

Supplementary Table 1. **Subjects who experienced serious adverse events (safety population)**

Subject number	Age/sex/race	Preferred term	Relative day ^a		Severity	Causality ^b	Treatment
			Onset	Resolution			
FCM							
113	72/F/C	Ovarian cancer ^c	34	Ongoing	Moderate	None	Surgical
126	45/M/C	Coronary artery disease	47	48	Severe	None	Other
140	45/M/Hisp	Skin infection	2	12	Severe	None	Surgical
		Postoperative fever	22	31	Severe	None	Surgical
182	56/F/Other	Pancreatitis acute	25	30	Moderate	None	None
186	46/M/Hisp	Cardiac failure congestive	3	5	Severe	None	Medication
		Upper respiratory tract infection	3	17	Severe	None	Medication
		Cardiac failure congestive	17	19	Severe	None	Medication
		Coronary artery disease	51	53	Severe	None	None
216	85/M/C	Sepsis ^{c,d}	33	36	Severe	None	Medication
238	73/M/C	Colon cancer	36	Ongoing	Severe	None	Other
253	50/F/C	Pulmonary embolism	57	71	Moderate	None	Medication
326	63/F/C	Cellulitis	40	Ongoing	Severe	None	Medication
335	73/F/Asian	Myocardial infarction ^c	10	10	Severe	None	Other
337	76/M/C	Polytraumatism ^{c,d}	45	46	Severe	None	None
342	54/F/C	Cardiac failure congestive	31	38	Severe	None	Medication
350	61/F/Afr. Am	Palpitations	47	49	Moderate	None	Medication
Oral iron							
103	72/F/Afr. Am	Renal failure chronic ^c	13	20	Severe	None	Other
109	53/M/Afr. Am	Renal failure chronic	34	Ongoing	Severe	Unlikely	Other
136	76/M/C	Gastrointestinal haemorrhage ^c	16	Ongoing	Severe	None	Other
248	75/M/Afr. Am	Dyspnoea	56	58	Moderate	None	None
262	78/F/Afr. Am	Blood potassium increased	57	Ongoing	Severe	None	Medication
291	56/F/C	Glomerulonephritis proliferative ^c	44	Ongoing	Severe	None	Medication
302	66/F/Afr. Am	Myocardial ischaemia	42	51	Severe	None	None
312	73/F/C	Intestinal haemorrhage	23	27	Severe	None	Medication
323	77/F/C	Cardiac failure congestive ^c	19	23	Severe	None	Other
		Gastrointestinal haemorrhage ^c	19	23	Severe	None	Other
333	76/F/C	Cerebrovascular accident	34	40	Severe	None	Medication

Afr. Am, African American; C, Caucasian; F, female; Hisp, Hispanic; M, male; Res, resolution.

^aRelative day = onset date - study medication date; ^bAs assessed by the investigator;

^cEvent led to premature discontinuation; ^dEvent led to death