 (34%)		20	12 (60%)	5 (25%)	3 (15%)	0
NAUSEA	≤63 Days (All)	151	80 (53%)	0.2462	95	44 (46%)	33 (35%)	18 (19%)	0
	≤49 Days (Group 1)	70	32 (46%)		36	16 (44%)	15 (42%)	5 (14%)	0
	50-56 Days (Group 2)	43	26 (60%)		32	16 (50%)	10 (31%)	6 (19%)	0
	57-63 Days (Group 3)	38	22 (58%)		27	12 (44%)	8 (30%)	7 (26%)	0
VOMITING	≤63 Days (All)	151	43 (28%)	0.1960	50	16 (32%)	19 (38%)	15 (30%)	0
	≤49 Days (Group 1)	70	15 (21%)		17	4 (24%)	9 (53%)	4 (24%)	0
	50-56 Days (Group 2)	43	15 (35%)		17	7 (41%)	3 (18%)	7 (41%)	0
	57-63 Days (Group 3)	38	13 (34%)		16	5 (31%)	7 (44%)	4 (25%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤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 nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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.)									
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
URINARY SYSTEM 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
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
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	151	7 (5%)	1.0000	7	1 (14%)	2 (29%)	4 (57%)	0
	≤49 Days (Group 1)	70	3 (4%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	43	2 (5%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	38	2 (5%)		2	0	0	2 (100%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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.)								
LEUKORRHOEA	≤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
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
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	137 (91%)	0.1814	253	55 (22%)	97 (38%)	101 (40%)	0
	≤49 Days (Group 1)	70	60 (86%)		97	25 (26%)	40 (41%)	32 (33%)	0
	50-56 Days (Group 2)	43	41 (95%)		84	16 (19%)	33 (39%)	35 (42%)	0
	57-63 Days (Group 3)	38	36 (95%)		72	14 (19%)	24 (33%)	34 (47%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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.)									
ABDOMINAL PAIN	≤63 Days (All)	151	137 (91%)	0.1814	236	47 (20%)	88 (37%)	101 (43%)	0
	≤49 Days (Group 1)	70	60 (86%)		94	24 (26%)	38 (40%)	32 (34%)	0
	50-56 Days (Group 2)	43	41 (95%)		74	11 (15%)	28 (38%)	35 (47%)	0
	57-63 Days (Group 3)	38	36 (95%)		68	12 (18%)	22 (32%)	34 (50%)	0
BACK PAIN	≤63 Days (All)	151	6 (4%)	0.5591	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	70	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	43	3 (7%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	38	1 (3%)		1	0	1 (100%)	0	0
FATIGUE	≤63 Days (All)	151	2 (1%)	0.1418	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	70	0		0	0	0	0	0
	50-56 Days (Group 2)	43	2 (5%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0
FEVER	≤63 Days (All)	151	2 (1%)	0.2861	2	2 (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	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

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: 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.)									
RIGORS	≤63 Days (All)	151	3 (2%)	0.1517	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	70	0		0	0	0	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
SYNCOPE	≤63 Days (All)	151	2 (1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	70	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	43	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	38	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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

Center: [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	88 (99%)	1.0000	505	165 (33%)	204 (40%)	135 (27%)	1 (<1%)
	≤49 Days (Group 1)	35	34 (97%)		175	59 (34%)	66 (38%)	49 (28%)	1 (<1%)
	50-56 Days (Group 2)	34	34 (100%)		210	67 (32%)	91 (43%)	52 (25%)	0
	57-63 Days (Group 3)	20	20 (100%)		120	39 (33%)	47 (39%)	34 (28%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤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
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
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤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 nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

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