SITE Nº: PROJECT CODE (Sponsor)	PATIENT Nº:	REPORT TYPE: ☐ INITIAL ☐ FOLLOW UP	RANDOMIZATION:

ADDITIONAL FORM STUDY DRUGS INFORMATION

11. STUDY DRUG (drug and brand name) (1)	12. DOSE (Units)	12a FREQUENCY	12b. ROUTE	13. STUDY DISEASE	14. RELATED	15. START DATE			15a LAST DATE PRIOR TO SAE		
					☐ YES ☐ NO	dd	mmm	yyyy	dd	mmm	yyyy

16. WAS DRUG REGIMEN ALTERED IN RESPONSE TO THE EVENT?

☐ YES, ☐ NO ☐ NA

☐ Reduced-specify (date and new dose-go to 1)

☐ Temporarily interrupted (go to 2 or 3)

☐ Permanently Discontinued (go to 4)

DATES WHEN DRUG REGIMEN ALTERED

	dd	mmm	yyyy
1. Reduced			
2. Stopped			
3. Restarted			
4. Discontinued			

DETAILS OF NEW DOSE

New Dose	Units	Frequency

17. DID REACTION ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☐ NA

18. DID THE EVENT REAPPEAR AFTER REINTRODUCTION?

☐ YES ☐ NO ☐ NA

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