

DAC Study Form 335 - Temporary Discontinuation of Therapy

This Form should be completed by a study coordinator when a patient discontinues and restarts therapy for either study. This form must be completed to document any time that a patient's medications are stopped prior to surgery.

- 1. Patient Identification Number__ __ __ __ __
- 2. Name Code.....__ __ __ __
- 3. Date of discontinuation..... __ __ / __ __ / __ __ __ __

Note: If the drug has not yet been started and must be temporarily discontinued, enter the randomization date as the "date of the discontinuation".

- 4. a. Date study therapy restarted (at any dose)..... __ __ / __ __ / __ __ __ __

Note: If the therapy is not restarted yet, leave this date blank and fill it in later. You will get weekly e-mail reminders that this information needs to be added.

- b. If the study therapy will never be re-started, give reason.....__
1 = permanently discontinued (file form 336)
2 = patient died (file forms 371 & 372)
3 = patient lost to follow-up (file form 338)

- 5. Was this associated with a hospitalization? (0 = no, 1 = yes)

- 6. If yes, what was the admission date of that hospitalization? __ __ / __ __ / __ __ __ __

- 7. Was the patient instructed to discontinue therapy by a health care provider?.....__
(0 = no, 1 = yes)

- 8. Was this temporary stop primarily due to a planned surgery, a patient medical condition, a possible side effect or a logistic problem?

- 1 = required discontinuation prior to surgery or medical procedure/test
- 2 = medical condition
- 3 = possible side effect
- 4 = logistic problem

- 9. Describe briefly what happened.

201. Date this form completed..... __ __ / __ __ / __ __ __ __

202. User ID of person completing this form.....__ __ __ __ __

<i>Clinical Center Use Only</i>
Date Form Entered __ __ / __ __ / __ __ __ __
Person Entering this Form _____