30909

AVID

Adverse Symptoms

Fax to: (206) 685-7569
or (800) 253-6404

Affix Patient ID # Here seqnum15

Complete this form at:

- Baseline hospital discharge.
- Each scheduled follow-up visit.
- Long-term change in AVID therapy due to adverse symptoms (e.g., dose reduction, crossover)

1 Date of evaluation:

days15

Month / Day / Year

reason15

2 Reason for evaluation:

1 O Hospital discharge, baseline hospitalization

2 O Scheduled follow-up:

follow15

1 O 1 mo	2 O 3 mo	3 O 6 mo	4 O 9 mo	5 O 1 yr
	6 O 1 yr 3 mo	7 O 1 yr 6 mo	8 O 1 yr 9 mo	9 O 2 yr
	10 O 2 yr 3 mo	11 O 2 yr 6 mo	12 O 2 yr 9 mo	13 O 3 yr
	14 O 3 yr 3 mo	15 O 3 yr 6 mo	16 O 3 yr 9 mo	17 O 4 yr

3 O Intended long-term change in AVID therapy due to adverse symptom (includes dose reduction).

Specify Change:

chgtyp15

1 O Dose reduction
2 O Crossover *(Complete a Change of Study Therapy form and report to CTC)*

3 Current antiarrhythmic therapy:

txnone15 O No Therapy
txicd15 O ICD
txanti15 O Antiarrhythmic drug

If antiarrhythmic drug, specify:

dramio15 O Amiodarone dose: amiomg15 mg/day

drsot15 O Sotalol dose: mg/day sotmg15

droth15 O Other:

dose: mg/day

dose: mg/day

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Date: ___ / ___ / ___ (Month / Day / Year)

___ - ___ - ___ Affix Patient ID # Here

advers15

4 Has the patient experienced any clinical adverse symptoms since last AVID contact (baseline or previous follow-up)?

0 ○ No - Skip to question 5

1 ○ Yes If YES, complete the following:

For each body system, indicate whether adverse symptoms have been noted, their severity and the action taken. Typical symptoms are listed on the facing page.

	Severity: None (0)	Severity: Mild/Moderate (1)	Severity: Severe (2)	Study therapy related? Yes (1)	Study therapy related? No (0)	Study therapy related? Unk (2)	Actions taken (mark all applicable): None	Study therapy: Stopped (1)	Study therapy: Changed* (2)	Other drug or dose change
CHF chfsev15	○	○	○ drchf15	○	○	○	○ chfnon15	○ chfstd15	○	○ chfoth15
Other cardiovascular carsev15	○	○	○ drcar15	○	○	○	○ carnon15	○ carstd15	○	○ caroth15
Pulmonary pulsev15	○	○	○ drpul15	○	○	○	○ pulnon15	○ pulstd15	○	○ puloth15
Neurologic neusev15	○	○	○ drneu15	○	○	○	○ neunon15	○ neustd15	○	○ neuoth15
Ocular ocusev15	○	○	○ drocu15	○	○	○	○ ocunon15	○ ocustd15	○	○ ocuoth15
Dermatologic drmsev15	○	○	○ drdrm15	○	○	○	○ drmnon15	○ drmstd15	○	○ drmoth15
Gastrointestinal gassev15	○	○	○ drgas15	○	○	○	○ gasnon15	○ gasstd15	○	○ gasoth15
Genitourinary gensev15	○	○	○ drgen15	○	○	○	○ gennon15	○ genstd15	○	○ genoth15
Musculoskeletal mussev15	○	○	○ drmus15	○	○	○	○ musnon15	○ musstd15	○	○ musoth15
Endocrine endsev15	○	○	○ drend15	○	○	○	○ endnon15	○ endstd15	○	○ endoth15
Non-ICD infection infsev15	○	○	○ drinf15	○	○	○	○ infnon15	○ infstd15	○	○ infoth15

ecgsym15

5 Has the patient experienced/demonstrated any ECG abnormalities since the last AVID contact?

2 ○ No ECG obtained -
0 ○ No abnormalities noted - — Skip to question 6

1 ○ Yes If YES, complete the following:

Yes (1)	No (0)		Study therapy related? Yes (1)	No (0)	Unk (2)	Actions taken (mark all applicable): None	Study therapy: Stopped (1)	Study therapy: Changed* (2)	Other drug or dose chg.	Pace-maker
brady15 ○	○	Bradycardia severe enough to prompt change in study therapy or other medications.	○ drbrd15	○	○	○ brdnon15	○ brdstd15	○	○ brdoth15	○ brdpac15
mobitz15 ○	○	Mobitz II, 2nd degree advanced or 3rd degree heart block.	○ drmob15	○	○	○ mobnon15	○ mobstd15	○	○ moboth15	○ mobpac15
qrslng15 ○	○	QRS two or more times baseline or QRS ≥200 msec.	○ drqrs15	○	○	○ qrsnon15	○ qrsstd15	○	○ qrsoth15	○ qrspac15
qtclng15 ○	○	QTc ≥ 500 msec.	○ drqtc15	○	○	○ qtcnon15	○ qtcstd15	○	○ qtcoth15	○ qtcpac15

* **Change in dose or reprogrammed**

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Date: ___ / ___ / ___ (Month / Day / Year)

___ - ___ - ___ ___
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Skip this question if no ICD

6 For patients with an ICD, has the patient experienced any LATE complications related to the ICD since last AVID follow-up? DO NOT include early complications (i.e., < 30 days after implantation or prior to baseline hospital discharge.)

icdcmp15

0 ○ No

1 ○ Yes If YES, complete the following:

Yes	No		
1	0	eros15	
○	○	Erosion/extrusion	
		seroma15	
○	○	Fluid accumulation/seroma	
		gnfail15	
○	○	Generator failure	*(Notify CTC immediately)*
		infect15	
○	○	ICD Infection	
		lddis15	
○	○	Lead dislodgement/migration	
		ldfail15	
○	○	Lead failure	*(Notify CTC immediately)*
		pain15	
○	○	Chronic pain	
		patch15	
○	○	Patch migration	
		othcmp15	
○	○	Other:	

Signature of person filling out this form

code number

For Clinical Trial Center Use Only: rtnum15

	Yes	No						
	○	○	2	1	5	0	4	0	0
CTC Code			ADVERSE page 3 of 3 6/01/95						