

Annotated Study Book for Study Design: PROSTAGRAM

Study Design Version: 5.0

PROSTAGRAM

Generated by Central Designer TM

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Time and Events Schedule For Study Design: PROSTAGRAM													
Element		System											
Assessment	CRF	System Screening (SCR) [S]	System Enrolment (ENR) [S]	Screening Visit 1 (SCRV) [S]	Results (RESULTS) [S]	BIOPSY Visit 2 (BIOPSY) [S/D]	FU Visit 3 (FU) [S]	Protocol Deviations (PROT DEVS) [U]	AE (AE) [S]	Device Deficiency (DD) [S]	EOS (EOS) [S]	Signoff (SIGNOFF) [S]	
Visit Start Hours		0	0	0	168	361	529	530	723	916	1109	1302	
1 System Screening	SYS SCR	1											
2 System Enrolment	SYS ENR		1										
3 Date of Visit	DOV			1	1	1	1			1			
4 Inclusion & Exclusion	INC EXC			2									
5 EBQ	EBQ			3									
6 QOL Questionnaires	QOLQ			4		3	2						
7 Baseline Questionnaire	BQ			5									
8 PBQ	PBQ			6									
9 Demographics	DEMO			7									
10 Phlebotomy Form	PHLEB			8-RF									
11 Charlson Co-morbidity Index	CCI			9									
12 History and US Procedure Form	US			10-RF									
13 MRI Procedure Form	MRI			11-RF									
14 PSA result	PSA				2								
15 MRI Reporting Form	MRI-R				3								
16 CAD Report Form	CAD				4								
17 Ultrasound report	US-R				5								
18 Randomisation	RAND				6								
19 Second MRI Report Form	SECOND MRI				7								
20 Episwitch result (Optional)	EPIS				8								
21 Targeted biopsy form	TBR					2							
22 Pathology Result	PATH					4							
23 Treatment Form	TRTMNT						3						
24 Protocol Deviations/Violations	PROT DEV							1-RF					
25 Adverse Events	AE								1-RF				
26 SAE Report Form	SAE REP								2-RF				
27 CI Review Form	CI REVIEW								3-RF				
28 Device Deficiency Worksheet	DEV DEF									2			
29 Study Exit	EOS										1		
30 Study Sign Off	SIGN OFF											1	
Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit C = Common Form DF = Dynamic Form RF = Repeating Form													

InForm Special Properties For Study Design: PROSTAGRAM			
InForm Special Property	Property Type	Data Object RefName	Data Object Path RefName
Screening	Visit	SCR	SCR
Enrollment	Visit	ENR	ENR
Screening	Form	frmSYSSCR	Copyofallforms.frmSYSSCR SCR.frmSYSSCR
Enrollment	Form	frmSYSENr	Copyofallforms.frmSYSENr ENR.frmSYSENr
Patient Identification	Form	frmDEMO	Copyofallforms.frmDEMO SCRv.frmDEMO
Study Completion	Form	frmEOS	Copyofallforms.frmEOS EOS.frmEOS
Reg Docs	Form	Unassigned	Unassigned
Visit Report	Form	Unassigned	Unassigned
Initials (Screening)	Item	itmSSInit	Copyofallforms.frmSYSSCR.secSC.itmSSInit SCR.frmSYSSCR.secSC.itmSSInit
DOB (Screening)	Item	Unassigned	Unassigned
Screening date (Screening)	Item	itmSSScrnDat	Copyofallforms.frmSYSSCR.secSC.itmSSScrnDat SCR.frmSYSSCR.secSC.itmSSScrnDat
Patient No. (Enrollment)	Item	itmDEMSubNo	Copyofallforms.frmDEMO.itmDEMSubNo Copyofallforms.frmSYSENr.secSE.itmDEMSubNo SCRv.frmDEMO.itmDEMSubNo ENR.frmSYSENr.secSE.itmDEMSubNo
Initials (Patient Identification)	Item	Unassigned	Unassigned
Completion status (Study Completion)	Item	itmEOSCompYN	Copyofallforms.frmEOS.itmEOSCompYN EOS.frmEOS.itmEOSCompYN
Drop out reason (Study Completion)	Item	itmEOSRsn	Copyofallforms.frmEOS.itmEOSNo.itmEOSRsn EOS.frmEOS.itmEOSNo.itmEOSRsn
DOV (Date of Visit)	Item	itmDOV	US.frmDOV.itmDOV Copyofallforms.frmDOV.itmDOV Results.frmDOV.itmDOV SCRv.frmDOV.itmDOV DD.frmDOV.itmDOV V2.frmDOV.itmDOV FUV3.frmDOV.itmDOV
Randomization field (Randomization)	Item	Unassigned	Unassigned

Personal/Protected Health Information Table: PROSTAGRAM		
Item RefName	Section RefName	Form RefName
No items have been defined as "Personal/Protected Health Information".		
Please note: emails sent from the trial server by the InForm application are not encrypted. If you are subject to HIPAA requirements, you should identify and block all Personal/Protected Health Information items that may be included in email notifications.		

Unit Conversions For Study Design: PROSTAGRAM
No unit conversion data.

Review States for Study: PROSTAGRAM			
Review State '1': Stage1			
Description		Stage1	
RefName		Stage1	
Activated		yes	
InForm Product Locale: English (United States)			
Review State Label		Stage1	
Review State Mnemonic		S1	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S1Stage1	S1S1	S1Stage1
2	S1Stage2	S1S2	S1Stage2
3	S1Stage3	S1S3	S1Stage3
InForm Product Locale: Japanese (Japan)			
Review State Label		Stage1J	
Review State Mnemonic		S1J	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S1Stage1	S1S1J	S1Stage1J
2	S1Stage2	S1S2J	S1Stage2J
3	S1Stage3	S1S3J	S1Stage3J
Review State '2': Stage2			
Description		Stage2	
RefName		Stage2	
Activated		yes	
InForm Product Locale: English (United States)			
Review State Label		Stage2	
Review State Mnemonic		S2	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S2Stage1	S2S1	S2Stage1
2	S2Stage2	S2S2	S2Stage2
3	S2Stage3	S2S3	S2Stage3
InForm Product Locale: Japanese (Japan)			
Review State Label		Stage2J	
Review State Mnemonic		S2J	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S2Stage1	S2S1J	S2Stage1J
2	S2Stage2	S2S2J	S2Stage2J
3	S2Stage3	S2S3	S2Stage3J
Review State '3': Stage3			
Description		Stage3	
RefName		Stage3	
Activated		yes	
InForm Product Locale: English (United States)			
Review State Label		Stage3	
Review State Mnemonic		S3	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S3Stage1	S3S1	S3Stage1
2	S3Stage2	S3S2	S3Stage2
3	S3Stage3	S3S3	S3Stage3
InForm Product Locale: Japanese (Japan)			
Review State Label		Stage3J	
Review State Mnemonic		S3J	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S3Stage1	S3S1J	S3Stage1J
2	S3Stage2	S3S2J	S3Stage2J
3	S3Stage3	S3S3J	S3Stage3J
Review State '4': Stage4			
Description		Stage4	
RefName		Stage4	
Activated		yes	
InForm Product Locale: English (United States)			

Review State Label		Stage4	
Review State Mnemonic		S4	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S4Stage1	S4S1J	S4Stage1
2	S4Stage2	S4S2	S4Stage2
3	S4Stage3	S4S3	S4Stage3
InForm Product Locale: Japanese (Japan)			
Review State Label		Stage4J	
Review State Mnemonic		S4J	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S4Stage1	S4S1J	S4Stage1J
2	S4Stage2	S4S2J	S4Stage2J
3	S4Stage3	S4S3J	S4Stage3J
Review State '5': Stage5			
Description		Stage5	
RefName		Stage5	
Activated		yes	
InForm Product Locale: English (United States)			
Review State Label		Stage5	
Review State Mnemonic		S5	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S5Stage1	S5S1	S5Stage1
2	S5Stage2	S5S2	S5Stage2
3	S5Stage3	S5S3	S5Stage3
InForm Product Locale: Japanese (Japan)			
Review State Label		Stage5J	
Review State Mnemonic		S5J	
Stage	Stage Name	Stage Mnemonic	Stage Label
1	S5Stage1	S5S1J	S5Stage1J
2	S5Stage2	S5S2J	S5Stage2J
3	S5Stage3	S5S3J	S5Stage3J