SCHEDULE OF PROCEDURES

(from Clinical Study Protocol IVA337 SSC POC – Version 2, 7 July 2015)

Study phase	**Pre-TTT**	**Treatment phase**														**Post TTT**
Visit	**V0**	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**	**V12**	**V13**	**V14**	**V15**
Outpatient			X	X	X	X	X	X		X	X	X	X	X		X
Weeks (target +/- 3 days)	-4 to -1	0	2	4	8	12	16	20	24	28	32	36	40	44	48	60
One day hospital (according to local facilities and procedures)	X	X							X						X	
Informed consent	X															
Demographics	X															
Medical History	X															
Eligibility criteria	X	X														
Concomitant & escape medication	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical exam / vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12 lead ECG	X								X						X	
MRSS	X	X				X			X		X				X	X
Pulmonary function (FVC% / cDLCO%)		X							X						X	
Digital ulcer count Joint/tendon assessment	X	X				X			X		X				X	X

Visit	**V0**	**V1**	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**	**V10**	**V11**	**V12**	**V13**	**V14**	**V15**
Weeks	-4 / -1	0	2	4	8	12	16	20	24	28	32	36	40	44	48	60
Cochin hand function scale	X	X				X			X		X				X	X
Raynaud assessment					X				X							
Patient reported outcome (SHAQ, PROMIS29, GIT, SF36)		X							X						X	X
Patient/physician overall (VAS)		X							X						X	X
Pregnancy test (urine)		X														
Blood sampling, safety (ml) & urinalysis	X (13.5)	X (9)	X (9)			X (9)		X (9)	X (9)		X (9)	X (9)		X (9)	X (11)	X (9)
Blood sampling, biomarkers (ml)		X (9)				X (9)			X (9)						X (9)	
Blood sampling, pharmacokinetics (ml)			X (9)						X (9)						X (9)	
Skin biopsy		X													X	
Randomization		X														
Dispense study medication		X		X	X	X	X	X	X	X	X	X	X	X		
Adverse event assessment		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X