

abbvie Risankizumab/ABBV-066 M16-244 Protocol Amendment 1 EudraCT 2016-003113-94

Appendix C. **Study Activities**

	Treatment					Follow-Up		
	V1	V2	V3	V4	V5 (EOT/Early EOT ^s)	V6	EOS (EOT/Early EOT + 16 Weeks)	Follow-up Phone Call
Week	0 ^a	4 ^t	12	24	36	48	52	56
Day	1	29 ± 4	85 ± 4	169 ± 4	253 ± 4	336 ± 4	365 ± 4	392 ± 4
Informed Consent ^b	X							
Inclusion/exclusion criteria	X							
Medical/Surgical History ^c	X ^a							
Patient's Global Assessment of Disease Activity (VAS) (PtGA) ^d	X ^a	X	X	X	X	X	X	
Patient's Assessment of PsA Pain Intensity (VAS) ^d	X ^a	X	X	X	X	X	X	
HAQ-DI ^d	X ^a	X	X	X	X	X	X	
BASDAI ^{d,m}	X ^a			X	X	X	X	
SF-36v2 ^d	X ^a	X	X	X	X	X	X	
FACIT-F ^d	X ^a			X	X	X		
Vital Signs ^e	X ^a	X	X	X	X	X	X	
ECG ^e	X ^a			X		X	X	
Physical Exam ^e (c = complete, t = targeted)	X-c ^a	X-t	X-t	X-t	X-t	X-t	X-c	
Concomitant Therapy ^f	X ^a	X	X	X	X	X	X	X