

DAC Study Form 333 – Visit/Symptom Form

This form is completed:

- at baseline, six weeks after the surgery and 30 days after the drug was discontinued for the fistula study
- at baseline, monthly during follow-up and 30 days after the drug was discontinued for the graft study.

1. Patient Identification Number..... _____
2. Patient Name Code _____
3. a. Visit Type _____
b. Visit Number..... _____
c. Visit sequence number _____
4. Date of Visit..... ____/____/____

These items are for follow-up visits. Code 0=No, 1=Yes.

5. Does the unit nurse or other health care provider report any hospitalizations for this patient since his last DAC visit? _____
If so, complete Form 361.
6. Does the unit nurse or other health care provider report any transfusions for this patient since his last DAC visit? _____
If so, complete Form 363 if the patient had a bleeding episode.
7. Does the patient report any hospitalizations since his last DAC visit? _____
If so, complete Form 361.
8. Does the patient report any transfusions since his last DAC visit? _____
If so, complete Form 363 if the patient had a bleeding episode.
9. Does the patient report any access outpatient procedure since the last visit? _____
If so, complete Form 355 for the graft patients and Form 352 for the fistula patients.
10. Is the patient currently taking the drug? _____
If q. 10 = No, complete Form 335 or 336, as appropriate. Answer no if the patient has completed the 6 week course of study medication for the fistula study or if this is 30 days after the drug was discontinued (safety call).

These items are for all visits, including Baseline:

Enter a 1= yes for any symptom or problem the patient reports as having occurred as follows: For baseline – within the last month, for follow-up - since the patient's last DAC visit. Ask explicitly about the symptoms marked with asterisks. For these, enter 0=no or 1=yes. The number in brackets after the symptom is the MedDRA code.

11. *Nosebleeds* (10029802) _____
12. *Subconjunctival hemorrhage* (10042341)..... _____
13. *Other minor bleeding that does not lead to a clinic visit or a hospitalization* _____

