

Time & Events MP8 Stage 1	Screen/Baseline		Preparatory	Experimental Session 1		Experimental Session 2			Experimental Session 3		Follow-Up
Visit #	Pre-Study	V1	V 2,3,4	V5	V 6,7,8	V9	V 10,11,12	V13	V14	V 15,16,17	V18
Type of Visit	Screening may take place over more than one day	Baseline	Preparatory Sessions	Experimental Session 1	Integrative Sessions	Experimental Session 2	Integrative Sessions	Outcome	Experimental Session 3	Integrative Sessions	Follow-Up & Outcome
Visit Timing or Study day or Window	Up to 1 month prior to Visit 1	Day 1	Approx 1 week apart	3-5 weeks post baseline	Approx. 1 week apart <sup>A</sup>	3-5 weeks post V5	Approx. 1 week apart <sup>A</sup>	1 month post V9	3-5 weeks post V9	Approx. 1 week apart <sup>A</sup>	May happen over more than 1 day. 2 months post V14
Initial Phone Screen	X										
Informed Consent	X										
Medical/Psychiatric History	X										
General Physical Exam (BP, Pulse, Temp, brief systems check)	X										
Brief Neurological Exam	X										
ECG	X										
SCID	X										
Clinical Lab Tests, w/ HIV test	X										
Collect Concomitant Medication	X	X	X	X	X	X	X		X	X	X
Medication Taper (if applicable)	X	X									
Study Enrollment after meeting I/E		X									
Record to Audio/Video			X	X	X	X	X		X	X	
General Well-Being		X	X	X	X	X	X		X	X	X
Drug Screen	X			X		X			X		
Pregnancy Screen (if applicable)	X			X		X			X		
Complete Randomization Procedure				X <sup>C</sup>							
CAPS, GAF, BDI and PTGI-C With Independent Rater	X		X <sup>B</sup>					X			X
C-SSRS		X	X <sup>H</sup>	X <sup>D, E, F</sup>	X	X <sup>D, E, F</sup>	X		X <sup>D, E, F</sup>	X	X
Administer IP Drug+Therapy				X		X					
Monitoring of BP, Pulse and Temp.				X							
SUDS				X <sup>E, G</sup>		X <sup>E, G</sup>			X <sup>E, G</sup>		
Beliefs of Condition Assignment				X		X			X		
Overnight Stay				X		X			X		
Integrative Therapy Session					X		X			X	
RRPQ											X <sup>I</sup>
7 days Integrative Telephone Contact					X <sup>J</sup>		X <sup>J</sup>			X <sup>J</sup>	
Adverse Events Requiring Dr. Visit			X	X	X	X	X		X	X	X
Spontaneously Reported Side Effects				X	X	X	X		X	X	
Adverse Events of Concern			X	X	X	X	X		X	X	
Serious Adverse Events		X	X	X	X	X	X		X	X	X
Unblinding <sup>K</sup>											X

<sup>A</sup>=First Integrative session is 1 day after exp session <sup>B</sup>=repeat before V5 ONLY if meds are tapered <sup>C</sup>= Within 24 hrs prior to 1st exp. session <sup>D</sup>=Approximately 6 hours post MDMA <sup>E</sup>=at the beginning of the session <sup>F</sup>=as needed <sup>G</sup>=Approximately every 60 minutes <sup>H</sup>=Given on 2nd preparatory session only (V3) <sup>I</sup>= Only for subjects starting Long term Follow up and not going to Stage 2 <sup>J</sup> =For 7 days post Exp. Session, CSSRS D2 and D7 of calls only, General well being for all 7 days <sup>K</sup>=Subjects will go onto 1 Year Long Term Follow up or Stage 2

Time & Events MP8 Stage 2	Preparatory	Experimental Session 1		Experimental Session 2			Experimental Session 3		Follow-Up	Long Term Follow-Up
	Visit #	V20	V 21,22,23	V24	V 25,26,27	V28	V29	V 30,31,32	V33	
Type of Visit	Preparatory Sessions	Experimental Session 1	Integrative Sessions	Experimental Session 2	Integrative Sessions	Outcome	Experimental Session 3	Integrative Sessions	Follow-Up & Outcome	1 Year Follow-up
Visit Timing or Study day or Window	Within 1 month of V18*	1 week post V19	Approx. 1 week apart <sup>A</sup>	3-5 weeks post V20	Approx. 1 week apart <sup>A</sup>		3-5 weeks post V24	Approx. 1 week apart <sup>A</sup>	May happen over more then 1 day. 2 months post V29	May happen over more then 1 day. One Year After V14 or V29
Confirm Informed Consent	X									
Confirm Inclusion/Exclusion	X									
Enrollment in Stage 2	X									
Collect Concomitant Medication	X	X	X	X	X		X	X	X	
Record to Audio/Video	X	X	X	X	X		X	X		
General Well-Being	X	X	X	X	X		X	X	X	
Drug Screen		X		X			X			
Pregnancy Screen (if applicable)		X		X			X			
CAPS, GAF, BDI and PTGI-C With Independent Rater	Use V18*								X	X
C-SSRS	X <sup>H</sup>	X <sup>D, E, F</sup>	X	X <sup>D, E, F</sup>	X		X <sup>D, E, F</sup>	X	X	X
Administer IP Drug+Therapy		X		X						
Monitoring of BP, Pulse and Temp.		X								
SUDS		X <sup>E, G</sup>		X <sup>E, G</sup>			X <sup>E, G</sup>			
Overnight Stay		X		X			X			
Integrative Therapy Session			X		X			X		
RRPQ									X	X
7 days Integrative Telephone Contact			X <sup>J</sup>		X <sup>J</sup>			X <sup>J</sup>		
Adverse Events Requiring Dr. Visit	X	X	X	X	X		X	X	X	
Spontaneously Reported Side Effects		X	X	X	X		X	X		
Adverse Events of Concern	X	X	X	X	X		X	X		
Serious Adverse Events	X	X	X	X	X		X	X	X	X
Complete Stage 2 go to 1yr Follow-up									X	
Termination Visit										X

Long Term Follow up after Stage 1 or Stage 2

\* If Visit 19 is more then 1 month after V18 then the measures from V18 will need to be repeated prior to starting Stage 2

<sup>A</sup>=first session is 1 day after exp session <sup>D</sup>=Approximately 6 hours post MDMA <sup>E</sup>=at the beginning of the session <sup>F</sup>=as needed <sup>G</sup>=Approximately every 60 minutes <sup>H</sup>=Given on 2nd preparatory session only (V3) <sup>J</sup>=For 7 days post Exp. Session, CSSRS D2 and D7 of calls only, General well being for all 7 days