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

adverss15

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			Study therapy related?			Actions taken (mark all applicable)			
	None	Mild/ Moderate	Severe	Yes	No	Unk	None	Study therapy Stopped	Study therapy Changed*	Other drug or dose change
	0	1	2	1	0	2		1	2	
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:

		Study therapy related?			Actions taken (mark all applicable)				
1 Yes	0 No		1 Yes	0 No	2 Unk	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

___ - ___ - ___ ____
Affix Patient ID # Here

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						