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

Center: MISHELL (#1)

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)	204	103 (50%)	0.8503	109	46 (42%)	51 (47%)	12 (11%)	0
	≤49 Days (Group 1)	145	72 (50%)		77	34 (44%)	35 (45%)	8 (10%)	0
	50-56 Days (Group 2)	40	22 (55%)		22	8 (36%)	12 (55%)	2 (9%)	0
	57-63 Days (Group 3)	19	9 (47%)		10	4 (40%)	4 (40%)	2 (20%)	0
ASTHENIA	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
BACK PAIN	≤63 Days (All)	204	6 (3%)	0.3678	6	4 (67%)	2 (33%)	0	0
	≤49 Days (Group 1)	145	5 (3%)		5	3 (60%)	2 (40%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
CHEST PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	204	4 (2%)	0.7159	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	145	4 (3%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MISHELL (#1)

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.)									
MALAISE	≤63 Days (All)	204	1 (<1%)	0.0931	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
RIGORS	≤63 Days (All)	204	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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)	238	201 (84%)	0.8111	553	260 (47%)	214 (39%)	79 (14%)	0
	≤49 Days (Group 1)	81	67 (83%)		177	81 (46%)	66 (37%)	30 (17%)	0
	50-56 Days (Group 2)	89	75 (84%)		201	104 (52%)	72 (36%)	25 (12%)	0
	57-63 Days (Group 3)	68	59 (87%)		175	75 (43%)	76 (43%)	24 (14%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	238	4 (2%)	0.8345	4	0	2 (50%)	2 (50%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
SWEATING INCREASED	≤63 Days (All)	238	4 (2%)	0.8345	4	0	2 (50%)	2 (50%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.0808	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
ARTHRALGIA	≤63 Days (All)	238	2 (<1%)	0.0808	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	41 (17%)	0.3182	55	22 (40%)	26 (47%)	7 (13%)	0
	≤49 Days (Group 1)	81	18 (22%)		23	7 (30%)	13 (57%)	3 (13%)	0
	50-56 Days (Group 2)	89	12 (13%)		15	7 (47%)	5 (33%)	3 (20%)	0
	57-63 Days (Group 3)	68	11 (16%)		17	8 (47%)	8 (47%)	1 (6%)	0
DIZZINESS	≤63 Days (All)	238	13 (5%)	0.0515	15	4 (27%)	8 (53%)	3 (20%)	0
	≤49 Days (Group 1)	81	7 (9%)		7	2 (29%)	3 (43%)	2 (29%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	5 (7%)		7	2 (29%)	5 (71%)	0	0
HEADACHE	≤63 Days (All)	238	32 (13%)	0.6228	38	17 (45%)	17 (45%)	4 (11%)	0
	≤49 Days (Group 1)	81	13 (16%)		16	5 (31%)	10 (63%)	1 (6%)	0
	50-56 Days (Group 2)	89	10 (11%)		12	6 (50%)	4 (33%)	2 (17%)	0
	57-63 Days (Group 3)	68	9 (13%)		10	6 (60%)	3 (30%)	1 (10%)	0
HYPERTONIA	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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.)									
TREMOR	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TINNITUS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
SPECIAL SENSES OTHER, DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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
SPECIAL SENSES OTHER, DISORDERS	**(cont.)**								
TASTE PERVERSION	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	238	9 (4%)	0.2917	10	3 (30%)	4 (40%)	3 (30%)	0
	≤49 Days (Group 1)	81	1 (1%)		2	0	0	2 (100%)	0
	50-56 Days (Group 2)	89	4 (4%)		4	1 (25%)	3 (75%)	0	0
	57-63 Days (Group 3)	68	4 (6%)		4	2 (50%)	1 (25%)	1 (25%)	0
ANXIETY	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
APPETITE INCREASED	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	4 (2%)	0.6841	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	2 (3%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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.)**								
HALLUCINATION	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
INSOMNIA	≤63 Days (All)	238	3 (1%)	1.0000	3	0	1 (33%)	2 (67%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	120 (50%)	0.0699	201	77 (38%)	91 (45%)	33 (16%)	0
	≤49 Days (Group 1)	81	33 (41%)		44	15 (34%)	20 (45%)	9 (20%)	0
	50-56 Days (Group 2)	89	52 (58%)		95	43 (45%)	40 (42%)	12 (13%)	0
	57-63 Days (Group 3)	68	35 (51%)		62	19 (31%)	31 (50%)	12 (19%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	4 (2%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	2 (2%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
DIARRHEA	≤63 Days (All)	238	7 (3%)	0.6314	7	3 (43%)	4 (57%)	0	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	89	4 (4%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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)	238	7 (3%)	0.6314	9	3 (33%)	5 (56%)	1 (11%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	89	4 (4%)		6	2 (33%)	3 (50%)	1 (17%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
FLATULENCE	≤63 Days (All)	238	3 (1%)	0.6361	3	0	2 (67%)	1 (33%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMATEMESIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	238	99 (42%)	0.0271	119	49 (41%)	49 (41%)	21 (18%)	0
	≤49 Days (Group 1)	81	24 (30%)		26	11 (42%)	10 (38%)	5 (19%)	0
	50-56 Days (Group 2)	89	43 (48%)		55	25 (45%)	22 (40%)	8 (15%)	0
	57-63 Days (Group 3)	68	32 (47%)		38	13 (34%)	17 (45%)	8 (21%)	0
VOMITING	≤63 Days (All)	238	47 (20%)	0.0980	58	20 (34%)	29 (50%)	9 (16%)	0
	≤49 Days (Group 1)	81	10 (12%)		11	2 (18%)	7 (64%)	2 (18%)	0
	50-56 Days (Group 2)	89	20 (22%)		26	12 (46%)	11 (42%)	3 (12%)	0
	57-63 Days (Group 3)	68	17 (25%)		21	6 (29%)	11 (52%)	4 (19%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.3861	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
DEHYDRATION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
THIRST	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
WEIGHT DECREASE	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.7790	4	3 (75%)	0	1 (25%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	238	1 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMOPTYSIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PULMONARY CONGESTION	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PLATELET, BLEEDING & CLOTTING DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
EPISTAXIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	238	13 (5%)	0.7221	14	3 (21%)	6 (43%)	5 (36%)	0
	≤49 Days (Group 1)	81	3 (4%)		4	0	2 (50%)	2 (50%)	0
	50-56 Days (Group 2)	89	6 (7%)		6	2 (33%)	2 (33%)	2 (33%)	0
	57-63 Days (Group 3)	68	4 (6%)		4	1 (25%)	2 (50%)	1 (25%)	0
LEUKORRHOEA	≤63 Days (All)	238	2 (<1%)	0.3345	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MENSTRUAL DISORDER	≤63 Days (All)	238	1 (<1%)	0.2857	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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.)								
OVARIAN DISORDER	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PREMENSTRUAL TENSION	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	238	8 (3%)	1.0000	9	0	4 (44%)	5 (56%)	0
	≤49 Days (Group 1)	81	3 (4%)		4	0	2 (50%)	2 (50%)	0
	50-56 Days (Group 2)	89	3 (3%)		3	0	1 (33%)	2 (67%)	0
	57-63 Days (Group 3)	68	2 (3%)		2	0	1 (50%)	1 (50%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	164 (69%)	0.0906	255	147 (58%)	82 (32%)	26 (10%)	0
	≤49 Days (Group 1)	81	58 (72%)		97	56 (58%)	29 (30%)	12 (12%)	0
	50-56 Days (Group 2)	89	54 (61%)		74	47 (64%)	21 (28%)	6 (8%)	0
	57-63 Days (Group 3)	68	52 (76%)		84	44 (52%)	32 (38%)	8 (10%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	158 (66%)	0.0910	226	131 (58%)	73 (32%)	22 (10%)	0
	≤49 Days (Group 1)	81	55 (68%)		85	47 (55%)	28 (33%)	10 (12%)	0
	50-56 Days (Group 2)	89	52 (58%)		66	43 (65%)	18 (27%)	5 (8%)	0
	57-63 Days (Group 3)	68	51 (75%)		75	41 (55%)	27 (36%)	7 (9%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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)	238	2 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
BACK PAIN	≤63 Days (All)	238	6 (3%)	0.7724	7	4 (57%)	2 (29%)	1 (14%)	0
	≤49 Days (Group 1)	81	3 (4%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
CHEST PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
FATIGUE	≤63 Days (All)	238	11 (5%)	0.8614	11	6 (55%)	4 (36%)	1 (9%)	0
	≤49 Days (Group 1)	81	3 (4%)		3	2 (67%)	0	1 (33%)	0
	50-56 Days (Group 2)	89	4 (4%)		4	3 (75%)	1 (25%)	0	0
	57-63 Days (Group 3)	68	4 (6%)		4	1 (25%)	3 (75%)	0	0
FEVER	≤63 Days (All)	238	2 (<1%)	0.5298	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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.)								
HOT FLUSHES	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
MALAISE	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
PAIN	≤63 Days (All)	238	1 (<1%)	0.6261	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RIGORS	≤63 Days (All)	238	2 (<1%)	0.7444	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
SYNCOPE	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: HASKELL (#2)

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									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	238	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: POPPEMA (#3)

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)	164	141 (86%)	0.9576	313	130 (42%)	119 (38%)	63 (20%)	1 (<1%)
	≤49 Days (Group 1)	65	56 (86%)		113	43 (38%)	48 (42%)	22 (19%)	0
	50-56 Days (Group 2)	65	55 (85%)		110	47 (43%)	41 (37%)	22 (20%)	0
	57-63 Days (Group 3)	34	30 (88%)		90	40 (44%)	30 (33%)	19 (21%)	1 (1%)
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
RASH MACULO-PAPULAR	≤63 Days (All)	164	1 (<1%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: POPPEMA (#3)

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)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	27 (16%)	0.2776	31	11 (35%)	13 (42%)	6 (19%)	1 (3%)
	≤49 Days (Group 1)	65	13 (20%)		13	6 (46%)	6 (46%)	1 (8%)	0
	50-56 Days (Group 2)	65	7 (11%)		8	3 (38%)	3 (38%)	2 (25%)	0
	57-63 Days (Group 3)	34	7 (21%)		10	2 (20%)	4 (40%)	3 (30%)	1 (10%)
DIZZINESS	≤63 Days (All)	164	3 (2%)	0.1093	3	0	1 (33%)	2 (67%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	1 (50%)	1 (50%)	0
HEADACHE	≤63 Days (All)	164	25 (15%)	0.4245	28	11 (39%)	12 (43%)	4 (14%)	1 (4%)
	≤49 Days (Group 1)	65	12 (18%)		12	6 (50%)	6 (50%)	0	0
	50-56 Days (Group 2)	65	7 (11%)		8	3 (38%)	3 (38%)	2 (25%)	0
	57-63 Days (Group 3)	34	6 (18%)		8	2 (25%)	3 (38%)	2 (25%)	1 (13%)
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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: POPPEMA (#3)

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.)								
ANXIETY	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	91 (55%)	0.1284	141	42 (30%)	62 (44%)	37 (26%)	0
	≤49 Days (Group 1)	65	33 (51%)		48	11 (23%)	25 (52%)	12 (25%)	0
	50-56 Days (Group 2)	65	34 (52%)		51	14 (27%)	24 (47%)	13 (25%)	0
	57-63 Days (Group 3)	34	24 (71%)		42	17 (40%)	13 (31%)	12 (29%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	4 (2%)	0.1553	5	3 (60%)	2 (40%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	2 (100%)	0	0	0
DIARRHEA	≤63 Days (All)	164	8 (5%)	0.7176	8	4 (50%)	3 (38%)	1 (13%)	0
	≤49 Days (Group 1)	65	4 (6%)		4	1 (25%)	2 (50%)	1 (25%)	0
	50-56 Days (Group 2)	65	2 (3%)		2	2 (100%)	0	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	1 (50%)	1 (50%)	0	0
DYSPEPSIA	≤63 Days (All)	164	4 (2%)	1.0000	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: POPPEMA (#3)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
FLATULENCE	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	164	79 (48%)	0.1305	94	28 (30%)	40 (43%)	26 (28%)	0
	≤49 Days (Group 1)	65	26 (40%)		30	8 (27%)	14 (47%)	8 (27%)	0
	50-56 Days (Group 2)	65	32 (49%)		36	10 (28%)	17 (47%)	9 (25%)	0
	57-63 Days (Group 3)	34	21 (62%)		28	10 (36%)	9 (32%)	9 (32%)	0
VOMITING	≤63 Days (All)	164	27 (16%)	0.4649	29	5 (17%)	14 (48%)	10 (34%)	0
	≤49 Days (Group 1)	65	9 (14%)		9	0	6 (67%)	3 (33%)	0
	50-56 Days (Group 2)	65	10 (15%)		11	1 (9%)	6 (55%)	4 (36%)	0
	57-63 Days (Group 3)	34	8 (24%)		9	4 (44%)	2 (22%)	3 (33%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
THIRST	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: POPPEMA (#3)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
ANAEMIA	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	104 (63%)	0.0948	135	76 (56%)	39 (29%)	20 (15%)	0
	≤49 Days (Group 1)	65	38 (58%)		52	26 (50%)	17 (33%)	9 (17%)	0
	50-56 Days (Group 2)	65	39 (60%)		48	29 (60%)	12 (25%)	7 (15%)	0
	57-63 Days (Group 3)	34	27 (79%)		35	21 (60%)	10 (29%)	4 (11%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	100 (61%)	0.1232	120	72 (60%)	34 (28%)	14 (12%)	0
	≤49 Days (Group 1)	65	37 (57%)		48	25 (52%)	16 (33%)	7 (15%)	0
	50-56 Days (Group 2)	65	37 (57%)		42	27 (64%)	10 (24%)	5 (12%)	0
	57-63 Days (Group 3)	34	26 (76%)		30	20 (67%)	8 (27%)	2 (7%)	0
ASTHENIA	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: POPPEMA (#3)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	164	3 (2%)	0.4263	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
FATIGUE	≤63 Days (All)	164	5 (3%)	1.0000	6	0	2 (33%)	4 (67%)	0
	≤49 Days (Group 1)	65	2 (3%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	65	2 (3%)		2	0	0	2 (100%)	0
	57-63 Days (Group 3)	34	1 (3%)		2	0	1 (50%)	1 (50%)	0
LEG PAIN	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
PAIN	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
RIGORS	≤63 Days (All)	164	3 (2%)	0.4263	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: TYSON (#4)

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)	102	82 (80%)	0.5284	169	80 (47%)	67 (40%)	22 (13%)	0
	≤49 Days (Group 1)	68	56 (82%)		120	61 (51%)	41 (34%)	18 (15%)	0
	50-56 Days (Group 2)	25	20 (80%)		42	18 (43%)	20 (48%)	4 (10%)	0
	57-63 Days (Group 3)	9	6 (67%)		7	1 (14%)	6 (86%)	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
MYALGIA	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	17 (17%)	0.5277	21	5 (24%)	13 (62%)	3 (14%)	0
	≤49 Days (Group 1)	68	13 (19%)		15	3 (20%)	9 (60%)	3 (20%)	0
	50-56 Days (Group 2)	25	4 (16%)		6	2 (33%)	4 (67%)	0	0
	57 63 Days (Group 3)	9	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: TYSON (#4)

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)	102	6 (6%)	0.3885	7	2 (29%)	4 (57%)	1 (14%)	0
	≤49 Days (Group 1)	68	3 (4%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	25	3 (12%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	102	13 (13%)	0.4070	13	3 (23%)	8 (62%)	2 (15%)	0
	≤49 Days (Group 1)	68	11 (16%)		11	3 (27%)	6 (55%)	2 (18%)	0
	50-56 Days (Group 2)	25	2 (8%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
TREMOR	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	102	5 (5%)	0.4397	5	2 (40%)	3 (60%)	0	0
	≤49 Days (Group 1)	68	5 (7%)		5	2 (40%)	3 (60%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: TYSON (#4)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
PSYCHIATRIC DISORDERS	(cont.)								
INSOMNIA	≤63 Days (All)	102	4 (4%)	0.7052	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	68	4 (6%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	35 (34%)	0.2754	47	22 (47%)	19 (40%)	6 (13%)	0
	≤49 Days (Group 1)	68	26 (38%)		33	18 (55%)	10 (30%)	5 (15%)	0
	50-56 Days (Group 2)	25	8 (32%)		13	4 (31%)	8 (62%)	1 (8%)	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
DIARRHEA	≤63 Days (All)	102	3 (3%)	0.6683	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	68	3 (4%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DYSPEPSIA	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	102	31 (30%)	0.0907	31	17 (55%)	10 (32%)	4 (13%)	0
	≤49 Days (Group 1)	68	24 (35%)		24	14 (58%)	6 (25%)	4 (17%)	0
	50-56 Days (Group 2)	25	7 (28%)		7	3 (43%)	4 (57%)	0	0
	57-63 Days (Group 3)	9	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: TYSON (#4)

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.)									
VOMITING	≤63 Days (All)	102	11 (11%)	0.1755	12	2 (17%)	9 (75%)	1 (8%)	0
	≤49 Days (Group 1)	68	5 (7%)		6	1 (17%)	4 (67%)	1 (17%)	0
	50-56 Days (Group 2)	25	5 (20%)		5	1 (20%)	4 (80%)	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	102	2 (2%)	1.0000	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: TYSON (#4)

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, FEMALE (cont.)									
UTERINE HAEMORRHAGE	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
VAGINAL DISCOMFORT	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	102	71 (70%)	0.7430	92	50 (54%)	31 (34%)	11 (12%)	0
	≤49 Days (Group 1)	68	46 (68%)		64	37 (58%)	19 (30%)	8 (13%)	0
	50-56 Days (Group 2)	25	19 (76%)		22	12 (55%)	7 (32%)	3 (14%)	0
	57-63 Days (Group 3)	9	6 (67%)		6	1 (17%)	5 (83%)	0	0
ABDOMINAL PAIN	≤63 Days (All)	102	71 (70%)	0.7430	82	46 (56%)	26 (32%)	10 (12%)	0
	≤49 Days (Group 1)	68	46 (68%)		54	33 (61%)	14 (26%)	7 (13%)	0
	50-56 Days (Group 2)	25	19 (76%)		22	12 (55%)	7 (32%)	3 (14%)	0
	57-63 Days (Group 3)	9	6 (67%)		6	1 (17%)	5 (83%)	0	0
ASTHENIA	≤63 Days (All)	102	2 (2%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: TYSON (#4)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	102	2 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	102	2 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	68	2 (3%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	102	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
RIGORS	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BLUMENTHAL (#5)

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)	44	38 (86%)	0.4418	89	33 (37%)	46 (52%)	10 (11%)	0
	≤49 Days (Group 1)	13	11 (85%)		30	10 (33%)	16 (53%)	4 (13%)	0
	50-56 Days (Group 2)	23	21 (91%)		48	16 (33%)	27 (56%)	5 (10%)	0
	57-63 Days (Group 3)	8	6 (75%)		11	7 (64%)	3 (27%)	1 (9%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	3 (7%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	23	2 (9%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
DIZZINESS	≤63 Days (All)	44	2 (5%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	44	1 (2%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	28 (64%)	0.7660	48	14 (29%)	28 (58%)	6 (13%)	0
	≤49 Days (Group 1)	13	9 (69%)		17	6 (35%)	9 (53%)	2 (12%)	0
	50-56 Days (Group 2)	23	15 (65%)		25	4 (16%)	18 (72%)	3 (12%)	0
	57-63 Days (Group 3)	8	4 (50%)		6	4 (67%)	1 (17%)	1 (17%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix A.1, Table 25

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FINAL

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

Center: BLUMENTHAL (#5)

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)	44	4 (9%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	23	2 (9%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	1 (100%)	0	0	0
FLATULENCE	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	44	22 (50%)	0.5197	27	10 (37%)	15 (56%)	2 (7%)	0
	≤49 Days (Group 1)	13	8 (62%)		12	5 (42%)	6 (50%)	1 (8%)	0
	50-56 Days (Group 2)	23	11 (48%)		12	3 (25%)	8 (67%)	1 (8%)	0
	57-63 Days (Group 3)	8	3 (38%)		3	2 (67%)	1 (33%)	0	0
VOMITING	≤63 Days (All)	44	12 (27%)	0.9042	16	3 (19%)	10 (63%)	3 (19%)	0
	≤49 Days (Group 1)	13	3 (23%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	23	7 (30%)		10	1 (10%)	7 (70%)	2 (20%)	0
	57-63 Days (Group 3)	8	2 (25%)		2	1 (50%)	0	1 (50%)	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BLUMENTHAL (#5)

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)	44	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	44	26 (59%)	0.9199	36	17 (47%)	16 (44%)	3 (8%)	0
	≤49 Days (Group 1)	13	7 (54%)		12	4 (33%)	7 (58%)	1 (8%)	0
	50-56 Days (Group 2)	23	14 (61%)		19	10 (53%)	7 (37%)	2 (11%)	0
	57-63 Days (Group 3)	8	5 (63%)		5	3 (60%)	2 (40%)	0	0
ABDOMINAL PAIN	≤63 Days (All)	44	24 (55%)	0.7166	30	15 (50%)	12 (40%)	3 (10%)	0
	≤49 Days (Group 1)	13	6 (46%)		8	4 (50%)	3 (38%)	1 (13%)	0
	50-56 Days (Group 2)	23	14 (61%)		18	9 (50%)	7 (39%)	2 (11%)	0
	57-63 Days (Group 3)	8	4 (50%)		4	2 (50%)	2 (50%)	0	0
FATIGUE	≤63 Days (All)	44	3 (7%)	0.4182	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	13	2 (15%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	44	1 (2%)	0.1818	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BLUMENTHAL (#5)

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.)									
MALAISE	≤63 Days (All)	44	1 (2%)	0.4773	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	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] NOS - Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

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)	64	49 (77%)	0.4049	133	50 (38%)	58 (44%)	25 (19%)	0
	≤49 Days (Group 1)	36	27 (75%)		67	23 (34%)	27 (40%)	17 (25%)	0
	50-56 Days (Group 2)	16	11 (69%)		35	19 (54%)	9 (26%)	7 (20%)	0
	57-63 Days (Group 3)	12	11 (92%)		31	8 (26%)	22 (71%)	1 (3%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RASH	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
MUSCULO-SKELETAL SYSTEM DISORDERS (cont.)									
ARTHRALGIA	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	14 (22%)	0.0501	18	8 (44%)	7 (39%)	3 (17%)	0
	≤49 Days (Group 1)	36	4 (11%)		4	1 (25%)	2 (50%)	1 (25%)	0
	50-56 Days (Group 2)	16	6 (38%)		9	5 (56%)	2 (22%)	2 (22%)	0
	57-63 Days (Group 3)	12	4 (33%)		5	2 (40%)	3 (60%)	0	0
DIZZINESS	≤63 Days (All)	64	2 (3%)	0.4018	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	64	11 (17%)	0.0107	15	6 (40%)	6 (40%)	3 (20%)	0
	≤49 Days (Group 1)	36	2 (6%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	16	6 (38%)		9	5 (56%)	2 (22%)	2 (22%)	0
	57-63 Days (Group 3)	12	3 (25%)		4	1 (25%)	3 (75%)	0	0
TREMOR	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

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									
ANY EVENT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	27 (42%)	1.0000	44	12 (27%)	19 (43%)	13 (30%)	0
	≤49 Days (Group 1)	36	15 (42%)		26	7 (27%)	10 (38%)	9 (35%)	0
	50-56 Days (Group 2)	16	7 (44%)		10	4 (40%)	2 (20%)	4 (40%)	0
	57-63 Days (Group 3)	12	5 (42%)		8	1 (13%)	7 (88%)	0	0
DIARRHEA	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
NAUSEA	≤63 Days (All)	64	24 (38%)	1.0000	30	9 (30%)	12 (40%)	9 (30%)	0
	≤49 Days (Group 1)	36	14 (39%)		17	5 (29%)	6 (35%)	6 (35%)	0
	50-56 Days (Group 2)	16	6 (38%)		8	3 (38%)	2 (25%)	3 (38%)	0
	57-63 Days (Group 3)	12	4 (33%)		5	1 (20%)	4 (80%)	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

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.)								
VOMITING	≤63 Days (All)	64	12 (19%)	0.8330	12	3 (25%)	5 (42%)	4 (33%)	0
	≤49 Days (Group 1)	36	8 (22%)		8	2 (25%)	3 (38%)	3 (38%)	0
	50-56 Days (Group 2)	16	2 (13%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	2 (100%)	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
ANAEMIA	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	64	2 (3%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

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)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
VAGINAL DISCOMFORT	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	64	40 (63%)	0.4684	64	28 (44%)	27 (42%)	9 (14%)	0
	≤49 Days (Group 1)	36	20 (56%)		31	13 (42%)	11 (35%)	7 (23%)	0
	50-56 Days (Group 2)	16	11 (69%)		16	10 (63%)	5 (31%)	1 (6%)	0
	57-63 Days (Group 3)	12	9 (75%)		17	5 (29%)	11 (65%)	1 (6%)	0
ABDOMINAL PAIN	≤63 Days (All)	64	35 (55%)	0.2693	42	22 (52%)	15 (36%)	5 (12%)	0
	≤49 Days (Group 1)	36	17 (47%)		21	10 (48%)	6 (29%)	5 (24%)	0
	50-56 Days (Group 2)	16	9 (56%)		9	7 (78%)	2 (22%)	0	0
	57-63 Days (Group 3)	12	9 (75%)		12	5 (42%)	7 (58%)	0	0
BACK PAIN	≤63 Days (All)	64	3 (5%)	0.4052	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FATIGUE	≤63 Days (All)	64	10 (16%)	0.8982	11	1 (9%)	7 (64%)	3 (27%)	0
	≤49 Days (Group 1)	36	5 (14%)		5	0	4 (80%)	1 (20%)	0
	50-56 Days (Group 2)	16	3 (19%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	12	2 (17%)		2	0	1 (50%)	1 (50%)	0
FEVER	≤63 Days (All)	64	2 (3%)	0.6875	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
HOT FLUSHES	≤63 Days (All)	64	1 (2%)	0.1875	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
MALAISE	≤63 Days (All)	64	3 (5%)	1.0000	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RIGORS	≤63 Days (All)	64	1 (2%)	0.1875	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: BORGATTA (#6)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
SYNCOPE	≤63 Days (All)	64	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MALLOY (#7)

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)	52	32 (62%)	0.5361	65	26 (40%)	26 (40%)	13 (20%)	0
	≤49 Days (Group 1)	19	10 (53%)		16	11 (69%)	5 (31%)	0	0
	50-56 Days (Group 2)	11	8 (73%)		14	6 (43%)	6 (43%)	2 (14%)	0
	57-63 Days (Group 3)	22	14 (64%)		35	9 (26%)	15 (43%)	11 (31%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	6 (12%)	1.0000	6	2 (33%)	4 (67%)	0	0
	≤49 Days (Group 1)	19	2 (11%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	3 (14%)		3	0	3 (100%)	0	0
DIZZINESS	≤63 Days (All)	52	3 (6%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
HEADACHE	≤63 Days (All)	52	3 (6%)	0.7919	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		2	0	2 (100%)	0	0
HEARING AND VESTIBULAR DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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: MALLOY (#7)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
HEARING AND VESTIBULAR DISORDERS	(cont.)								
TINNITUS	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
INSOMNIA	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	16 (31%)	0.9263	25	8 (32%)	8 (32%)	9 (36%)	0
	≤49 Days (Group 1)	19	6 (32%)		8	6 (75%)	2 (25%)	0	0
	50-56 Days (Group 2)	11	4 (36%)		6	1 (17%)	4 (67%)	1 (17%)	0
	57-63 Days (Group 3)	22	6 (27%)		11	1 (9%)	2 (18%)	8 (73%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MALLOY (#7)

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)	52	1 (2%)	0.5769	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	1 (5%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	52	1 (2%)	0.2115	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	52	13 (25%)	0.9204	17	6 (35%)	6 (35%)	5 (29%)	0
	≤49 Days (Group 1)	19	5 (26%)		7	5 (71%)	2 (29%)	0	0
	50-56 Days (Group 2)	11	2 (18%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	22	6 (27%)		8	1 (13%)	2 (25%)	5 (63%)	0
VOMITING	≤63 Days (All)	52	4 (8%)	0.1886	6	1 (17%)	1 (17%)	4 (67%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	2 (18%)		3	1 (33%)	1 (33%)	1 (33%)	0
	57-63 Days (Group 3)	22	2 (9%)		3	0	0	3 (100%)	0
ENDOCRINE DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MALLOY (#7)

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
ENDOCRINE DISORDERS	**(cont.)**								
ENDOCRINE DISORDER NOS	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
TACHYCARDIA	≤63 Days (All)	52	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	1 (100%)	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	1 (2%)	0.2115	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MALLOY (#7)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
URINARY SYSTEM DISORDERS	(cont.)								
MICTURITION FREQUENCY	≤63 Days (All)	52	1 (2%)	0.2115	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	22	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	52	24 (46%)	0.2845	29	12 (41%)	13 (45%)	4 (14%)	0
	≤49 Days (Group 1)	19	6 (32%)		6	4 (67%)	2 (33%)	0	0
	50-56 Days (Group 2)	11	6 (55%)		6	4 (67%)	1 (17%)	1 (17%)	0
	57-63 Days (Group 3)	22	12 (55%)		17	4 (24%)	10 (59%)	3 (18%)	0
ABDOMINAL PAIN	≤63 Days (All)	52	23 (44%)	0.4225	24	12 (50%)	9 (38%)	3 (13%)	0
	≤49 Days (Group 1)	19	6 (32%)		6	4 (67%)	2 (33%)	0	0
	50-56 Days (Group 2)	11	6 (55%)		6	4 (67%)	1 (17%)	1 (17%)	0
	57-63 Days (Group 3)	22	11 (50%)		12	4 (33%)	6 (50%)	2 (17%)	0
BACK PAIN	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
FATIGUE	≤63 Days (All)	52	2 (4%)	0.5023	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MALLOY (#7)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
FEVER	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	1 (100%)	0	0
LEG PAIN	≤63 Days (All)	52	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	19	0		0	0	0	0	0
	50-56 Days (Group 2)	11	0		0	0	0	0	0
	57-63 Days (Group 3)	22	1 (5%)		1	0	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: ROTHENBERG (#8)

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)	21	18 (86%)	0.7068	29	14 (48%)	8 (28%)	7 (24%)	0
	≤49 Days (Group 1)	13	10 (77%)		16	9 (56%)	4 (25%)	3 (19%)	0
	50-56 Days (Group 2)	5	5 (100%)		9	3 (33%)	4 (44%)	2 (22%)	0
	57-63 Days (Group 3)	3	3 (100%)		4	2 (50%)	0	2 (50%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	2 (10%)	0.6286	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	21	2 (10%)	0.6286	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	9 (43%)	0.0255	14	6 (43%)	3 (21%)	5 (36%)	0
	≤49 Days (Group 1)	13	3 (23%)		4	3 (75%)	0	1 (25%)	0
	50-56 Days (Group 2)	5	3 (60%)		7	2 (29%)	3 (43%)	2 (29%)	0
	57-63 Days (Group 3)	3	3 (100%)		3	1 (33%)	0	2 (67%)	0

[1] Includes all events for which the relationship to study drug was reported as possibly or probably related to mifepristone.
[2] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: ROTHENBERG (#8)

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)	21	1 (5%)	0.3810	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	21	6 (29%)	0.1910	7	3 (43%)	2 (29%)	2 (29%)	0
	≤49 Days (Group 1)	13	2 (15%)		2	1 (50%)	0	1 (50%)	0
	50-56 Days (Group 2)	5	3 (60%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	3	1 (33%)		1	1 (100%)	0	0	0
VOMITING	≤63 Days (All)	21	4 (19%)	0.0682	6	2 (33%)	1 (17%)	3 (50%)	0
	≤49 Days (Group 1)	13	1 (8%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	5	1 (20%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	3	2 (67%)		2	0	0	2 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	21	10 (48%)	0.3797	13	8 (62%)	4 (31%)	1 (8%)	0
	≤49 Days (Group 1)	13	8 (62%)		11	6 (55%)	4 (36%)	1 (9%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	3	1 (33%)		1	1 (100%)	0	0	0
ABDOMINAL PAIN	≤63 Days (All)	21	10 (48%)	0.3797	12	8 (67%)	3 (25%)	1 (8%)	0
	≤49 Days (Group 1)	13	8 (62%)		10	6 (60%)	3 (30%)	1 (10%)	0
	50-56 Days (Group 2)	5	1 (20%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	3	1 (33%)		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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: ROTHENBERG (#8)

Body System/Event [2]	Gestational Age Group [3]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	21	1 (5%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	5	0		0	0	0	0	0
	57-63 Days (Group 3)	3	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] NOS = Not otherwise specified
[3] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: MISHELL (#1)

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)	204	194 (95%)	0.1456	711	233 (33%)	224 (32%)	254 (36%)	0
	≤49 Days (Group 1)	145	135 (93%)		459	166 (36%)	139 (30%)	154 (34%)	0
	50-56 Days (Group 2)	40	40 (100%)		176	45 (26%)	62 (35%)	69 (39%)	0
	57-63 Days (Group 3)	19	19 (100%)		76	22 (29%)	23 (30%)	31 (41%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	204	3 (1%)	0.1201	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	1 (100%)	0	0
PRURITUS GENITAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	204	2 (<1%)	0.0450	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	1 (100%)	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	28 (14%)	0.6366	42	20 (48%)	11 (26%)	11 (26%)	0
	≤49 Days (Group 1)	145	18 (12%)		29	15 (52%)	8 (28%)	6 (21%)	0
	50-56 Days (Group 2)	40	7 (18%)		9	3 (33%)	2 (22%)	4 (44%)	0
	57-63 Days (Group 3)	19	3 (16%)		4	2 (50%)	1 (25%)	1 (25%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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)	204	14 (7%)	0.1824	19	9 (47%)	3 (16%)	7 (37%)	0
	≤49 Days (Group 1)	145	8 (6%)		11	6 (55%)	1 (9%)	4 (36%)	0
	50-56 Days (Group 2)	40	3 (8%)		5	2 (40%)	1 (20%)	2 (40%)	0
	57-63 Days (Group 3)	19	3 (16%)		3	1 (33%)	1 (33%)	1 (33%)	0
HEADACHE	≤63 Days (All)	204	16 (8%)	0.9098	22	10 (45%)	8 (36%)	4 (18%)	0
	≤49 Days (Group 1)	145	11 (8%)		17	8 (47%)	7 (41%)	2 (12%)	0
	50-56 Days (Group 2)	40	4 (10%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
NEURALGIA	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	204	116 (57%)	0.2442	196	73 (37%)	41 (21%)	82 (42%)	0
	≤49 Days (Group 1)	145	77 (53%)		123	51 (41%)	21 (17%)	51 (41%)	0
	50-56 Days (Group 2)	40	26 (65%)		47	12 (26%)	13 (28%)	22 (47%)	0
	57-63 Days (Group 3)	19	13 (68%)		26	10 (38%)	7 (27%)	9 (35%)	0
ABDOMINAL PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

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

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

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS (cont.)									
CONSTIPATION	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	204	26 (13%)	0.0380	28	19 (68%)	6 (21%)	3 (11%)	0
	≤49 Days (Group 1)	145	17 (12%)		18	12 (67%)	3 (17%)	3 (17%)	0
	50-56 Days (Group 2)	40	3 (8%)		4	3 (75%)	1 (25%)	0	0
	57-63 Days (Group 3)	19	6 (32%)		6	4 (67%)	2 (33%)	0	0
DYSPEPSIA	≤63 Days (All)	204	3 (1%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	145	3 (2%)		4	1 (25%)	2 (50%)	1 (25%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	204	104 (51%)	0.1802	128	41 (32%)	22 (17%)	65 (51%)	0
	≤49 Days (Group 1)	145	68 (47%)		82	31 (38%)	12 (15%)	39 (48%)	0
	50-56 Days (Group 2)	40	25 (63%)		33	7 (21%)	8 (24%)	18 (55%)	0
	57-63 Days (Group 3)	19	11 (58%)		13	3 (23%)	2 (15%)	8 (62%)	0
VOMITING	≤63 Days (All)	204	30 (15%)	0.1325	34	10 (29%)	11 (32%)	13 (38%)	0
	≤49 Days (Group 1)	145	17 (12%)		17	5 (29%)	4 (24%)	8 (47%)	0
	50-56 Days (Group 2)	40	8 (20%)		10	2 (20%)	4 (40%)	4 (40%)	0
	57-63 Days (Group 3)	19	5 (26%)		7	3 (43%)	3 (43%)	1 (14%)	0

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

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

Center: MISHELL (#1)

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									
ANY EVENT	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
DEHYDRATION	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
HEART RATE AND RHYTHM DISORDERS									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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)	204	1 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	145	1 (<1%)		2	0	1 (50%)	1 (50%)	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	204	7 (3%)	0.1476	7	3 (43%)	1 (14%)	3 (43%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	0	1 (33%)	2 (67%)	0
	50-56 Days (Group 2)	40	3 (8%)		3	2 (67%)	0	1 (33%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
ANAEMIA	≤63 Days (All)	204	6 (3%)	0.2660	6	2 (33%)	1 (17%)	3 (50%)	0
	≤49 Days (Group 1)	145	3 (2%)		3	0	1 (33%)	2 (67%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	1 (100%)	0	0	0
ANAEMIA HYPOCHROMIC	≤63 Days (All)	204	1 (<1%)	0.2892	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	204	14 (7%)	0.0017	14	0	2 (14%)	12 (86%)	0
	≤49 Days (Group 1)	145	5 (3%)		5	0	1 (20%)	4 (80%)	0
	50-56 Days (Group 2)	40	4 (10%)		4	0	1 (25%)	3 (75%)	0
	57-63 Days (Group 3)	19	5 (26%)		5	0	0	5 (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] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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.)									
ENDOMETRITIS	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
OVARIAN DISORDER	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	204	12 (6%)	0.0015	12	0	0	12 (100%)	0
	≤49 Days (Group 1)	145	4 (3%)		4	0	0	4 (100%)	0
	50-56 Days (Group 2)	40	3 (8%)		3	0	0	3 (100%)	0
	57-63 Days (Group 3)	19	5 (26%)		5	0	0	5 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	204	191 (94%)	0.0744	443	133 (30%)	167 (38%)	143 (32%)	0
	≤49 Days (Group 1)	145	132 (91%)		293	97 (33%)	107 (37%)	89 (30%)	0
	50-56 Days (Group 2)	40	40 (100%)		111	27 (24%)	46 (41%)	38 (34%)	0
	57-63 Days (Group 3)	19	19 (100%)		39	9 (23%)	14 (36%)	16 (41%)	0
ABDOMINAL PAIN	≤63 Days (All)	204	189 (93%)	0.0344	414	123 (30%)	154 (37%)	137 (33%)	0
	≤49 Days (Group 1)	145	130 (90%)		271	88 (32%)	97 (36%)	86 (32%)	0
	50-56 Days (Group 2)	40	40 (100%)		105	26 (25%)	43 (41%)	36 (34%)	0
	57-63 Days (Group 3)	19	19 (100%)		38	9 (24%)	14 (37%)	15 (39%)	0

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

Appendix A.1, Tables 16 and 25

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

Center: MISHELL (#1)

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.)									
ASTHENIA	≤63 Days (All)	204	2 (<1%)	0.0450	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	19	1 (5%)		1	0	0	1 (100%)	0
BACK PAIN	≤63 Days (All)	204	11 (5%)	0.8783	14	3 (21%)	7 (50%)	4 (29%)	0
	≤49 Days (Group 1)	145	9 (6%)		12	3 (25%)	6 (50%)	3 (25%)	0
	50-56 Days (Group 2)	40	2 (5%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
CHEST PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	204	3 (1%)	0.6431	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	145	2 (1%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
FEVER	≤63 Days (All)	204	2 (<1%)	0.4958	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

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

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

Center: MISHELL (#1)

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.)									
HOT FLUSHES	≤63 Days (All)	204	1 (<1%)	0.2892	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	0		0	0	0	0	0
	50-56 Days (Group 2)	40	1 (3%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
RIGORS	≤63 Days (All)	204	3 (1%)	1.0000	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	145	3 (2%)		3	3 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
SYNCOPE	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	204	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

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

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

Center: HASKELL (#2)

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)	238	230 (97%)	0.2541	1171	346 (30%)	429 (37%)	395 (34%)	1 (<1%)
	≤49 Days (Group 1)	81	76 (94%)		354	124 (35%)	134 (38%)	95 (27%)	1 (<1%)
	50-56 Days (Group 2)	89	87 (98%)		441	127 (29%)	153 (35%)	161 (37%)	0
	57-63 Days (Group 3)	68	67 (99%)		376	95 (25%)	142 (38%)	139 (37%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
ARTHRITIS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	48 (20%)	0.3622	74	19 (26%)	46 (62%)	9 (12%)	0
	≤49 Days (Group 1)	81	13 (16%)		22	7 (32%)	14 (64%)	1 (5%)	0
	50-56 Days (Group 2)	89	22 (25%)		32	10 (31%)	17 (53%)	5 (16%)	0
	57-63 Days (Group 3)	68	13 (19%)		20	2 (10%)	15 (75%)	3 (15%)	0

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

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

Center: MISHELL (#1)

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									
ANY EVENT	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	204	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	145	1 (<1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	40	0		0	0	0	0	0
	57-63 Days (Group 3)	19	0		0	0	0	0	0

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

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

Center: HASKELL (#2)

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)	238	6 (3%)	0.8780	7	4 (57%)	2 (29%)	1 (14%)	0
	≤49 Days (Group 1)	81	2 (2%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	89	3 (3%)		3	2 (67%)	0	1 (33%)	0
	57 63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
HEADACHE	≤63 Days (All)	238	43 (18%)	0.6564	65	15 (23%)	43 (66%)	7 (11%)	0
	≤49 Days (Group 1)	81	12 (15%)		19	6 (32%)	12 (63%)	1 (5%)	0
	50-56 Days (Group 2)	89	18 (20%)		27	8 (30%)	16 (59%)	3 (11%)	0
	57-63 Days (Group 3)	68	13 (19%)		19	1 (5%)	15 (79%)	3 (16%)	0
MIGRAINE	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
TREMOR	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	238	6 (3%)	1.0000	6	1 (17%)	4 (67%)	1 (17%)	0
	≤49 Days (Group 1)	81	2 (2%)		2	0	2 (100%)	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	2 (3%)		2	1 (50%)	1 (50%)	0	0

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

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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)	238	2 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
EMOTIONAL LABILITY	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
INSOMNIA	≤63 Days (All)	238	2 (<1%)	0.7444	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	141 (59%)	0.1442	284	121 (43%)	92 (32%)	71 (25%)	0
	≤49 Days (Group 1)	81	41 (51%)		82	43 (52%)	23 (28%)	16 (20%)	0
	50-56 Days (Group 2)	89	58 (65%)		118	50 (42%)	36 (31%)	32 (27%)	0
	57-63 Days (Group 3)	68	42 (62%)		84	28 (33%)	33 (39%)	23 (27%)	0

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

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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	≤63 Days (All)	238	1 (<1%)	0.2857	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		2	0	2 (100%)	0	0
DIARRHEA	≤63 Days (All)	238	54 (23%)	0.9422	70	41 (59%)	22 (31%)	7 (10%)	0
	≤49 Days (Group 1)	81	19 (23%)		22	15 (68%)	5 (23%)	2 (9%)	0
	50-56 Days (Group 2)	89	19 (21%)		28	16 (57%)	11 (39%)	1 (4%)	0
	57-63 Days (Group 3)	68	16 (24%)		20	10 (50%)	6 (30%)	4 (20%)	0
DYSPEPSIA	≤63 Days (All)	238	2 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	238	2 (<1%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HAEMORRHOIDS	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

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

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

Center: HASKELL (#2)

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)	238	117 (49%)	0.0679	147	57 (39%)	44 (30%)	46 (31%)	0
	≤49 Days (Group 1)	81	32 (40%)		42	18 (43%)	12 (29%)	12 (29%)	0
	50-56 Days (Group 2)	89	51 (57%)		61	25 (41%)	17 (28%)	19 (31%)	0
	57-63 Days (Group 3)	68	34 (50%)		44	14 (32%)	15 (34%)	15 (34%)	0
VOMITING	≤63 Days (All)	238	54 (23%)	0.5626	60	21 (35%)	22 (37%)	17 (28%)	0
	≤49 Days (Group 1)	81	15 (19%)		16	9 (56%)	5 (31%)	2 (13%)	0
	50-56 Days (Group 2)	89	22 (25%)		26	8 (31%)	7 (27%)	11 (42%)	0
	57-63 Days (Group 3)	68	17 (25%)		18	4 (22%)	10 (56%)	4 (22%)	0
METABOLIC AND NUTRITIONAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
WEIGHT DECREASE	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

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
CARDIOVASCULAR DISORDERS, GENERAL (cont.)									
HYPOTENSION	≤63 Days (All)	238	2 (<1%)	0.3345	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	2 (<1%)	0.0808	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		3	0	3 (100%)	0	0
PLEURAL PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
SINUSITIS	≤63 Days (All)	238	1 (<1%)	0.2857	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		2	0	2 (100%)	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	68	1 (1%)		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] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
RED BLOOD CELL DISORDERS (cont.)									
ANAEMIA	≤63 Days (All)	238	3 (1%)	0.5061	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	2 (2%)		2	0	2 (100%)	0	0
	57 63 Days (Group 3)	68	1 (1%)		1	1 (100%)	0	0	0
URINARY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50 56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
URINARY TRACT INFECTION	≤63 Days (All)	238	1 (<1%)	0.6261	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	238	50 (21%)	0.6448	57	2 (4%)	8 (14%)	47 (82%)	0
	≤49 Days (Group 1)	81	16 (20%)		17	1 (6%)	4 (24%)	12 (71%)	0
	50-56 Days (Group 2)	89	17 (19%)		18	1 (6%)	1 (6%)	16 (89%)	0
	57-63 Days (Group 3)	68	17 (25%)		22	0	3 (14%)	19 (86%)	0

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

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

Center: HASKELL (#2)

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.)									
UTERINE DISORDER NOS	≤63 Days (All)	238	2 (<1%)	0.5298	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50 56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	238	48 (20%)	0.7241	54	2 (4%)	5 (9%)	47 (87%)	0
	≤49 Days (Group 1)	81	15 (19%)		16	1 (6%)	3 (19%)	12 (75%)	0
	50-56 Days (Group 2)	89	17 (19%)		18	1 (6%)	1 (6%)	16 (89%)	0
	57-63 Days (Group 3)	68	16 (24%)		20	0	1 (5%)	19 (95%)	0
VAGINITIS	≤63 Days (All)	238	1 (<1%)	0.2857	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	238	229 (96%)	0.1434	739	202 (27%)	272 (37%)	264 (36%)	1 (<1%)
	≤49 Days (Group 1)	81	75 (93%)		230	73 (32%)	91 (40%)	65 (28%)	1 (<1%)
	50-56 Days (Group 2)	89	87 (98%)		266	66 (25%)	95 (36%)	105 (39%)	0
	57-63 Days (Group 3)	68	67 (99%)		243	63 (26%)	86 (35%)	94 (39%)	0
ABDOMINAL PAIN	≤63 Days (All)	238	228 (96%)	0.0667	700	189 (27%)	257 (37%)	253 (36%)	1 (<1%)
	≤49 Days (Group 1)	81	74 (91%)		215	68 (32%)	83 (39%)	63 (29%)	1 (<1%)
	50-56 Days (Group 2)	89	87 (98%)		256	62 (24%)	92 (36%)	102 (40%)	0
	57-63 Days (Group 3)	68	67 (99%)		229	59 (26%)	82 (36%)	88 (38%)	0

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

Appendix A.1, Tables 16 and 25

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

Center: HASKELL (#2)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	238	12 (5%)	0.6598	14	4 (29%)	7 (50%)	3 (21%)	0
	≤49 Days (Group 1)	81	5 (6%)		7	1 (14%)	4 (57%)	2 (29%)	0
	50-56 Days (Group 2)	89	3 (3%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	68	4 (6%)		4	2 (50%)	1 (25%)	1 (25%)	0
FATIGUE	≤63 Days (All)	238	7 (3%)	0.3419	7	6 (86%)	1 (14%)	0	0
	≤49 Days (Group 1)	81	4 (5%)		4	3 (75%)	1 (25%)	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	2 (3%)		2	2 (100%)	0	0	0
FEVER	≤63 Days (All)	238	2 (<1%)	0.5298	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (100%)	0
HOT FLUSHES	≤63 Days (All)	238	2 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	81	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0
HYPOVOLAEMIA	≤63 Days (All)	238	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	0		0	0	0	0	0

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

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

Center: HASKELL (#2)

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.)									
LEG PAIN	≤63 Days (All)	238	3 (1%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50 56 Days (Group 2)	89	1 (1%)		2	1 (50%)	0	1 (50%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	1 (100%)	0	0
PAIN	≤63 Days (All)	238	1 (<1%)	0.2857	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	0		0	0	0	0	0
	57-63 Days (Group 3)	68	1 (1%)		2	0	0	2 (100%)	0
RIGORS	≤63 Days (All)	238	5 (2%)	0.3849	5	0	4 (80%)	1 (20%)	0
	≤49 Days (Group 1)	81	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	68	3 (4%)		3	0	2 (67%)	1 (33%)	0
SYNCOPE	≤63 Days (All)	238	2 (<1%)	0.7444	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	81	0		0	0	0	0	0
	50-56 Days (Group 2)	89	1 (1%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	68	1 (1%)		1	0	0	1 (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] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

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

Center: POPPEMA (#3)

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)	164	159 (97%)	0.2754	692	188 (27%)	248 (36%)	252 (36%)	4 (<1%)
	≤49 Days (Group 1)	65	61 (94%)		242	73 (30%)	91 (38%)	76 (31%)	2 (<1%)
	50-56 Days (Group 2)	65	64 (98%)		297	82 (28%)	101 (34%)	112 (38%)	2 (<1%)
	57-63 Days (Group 3)	34	34 (100%)		153	33 (22%)	56 (37%)	64 (42%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	164	3 (2%)	0.4263	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
SWEATING INCREASED	≤63 Days (All)	164	3 (2%)	0.4263	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	1 (<1%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	1 (2%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

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

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

Center: POPPEMA (#3)

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	≤63 Days (All)	164	1 (<1%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	1 (2%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	17 (10%)	0.9458	18	6 (33%)	8 (44%)	4 (22%)	0
	≤49 Days (Group 1)	65	6 (9%)		7	3 (43%)	2 (29%)	2 (29%)	0
	50-56 Days (Group 2)	65	7 (11%)		7	3 (43%)	2 (29%)	2 (29%)	0
	57-63 Days (Group 3)	34	4 (12%)		4	0	4 (100%)	0	0
DIZZINESS	≤63 Days (All)	164	9 (5%)	0.5521	9	4 (44%)	3 (33%)	2 (22%)	0
	≤49 Days (Group 1)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	5 (8%)		5	3 (60%)	0	2 (40%)	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	2 (100%)	0	0
HEADACHE	≤63 Days (All)	164	8 (5%)	0.7176	9	2 (22%)	5 (56%)	2 (22%)	0
	≤49 Days (Group 1)	65	4 (6%)		5	2 (40%)	1 (20%)	2 (40%)	0
	50-56 Days (Group 2)	65	2 (3%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	2 (100%)	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	164	103 (63%)	0.0039	195	53 (27%)	74 (38%)	68 (35%)	0
	≤49 Days (Group 1)	65	32 (49%)		58	19 (33%)	26 (45%)	13 (22%)	0
	50-56 Days (Group 2)	65	43 (66%)		85	23 (27%)	29 (34%)	33 (39%)	0
	57-63 Days (Group 3)	34	28 (82%)		52	11 (21%)	19 (37%)	22 (42%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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	≤63 Days (All)	164	1 (<1%)	0.2073	4	1 (25%)	1 (25%)	2 (50%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		4	1 (25%)	1 (25%)	2 (50%)	0
DIARRHEA	≤63 Days (All)	164	28 (17%)	0.4569	31	11 (35%)	16 (52%)	4 (13%)	0
	≤49 Days (Group 1)	65	10 (15%)		12	5 (42%)	6 (50%)	1 (8%)	0
	50-56 Days (Group 2)	65	14 (22%)		14	5 (36%)	6 (43%)	3 (21%)	0
	57-63 Days (Group 3)	34	4 (12%)		5	1 (20%)	4 (80%)	0	0
NAUSEA	≤63 Days (All)	164	90 (55%)	0.0255	112	37 (33%)	35 (31%)	40 (36%)	0
	≤49 Days (Group 1)	65	28 (43%)		35	12 (34%)	15 (43%)	8 (23%)	0
	50-56 Days (Group 2)	65	38 (58%)		50	16 (32%)	14 (28%)	20 (40%)	0
	57-63 Days (Group 3)	34	24 (71%)		27	9 (33%)	6 (22%)	12 (44%)	0
VOMITING	≤63 Days (All)	164	43 (26%)	0.0152	48	4 (8%)	22 (46%)	22 (46%)	0
	≤49 Days (Group 1)	65	10 (15%)		11	2 (18%)	5 (45%)	4 (36%)	0
	50-56 Days (Group 2)	65	19 (29%)		21	2 (10%)	9 (43%)	10 (48%)	0
	57-63 Days (Group 3)	34	14 (41%)		16	0	8 (50%)	8 (50%)	0
CARDIOVASCULAR DISORDERS, GENERAL									
ANY EVENT	≤63 Days (All)	164	2 (1%)	0.6839	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	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] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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
CARDIOVASCULAR DISORDERS, GENERAL (cont.)									
HYPOTENSION	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
HYPOTENSION POSTURAL	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
RED BLOOD CELL DISORDERS									
ANY EVENT	≤63 Days (All)	164	3 (2%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
ANAEMIA	≤63 Days (All)	164	3 (2%)	1.0000	3	1 (33%)	2 (67%)	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	164	18 (11%)	0.0801	25	6 (24%)	11 (44%)	8 (32%)	0
	≤49 Days (Group 1)	65	3 (5%)		6	2 (33%)	3 (50%)	1 (17%)	0
	50-56 Days (Group 2)	65	9 (14%)		11	3 (27%)	3 (27%)	5 (45%)	0
	57 63 Days (Group 3)	34	6 (18%)		8	1 (13%)	5 (63%)	2 (25%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post-misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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.)									
ENDOMETRITIS	≤63 Days (All)	164	7 (4%)	0.8833	7	2 (29%)	5 (71%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	3 (5%)		3	1 (33%)	2 (67%)	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	2 (100%)	0	0
LEUKORRHOEA	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
SALPINGITIS	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
UTERINE DISORDER NOS	≤63 Days (All)	164	1 (<1%)	0.2073	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
UTERINE HAEMORRHAGE	≤63 Days (All)	164	14 (9%)	0.2183	14	1 (7%)	5 (36%)	8 (57%)	0
	≤49 Days (Group 1)	65	3 (5%)		3	0	2 (67%)	1 (33%)	0
	50-56 Days (Group 2)	65	6 (9%)		6	0	1 (17%)	5 (83%)	0
	57-63 Days (Group 3)	34	5 (15%)		5	1 (20%)	2 (40%)	2 (40%)	0

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

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

Center: POPPEMA (#3)

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
REPRODUCTIVE DISORDERS, FEMALE (cont.)									
VAGINAL DISCOMFORT	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	164	158 (96%)	0.4439	443	120 (27%)	149 (34%)	170 (38%)	4 (<1%)
	≤49 Days (Group 1)	65	61 (94%)		167	47 (28%)	59 (35%)	59 (35%)	2 (1%)
	50-56 Days (Group 2)	65	64 (98%)		190	52 (27%)	64 (34%)	72 (38%)	2 (1%)
	57-63 Days (Group 3)	34	33 (97%)		86	21 (24%)	26 (30%)	39 (45%)	0
ABDOMINAL PAIN	≤63 Days (All)	164	158 (96%)	0.4439	420	114 (27%)	138 (33%)	165 (39%)	3 (<1%)
	≤49 Days (Group 1)	65	61 (94%)		157	43 (27%)	55 (35%)	58 (37%)	1 (<1%)
	50-56 Days (Group 2)	65	64 (98%)		181	50 (28%)	59 (33%)	70 (39%)	2 (1%)
	57-63 Days (Group 3)	34	33 (97%)		82	21 (26%)	24 (29%)	37 (45%)	0
ASTHENIA	≤63 Days (All)	164	3 (2%)	0.8010	3	2 (67%)	1 (33%)	0	0
	≤49 Days (Group 1)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
BACK PAIN	≤63 Days (All)	164	7 (4%)	0.8833	7	1 (14%)	3 (43%)	2 (29%)	1 (14%)
	≤49 Days (Group 1)	65	3 (5%)		3	0	1 (33%)	1 (33%)	1 (33%)
	50-56 Days (Group 2)	65	2 (3%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	34	2 (6%)		2	0	1 (50%)	1 (50%)	0

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

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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.)									
FATIGUE	≤63 Days (All)	164	3 (2%)	1.0000	3	1 (33%)	1 (33%)	1 (33%)	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	0	1 (100%)	0
FEVER	≤63 Days (All)	164	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	65	1 (2%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	65	0		0	0	0	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
HOT FLUSHES	≤63 Days (All)	164	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	164	2 (1%)	0.6839	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	1 (3%)		1	0	1 (100%)	0	0
RIGORS	≤63 Days (All)	164	4 (2%)	0.5346	4	1 (25%)	3 (75%)	0	0
	≤49 Days (Group 1)	65	3 (5%)		3	1 (33%)	2 (67%)	0	0
	50-56 Days (Group 2)	65	1 (2%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

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

Appendix A.1, Tables 16 and 25

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

Center: POPPEMA (#3)

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)	164	2 (1%)	0.3532	2	0	0	2 (100%)	0
	≤49 Days (Group 1)	65	0		0	0	0	0	0
	50-56 Days (Group 2)	65	2 (3%)		2	0	0	2 (100%)	0
	57-63 Days (Group 3)	34	0		0	0	0	0	0

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

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

Center: TYSON (#4)

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)	102	98 (96%)	1.0000	403	148 (37%)	156 (39%)	99 (25%)	0
	≤49 Days (Group 1)	68	65 (96%)		271	101 (37%)	110 (41%)	60 (22%)	0
	50-56 Days (Group 2)	25	24 (96%)		106	39 (37%)	40 (38%)	27 (25%)	0
	57-63 Days (Group 3)	9	9 (100%)		26	8 (31%)	6 (23%)	12 (46%)	0
SKIN AND APPENDAGES DISORDERS									
ANY EVENT	≤63 Days (All)	102	2 (2%)	0.5578	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
SWEATING INCREASED	≤63 Days (All)	102	2 (2%)	0.5578	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
MUSCULO-SKELETAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

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

Center: TYSON (#4)

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	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	24 (24%)	0.6176	35	13 (37%)	19 (54%)	3 (9%)	0
	≤49 Days (Group 1)	68	18 (26%)		27	10 (37%)	14 (52%)	3 (11%)	0
	50-56 Days (Group 2)	25	5 (20%)		7	3 (43%)	4 (57%)	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
DIZZINESS	≤63 Days (All)	102	7 (7%)	0.0493	8	5 (63%)	3 (38%)	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	4 (16%)		5	3 (60%)	2 (40%)	0	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	1 (100%)	0	0
HEADACHE	≤63 Days (All)	102	16 (16%)	0.1821	24	6 (25%)	16 (67%)	2 (8%)	0
	≤49 Days (Group 1)	68	14 (21%)		22	6 (27%)	14 (64%)	2 (9%)	0
	50-56 Days (Group 2)	25	2 (8%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
MIGRAINE	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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.)									
TREMOR	≤63 Days (All)	102	2 (2%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	68	2 (3%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	60 (59%)	0.9501	104	42 (40%)	34 (33%)	28 (27%)	0
	≤49 Days (Group 1)	68	41 (60%)		69	27 (39%)	24 (35%)	18 (26%)	0
	50-56 Days (Group 2)	25	14 (56%)		27	12 (44%)	8 (30%)	7 (26%)	0
	57-63 Days (Group 3)	9	5 (56%)		8	3 (38%)	2 (25%)	3 (38%)	0
CONSTIPATION	≤63 Days (All)	102	1 (<1%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DIARRHEA	≤63 Days (All)	102	19 (19%)	0.7838	22	14 (64%)	4 (18%)	4 (18%)	0
	≤49 Days (Group 1)	68	12 (18%)		14	10 (71%)	2 (14%)	2 (14%)	0
	50-56 Days (Group 2)	25	5 (20%)		6	3 (50%)	2 (33%)	1 (17%)	0
	57-63 Days (Group 3)	9	2 (22%)		2	1 (50%)	0	1 (50%)	0
DYSPEPSIA	≤63 Days (All)	102	2 (2%)	0.5578	3	1 (33%)	0	2 (67%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		2	0	0	2 (100%)	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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)	102	1 (<1%)	1.0000	2	2 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	102	43 (42%)	1.0000	45	19 (42%)	13 (29%)	13 (29%)	0
	≤49 Days (Group 1)	68	29 (43%)		31	11 (35%)	10 (32%)	10 (32%)	0
	50-56 Days (Group 2)	25	10 (40%)		10	6 (60%)	2 (20%)	2 (20%)	0
	57-63 Days (Group 3)	9	4 (44%)		4	2 (50%)	1 (25%)	1 (25%)	0
VOMITING	≤63 Days (All)	102	26 (25%)	1.0000	31	6 (19%)	16 (52%)	9 (29%)	0
	≤49 Days (Group 1)	68	18 (26%)		20	3 (15%)	11 (55%)	6 (30%)	0
	50-56 Days (Group 2)	25	6 (24%)		9	3 (33%)	4 (44%)	2 (22%)	0
	57-63 Days (Group 3)	9	2 (22%)		2	0	1 (50%)	1 (50%)	0
RESPIRATORY SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
DYSPNOEA	≤63 Days (All)	102	1 (<1%)	0.3333	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

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

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

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)	102	7 (7%)	0.0060	7	0	1 (14%)	6 (86%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	5 (20%)		5	0	1 (20%)	4 (80%)	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	0	1 (100%)	0
UTERINE HAEMORRHAGE	≤63 Days (All)	102	7 (7%)	0.0060	7	0	1 (14%)	6 (86%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	5 (20%)		5	0	1 (20%)	4 (80%)	0
	57-63 Days (Group 3)	9	1 (11%)		1	0	0	1 (100%)	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	102	98 (96%)	1.0000	252	91 (36%)	100 (40%)	61 (24%)	0
	≤49 Days (Group 1)	68	65 (96%)		171	63 (37%)	71 (42%)	37 (22%)	0
	50-56 Days (Group 2)	25	24 (96%)		65	23 (35%)	26 (40%)	16 (25%)	0
	57-63 Days (Group 3)	9	9 (100%)		16	5 (31%)	3 (19%)	8 (50%)	0
ABDOMINAL PAIN	≤63 Days (All)	102	98 (96%)	1.0000	226	78 (35%)	90 (40%)	58 (26%)	0
	≤49 Days (Group 1)	68	65 (96%)		153	54 (35%)	65 (42%)	34 (22%)	0
	50-56 Days (Group 2)	25	24 (96%)		57	19 (33%)	22 (39%)	16 (28%)	0
	57-63 Days (Group 3)	9	9 (100%)		16	5 (31%)	3 (19%)	8 (50%)	0
ASTHENIA	≤63 Days (All)	102	4 (4%)	0.0828	4	2 (50%)	1 (25%)	1 (25%)	0
	≤49 Days (Group 1)	68	1 (1%)		1	0	0	1 (100%)	0
	50-56 Days (Group 2)	25	3 (12%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

Appendix A.1, Tables 16 and 25

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

Center: TYSON (#4)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	102	8 (8%)	0.1432	8	3 (38%)	4 (50%)	1 (13%)	0
	≤49 Days (Group 1)	68	8 (12%)		8	3 (38%)	4 (50%)	1 (13%)	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	102	3 (3%)	1.0000	4	1 (25%)	2 (50%)	1 (25%)	0
	≤49 Days (Group 1)	68	2 (3%)		3	1 (33%)	1 (33%)	1 (33%)	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
MALAISE	≤63 Days (All)	102	1 (<1%)	0.3333	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	68	0		0	0	0	0	0
	50-56 Days (Group 2)	25	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
RIGORS	≤63 Days (All)	102	8 (8%)	0.4991	8	6 (75%)	2 (25%)	0	0
	≤49 Days (Group 1)	68	5 (7%)		5	4 (80%)	1 (20%)	0	0
	50-56 Days (Group 2)	25	3 (12%)		3	2 (67%)	1 (33%)	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
TEMPERATURE CHANGED SENSATION	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

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

Center: TYSON (#4)

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									
ANY EVENT	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	102	1 (<1%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	68	1 (1%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	25	0		0	0	0	0	0
	57-63 Days (Group 3)	9	0		0	0	0	0	0

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

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

Center: BLUMENTHAL (#5)

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)	44	43 (98%)	0.1818	166	84 (51%)	60 (36%)	22 (13%)	0
	≤49 Days (Group 1)	13	13 (100%)		41	21 (51%)	17 (41%)	3 (7%)	0
	50-56 Days (Group 2)	23	23 (100%)		97	47 (48%)	32 (33%)	18 (19%)	0
	57-63 Days (Group 3)	8	7 (88%)		28	16 (57%)	11 (39%)	1 (4%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	10 (23%)	0.2801	14	1 (7%)	10 (71%)	3 (21%)	0
	≤49 Days (Group 1)	13	4 (31%)		5	0	5 (100%)	0	0
	50-56 Days (Group 2)	23	6 (26%)		9	1 (11%)	5 (56%)	3 (33%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
DIZZINESS	≤63 Days (All)	44	2 (5%)	1.0000	2	1 (50%)	1 (50%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	44	8 (18%)	0.3926	12	0	9 (75%)	3 (25%)	0
	≤49 Days (Group 1)	13	3 (23%)		4	0	4 (100%)	0	0
	50-56 Days (Group 2)	23	5 (22%)		8	0	5 (63%)	3 (38%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	44	28 (64%)	0.7071	49	31 (63%)	10 (20%)	8 (16%)	0
	≤49 Days (Group 1)	13	7 (54%)		14	8 (57%)	4 (29%)	2 (14%)	0
	50-56 Days (Group 2)	23	16 (70%)		26	16 (62%)	4 (15%)	6 (23%)	0
	57-63 Days (Group 3)	8	5 (63%)		9	7 (78%)	2 (22%)	0	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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)	44	5 (11%)	0.6850	6	2 (33%)	2 (33%)	2 (33%)	0
	≤49 Days (Group 1)	13	2 (15%)		2	1 (50%)	1 (50%)	0	0
	50-56 Days (Group 2)	23	3 (13%)		4	1 (25%)	1 (25%)	2 (50%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
FLATULENCE	≤63 Days (All)	44	1 (2%)	1.0000	2	0	1 (50%)	1 (50%)	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
NAUSEA	≤63 Days (All)	44	28 (64%)	0.7071	32	24 (75%)	4 (13%)	4 (13%)	0
	≤49 Days (Group 1)	13	7 (54%)		8	5 (63%)	2 (25%)	1 (13%)	0
	50-56 Days (Group 2)	23	16 (70%)		19	14 (74%)	2 (11%)	3 (16%)	0
	57-63 Days (Group 3)	8	5 (63%)		5	5 (100%)	0	0	0
VOMITING	≤63 Days (All)	44	7 (16%)	0.0601	9	5 (56%)	3 (33%)	1 (11%)	0
	≤49 Days (Group 1)	13	4 (31%)		4	2 (50%)	1 (25%)	1 (25%)	0
	50-56 Days (Group 2)	23	1 (4%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	8	2 (25%)		4	2 (50%)	2 (50%)	0	0
REPRODUCTIVE DISORDERS, FEMALE									
ANY EVENT	≤63 Days (All)	44	1 (2%)	1.0000	3	0	3 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		3	0	3 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

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

Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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.)									
BREAST ENGORGEMENT	≤63 Days (All)	44	1 (2%)	1.0000	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		2	0	2 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
BREAST PAIN FEMALE	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
BODY AS A WHOLE - GENERAL DISORDERS									
ANY EVENT	≤63 Days (All)	44	43 (98%)	0.1818	100	52 (52%)	37 (37%)	11 (11%)	0
	≤49 Days (Group 1)	13	13 (100%)		22	13 (59%)	8 (36%)	1 (5%)	0
	50-56 Days (Group 2)	23	23 (100%)		59	30 (51%)	20 (34%)	9 (15%)	0
	57-63 Days (Group 3)	8	7 (88%)		19	9 (47%)	9 (47%)	1 (5%)	0
ABDOMINAL PAIN	≤63 Days (All)	44	43 (98%)	0.1818	95	52 (55%)	33 (35%)	10 (11%)	0
	≤49 Days (Group 1)	13	13 (100%)		21	13 (62%)	7 (33%)	1 (5%)	0
	50-56 Days (Group 2)	23	23 (100%)		56	30 (54%)	18 (32%)	8 (14%)	0
	57-63 Days (Group 3)	8	7 (88%)		18	9 (50%)	8 (44%)	1 (6%)	0
FEVER	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

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

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

Appendix A.1, Tables 16 and 25

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

Center: BLUMENTHAL (#5)

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.)									
LEG PAIN	≤63 Days (All)	44	2 (5%)	0.2220	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	23	0		0	0	0	0	0
	57-63 Days (Group 3)	8	1 (13%)		1	0	1 (100%)	0	0
OEDEMA	≤63 Days (All)	44	1 (2%)	1.0000	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0
PAIN	≤63 Days (All)	44	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	23	1 (4%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	8	0		0	0	0	0	0

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

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

Center: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	64	59 (92%)	0.8202	255	109 (43%)	92 (36%)	54 (21%)	0
	≤49 Days (Group 1)	36	32 (89%)		149	69 (46%)	49 (33%)	31 (21%)	0
	50-56 Days (Group 2)	16	15 (94%)		62	22 (35%)	25 (40%)	15 (24%)	0
	57-63 Days (Group 3)	12	12 (100%)		44	18 (41%)	18 (41%)	8 (18%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	12 (19%)	0.2844	21	8 (38%)	9 (43%)	4 (19%)	0
	≤49 Days (Group 1)	36	6 (17%)		9	3 (33%)	5 (56%)	1 (11%)	0
	50-56 Days (Group 2)	16	5 (31%)		10	4 (40%)	3 (30%)	3 (30%)	0
	57-63 Days (Group 3)	12	1 (8%)		2	1 (50%)	1 (50%)	0	0
DIZZINESS	≤63 Days (All)	64	3 (5%)	1.0000	3	3 (100%)	0	0	0
	≤49 Days (Group 1)	36	2 (6%)		2	2 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
HEADACHE	≤63 Days (All)	64	9 (14%)	0.3812	17	5 (29%)	8 (47%)	4 (24%)	0
	≤49 Days (Group 1)	36	4 (11%)		6	1 (17%)	4 (67%)	1 (17%)	0
	50-56 Days (Group 2)	16	4 (25%)		9	3 (33%)	3 (33%)	3 (33%)	0
	57-63 Days (Group 3)	12	1 (8%)		2	1 (50%)	1 (50%)	0	0
PARAESTHESIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

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

Appendix 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: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
PSYCHIATRIC DISORDERS									
ANY EVENT	≤63 Days (All)	64	4 (6%)	0.3760	4	2 (50%)	2 (50%)	0	0
	≤49 Days (Group 1)	36	4 (11%)		4	2 (50%)	2 (50%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
ANOREXIA	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
ANXIETY	≤63 Days (All)	64	1 (2%)	1.0000	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
DEPRESSION	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
EMOTIONAL LABILITY	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

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

Appendix 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: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	64	40 (63%)	0.3372	78	35 (45%)	25 (32%)	18 (23%)	0
	≤49 Days (Group 1)	36	25 (69%)		51	21 (41%)	16 (31%)	14 (27%)	0
	50-56 Days (Group 2)	16	8 (50%)		15	8 (53%)	5 (33%)	2 (13%)	0
	57-63 Days (Group 3)	12	7 (58%)		12	6 (50%)	4 (33%)	2 (17%)	0
DIARRHEA	≤63 Days (All)	64	13 (20%)	0.5833	13	7 (54%)	4 (31%)	2 (15%)	0
	≤49 Days (Group 1)	36	8 (22%)		8	4 (50%)	2 (25%)	2 (25%)	0
	50-56 Days (Group 2)	16	4 (25%)		4	2 (50%)	2 (50%)	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0
DYSPEPSIA	≤63 Days (All)	64	2 (3%)	0.4018	2	0	2 (100%)	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	1 (100%)	0	0
FLATULENCE	≤63 Days (All)	64	1 (2%)	0.1875	1	0	0	1 (100%)	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	0	0	1 (100%)	0
NAUSEA	≤63 Days (All)	64	35 (55%)	0.8347	46	22 (48%)	14 (30%)	10 (22%)	0
	≤49 Days (Group 1)	36	21 (58%)		29	12 (41%)	9 (31%)	8 (28%)	0
	50-56 Days (Group 2)	16	8 (50%)		9	5 (56%)	3 (33%)	1 (11%)	0
	57-63 Days (Group 3)	12	6 (50%)		8	5 (63%)	2 (25%)	1 (13%)	0

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

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

Center: BORGATTA (#6)

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

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

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

Center: BORGATTA (#6)

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

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

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

Center: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Severity: Moderate	Severity: Severe	Severity: Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
ABDOMINAL PAIN	≤63 Days (All)	64	57 (89%)	0.3526	131	53 (40%)	50 (38%)	28 (21%)	0
	≤49 Days (Group 1)	36	30 (83%)		70	35 (50%)	22 (31%)	13 (19%)	0
	50-56 Days (Group 2)	16	15 (94%)		32	8 (25%)	15 (47%)	9 (28%)	0
	57-63 Days (Group 3)	12	12 (100%)		29	10 (34%)	13 (45%)	6 (21%)	0
BACK PAIN	≤63 Days (All)	64	4 (6%)	0.8096	6	3 (50%)	1 (17%)	2 (33%)	0
	≤49 Days (Group 1)	36	3 (8%)		5	2 (40%)	1 (20%)	2 (40%)	0
	50-56 Days (Group 2)	16	1 (6%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
FATIGUE	≤63 Days (All)	64	5 (8%)	1.0000	6	2 (33%)	4 (67%)	0	0
	≤49 Days (Group 1)	36	3 (8%)		3	0	3 (100%)	0	0
	50-56 Days (Group 2)	16	1 (6%)		2	1 (50%)	1 (50%)	0	0
	57-63 Days (Group 3)	12	1 (8%)		1	1 (100%)	0	0	0
HOT FLUSHES	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
LEG PAIN	≤63 Days (All)	64	2 (3%)	0.6875	2	1 (50%)	0	1 (50%)	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	0	1 (100%)	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

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

Appendix 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: BORGATTA (#6)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
MALAISE	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RIGORS	≤63 Days (All)	64	1 (2%)	1.0000	1	1 (100%)	0	0	0
	≤49 Days (Group 1)	36	1 (3%)		1	1 (100%)	0	0	0
	50-56 Days (Group 2)	16	0		0	0	0	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
RESISTANCE MECHANISM DISORDERS									
ANY EVENT	≤63 Days (All)	64	1 (2%)	0.4375	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0
INFECTION VIRAL	≤63 Days (All)	64	1 (2%)	0.4375	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	36	0		0	0	0	0	0
	50-56 Days (Group 2)	16	1 (6%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	12	0		0	0	0	0	0

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

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

Center: MALLOY (#7)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	52	52 (100%)		259	100 (39%)	92 (36%)	67 (26%)	0
	≤49 Days (Group 1)	19	19 (100%)		84	31 (37%)	28 (33%)	25 (30%)	0
	50-56 Days (Group 2)	11	11 (100%)		58	27 (47%)	21 (36%)	10 (17%)	0
	57-63 Days (Group 3)	22	22 (100%)		117	42 (36%)	43 (37%)	32 (27%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	11 (21%)	0.7522	26	11 (42%)	11 (42%)	4 (15%)	0
	≤49 Days (Group 1)	19	3 (16%)		5	1 (20%)	4 (80%)	0	0
	50-56 Days (Group 2)	11	3 (27%)		6	5 (83%)	0	1 (17%)	0
	57-63 Days (Group 3)	22	5 (23%)		15	5 (33%)	7 (47%)	3 (20%)	0
DIZZINESS	≤63 Days (All)	52	4 (8%)	1.0000	7	4 (57%)	2 (29%)	1 (14%)	0
	≤49 Days (Group 1)	19	1 (5%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	11	1 (9%)		1	1 (100%)	0	0	0
	57-63 Days (Group 3)	22	2 (9%)		5	3 (60%)	1 (20%)	1 (20%)	0
HEADACHE	≤63 Days (All)	52	9 (17%)	0.5764	19	7 (37%)	9 (47%)	3 (16%)	0
	≤49 Days (Group 1)	19	3 (16%)		4	1 (25%)	3 (75%)	0	0
	50-56 Days (Group 2)	11	3 (27%)		5	4 (80%)	0	1 (20%)	0
	57-63 Days (Group 3)	22	3 (14%)		10	2 (20%)	6 (60%)	2 (20%)	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	52	35 (67%)	1.0000	76	30 (39%)	22 (29%)	24 (32%)	0
	≤49 Days (Group 1)	19	13 (68%)		23	8 (35%)	6 (26%)	9 (39%)	0
	50-56 Days (Group 2)	11	7 (64%)		18	10 (56%)	6 (33%)	2 (11%)	0
	57-63 Days (Group 3)	22	15 (68%)		35	12 (34%)	10 (29%)	13 (37%)	0

[1] Includes nausea, vomiting, diarrhea and abdominal pain reported during the post misoprostol observation period and all events for which the relationship to study drug was reported as possibly or probably related to misoprostol or the combination of mifepristone and misoprostol or for which the relationship was not assessed.
[2] Gestational age group was assigned by the investigator based upon menstrual history, pelvic examination and vaginal ultrasonography.
Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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

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

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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

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

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

Center: MALLOY (#7)

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

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

Appendix A.1, Tables 16 and 25

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

Center: MALLOY (#7)

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

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

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

Center: ROTHENBERG (#8)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
ANY EVENT	≤63 Days (All)	21	17 (81%)	0.2919	51	20 (39%)	19 (37%)	12 (24%)	0
	≤49 Days (Group 1)	13	9 (69%)		23	13 (57%)	7 (30%)	3 (13%)	0
	50-56 Days (Group 2)	5	5 (100%)		18	4 (22%)	8 (44%)	6 (33%)	0
	57-63 Days (Group 3)	3	3 (100%)		10	3 (30%)	4 (40%)	3 (30%)	0
CENTR & PERIPH NERVOUS SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	4 (19%)	0.1724	4	0	3 (75%)	1 (25%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	5	2 (40%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	3	1 (33%)		1	0	1 (100%)	0	0
HEADACHE	≤63 Days (All)	21	4 (19%)	0.1724	4	0	3 (75%)	1 (25%)	0
	≤49 Days (Group 1)	13	1 (8%)		1	0	1 (100%)	0	0
	50-56 Days (Group 2)	5	2 (40%)		2	0	1 (50%)	1 (50%)	0
	57-63 Days (Group 3)	3	1 (33%)		1	0	1 (100%)	0	0
GASTRO-INTESTINAL SYSTEM DISORDERS									
ANY EVENT	≤63 Days (All)	21	12 (57%)	0.3140	21	12 (57%)	6 (29%)	3 (14%)	0
	≤49 Days (Group 1)	13	6 (46%)		13	8 (62%)	3 (23%)	2 (15%)	0
	50-56 Days (Group 2)	5	3 (60%)		4	1 (25%)	2 (50%)	1 (25%)	0
	57-63 Days (Group 3)	3	3 (100%)		4	3 (75%)	1 (25%)	0	0

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

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

Center: ROTHENBERG (#8)

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

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

Appendix A.1, Tables 16 and 25

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

Center: ROTHENBERG (#8)

Body System/Event	Gestational Age Group [2]	Total Number of Pts	Number of Pts w/Event	Fisher's exact p-value	Number of Events	Severity: Mild	Moderate	Severe	Unknown
BODY AS A WHOLE - GENERAL DISORDERS (cont.)									
BACK PAIN	≤63 Days (All)	21	1 (5%)	0.3810	1	0	1 (100%)	0	0
	≤49 Days (Group 1)	13	0		0	0	0	0	0
	50-56 Days (Group 2)	5	1 (20%)		1	0	1 (100%)	0	0
	57-63 Days (Group 3)	3	0		0	0	0	0	0

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