

VALVULOPATHY			
Protocol Identifier	Subject Identifier	Visit Description	
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Treatment Period ABD Visit XYZ	

PRESENTATION

Did subject require hospitalization as a result of the valvulopathy? [Y] Yes [N] No

If Yes, admission date and time Day Month Year HR: Min(00:-23:59)

History

Did the subject have known valvulopathy prior to the reported event? [Y] Yes [N] No [NK] Not known

Did subject have any prior/concomitant medical condition known to cause or contribute to valvulopathy? [Y] Yes [N] No [NK] Not known

If Yes and this event is reported as an SAE, record details in _____ Section of SAE.

If Yes and this event has not been reported as an SAE, record details: _____

MEDICATIONS USED IN THE PAST KNOWN TO CAUSE/CONTRIBUTE TO VALVULOPATHY

Fenfluramine [Y] Yes [N] No [NK] Not known

Selective serotonin reuptake inhibitor [Y] Yes [N] No [NK] Not known

Amphetamine [Y] Yes [N] No [NK] Not known

Ergot derivatives [Y] Yes [N] No [NK] Not known

Other, specify [Y] Yes [N] No [NK] Not known

If Yes, specify: _____

PHYSICAL EXAM

Did subject have an abnormal physical exam findings consistent with the valvulopathy? [Y] Yes [N] No

If Yes, describe: _____

DIAGNOSTIC TESTS

Was an echocardiogram performed [Y] Yes [N] No

If Yes, complete the following:

Date and time of echocardiogram Day Month Year HR: Min(00:-23:59)

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Valves ¹	Appearance of Valves 1=Normal 2=Abnormal 3=Technically inadequate study 4=Test results not known	Stenosis		Regurgitation	
		Y=Yes N=No	If yes, degree of stenosis 3=None 4=Trace 5=Mild 6=Mild to Moderate 7=Moderate8=Moderate to Severe 9 = Severe	Y=Yes N=No	If yes, degree of stenosis 3=None 4=Trace 5=Mild 6=Mild to Moderate 7=Moderate8=Moderate to Severe 9 = Severe
	1	N		Y	3
Mitral					
Tricuspid					
Aortic					
Pulmonic					

Cardiac catheterisation [Y] Yes [N] No

If Yes, date and time of cardiac catheterisation

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Day		Month		Year		HR: Min(00:-23:59)	

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	1	N		Y	3
Mitral					
Tricuspid					
Aortic					
Pulmonic					

THERAPY REQUIRED

Was medication required for treatment of valvulopathy? [Y] Yes [N] No [U] Unknown

If Yes, specify medication & dose: _____

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Was surgical therapy required for treatment of valvulopathy?	[Y] <input type="checkbox"/> Yes	[N] <input type="checkbox"/> No	[NK] <input type="checkbox"/> Not Known
If Yes, note type of surgical therapy below:			
Mitral valve repair or replacement	[Y] <input type="checkbox"/> Yes	[N] <input type="checkbox"/> No	[NK] <input type="checkbox"/> Not Known
Tricuspid valve repair or replacement	[Y] <input type="checkbox"/> Yes	[N] <input type="checkbox"/> No	[NK] <input type="checkbox"/> Not Known
Aortic valve repair or replacement	[Y] <input type="checkbox"/> Yes	[N] <input type="checkbox"/> No	[NK] <input type="checkbox"/> Not Known
Pulmonary valve repair or replacement	[Y] <input type="checkbox"/> Yes	[N] <input type="checkbox"/> No	[NK] <input type="checkbox"/> Not Known
Other			
If Yes, specify: _____			

Add to comments re: be able to have each document stand alone with regards to understanding implication of not known vs requiring queries up front