Visit:	REVISIT-C																			
☐ Week 0 ☐ Week 4 ☐ Week 8 ☐ Week 16 ☐ Week 24 ☐ Other: _____	Rater Initials:			Site Number:				Subject Initials:						A		B		C		
	A	B	C	#	#	#	#	Date:	D	D	M	M	M	Y	Y	Y	Y		
	Subject Number:								Start Time:		H		H	:		M		M		
	#	#	#	#	#	#	#	#	#	End Time:		H		H	:		M		M	

Modified Systematic Assessment for Treatment Emergent Events (SAFTEE)

INSTRUCTIONS: Carefully read each event. If an event is specifically asked for, and reported to be absent, indicate its severity as "none." When an event is present, record its SEVERITY as either None (0), Mild (1), Moderate (2), or Severe (3). The time period under consideration is since the previous study visit. Please note that any event coded above a '0' would be considered an adverse event unless it was already present at baseline and was scored at the same or lower level.

MYOCARDITIS-RELATED	None	Mild	Moderate	Severe
	0	1	2	3
1. Tachycardia/palpitations	☐	☐	☐	☐
2. Chest pain	☐	☐	☐	☐
3. Shortness of breath/dyspnea	☐	☐	☐	☐
4. Fever	☐	☐	☐	☐
5. Fatigue/weakness/malaise	☐	☐	☐	☐
OTHER	None	Mild	Moderate	Severe
	0	1	2	3
1. Constipation	☐	☐	☐	☐
2. Urination problems	☐	☐	☐	☐
3. Appetite increase	☐	☐	☐	☐
4. Weight gain	☐	☐	☐	☐
5. Dermatitis/allergy	☐	☐	☐	☐
6. Sedation/drowsiness/hypersomnia	☐	☐	☐	☐
7. Dizziness/faintness	☐	☐	☐	☐
8. Dry mouth	☐	☐	☐	☐
9. Salivation increased	☐	☐	☐	☐
10. Other _____	☐	☐	☐	☐
Comments:				