

Annotated Study Book for Study Design: PROSTAGRAM

Study Design Version: 5.0

PROSTAGRAM

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May 3, 2019 3:33PM

PROSTAGRAM: System Screening (SYS SCR) [frmSYSSCR]		
System Screening [secSC]		
1.*	Subject Initials <i>[hidden]</i> [Sub Inits]	[itmSSInit] <input type="text" value="A3"/>
2.*	Screening date <input checked="" type="checkbox"/> [Screening Date]	[itmSSScrnDat] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
Key: [*] = Item is required <input checked="" type="checkbox"/> = Source verification critical Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: System Screening		
Type	RefName	Description
Form	frmSYSSCR	System screening
Section	secSC	System Screening
Item	itmSSInit	Patient Initials

RDE Analytics: RD_FRMSYSSCR			
Data Variable	RefName	RD Column Name	Column Data Type
itmSSInit		ITMSSINIT	VARCHAR2
		ITMSSINIT_ND	VARCHAR2
itmSSScrnDat		ITMSSSCRNDAT	DATE
		ITMSSSCRNDAT_DTS	VARCHAR2
		ITMSSSCRNDAT_ND	VARCHAR2

PROSTAGRAM: System Enrolment (SYS ENR) [frmSYSENR]

System Enrolment [secSE]

1.

Subject number *[read-only]*
[Sub no]

[itmDEMSubNo]

N3

2.*

Date the consent was signed
[Consent date]

[itmSEDOC]






Req / Req / Req (2018-2030)

Key: [*] = Item is required [] = Source verification critical

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Study Object Descriptions: System Enrolment		
Type	RefName	Description
Form	frmSYSENR	Enrolment Form
Section	secSE	System Enrolment
Item	itmDEMSubNo	Patient Number
Item	itmSEDOC	Date of Consent

RDE Analytics: RD_FRMSYSENR		
Data Variable RefName	RD Column Name	Column Data Type
itmDEMSubNo	ITMDEMSUBNO	NUMBER
	ITMDEMSUBNO_ND	VARCHAR2
itmSEDOC	ITMSEDOC	DATE
	ITMSEDOC_DTS	VARCHAR2
	ITMSEDOC_ND	VARCHAR2

PROSTAGRAM: Date of Visit (DOV) [frmDOV]		
Date of Visit [frmDOV]		
1.* 	Date of Visit [Date of Visit]	[itmDOV] Req  / Req  / Req  (2018-2030)
Key: [*] = Item is required  = Source verification critical Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: Date of Visit		
Type	RefName	Description
Form	frmDOV	Date of Visit
Item	itmDOV	Date of Visit

RDE Analytics: RD_FRMDOV		
Data Variable RefName	RD Column Name	Column Data Type
itmDOV	ITMDOV	DATE
	ITMDOV_DTS	VARCHAR2
	ITMDOV_ND	VARCHAR2



PROSTAGRAM: Inclusion & Exclusion (INC EXC) [frmINC]		
INCLUSION [secINCLUSION]		
1.* <input checked="" type="checkbox"/>	Age ≥50 and ≤69 years at time of consent [Age]	[itmINC1Age] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
2.* <input checked="" type="checkbox"/>	An understanding of the English language sufficient to understand written and verbal information about the trial and consent process [An understanding of the English language]	[itmINC2Langag] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
3.* <input checked="" type="checkbox"/>	Willing and able to provide written informed consent [Willing and able to provide written informed consent]	[itmINC3Cnsnt] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
4.* <input checked="" type="checkbox"/>	Able and willing to comply with all study procedures [Procedure]	[itmINC4Procd] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
5.* <input checked="" type="checkbox"/>	Estimated life expectancy of 10 years or more [Estimated life expectancy]	[itmINC5Expct] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
EXCLUSION [secEXCLUSION]		
6.* <input checked="" type="checkbox"/>	Previous PSA test or prostate MRI within the prior two years of screening/consent visit [PSA]	[itmEXC1PSA] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
7.* <input checked="" type="checkbox"/>	Evidence of a urinary tract infection or history of acute prostatitis within the last 6 months [Evidence of a urinary tract infection]	[itmEXC2infectn] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
8.* <input checked="" type="checkbox"/>	Previous history of prostate cancer, prostate biopsy or treatment for prostate cancer (interventions for benign prostatic hyperplasia/bladder outflow obstruction is acceptable) [Previous history of prostate cancer]	[itmEXC3Cncr] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
9.* <input checked="" type="checkbox"/>	Any potential contraindication to MRI, including but not limited to: a. Devices or metallic foreign bodies such as pacemakers, implantable defibrillators, neurostimulators, cochlear implants, coronary stents, prosthetic heart valves, aneurysm clips and other intravascular devices b. Previous history of hip replacement surgery, metallic hip replacement or extensive pelvic orthopaedic metal c. Claustrophobia [Any potential contraindication to MRI]	[itmEXC4MRI] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
10.* <input checked="" type="checkbox"/>	Any potential contraindication to prostate biopsy [Prostate biopsy]	[itmEXC5Biop] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
11.* <input checked="" type="checkbox"/>	Dementia or altered mental status that would prohibit the understanding or rendering of informed consent. [Dementia or altered mental status]	[itmEXC6] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
12.* <input checked="" type="checkbox"/>	Any other medical condition precluding procedures described in the protocol [Any other medical condition precluding procedures]	[itmEXC7] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
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Study Object Descriptions: Inclusion & Exclusion		

Type	RefName	Description
Form	frmINC	Inclusion Criteria
Section	secINCLUSION	INCLUSION
Section	secEXCLUSION	EXCLUSION

RDE Analytics: RD_FRMINC		
Data Variable RefName	RD Column Name	Column Data Type
itmINC1Age	ITMINC1AGE_C	NUMBER
	ITMINC1AGE	VARCHAR2
	ITMINC1AGE_ND	VARCHAR2
itmINC2Langag	ITMINC2LANGAG_C	NUMBER
	ITMINC2LANGAG	VARCHAR2
	ITMINC2LANGAG_ND	VARCHAR2
itmINC3Cnsnt	ITMINC3CNSNT_C	NUMBER
	ITMINC3CNSNT	VARCHAR2
	ITMINC3CNSNT_ND	VARCHAR2
itmINC4Procd	ITMINC4PROCD_C	NUMBER
	ITMINC4PROCD	VARCHAR2
	ITMINC4PROCD_ND	VARCHAR2
itmINC5Expct	ITMINC5EXPCT_C	NUMBER
	ITMINC5EXPCT	VARCHAR2
	ITMINC5EXPCT_ND	VARCHAR2
itmEXC1PSA	ITMEXC1PSA_C	NUMBER
	ITMEXC1PSA	VARCHAR2
	ITMEXC1PSA_ND	VARCHAR2
itmEXC2infectn	ITMEXC2INFECTN_C	NUMBER
	ITMEXC2INFECTN	VARCHAR2
	ITMEXC2INFECTN_ND	VARCHAR2
itmEXC3Cncr	ITMEXC3CNCR_C	NUMBER
	ITMEXC3CNCR	VARCHAR2
	ITMEXC3CNCR_ND	VARCHAR2
itmEXC4MRI	ITMEXC4MRI_C	NUMBER
	ITMEXC4MRI	VARCHAR2
	ITMEXC4MRI_ND	VARCHAR2
itmEXC5Biop	ITMEXC5BIOP_C	NUMBER
	ITMEXC5BIOP	VARCHAR2
	ITMEXC5BIOP_ND	VARCHAR2
itmEXC6	ITMEXC6_C	NUMBER
	ITMEXC6	VARCHAR2
	ITMEXC6_ND	VARCHAR2

itmEXC7	ITMEXC7_C	NUMBER
	ITMEXC7	VARCHAR2
	ITMEXC7_ND	VARCHAR2




PROSTAGRAM: EBQ (EBQ) [frmEBQ]		
PSA Expected Burden Questionnaire (EBQ) Details [secEBQ]		
# ✓	EBQ Details	Scores*
1.a	How embarrassing do you expect the PSA blood test to be?	
1.b	How painful do you expect the PSA blood test procedure to be?	
1.c	How burdensome do you expect the PSA blood test to be?	
1.d	How anxious do you expect to feel during the PSA blood test?	
PSA Expected Burden Questionnaire (EBQ) Details Entry [secEBQ]		
1.1 ✓ 	EBQ Details [read-only] [EBQ Details]	[itmEBQDtl] [N:1] <input type="radio"/> How embarrassing do you expect the PSA blood test to be? [N:2] <input type="radio"/> How painful do you expect the PSA blood test procedure to be? [N:3] <input type="radio"/> How burdensome do you expect the PSA blood test to be? [N:4] <input type="radio"/> How anxious do you expect to feel during the PSA blood test?
1.2* ✓	Scores [Scores]	[itmEBQscr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Slightly [N:2] <input type="radio"/> Somewhat [N:3] <input type="radio"/> Rather [N:4] <input type="radio"/> Extremely
Ultrasound Expected Burden Questionnaire (EBQ) Details [secUEBQ]		
# ✓	EBQ Details	Scores*
2.a	How embarrassing do you expect the prostate ultrasound test to be?	
2.b	How painful do you expect the prostate ultrasound procedure to be?	
2.c	How burdensome do you expect the prostate ultrasound procedure to be?	
2.d	How anxious do you expect to feel during the prostate ultrasound?	
Ultrasound Expected Burden Questionnaire (EBQ) Details Entry [secUEBQ]		
2.1 ✓ 	EBQ Details [read-only] [EBQ Details]	[itmUEBQdtl] [N:0] <input type="radio"/> How embarrassing do you expect the prostate ultrasound test to be? [N:1] <input type="radio"/> How painful do you expect the prostate ultrasound procedure to be? [N:2] <input type="radio"/> How burdensome do you expect the prostate ultrasound procedure to be? [N:3] <input type="radio"/> How anxious do you expect to feel during the prostate ultrasound?
2.2* ✓	Scores [Scores]	[itmUEBQScr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Slightly [N:2] <input type="radio"/> Somewhat [N:3] <input type="radio"/> Rather [N:4] <input type="radio"/> Extremely
MRI Expected Burden Questionnaire (EBQ) Details [secMEBQ]		
# ✓	EBQ Details	Scores*
3.a	How embarrassing do you expect the prostate MRI test to be?	
3.b	How painful do you expect the prostate MRI procedure to be?	
3.c	How burdensome do you expect the prostate MRI procedure to be?	


3.d	How anxious do you expect to feel during the prostate MRI?	
MRI Expected Burden Questionnaire (EBQ) Details Entry [secMEBQ]		
3.1 ✓ 	EBQ Details <i>[read-only]</i> [EBQ Details]	[itmMEBQDtl] [N:1] <input type="radio"/> How embarrassing do you expect the prostate MRI test to be? [N:2] <input type="radio"/> How painful do you expect the prostate MRI procedure to be? [N:3] <input type="radio"/> How burdensome do you expect the prostate MRI procedure to be? [N:4] <input type="radio"/> How anxious do you expect to feel during the prostate MRI?
3.2* ✓	Scores [Scores]	[itmMEBQScr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Slightly [N:2] <input type="radio"/> Somewhat [N:3] <input type="radio"/> Rather [N:4] <input type="radio"/> Extremely
Prefer MRI Test [secPMI]		
4.* ✓	Overall which test do you expect to prefer? [Overall which test do you expect to prefer]	[itmMRIEBqPrefr] [N:0] <input type="radio"/> No preference [N:1] <input type="radio"/> PSA test [N:2] <input type="radio"/> Ultrasound [N:3] <input type="radio"/> MRI
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Study Object Descriptions: EBQ		
Type	RefName	Description
Form	frmEBQ	PSA Expected Burden Questionnaire (PSA EBQ)
Section	secEBQ	PSA Expected Burden Questionnaire (EBQ) Details
Section	secUEBQ	Ultrasound Expected Burden Questionnaire (EBQ) Details
Section	secMEBQ	MRI Expected Burden Questionnaire (EBQ) Details
Section	secPMI	Prefer MRI Test

RDE Analytics: RD_FRMEBQ		
Data Variable RefName	RD Column Name	Column Data Type
itmMRIEBqPrefr	ITMMRIEBQPREFR_C	NUMBER
	ITMMRIEBQPREFR	VARCHAR2
	ITMMRIEBQPREFR_ND	VARCHAR2
RD_FRMEBQ_SECEBQ		
itmEBQDtl	ITMEBQDTL_C	NUMBER
	ITMEBQDTL	VARCHAR2
	ITMEBQDTL_ND	VARCHAR2
itmEBQscr	ITMEBQSCR_C	NUMBER
	ITMEBQSCR	VARCHAR2
	ITMEBQSCR_ND	VARCHAR2
RD_FRMEBQ_SECUEBQ		

itmUEBQdtl	ITMUEBQDTL_C	NUMBER
	ITMUEBQDTL	VARCHAR2
	ITMUEBQDTL_ND	VARCHAR2
itmUEBQScr	ITMUEBQSCR_C	NUMBER
	ITMUEBQSCR	VARCHAR2
	ITMUEBQSCR_ND	VARCHAR2
RD_FRMEBQ_SECMEBQ		
itmMEBQDtl	ITMMEBQDTL_C	NUMBER
	ITMMEBQDTL	VARCHAR2
	ITMMEBQDTL_ND	VARCHAR2
itmMEBQScr	ITMMEBQSCR_C	NUMBER
	ITMMEBQSCR	VARCHAR2
	ITMMEBQSCR_ND	VARCHAR2

PROSTAGRAM: QOL Questionnaires (QOLQ) [frmQOLQ]		
STAI-6 [SecSTAI6]		
# ✓	STAI-6 Score details	Scores*
1.a	I feel calm	
1.b	I am tense	
1.c	I feel upset	
1.d	I am relaxed	
1.e	I feel content	
STAI-6 Entry [SecSTAI6]		
1.1 ✓ 	STAI-6 Score details <i>[read-only]</i> [STAI-6 Score details]	[itmSTATscr] [N:0] <input type="radio"/> I feel calm [N:1] <input type="radio"/> I am tense [N:2] <input type="radio"/> I feel upset [N:3] <input type="radio"/> I am relaxed [N:4] <input type="radio"/> I feel content
1.2* ✓	Scores [Scores]	[itmSTAIScr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Somewhat [N:2] <input type="radio"/> Moderately [N:3] <input type="radio"/> Very much
PCQ Details [secPCQ]		
# ✓	PCQ Details	Scores*
2.a	Had trouble sleeping	
2.b	Experienced a change in appetite	
2.c	Been unhappy or depressed	
2.d	Been scared and panicky	
2.e	Felt nervous or strung up	
2.f	Felt under strain	
2.g	Found you have been keeping things from those who are close to you	
2.h	Found yourself taking things out on other people	
2.i	Found yourself noticeably withdrawing from those who are close to you	
2.j	Had difficulty doing things around the house that you normally do	
2.k	Had difficulty meeting work or other commitments	
2.l	Felt worried about your future	
PCQ Details Entry [secPCQ]		
2.1 ✓ 	PCQ Details <i>[read-only]</i> [PCQ Details]	[itmPCQdtl] [clPCQdtl] 
2.2* ✓	Scores [Scores]	[itmPCQScr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Rarely [N:2] <input type="radio"/> Some of the time

		[N:3] <input type="radio"/> Quite a lot of the time
Cancer Worry Scale (CWS) During the past month [secPM]		
# ✓	CWS Details	Scales*
3.a	How often have you thought about your chances of getting prostate cancer?	
3.b	Have these thoughts affected your mood?	
3.c	Have these thoughts interfered with your daily activities?	
Cancer Worry Scale (CWS) During the past month Entry [secPM]		
3.1 ✓ 	CWS Details [read-only] [CWS Details]	[itmCWSdtl] [N:0] <input type="radio"/> How often have you thought about your chances of getting prostate cancer? [N:1] <input type="radio"/> Have these thoughts affected your mood? [N:2] <input type="radio"/> Have these thoughts interfered with your daily activities?
3.2* ✓	Scales [Scales]	[itmCWSScl] [N:0] <input type="radio"/> Rarely/Never [N:1] <input type="radio"/> Sometimes [N:2] <input type="radio"/> Often [N:3] <input type="radio"/> All of the time
Concerned about getting prostate cancer [secConcrn]		
4.* ✓	How concerned are you about getting prostate cancer one day [How concerned are you about getting prostate cancer one day]	[itmCWSConcrn] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Somewhat [N:2] <input type="radio"/> Moderately concerned [N:3] <input type="radio"/> Very concerned
SF-12 This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can. [secGenrl]		
5.* ✓	In general, would you say your health is? [In general]	[itmSF12gen] [N:0] <input type="radio"/> Excellent [N:1] <input type="radio"/> Very Good [N:2] <input type="radio"/> Good [N:3] <input type="radio"/> Fair [N:4] <input type="radio"/> Poor
The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [secMA]		
6.* ✓	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf [Moderate activities]	[itmSF12Ma] [N:0] <input type="radio"/> Yes, limited a lot [N:1] <input type="radio"/> Yes, limited a little [N:2] <input type="radio"/> No, not limited at all
7.* ✓	Climbing several flights of stairs [Climbing several flights of stairs]	[itmSF12Climb] [N:0] <input type="radio"/> Yes, limited a lot [N:1] <input type="radio"/> Yes, limited a little [N:2] <input type="radio"/> No, not limited at all
During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? [secPH]		
8.* ✓	Accomplished less than you would like [Accomplished less than you would like]	[itmPHAccomp] [N:1] <input type="radio"/> Yes

		[N:0] <input type="radio"/> No
9.* ✓	Were limited in the kind of work or other activities [Were limited in the kind of work or other activities]	[itmPHlimtd] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? [secEP]		
10.* ✓	Accomplished less than you would like [Accomplished less than you would like]	[itmEpAccomp] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
11.* ✓	Did work or other activities less carefully than usual [Other Activities]	[itmEpOA] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
During the past 4 weeks, how much did pain interfere with your normal work [secNW]		
12.* ✓	During the past 4 weeks, how much did pain interfere with your normal work(including both work outside the home and housework)?	[itmSF12NW] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> A little bit [N:2] <input type="radio"/> Moderately [N:3] <input type="radio"/> Quite a bit [N:4] <input type="radio"/> Extremely
These questions are about how you feel & how things have been with you during the past 4 weeks. For each question, please give the 1 answer that comes closest to the way you have been feeling. How much of the time in the past 4 weeks [sec4Wks]		
13.* ✓	Have you felt calm and peaceful? [Peaceful]	[itmWksPeace] [N:0] <input type="radio"/> All of the time [N:1] <input type="radio"/> Most of the time [N:2] <input type="radio"/> Some of the time [N:3] <input type="radio"/> A little of the time [N:4] <input type="radio"/> None of the time
14.* ✓	Did you have a lot of energy? [Lot of energy]	[itmWksEnrgy] [N:0] <input type="radio"/> All of the time [N:1] <input type="radio"/> Most of the time [N:2] <input type="radio"/> Some of the time [N:3] <input type="radio"/> A little of the time [N:4] <input type="radio"/> None of the time
15.* ✓	Have you felt downhearted and depressed? [Felt downhearted]	[itmWksDwnhrtd] [N:0] <input type="radio"/> All of the time [N:1] <input type="radio"/> Most of the time [N:2] <input type="radio"/> Some of the time [N:3] <input type="radio"/> A little of the time [N:4] <input type="radio"/> None of the time
During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities [secSA]		
16.* ✓	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? [Social Activities]	[itmSF12SA] [N:0] <input type="radio"/> All of the time [N:1] <input type="radio"/> Most of the time [N:2] <input type="radio"/> Some of the time [N:3] <input type="radio"/> A little of the time [N:4] <input type="radio"/> None of the time

Key: [*] = Item is required [✓] = Source verification required [F] = Fixed item
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Study Object Descriptions: QOL Questionnaires		
Type	RefName	Description
Form	frmQOLQ	Short Spielberger State-Trait Anxiety Inventory (STAI-6)
Section	SecSTAI6	STAI-6
Section	secPCQ	PCQ
Section	secPM	During the past month
Section	secConcrn	Concerned about getting prostate cancer
Section	secGenrl	This survey asks for your views about your health
Section	secMA	Moderate activities
Section	secPH	Physical health
Section	secEP	Emotional problems
Section	secNW	During the past 4 weeks, how much did pain interfere with your normal work
Section	sec4Wks	These questions are about how you feel & how things have been with you during the past 4 weeks. For each question, please give the 1 answer that comes closest to the way you have been feeling. How much of the time in the past 4 weeks
Section	secSA	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities

Codelist Values Tables: QOL Questionnaires					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cIPCQdtl	Integer	Had trouble sleeping	0	citmDtl0	itmPCQdtl
		Experienced a change in appetite	1	citmDtl1	
		Been unhappy or depressed	2	citmDtl2	
		Been scared and panicky	3	citmDtl3	
		Felt nervous or strung up	4	citmDtl4	
		Felt under strain	5	citmDtl5	
		Found you have been keeping things from those who are close to you	6	citmDtl6	
		Found yourself taking things out on other people	7	citmDtl7	
		Found yourself noticeably withdrawing from those who are close to you	8	citmDtl8	
		Had difficulty doing things around the house that you normally do	9	citmDtl9	
		Had difficulty meeting work or other commitments	10	citmDtl10	
		Felt worried about your future	11	citmDtl11	

RDE Analytics: RD_FRMQOLQ		
Data Variable RefName	RD Column Name	Column Data Type
itmCWSSconcrn	ITMCWSSCONCRN_C	NUMBER
	ITMCWSSCONCRN	VARCHAR2
	ITMCWSSCONCRN_ND	VARCHAR2
itmSF12gen	ITMSF12GEN_C	NUMBER
	ITMSF12GEN	VARCHAR2

	ITMSF12GEN_ND	VARCHAR2
itmSF12Ma	ITMSF12MA_C	NUMBER
	ITMSF12MA	VARCHAR2
	ITMSF12MA_ND	VARCHAR2
itmSF12Climb	ITMSF12CLIMB_C	NUMBER
	ITMSF12CLIMB	VARCHAR2
	ITMSF12CLIMB_ND	VARCHAR2
itmPHAcomp	ITMPHACCOMP_C	NUMBER
	ITMPHACCOMP	VARCHAR2
	ITMPHACCOMP_ND	VARCHAR2
itmPHlimtd	ITMPHLIMTD_C	NUMBER
	ITMPHLIMTD	VARCHAR2
	ITMPHLIMTD_ND	VARCHAR2
itmEpAccomp	ITMEPACCOMP_C	NUMBER
	ITMEPACCOMP	VARCHAR2
	ITMEPACCOMP_ND	VARCHAR2
itmEpOA	ITMEPOA_C	NUMBER
	ITMEPOA	VARCHAR2
	ITMEPOA_ND	VARCHAR2
itmSF12NW	ITMSF12NW_C	NUMBER
	ITMSF12NW	VARCHAR2
	ITMSF12NW_ND	VARCHAR2
itmWksPeace	ITMWKSPEACE_C	NUMBER
	ITMWKSPEACE	VARCHAR2
	ITMWKSPEACE_ND	VARCHAR2
itmWksEnrgy	ITMWKSENRGY_C	NUMBER
	ITMWKSENRGY	VARCHAR2
	ITMWKSENRGY_ND	VARCHAR2
itmWksDwnhrt	ITMWKSDWNHRTD_C	NUMBER
	ITMWKSDWNHRTD	VARCHAR2
	ITMWKSDWNHRTD_ND	VARCHAR2
itmSF12SA	ITMSF12SA_C	NUMBER
	ITMSF12SA	VARCHAR2
	ITMSF12SA_ND	VARCHAR2
RD_FRMQLQ_SECSTAI6		
itmSTATscr	ITMSTATSCR_C	NUMBER
	ITMSTATSCR	VARCHAR2
	ITMSTATSCR_ND	VARCHAR2
itmSTAIscr	ITMSTAIscr_C	NUMBER
	ITMSTAIscr	VARCHAR2
	ITMSTAIscr_ND	VARCHAR2

RD_FRMQOLQ_SEPCQ		
itmPCQdtl	ITMPCQDTL_C	NUMBER
	ITMPCQDTL	VARCHAR2
	ITMPCQDTL_ND	VARCHAR2
itmPCQScr	ITMPCQSCR_C	NUMBER
	ITMPCQSCR	VARCHAR2
	ITMPCQSCR_ND	VARCHAR2
RD_FRMQOLQ_SECPM		
itmCWSdtl	ITMCWSDTL_C	NUMBER
	ITMCWSDTL	VARCHAR2
	ITMCWSDTL_ND	VARCHAR2
itmCWSScl	ITMCWSSCL_C	NUMBER
	ITMCWSSCL	VARCHAR2
	ITMCWSSCL_ND	VARCHAR2

PROSTAGRAM: Baseline Questionnaire (BQ) [frmBQ]		
Demographics [sceBQDemo]		
1.* ✓	Please tick the box which best describes your ethnic origin [Ethnicity]	<p>[itmDEMethnic]</p> <p>[N:1] <input type="radio"/> [itmDEMethWhite] <input type="checkbox"/> White [N:1] <input type="radio"/> White British [N:2] <input type="radio"/> White Irish [N:3] <input type="radio"/> Other White</p> <p>[N:2] <input type="radio"/> [itmDEMethMix] <input type="checkbox"/> Mixed [N:1] <input type="radio"/> Mixed White & Black Caribbean [N:2] <input type="radio"/> Mixed White & Black African [N:3] <input type="radio"/> Mixed White & Asian [N:4] <input type="radio"/> Other Mixed</p> <p>[N:3] <input type="radio"/> [itmDEMethAsn] <input type="checkbox"/> Asian [N:1] <input type="radio"/> Indian [N:2] <input type="radio"/> Pakistani [N:3] <input type="radio"/> Bangladeshi [N:4] <input type="radio"/> Chinese [N:5] <input type="radio"/> Other Asian</p> <p>[N:4] <input type="radio"/> [itmDEMethBlk] <input type="checkbox"/> Black [N:1] <input type="radio"/> Black Caribbean [N:2] <input type="radio"/> Black African [N:3] <input type="radio"/> Other Black</p> <p>[N:5] <input type="radio"/> Arab [N:6] <input type="radio"/> Any Other Ethnic Group [N:7] <input type="radio"/> Not Reported</p>
2.* ✓	What is the highest level of qualification you have either obtained or are currently studying for? (If your qualification is not listed tick the box that contains its nearest equivalent) [Highest level of qualification]	<p>[itmBQHq]</p> <p>[N:0] <input type="radio"/> No formal qualifications [N:1] <input type="radio"/> GCSEs/O levels/CSEs [N:2] <input type="radio"/> A-levels or equivalent [N:3] <input type="radio"/> Higher education below degree [N:4] <input type="radio"/> University degree [N:5] <input type="radio"/> [itmBQHqotr] <input type="checkbox"/> Other qualifications [itmHQotr] Please specify <input type="text" value="A40"/></p>
3.* ✓	What is your legal marital or civil partnership status [Partnership Status]	<p>[itmBQStatus]</p> <p>[N:0] <input type="radio"/> Married [N:1] <input type="radio"/> Civil partnership [N:2] <input type="radio"/> Cohabiting [N:3] <input type="radio"/> Single(including divorced, widowed, separated)</p>
4.* ✓	What is your current employment status [Employment Status]	<p>[itmBQEmpty]</p> <p>[N:0] <input type="radio"/> Employed [N:1] <input type="radio"/> Unemployed [N:2] <input type="radio"/> Unable to work [N:3] <input type="radio"/> Homemaker</p>

		[N:4] <input type="radio"/> Retired [N:5] <input type="radio"/> Student
5.* ✓	How many times have you seen your General Practitioner (GP) in the last 12 months? [Seen your General Practitioner]	[itmBQGP] [N:0] <input type="radio"/> 0 [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> ≥4
Smoking [secSmkng]		
6.* ✓	Do you smoke cigarettes? <i>(Defined as having smoked as much as 1 cigarette a day for as long as a year)</i> [Do you smoke cigarettes]	[itmBQSmkcgir] [N:0] <input type="radio"/> No – Never smoked [N:1] <input type="radio"/> [cmpSMKNq] <input type="checkbox"/> No – Quit [itmSMKAgeNQ] How old were you when you started smoking? (Enter age in years) <input type="text" value="N2"/> [itmSMKcigrNQ] How many cigarettes do you smoke or were you smoking per day on average?(Cigarettes) <input type="text" value="N3"/> [itmSMKOldQ] How old were you when you quit smoking? (Enter age in years) <input type="text" value="N2"/> [N:2] <input type="radio"/> [SmkYes] <input type="checkbox"/> Yes [itmSmkYsAge] How old were you when you started smoking? (Enter age in years) <input type="text" value="N2"/> [itmSmkYsSugr] How many cigarettes do you smoke or were you smoking per day on average?(Cigarettes) <input type="text" value="N3"/>
Diet [Diet]		
7.* ✓	How many servings of milk or dairy products do you have on most days? (One serving is a cup of milk, a cup of yogurt or about 1 ½ oz of cheese) [Servings of milk or dairy products]	[itmSmksrv] [N:0] <input type="radio"/> Less than 1 [N:1] <input type="radio"/> 1-2 [N:2] <input type="radio"/> 3 or more
8.* ✓	Do you take calcium supplements on most days [Calcium supplements]	[itmSmkCs] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
9.* ✓	Do you eat 5 or more servings of tomato-based foods a week? These foods include spaghetti sauce and salsa. (One serving is about ½ cup of sauce) [Eat 5 or more servings of tomato-based foods]	[itmSmkEat] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
Prostate History [secPrsH]		
10.* ✓	Compared with other men your age, what do you think your chances of getting prostate cancer are? [Compared with other men your age]	[itmPHage] [N:0] <input type="radio"/> Much lower [N:1] <input type="radio"/> Lower [N:2] <input type="radio"/> About the same [N:3] <input type="radio"/> Higher

		[N:4] <input type="radio"/> Much Higher
11.* ✓	How likely do you think it is that you will get prostate cancer sometime in your life? [How likely]	[itmPHPrC] [N:0] <input type="radio"/> Very Unlikely [N:1] <input type="radio"/> Unlikely [N:2] <input type="radio"/> Not likely or unlikely [N:3] <input type="radio"/> Likely [N:4] <input type="radio"/> Very likely
12.* ✓	Have you ever had a prostate-specific antigen (PSA) blood test? [Prostate-specific antigen (PSA)]	[itmPHPSA] [N:1] <input type="radio"/> [itmPHPSAYs] <input type="checkbox"/> Yes [itmPSAYsrRcnt] When did you have your most recent PSA blood test? [N:0] <input type="radio"/> Within the last 3 years [N:1] <input type="radio"/> 3 to 5 years ago [N:2] <input type="radio"/> More than 5 years ago [N:3] <input type="radio"/> Don't know [itmPSAYsrsn] What was the main reason you had this PSA blood test? [N:0] <input type="radio"/> Part of a routine check-up [N:1] <input type="radio"/> Because of a specific prostate problem [N:2] <input type="radio"/> Don't know [N:0] <input type="radio"/> No
Have you ever had [secEver]		
13.* ✓	Rectal examination (examination of the back passage) to check the prostate [Rectal examination]	[itmPHRctI] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
14.* ✓	Biopsy of the prostate gland for suspected prostate cancer [Biopsy of the prostate gland]	[itmPHBiop] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
15.* ✓	Any other operations on your prostate gland [Any other operations]	[itmPHopern] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
Family History [secFH]		
16.* ✓	Did your relatives have had prostate cancer? [Did your relatives have had prostate cancer]	[itmFHReltvs] [N:0] <input type="radio"/> [itmFHRelYs] <input type="checkbox"/> Yes [itmFHPcReltv] Select which relatives have had prostate cancer <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> [N:0] <input type="checkbox"/> </div> <div style="width: 45%;"> [cmpFHFathr] <input type="checkbox"/> Father [itmFHFthrPs] Please specify <input style="width: 100%;" type="text" value="A100"/> </div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> [N:1] <input type="checkbox"/> </div> <div style="width: 45%;"> [cmpFHBro] <input type="checkbox"/> Brother(s) [itmFHBroPs] Please specify <input style="width: 100%;" type="text" value="A100"/> </div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> [N:2] </div> <div style="width: 45%;"> [cmpFHGran] <input type="checkbox"/> </div> </div>

		<input type="checkbox"/>	Grandfather [itmFHGranPs] Please specify A100
	[N:3]	<input type="checkbox"/>	[cmpFHUncl] ▾ Uncle(s) [itmFHUncl] Please specify A100
	[N:4]	<input type="checkbox"/>	[cmpFHNphw] ▾ Nephew(s) [itmFHNephPs] Please specify A100
	[N:5]	<input type="checkbox"/>	[cmpFHCousn] ▾ Cousin(s) [itmFHCousnPs] Please specify A100
	[N:6]	<input type="checkbox"/>	[itmFHPcrltvOr] ▾ Other [itmOrspec] Please specify A100
	[N:1] <input type="radio"/> None		

IPSS Score
Please enter the response that best describes you for the following questions: [secRspns]

# ✓	IPSS Score Details	Scores*
17.a	Incomplete Emptying Over the past month, how often have you had the sensation of not emptying your bladder?	
17.b	Frequency Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	
17.c	Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	
17.d	Urgency Over the past month, how often have you found it difficult to postpone urination?	
17.e	Weak Stream Over the past month, how often have you had a weak urinary stream?	
17.f	Straining Over the past month, how often have you had to strain to start urination?	
17.g	Nocturia Over the past month how many times did you most typically get up each night to urinate from the time you went to bed until the time you got up in the morning?	

IPSS Score
Please enter the response that best describes you for the following questions: Entry [secRspns]

17.1 ✓ 📄	IPSS Score Details [read-only] [IPSS Score Details]	[itmIPSS] [clIPSSScr] ▾
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17.2*	Scores [Scores]	[itmScrs] [N:0] <input type="radio"/> 0 = Not at all [N:1] <input type="radio"/> 1 = Less than 1 in 5 times [N:2] <input type="radio"/> 2 = Less than half of the time [N:3] <input type="radio"/> 3 = About half of the time [N:4] <input type="radio"/> 4 = More than half of the time [N:5] <input type="radio"/> 5 = Almost always
Quality of life due to urinary symptoms [secQuality]		
18.*	If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that? [Urinary condition]	[itmUrn] [N:0] <input type="radio"/> 0 = Delighted [N:1] <input type="radio"/> 1 = Pleased [N:2] <input type="radio"/> 2 = Mostly satisfied [N:3] <input type="radio"/> 3 = Mixed [N:4] <input type="radio"/> 4 = Mostly unhappy [N:5] <input type="radio"/> 5 = Unhappy [N:6] <input type="radio"/> 6 = Terrible
Key: [*] = Item is required [✓] = Source verification required [] = Item is collapsible [] = Fixed item Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.		

Study Object Descriptions: Baseline Questionnaire

Type	RefName	Description
Form	frmBQ	Exclusion Criteria
Section	sceBQDemo	Demographics
Section	secSmkng	Smoking
Section	Diet	Diet
Section	secPrsH	Prostate History
Section	secEver	Have you ever had
Section	secFH	Family History
Section	secRspns	Please enter the response that best describes you for the following questions:
Section	secQuality	Quality of life due to urinary symptoms

Codelist Values Tables: Baseline Questionnaire



Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cIIPSSScr	Integer	Incomplete Emptying Over the past month, how often have you had the sensation of not emptying your bladder?	0	citmIE	itmIPSS
		Frequency Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	1	citmFreq	
		Intermittency Over the past month, how often have you found you stopped and started again several times when you urinated?	2	citmIntrmt	
		Urgency Over the past month, how often have you found it difficult to postpone urination?	3	citmUrgnt	
		Weak Stream Over the past month, how often have you had a weak urinary stream?	4	citmWeak	
		Straining Over the past month, how often have you had to strain to start urination?	5	citmStrain	

		Nocturia Over the past month how many times did you most typically get up each night to urinate from the time you went to bed until the time you got up in the morning?	6	citmNoct	
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RDE Analytics: RD_FRMBQ		
Data Variable RefName	RD Column Name	Column Data Type
itmDEMethnic	ITMDEMETHNIC_C	**NUMBER
	ITMDEMETHNIC	VARCHAR2
	ITMDEMETHNIC_ND	VARCHAR2
itmDEMethnic - itmDEMethWhite	ITMDEMETHWHITE_C	NUMBER
	ITMDEMETHWHITE	VARCHAR2
itmDEMethnic - itmDEMethMix	ITMDEMETHMIX_C	NUMBER
	ITMDEMETHMIX	VARCHAR2
itmDEMethnic - itmDEMethAsn	ITMDEMETHASN_C	NUMBER
	ITMDEMETHASN	VARCHAR2
itmDEMethnic - itmDEMethBlk	ITMDEMETHBLK_C	NUMBER
	ITMDEMETHBLK	VARCHAR2
itmBQHQ	ITMBQHQ_C	NUMBER
	ITMBQHQ	VARCHAR2
	ITMBQHQ_ND	VARCHAR2
itmBQHQ - itmHQOtr	ITMHQOTR	VARCHAR2
itmBQStatus	ITMBQSTATUS_C	NUMBER
	ITMBQSTATUS	VARCHAR2
	ITMBQSTATUS_ND	VARCHAR2
itmBQEmpty	ITMBQEMPTY_C	NUMBER
	ITMBQEMPTY	VARCHAR2
	ITMBQEMPTY_ND	VARCHAR2
itmBQGP	ITMBQGP_C	NUMBER
	ITMBQGP	VARCHAR2
	ITMBQGP_ND	VARCHAR2
itmBQSmkcigar	ITMBQSMKCIGAR_C	NUMBER
	ITMBQSMKCIGAR	VARCHAR2
	ITMBQSMKCIGAR_ND	VARCHAR2
itmBQSmkcigar - itmSMKAgeNQ	ITMSMKAGENQ	NUMBER
itmBQSmkcigar - itmSMKcigrNQ	ITMSMKCIGRNQ	NUMBER
itmBQSmkcigar - itmSMKOldQ	ITMSMKOLDQ	NUMBER
itmBQSmkcigar - itmSmkYsAge	ITMSMKYSAGE	NUMBER
itmBQSmkcigar - itmSmkYsSugr	ITMSMKYSSUGR	NUMBER
itmSmksrv	ITMSMKSrv_C	NUMBER
	ITMSMKSrv	VARCHAR2
	ITMSMKSrv_ND	VARCHAR2

itmSmkCs	ITMSMKCS_C	NUMBER
	ITMSMKCS	VARCHAR2
	ITMSMKCS_ND	VARCHAR2
itmSmkEat	ITMSMKEAT_C	NUMBER
	ITMSMKEAT	VARCHAR2
	ITMSMKEAT_ND	VARCHAR2
itmPHage	ITMPHAGE_C	NUMBER
	ITMPHAGE	VARCHAR2
	ITMPHAGE_ND	VARCHAR2
itmPHPrc	ITMPHPRC_C	NUMBER
	ITMPHPRC	VARCHAR2
	ITMPHPRC_ND	VARCHAR2
itmPHPSA	ITMPHPSA_C	**NUMBER
	ITMPHPSA	VARCHAR2
	ITMPHPSA_ND	VARCHAR2
itmPHPSA - itmPSAYsrRcnt	ITMPSAYSRRCNT_C	NUMBER
	ITMPSAYSRRCNT	VARCHAR2
itmPHPSA - itmPSAYsrSn	ITMPSAYSRSN_C	NUMBER
	ITMPSAYSRSN	VARCHAR2
itmPHRctl	ITMPHRCTL_C	NUMBER
	ITMPHRCTL	VARCHAR2
	ITMPHRCTL_ND	VARCHAR2
itmPHBiop	ITMPHBIOP_C	NUMBER
	ITMPHBIOP	VARCHAR2
	ITMPHBIOP_ND	VARCHAR2
itmPHopern	ITMPHOPERN_C	NUMBER
	ITMPHOPERN	VARCHAR2
	ITMPHOPERN_ND	VARCHAR2
itmFHReltvs	ITMFHRELTVS_C	**NUMBER
	ITMFHRELTVS	VARCHAR2
	ITMFHRELTVS_ND	VARCHAR2
itmFHReltvs - Father	ITMFHPCRELTV_CMPHFHATHR_C	**NUMBER
	ITMFHPCRELTV_CMPHFHATHR	VARCHAR2
itmFHReltvs - itmFHFthrPs	ITMFHFTHRPS	VARCHAR2
itmFHReltvs - Brother(s)	ITMFHPCRELTV_CMPFHBRO_C	**NUMBER
	ITMFHPCRELTV_CMPFHBRO	VARCHAR2
itmFHReltvs - itmFHBroPs	ITMFHBROPS	VARCHAR2
itmFHReltvs - Grandfather	ITMFHPCRELTV_CMPFHGRAN_C	**NUMBER
	ITMFHPCRELTV_CMPFHGRAN	VARCHAR2
itmFHReltvs - itmFHGranPs	ITMFHGRANPS	VARCHAR2
itmFHReltvs - Uncle(s)	ITMFHPCRELTV_CMPFHUNCL_C	**NUMBER

	ITMFHPCRELTV_CMPFHUNCL	VARCHAR2
itmFHReltvs - itmFHUncl	ITMFHUNCL	VARCHAR2
itmFHReltvs - Nephew(s)	ITMFHPCRELTV_CMPFHNPBW_C	**NUMBER
	ITMFHPCRELTV_CMPFHNPBW	VARCHAR2
itmFHReltvs - itmFHNephPs	ITMFHNEPHPS	VARCHAR2
itmFHReltvs - Cousin(s)	ITMFHPCRELTV_CMPFHCOUSN_C	**NUMBER
	ITMFHPCRELTV_CMPFHCOUSN	VARCHAR2
itmFHReltvs - itmFHCousnPs	ITMFHCOUSNPS	VARCHAR2
itmFHReltvs - Other	*ITMFHPCRELTV_ITMFHPCRLTVOR_C	**NUMBER
	*ITMFHPCRELTV_ITMFHPCRLTVOR	VARCHAR2
itmFHReltvs - itmOrspec	ITMORSPEC	VARCHAR2
itmUrn	ITMURN_C	NUMBER
	ITMURN	VARCHAR2
	ITMURN_ND	VARCHAR2
RD_FRMBQ_SECRSPNS		
itmIPSS	ITMIPSS_C	NUMBER
	ITMIPSS	VARCHAR2
	ITMIPSS_ND	VARCHAR2
itmScrs	ITMSCRS_C	NUMBER
	ITMSCRS	VARCHAR2
	ITMSCRS_ND	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: PBQ (PBQ) [frmPBQ]			
PSA Perceived Burden Questionnaire (PBQ) Details [secPBQ]			
#	PBQ Details		Scores*
1.a	How embarrassing did you find the PSA blood test?		
1.b	How painful did you find the PSA blood test?		
1.c	How burdensome do you find the PSA blood test?		
1.d	How anxious do you find having the PSA blood test?		
1.e	If your doctor recommended repeat testing with a PSA blood test how likely would you be to have another test?		
PSA Perceived Burden Questionnaire (PBQ) Details Entry [secPBQ]			
1.1 ✓ 	PBQ Details <i>[read-only]</i> [PBQ Details]	[itmPBQDtl] [N:1] <input type="radio"/> How embarrassing did you find the PSA blood test? [N:2] <input type="radio"/> How painful did you find the PSA blood test? [N:3] <input type="radio"/> How burdensome do you find the PSA blood test? [N:4] <input type="radio"/> How anxious do you find having the PSA blood test? [N:5] <input type="radio"/> If your doctor recommended repeat testing with a PSA blood test how likely would you be to have another test?	
1.2* ✓	Scores [Scores]	[itmPBQscr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Slightly [N:2] <input type="radio"/> Somewhat [N:3] <input type="radio"/> Rather [N:4] <input type="radio"/> Extremely	
Ultrasound Perceived Burden Questionnaire (PBQ) Details [secUPBQ]			
#	PBQ Details		Scores*
2.a	How embarrassing did you find the ultrasound test?		
2.b	How painful did you find the ultrasound test?		
2.c	How burdensome do you find the ultrasound test?		
2.d	How anxious do you find having the ultrasound test?		
2.e	If your doctor recommended repeat testing with a prostate ultrasound how likely would you be to have a future test?		
Ultrasound Perceived Burden Questionnaire (PBQ) Details Entry [secUPBQ]			
2.1 ✓ 	PBQ Details <i>[read-only]</i> [PBQ Details]	[itmUPBQdtl] [N:1] <input type="radio"/> How embarrassing did you find the ultrasound test? [N:2] <input type="radio"/> How painful did you find the ultrasound test? [N:3] <input type="radio"/> How burdensome do you find the ultrasound test? [N:4] <input type="radio"/> How anxious do you find having the ultrasound test? [N:5] <input type="radio"/> If your doctor recommended repeat testing with a prostate ultrasound how likely would you be to have a future test?	
2.2* ✓	Scores [Scores]	[itmUPBQscr] [N:0] <input type="radio"/> Not at all [N:1] <input type="radio"/> Slightly [N:2] <input type="radio"/> Somewhat [N:3] <input type="radio"/> Rather [N:4] <input type="radio"/> Extremely	
MRI Perceived Burden Questionnaire (PBQ) Details [secMPBQ]			
#	PBQ Details		Scores*

Type	RefName	Description
Form	frmPBQ	PSA Perceived Burden Questionnaire (PSA PBQ)
Section	secPBQ	PSA Perceived Burden Questionnaire (PBQ) Details
Section	secUPBQ	Ultrasound Expected Burden Questionnaire (PBQ) Details
Section	secMPBQ	MRI Perceived Burden Questionnaire (PBQ) Details
Section	secMPBQPt	Prefer Test

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe 137e31086639fb5d 0002.0000 c16... 03/05/2019

	ITMPBQDTL	VARCHAR2
	ITMPBQDTL_ND	VARCHAR2
itmPBQscr	ITMPBQSCR_C	NUMBER
	ITMPBQSCR	VARCHAR2
	ITMPBQSCR_ND	VARCHAR2
RD_FRMPBQ_SECUPBQ		
itmUPBQdtl	ITMUPBQDTL_C	NUMBER
	ITMUPBQDTL	VARCHAR2
	ITMUPBQDTL_ND	VARCHAR2
itmUPBQScr	ITMUPBQSCR_C	NUMBER
	ITMUPBQSCR	VARCHAR2
	ITMUPBQSCR_ND	VARCHAR2
RD_FRMPBQ_SECMPBQ		
itmMPBQDtl	ITMMPBQDTL_C	NUMBER
	ITMMPBQDTL	VARCHAR2
	ITMMPBQDTL_ND	VARCHAR2
itmMPBQScr	ITMMPBQSCR_C	NUMBER
	ITMMPBQSCR	VARCHAR2
	ITMMPBQSCR_ND	VARCHAR2

PROSTAGRAM: Demographics (DEMO) [frmDEMO]

Demographics [frmDEMO]

1.

✓

Subject number *[read-only]*
[Sub no]

[itmDEMSubNo]

N3

2.

✓

Age at consent
[Age]

[itmDEMAge]

N3

3.*

✓

Partial Date of Birth
[Partial Date of Birth]

[itmDEMDOB]

Req

▼

 / Req

▼

 (1947-1971)

4.*

✓

How did they hear about the prostate health check?
[Prostate health check]

[itmBQProst]

[N:1]

Letter from GP

[N:2]

SMS / Text from GP

[N:3]

Verbal from GP

[N:4]

Stephen Fry Twitter

[N:5]

Gamal Turawa Facebook

[N:6]

Search engine / other internet source

[N:7]

[N:8]

[N:9]

[N:10]

[N:11]

[N:12]

[N:13]

[N:14]

[cmpBQPrstOr]

Other

[itmPrshHChkops]

Please specify

A100

5.

✓

Index of Multiple Deprivation
[Index of Multiple Deprivation]

[itmDEMIndx]

xx.xxx

Key: [✓] = Source verification required [✓] = Source verification critical [] = Item is collapsible

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Demographics		
Type	RefName	Description
Form	frmDEMO	Demographics
Item	itmDEMSubNo	Patient Number

RDE Analytics: RD_FRMDEMO		
Data Variable RefName	RD Column Name	Column Data Type
itmDEMSubNo	ITMDEMSUBNO	NUMBER
	ITMDEMSUBNO_ND	VARCHAR2
itmDEMAge	ITMDEMAge	NUMBER
	ITMDEMAge_ND	VARCHAR2

itmDEMDOB	ITMDEMDOB_DTS	VARCHAR2
	ITMDEMDOB_ND	VARCHAR2
itmBQProst	ITMBQPROST_C	NUMBER
	ITMBQPROST	VARCHAR2
	ITMBQPROST_ND	VARCHAR2
itmBQProst - itmPrshHChkops	ITMPRSHHCHKOPS	VARCHAR2
itmDEMIndx	ITMDEMINDX	FLOAT
	ITMDEMINDX_ND	VARCHAR2

PROSTAGRAM: Phlebotomy Form (PHLEB) - Repeating Form [frmPhlb]									
#	Weight	Height	BMI	Sample taken	Was an adequate PSA sample collected?	Length of phlebotomy procedure	Length of phlebotomy procedure and set up	Was an optional serum sample taken for Episwitch biomarker	Were optional blood samples given for storage for future biomarker work
1									
Phlebotomy Form [frmPhlb]									
1.* ✓	Weight [Weight]				[itmVSWght] xxx.x kg ^[b]				
2.* ✓	Height [Height]				[itmVSHght] N3 cm ^[b]				
3. ✓	Body Mass Index <i>[read-only]</i> [BMI]				[itmVSBMI] xxxx.x Kg/m ²				
4.* ✓	Sample taken [Sample taken]				[itmPhbsamp] [N:1] <input type="radio"/> [itmPhbSmpYs] <input type="checkbox"/> Yes [itmPhbSmpdt] Date sample taken Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030) [itmPhbTimst] Time started phlebotomy set up NReq/Unk <input type="text"/> : NReq/Unk <input type="text"/> 24-hour clock [itmPhbTimCm] Time phlebotomy commenced NReq/Unk <input type="text"/> : NReq/Unk <input type="text"/> 24-hour clock [itmPhbTimFin] Time phlebotomy finished Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock [N:0] <input type="radio"/> No				
5.* ✓	Was an adequate PSA sample collected? [Was an adequate PSA sample collected?]				[itmPhbAdeqt] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> [itmPhbsmpNo] <input type="checkbox"/> No [itmPSARsn] Reason for no sample collected [N:0] <input type="radio"/> Patient choice/ Discomfort [N:1] <input type="radio"/> Technical factors (e.g. difficult veins) [itmPSAArrang] Was this procedure re-arranged [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No				
6. ✓	Length of phlebotomy procedure <i>[read-only]</i> [Length of phlebotomy procedure]				[itmPhbsmpLth] N4 minutes				
7. ✓	Length of phlebotomy procedure and set up <i>[read-only]</i> [Length of phlebotomy procedure and set up]				[itmPhblth] N4 minutes				
Optional Sample Donation [secOSD]									
8.* ✓	Was an optional serum sample taken for Episwitch biomarker [Was an optional serum sample taken for Episwitch biomarker]				[itmOSDserm] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No				

9.* ✓	Were optional blood samples given for storage for future biomarker work [Were optional blood samples given for storage for future biomarker work]	[itmOSDBId] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit [☐] = Item is collapsible Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.		

Study Object Descriptions: Phlebotomy Form		
Type	RefName	Description
Form	frmPhlb	Phlebotomy Form
Section	secOSD	Optional Sample Donation

RDE Analytics: RD_FRMPHLB		
Data Variable RefName	RD Column Name	Column Data Type
itmVSWght	ITMVSWGHT	FLOAT
	ITMVSWGHT_U	VARCHAR2
	ITMVSWGHT_ND	VARCHAR2
itmVSHght	ITMVSHGHT	NUMBER
	ITMVSHGHT_U	VARCHAR2
	ITMVSHGHT_ND	VARCHAR2
itmVSBMI	ITMVSBMI	FLOAT
	ITMVSBMI_ND	VARCHAR2
itmPhbsamp	ITMPHBSAMP_C	**NUMBER
	ITMPHBSAMP	VARCHAR2
	ITMPHBSAMP_ND	VARCHAR2
itmPhbsamp - itmPhbSmpdt	ITMPHBSMPDT	DATE
	ITMPHBSMPDT_DTS	VARCHAR2
itmPhbsamp - itmPhbTimst	ITMPHBTIMST	DATE
	ITMPHBTIMST_TMS	VARCHAR2
	ITMPHBTIMST_TMR	VARCHAR2
itmPhbsamp - itmPhbTimCm	ITMPHBTIMCM	DATE
	ITMPHBTIMCM_TMS	VARCHAR2
	ITMPHBTIMCM_TMR	VARCHAR2
itmPhbsamp - itmPhbTimFin	ITMPHBTIMFIN	DATE
	ITMPHBTIMFIN_TMS	VARCHAR2
	ITMPHBTIMFIN_TMR	VARCHAR2
itmPhbAdeqt	ITMPHBADEQT_C	NUMBER
	ITMPHBADEQT	VARCHAR2
	ITMPHBADEQT_ND	VARCHAR2
itmPhbAdeqt - itmPSARsn	ITMPSARSN_C	NUMBER
	ITMPSARSN	VARCHAR2

itmPhbAdeqt - itmPSAArrang	ITMPSAARRANG_C	NUMBER
	ITMPSAARRANG	VARCHAR2
itmPhbsmpLth	ITMPHBSMPLTH	NUMBER
	ITMPHBSMPLTH_ND	VARCHAR2
itmPhblth	ITMPHBLTH	NUMBER
	ITMPHBLTH_ND	VARCHAR2
itmOSDserm	ITMOSDSERM_C	NUMBER
	ITMOSDSERM	VARCHAR2
	ITMOSDSERM_ND	VARCHAR2
itmOSDBld	ITMOSDBLD_C	NUMBER
	ITMOSDBLD	VARCHAR2
	ITMOSDBLD_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: Charlson Co-Morbidity Index (CCI) [frmCCI]		
Charlson Co-Morbidity Index [frmCCI]		
1.* ✓	Have you ever had a heart attack? [Heart attack]	[itmCCIHrt] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
2.* ✓	Have you ever been treated for heart failure? (You may have been short of breath and the doctor may have told you that you had fluid in your lungs or that your heart was not pumping well) [Heart failure]	[itmCCIHrtfl] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
3.* ✓	Have you had an operation to unclog or bypass the arteries in your legs? [Operation to unclog or bypass the arteries in your legs]	[itmCCIArtris] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
4.* ✓	Have you had a stroke, cerebrovascular accident, blood clot or bleeding in the brain or transient ischaemic attack (TIA)? [Stroke, cerebrovascular accident]	[itmCCIStrke] [N:1] <input type="radio"/> [itmCCISrkYs] <input type="checkbox"/> Yes [itmStrkYsDiff] Do you have difficulty moving an arm or leg as a result of the stroke or cerebral vascular accident [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:0] <input type="radio"/> No
5.* ✓	Do you have asthma? [Asthma]	[itmCCIAsthma] [N:1] <input type="radio"/> [itmCCIAshmYs] <input type="checkbox"/> Yes [itmAshmaMed] Do you take medicines for your asthma [N:0] <input type="radio"/> No [N:1] <input type="radio"/> Yes, only with flare-ups [N:2] <input type="radio"/> Yes I take medicines regularly, even when I'm not having an attack [N:0] <input type="radio"/> No
6.* ✓	Do you have emphysema, chronic bronchitis, or chronic obstructive lung disease? [Do you have emphysema]	[itmCCIEmphy] [N:1] <input type="radio"/> [itmCCIEmphyYs] <input type="checkbox"/> Yes [itmEmphyYs] Do you take medicines for your lung disease [N:1] <input type="radio"/> No [N:2] <input type="radio"/> Yes, Only with flare-ups [N:3] <input type="radio"/> I take medicines regularly, Even when I'm not having an attack [N:0] <input type="radio"/> No
7.* ✓	Do you have stomach ulcers or peptic ulcer disease? [Stomach ulcers or peptic ulcer]	[itmCCIStomch] [N:1] <input type="radio"/> [itmCCIStomchYs] <input type="checkbox"/> Yes [itmStmchDig] Has this condition been diagnosed by endoscopy (where a doctor looks into your stomach through a scope) or an upper GI or barium swallow study (where you swallow chalk dye and then x-rays are taken) [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:0] <input type="radio"/> No
8.* ✓	Do you have diabetes (high blood sugar)? [Diabetes]	[itmCCIDiabts] [N:1] <input type="radio"/> [itmCCIDiabtsYs] <input type="checkbox"/> Yes [itmDibS]

		<p>[N:1] <input type="radio"/> Yes, Treated by modifying my diet</p> <p>[N:2] <input type="radio"/> Yes, Treated by medications taken by mouth</p> <p>[N:3] <input type="radio"/> Yes, Treated by insulin injections</p> <p>[itmDibkidny] Has the diabetes caused problems with your kidneys?</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmDibEyes] Has the diabetes caused problems with yours eyes, treated by an ophthalmologist?</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:0] <input type="radio"/> No</p>
9.* ✓	Have you ever had the following problems with your kidneys: [Have you ever had the following problems with your kidneys]	<p>[itmCCIKidny] [itmCCIPoor] Poor kidney function (blood tests show high creatinine)</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmCCIHemo] Have used haemodialysis or peritoneal dialysis</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmCCITrnsplnt] Have received kidney transplantation</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p>
10.* ✓	Do you have rheumatoid arthritis, lupus or polymyalgia rheumatica [Rheumatoid arthritis]	<p>[itmCCIRheumtd] [N:1] <input type="radio"/> [itmCCIRhemotdYs] <input type="checkbox"/> Yes</p> <p>[itmRhemotdYsMed] Do you take medications for it regularly</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:0] <input type="radio"/> No</p>
11.* ✓	Do you have any of the following conditions [Do you have any of the following conditions]	<p>[itmCCICond] [itmCCIAIzmr] Alzheimer's disease, or another form of dementia</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmCCICirr] Cirrhosis or serious liver damage</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmCCILuckm] Leukaemia or polycythemia vera</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmCCILymph] Lymphoma</p> <p>[N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[itmCCIAids]</p>

			<div>AIDS [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No</div> <div>[itmCCICancr] Cancer, other than skin cancer, leukaemia or lymphoma [N:1] <input type="radio"/> [itmCCICancrYs] <input type="checkbox"/> Yes [itmCCICncrSprd] Has the cancer spread or metastasized to other parts of your body [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No [N:0] <input type="radio"/> No</div>
<div>Key: [*] = Item is required [✓] = Source verification required [☐] = Item is collapsible Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.</div>			

Study Object Descriptions: Charlson Co-Morbidity Index

Type	RefName	Description
Form	frmCCI	Charlson Co-morbidity Index

RDE Analytics: RD_FRMCCI		
Data Variable RefName	RD Column Name	Column Data Type
itmCCIHrt	ITMCCIHRT_C	NUMBER
	ITMCCIHRT	VARCHAR2
	ITMCCIHRT_ND	VARCHAR2
itmCCIHrtfl	ITMCCIHRTFL_C	NUMBER
	ITMCCIHRTFL	VARCHAR2
	ITMCCIHRTFL_ND	VARCHAR2
itmCCIArtris	ITMCCIARTRIS_C	NUMBER
	ITMCCIARTRIS	VARCHAR2
	ITMCCIARTRIS_ND	VARCHAR2
itmCCIStroke	ITMCCISTRKE_C	**NUMBER
	ITMCCISTRKE	VARCHAR2
	ITMCCISTRKE_ND	VARCHAR2
itmCCIStroke - itmStrkYsDiff	ITMSTRKYSDIFF_C	NUMBER
	ITMSTRKYSDIFF	VARCHAR2
itmCCIAsthma	ITMCCIASTHMA_C	**NUMBER
	ITMCCIASTHMA	VARCHAR2
	ITMCCIASTHMA_ND	VARCHAR2
itmCCIAsthma - itmAshmaMed	ITMASHMAMED_C	NUMBER
	ITMASHMAMED	VARCHAR2
itmCCIEmphy	ITMCCIEMPHY_C	**NUMBER
	ITMCCIEMPHY	VARCHAR2
	ITMCCIEMPHY_ND	VARCHAR2

itmCCIEmpy - itmEmpyYs	ITMEMPHYYS_C	NUMBER
	ITMEMPHYYS	VARCHAR2
itmCCISTomch	ITMCCISTOMCH_C	**NUMBER
	ITMCCISTOMCH	VARCHAR2
	ITMCCISTOMCH_ND	VARCHAR2
itmCCISTomch - itmStmchDig	ITMSTMCHDIG_C	NUMBER
	ITMSTMCHDIG	VARCHAR2
itmCCIDiabts	ITMCCIDIABTS_C	**NUMBER
	ITMCCIDIABTS	VARCHAR2
	ITMCCIDIABTS_ND	VARCHAR2
itmCCIDiabts - itmDibS	ITMDIBS_C	NUMBER
	ITMDIBS	VARCHAR2
itmCCIDiabts - itmDibkidny	ITMDIBKIDNY_C	NUMBER
	ITMDIBKIDNY	VARCHAR2
itmCCIDiabts - itmDibEyes	ITMDIBEYES_C	NUMBER
	ITMDIBEYES	VARCHAR2
itmCCIKidny	ITMCCIKIDNY_ND	VARCHAR2
itmCCIKidny - itmCCIPoor	ITMCCIPOOR_C	NUMBER
	ITMCCIPOOR	VARCHAR2
itmCCIKidny - itmCCIHemo	ITMCCIHEMO_C	NUMBER
	ITMCCIHEMO	VARCHAR2
itmCCIKidny - itmCCITrnsplnt	ITMCCITRNSPLNT_C	NUMBER
	ITMCCITRNSPLNT	VARCHAR2
itmCCIRheumtd	ITMCCIRHEUMTD_C	**NUMBER
	ITMCCIRHEUMTD	VARCHAR2
	ITMCCIRHEUMTD_ND	VARCHAR2
itmCCIRheumtd - itmRhemotdYsMed	ITMRHEMOTDYSMED_C	NUMBER
	ITMRHEMOTDYSMED	VARCHAR2
itmCCIcond	ITMCCICOND_ND	VARCHAR2
itmCCIcond - itmCCIAIzmr	ITMCCIAIZMR_C	NUMBER
	ITMCCIAIZMR	VARCHAR2
itmCCIcond - itmCCICirr	ITMCCICIRR_C	NUMBER
	ITMCCICIRR	VARCHAR2
itmCCIcond - itmCCILuckm	ITMCCILUCKM_C	NUMBER
	ITMCCILUCKM	VARCHAR2
itmCCIcond - itmCCILymph	ITMCCILYMPH_C	NUMBER
	ITMCCILYMPH	VARCHAR2
itmCCIcond - itmCCIAids	ITMCCIAIDS_C	NUMBER
	ITMCCIAIDS	VARCHAR2
itmCCIcond - itmCCICancr	ITMCCICANCR_C	**NUMBER
	ITMCCICANCR	VARCHAR2

itmCCICond - itmCCICncrSprd	ITMCCICNCRSPRD_C	NUMBER
	ITMCCICNCRSPRD	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: History and US Procedure Form (US) - Repeating Form [frmExam]												
#	Suggestive of a urinary tract infection	Taking 5-alpha reductase inhibitors	Taking an alpha blocker	Date of procedure	Time started US set up	Digital rectal examination	Time US commenced	Time US finished	US completed with adequate images?	Length of US procedure	Length of US procedure and set up	Examination performed by
1												
Medical History [secMH]												
1.* ✓	Does the participant have symptom(s) suggestive of a urinary tract infection? [Suggestive of a urinary tract infection]				<div>[itmExamSugs]</div> <div>[N:1] <input type="radio"/> [itmExamSugYs] <input type="checkbox"/></div> <div>Yes</div> <div>[itmEsuUrn]</div> <div>What was the urinalysis result?</div> <div>[N:1] <input type="radio"/> [itmExamPos] <input type="checkbox"/></div> <div>Positive</div> <div>[itmExmMSU]</div> <div>What was the MSU result</div> <div>[N:0] <input type="radio"/> Positive</div> <div>[N:1] <input type="radio"/> Negative</div> <div>[N:2] <input type="radio"/> No result</div> <div>[N:2] <input type="radio"/> Negative</div> <div>[N:0] <input type="radio"/> No</div>							
2.* ✓	Taking 5-alpha reductase inhibitors [Taking 5-alpha reductase inhibitors]				<div>[itmExaminhib]</div> <div>[N:1] <input type="radio"/> Yes</div> <div>[N:0] <input type="radio"/> No</div>							
3.* ✓	Taking an alpha blocker [Taking an alpha blocker]				<div>[itmExmBlockr]</div> <div>[N:1] <input type="radio"/> Yes</div> <div>[N:0] <input type="radio"/> No</div>							
Ultrasound [secUltrasound]												
4.* ✓	Date of procedure [Date of procedure]				<div>[itmUltDt]</div> <div>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)</div>							
5.* ✓	Time started US set up [Time started US set up]				<div>[itmULTTimst]</div> <div>Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock</div>							
6.* ✓	Digital rectal examination [Digital rectal examination]				<div>[itmExmDigitl]</div> <div>[N:0] <input type="radio"/> No nodule</div> <div>[N:1] <input type="radio"/> Nodule</div> <div>[N:2] <input type="radio"/> Evidence of locally advanced disease</div>							
7.* ✓	Time US commenced [Time US commenced]				<div>[itmULTcmnce]</div> <div>Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock</div>							
8.* ✓	Time US finished [Time US finished]				<div>[itmULTFin]</div> <div>Req/Unk <input type="text"/> : Req/Unk <input type="text"/> 24-hour clock</div>							
9.* ✓	US completed with adequate images? [US completed with adequate images?]				<div>[itmUltcomp]</div> <div>[N:1] <input type="radio"/> Yes</div> <div>[N:0] <input type="radio"/> [itmUltcmpNo] <input type="checkbox"/></div> <div>No</div> <div>[itmUltRsn]</div> <div>Reason for incomplete scan</div> <div>[N:0] <input type="radio"/> Patient choice/ Discomfort</div> <div>[N:1] <input type="radio"/> Technical factors (e.g. difficult veins)</div> <div>[itmUltPrd]</div>							

		Was this procedure re-arranged [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
10. ✓	Length of US procedure <i>[read-only]</i> [Length of US procedure]	[itmULTPrdL] <input type="text" value="N4"/> minutes
11. ✓	Length of US procedure and set up <i>[read-only]</i> [Length of US procedure and set up]	[itmULTPset] <input type="text" value="N4"/> minutes
12.* ✓	Examination performed by [Examination performed by]	[itmULTExm] [N:1] <input type="radio"/> Mr D Eldred-Evans [N:2] <input type="radio"/> Mr Alistair Grey [N:3] <input type="radio"/> Mr Martin Connor [N:4] <input type="radio"/> [itmExamOr] <input type="button" value="⊞"/> Other [itmExmOrPs] Please specify <input type="text" value="A50"/>

Key: [*] = Item is required [✓] = Source verification required [⊞] = Item is collapsible
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: History and US Procedure Form		
Type	RefName	Description
Form	frmExam	Examination and US Procedure Form
Section	secMH	Examination
Section	secUltrasound	Ultrasound

RDE Analytics: RD_FRMEXAM		
Data Variable RefName	RD Column Name	Column Data Type
itmExamSugs	ITMEXAMSUGS_C	**NUMBER
	ITMEXAMSUGS	VARCHAR2
	ITMEXAMSUGS_ND	VARCHAR2
itmExamSugs - itmEsuUrn	ITMESUURN_C	**NUMBER
	ITMESUURN	VARCHAR2
itmExamSugs - itmExmMSU	ITMEXMMSU_C	NUMBER
	ITMEXMMSU	VARCHAR2
itmExamInhib	ITMEXAMINHIB_C	NUMBER
	ITMEXAMINHIB	VARCHAR2
	ITMEXAMINHIB_ND	VARCHAR2
itmExmBlockr	ITMEXMBLOCKR_C	NUMBER
	ITMEXMBLOCKR	VARCHAR2
	ITMEXMBLOCKR_ND	VARCHAR2
itmUltDt	ITMULTDT	DATE
	ITMULTDT_DTS	VARCHAR2

	ITMULTDT_ND	VARCHAR2
itmULTTimst	ITMULTTIMST	DATE
	ITMULTTIMST_TMS	VARCHAR2
	ITMULTTIMST_TMR	VARCHAR2
	ITMULTTIMST_ND	VARCHAR2
itmExmDigitl	ITMEXMDIGITL_C	NUMBER
	ITMEXMDIGITL	VARCHAR2
	ITMEXMDIGITL_ND	VARCHAR2
itmULTcomnce	ITMULTCOMNCE	DATE
	ITMULTCOMNCE_TMS	VARCHAR2
	ITMULTCOMNCE_TMR	VARCHAR2
	ITMULTCOMNCE_ND	VARCHAR2
itmULTFin	ITMULTFIN	DATE
	ITMULTFIN_TMS	VARCHAR2
	ITMULTFIN_TMR	VARCHAR2
	ITMULTFIN_ND	VARCHAR2
itmUltcomp	ITMULTCOMP_C	NUMBER
	ITMULTCOMP	VARCHAR2
	ITMULTCOMP_ND	VARCHAR2
itmUltcomp - itmUltRsn	ITMULTRSN_C	NUMBER
	ITMULTRSN	VARCHAR2
itmUltcomp - itmUltPrd	ITMULTPRD_C	NUMBER
	ITMULTPRD	VARCHAR2
itmULTPrdL	ITMULTPRDL	NUMBER
	ITMULTPRDL_ND	VARCHAR2
itmULTPset	ITMULTPSET	NUMBER
	ITMULTPSET_ND	VARCHAR2
itmULTExm	ITMULTEXM_C	NUMBER
	ITMULTEXM	VARCHAR2
	ITMULTEXM_ND	VARCHAR2
itmULTExm - itmExmOrPs	ITMEXMORPS	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: MRI Procedure Form (MRI) - Repeating Form [frmProcd]

#	MRI completed	MRI completed with adequate images	Length of MRI procedure	Length of MRI procedure and set up
1				

MRI Procedure Form [frmProcd]

1.*
✓

MRI completed?
[MRI completed]

[itmMPrdcmp]
[N:1] ☐ [itmMPrdAdcYs]

Yes

[itmMPrdDt]
Date of MRI

Req / Req / Req (2018-2030)

[itmMprdsttim]
Time started MRI set up

Req : Req 24-hour clock

[itmMprdcmmc]
Time MRI commenced

Req : Req 24-hour clock

[itmMprdfinish]
Time MRI finished

Req : Req 24-hour clock

[N:0] ☐ No

2.*
✓

MRI completed with adequate images
[MRI completed with adequate images]

[itmMPrdAdc]
[N:1] ☐ Yes

[N:0] ☐ [itmMPrdAdcNo]

No

[itmMprdRsn]
Reason for incomplete scan

[N:0] ☐ Patient choice/ Discomfort

[N:1] ☐ Technical factors (e.g. difficult veins)

[itmMprdRarng]
Was this procedure re-arranged

[N:1] ☐ Yes

[N:0] ☐ No

3.
✓

Length of MRI procedure [read-only]
[Length of MRI procedure]

[itmMprdPrd]
N4 minutes

4.
✓

Length of MRI procedure and set up [read-only]
[Length of MRI procedure and set up]

[itmMprdSetup]
N4 minutes

Key: [✓] = Source verification required [] = Item is collapsible

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: MRI Procedure Form		
Type	RefName	Description
Form	frmProcd	MRI procedure form


RDE Analytics: RD_FRMPROCD		
Data Variable RefName	RD Column Name	Column Data Type
itmMPrdcmp	ITMMPRDCMP_C	**NUMBER

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe_137e31086639fb5d_0002.0000_c16... 03/05/2019

	ITMMPRDCMP	VARCHAR2
	ITMMPRDCMP_ND	VARCHAR2
itmMPrdcmp - itmMPrdDt	ITMMPRDDT	DATE
	ITMMPRDDT_DTS	VARCHAR2
itmMPrdcmp - itmMprdsttim	ITMMPRDTSTTIM	DATE
	ITMMPRDTSTTIM_TMS	VARCHAR2
itmMPrdcmp - itmMprdcomnc	ITMMPRDCOMNC	DATE
	ITMMPRDCOMNC_TMS	VARCHAR2
itmMPrdcmp - itmMprdfinish	ITMMPRDFINISH	DATE
	ITMMPRDFINISH_TMS	VARCHAR2
itmMPrdAdc	ITMMPRDADC_C	NUMBER
	ITMMPRDADC	VARCHAR2
	ITMMPRDADC_ND	VARCHAR2
itmMPrdAdc - itmMprdRsn	ITMMPRDRSN_C	NUMBER
	ITMMPRDRSN	VARCHAR2
itmMPrdAdc - itmMprdRarng	ITMMPRDRARNG_C	NUMBER
	ITMMPRDRARNG	VARCHAR2
itmMprdPrd	ITMMPRDPRD	NUMBER
	ITMMPRDPRD_ND	VARCHAR2
itmMprdSetup	ITMMPRDSETUP	NUMBER
	ITMMPRDSETUP_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		





Study Object Descriptions: PSA result		
Type	RefName	Description
Form	frmPSA	PSA result

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe 137e31086639fb5d 0002.0000 c16... 03/05/2019

PROSTAGRAM: MRI Reporting Form (MRI-R) [frmMRIR]							
MRI Reporting Form [frmMRIR]							
1.* ✓	MRI report completed? [MRI report completed]	<div>[itmMRIRcomp] [N:1] <input type="radio"/> [itmMRIYs] <input type="checkbox"/> Yes [itmMRITs] Transverse size <input type="text" value="xx.x"/> cm^[b] [itmMRIAP] AP size <input type="text" value="xx.x"/> cm^[b] [itmMRICran] Cranio-caudal size <input type="text" value="xx.x"/> cm^[b] [itmMRIscndt] Scan date Req <input type="text" value=""/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2030) [N:0] <input type="radio"/> No</div>					
2. ✓	Volume <i>[read-only]</i> [Volume]	<div>[itmMRIVol] <input type="text" value="xxxxxx.x"/> cm³</div>					
3.* ✓	Are there any lesions with an MRI score ≥ 3? [Are there any lesions with an MRI score ≥ 3]	<div>[itmMRIScr] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No</div>					
MRI Lesion Details [secMRPLdetl]							
# ✓	Number of MRI Lesions	Maximum Diameter	Modified PIRADS Score	LIKERT Score	Location	CAD Positive?	CAD score
4.a	MRI Lesion 1						
4.b	MRI Lesion 2						
4.c	MRI Lesion 3						
4.d	MRI Lesion 4						
MRI Lesion Details Entry [secMRPLdetl]							
4.1 ✓ 	Number of MRI Lesions <i>[read-only]</i> [Number of MRI Lesions]	<div>[itmMRILno] [N:0] <input type="radio"/> MRI Lesion 1 [N:1] <input type="radio"/> MRI Lesion 2 [N:2] <input type="radio"/> MRI Lesion 3 [N:3] <input type="radio"/> MRI Lesion 4</div>					
4.2 ✓	Maximum Diameter [Maximum Diameter]	<div>[itmMRMxd] <input type="text" value="N3"/> mm^[b]</div>					
4.3 ✓	Modified PIRADS Score [Modified PIRADS Score]	<div>[itmMRMod] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5</div>					
4.4 ✓	LIKERT Score [LIKERT Score]	<div>[cmpMRLikrt] [itmMRLikert] LIKERT Score</div>					

		<div><div>[N:1] <input type="radio"/> 1</div><div>[N:2] <input type="radio"/> 2</div><div>[N:3] <input type="radio"/> 3</div><div>[N:4] <input type="radio"/> 4</div><div>[N:5] <input type="radio"/> 5</div><div>[itmMRFD]</div><div>Focal or Diffuse (if score = 3)</div><div>[N:0] <input type="radio"/> Focal</div><div>[N:1] <input type="radio"/> Diffuse</div><div>[N:2] <input type="radio"/> Not Applicable</div></div>
4.5 ✓	Location [Location]	<div><div>[itmMRLocn]</div><div>[N:1] <input type="checkbox"/> 1</div><div>[N:2] <input type="checkbox"/> 2</div><div>[N:3] <input type="checkbox"/> 3</div><div>[N:4] <input type="checkbox"/> 4</div><div>[N:5] <input type="checkbox"/> 5</div><div>[N:6] <input type="checkbox"/> 6</div><div>[N:7] <input type="checkbox"/> 7</div><div>[N:8] <input type="checkbox"/> 8</div><div>[N:9] <input type="checkbox"/> 9</div><div>[N:10] <input type="checkbox"/> 10</div><div>[N:11] <input type="checkbox"/> 11</div><div>[N:12] <input type="checkbox"/> 12</div><div>[N:13] <input type="checkbox"/> 13</div><div>[N:14] <input type="checkbox"/> 14</div><div>[N:15] <input type="checkbox"/> 15</div><div>[N:16] <input type="checkbox"/> 16</div><div>[N:17] <input type="checkbox"/> 17</div><div>[N:18] <input type="checkbox"/> 18</div><div>[N:19] <input type="checkbox"/> 19</div><div>[N:20] <input type="checkbox"/> 20</div><div>[N:21] <input type="checkbox"/> 21</div><div>[N:22] <input type="checkbox"/> 22</div><div>[N:23] <input type="checkbox"/> 23</div><div>[N:24] <input type="checkbox"/> 24</div><div>[N:25] <input type="checkbox"/> 25</div><div>[N:26] <input type="checkbox"/> 26</div><div>[N:27] <input type="checkbox"/> 27</div><div>[N:28] <input type="checkbox"/> 28</div><div>[N:29] <input type="checkbox"/> 29</div><div>[N:30] <input type="checkbox"/> 30</div><div>[N:31] <input type="checkbox"/> 31</div><div>[N:32] <input type="checkbox"/> 32</div><div>[N:33] <input type="checkbox"/> 33</div><div>[N:34] <input type="checkbox"/> 34</div><div>[N:35] <input type="checkbox"/> 35</div><div>[N:36] <input type="checkbox"/> 36</div><div>[N:37] <input type="checkbox"/> 37</div><div>[N:38] <input type="checkbox"/> 38</div><div>[N:39] <input type="checkbox"/> 39</div></div>

		[N:40] <input type="checkbox"/> 40 [N:41] <input type="checkbox"/> 41
4.6 ✓	CAD Positive? [CAD Positive?]	[itmMRCAD] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
4.7 ✓	CAD score [CAD score]	[itmMRCADScr] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5
Other Findings [secOF]		
5.* ✓	Radiological stage if subsequently found to have cancer [Radiological stage if subsequently found to have cancer]	[itmMROFRadio] [N:0] <input type="radio"/> ≤T2 [N:1] <input type="radio"/> T2a [N:2] <input type="radio"/> T2b [N:3] <input type="radio"/> T2c [N:4] <input type="radio"/> T3a [N:5] <input type="radio"/> T3b [N:6] <input type="radio"/> [itmMRRadioT4] <input type="checkbox"/> T4 [itmRadT4] [N:0] <input type="checkbox"/> Sphincter [N:1] <input type="checkbox"/> Rectum [N:2] <input type="checkbox"/> Bladder
6.* ✓	Any incidental findings [Any incidental findings]	[itmMRincidnt] [A:A] <input type="checkbox"/> None [A:B] <input type="checkbox"/> Bladder Tumour [A:C] <input type="checkbox"/> Rectal Tumour [A:D] <input type="checkbox"/> [itmIncdntOthr] <input type="checkbox"/> Other [citmIncdntOrPs] Please specify A80
7.* ✓	Is there a reason why the MRI needs to be repeated [Is there a reason why the MRI needs to be repeated]	[itmMRPrb] [N:0] <input type="checkbox"/> None [N:1] <input type="checkbox"/> Geometric distortion [N:2] <input type="checkbox"/> Susceptibility [N:3] <input type="checkbox"/> Internal motion [N:4] <input type="checkbox"/> Signal Graininess [N:5] <input type="checkbox"/> Blurring [N:6] <input type="checkbox"/> External motion [N:7] <input type="checkbox"/> Ghosting [N:8] <input type="checkbox"/> [itmMRPrbOth] <input type="checkbox"/> Other [itmPrbOrPs] Please specify A80

8.* ✓	Are there any additional/new lesions on CAD [Are there any additional/new lesions on CAD]	[itmMRAdd] [N:1] <input type="radio"/> Yes [N:2] <input type="radio"/> No [N:3] <input type="radio"/> Excluded		
CAD Details [secCADDet]				
# ✓	Target Details	Maximum Diameter	Modified PIRADS Score	LIKERT Score
9.a	New CAD Target			
9.b	New CAD Target			
CAD Details Entry [secCADDet]				
9.1 ✓ 	Target Details <i>[read-only]</i> [Target Details]	[itmMRTrgt] [N:0] <input type="radio"/> New CAD Target		
9.2 ✓	Maximum Diameter [Maximum Diameter]	[itmMRmax] N3 mm ^[b]		
9.3 ✓	Modified PIRADS Score [Modified PIRADS Score]	[itmCADMod] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5		
9.4 ✓	LIKERT Score [LIKERT Score]	[itmCADLikert] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5		
Declaration [secDeclr]				
10.* ✓	Radiologist [Radiologist]	[itmMRDeclr] [N:1] <input type="radio"/> Prof A Padhani [N:2] <input type="radio"/> Dr H Sokhi [N:3] <input type="radio"/> Dr H Tam [N:4] <input type="radio"/> [itmMRradOr]  Other [itmRadOrps] Please specify A50		
Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit  = Item is collapsible  = Fixed item Note: Source verification critical settings made in InForm will override any settings made in Central Designer. Note: Collapsible settings are only available to users who have the rights to edit the item.				

Study Object Descriptions: MRI Reporting Form		
Type	RefName	Description
Form	frmMRIR	MRI result
Section	secMRPLdetl	MRI Lesion Details
Section	secOF	Other Findings
Section	secCADDet	CAD Details

Section	secDeclr	Declaration
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RDE Analytics: RD_FRMMRIR		
Data Variable RefName	RD Column Name	Column Data Type
itmMRIRcomp	ITMMRIRCOMP_C	**NUMBER
	ITMMRIRCOMP	VARCHAR2
	ITMMRIRCOMP_ND	VARCHAR2
itmMRIRcomp - itmMRITs	ITMMRITS	FLOAT
	ITMMRITS_U	VARCHAR2
itmMRIRcomp - itmMRIAP	ITMMRIAP	FLOAT
	ITMMRIAP_U	VARCHAR2
itmMRIRcomp - itmMRICran	ITMMRICRAN	FLOAT
	ITMMRICRAN_U	VARCHAR2
itmMRIRcomp - itmMRIscondt	ITMMRISCNDT	DATE
	ITMMRISCNDT_DTS	VARCHAR2
itmMRIVol	ITMMRIVOL	FLOAT
	ITMMRIVOL_ND	VARCHAR2
itmMRIScr	ITMMRISCR_C	NUMBER
	ITMMRISCR	VARCHAR2
	ITMMRISCR_ND	VARCHAR2
itmMROFRadio	ITMMROFRADIO_C	NUMBER
	ITMMROFRADIO	VARCHAR2
	ITMMROFRADIO_ND	VARCHAR2
itmMROFRadio - Sphincter	ITMRADT4_CITMT40_C	NUMBER
	ITMRADT4_CITMT40	VARCHAR2
itmMROFRadio - Rectum	ITMRADT4_CITMT41_C	NUMBER
	ITMRADT4_CITMT41	VARCHAR2
itmMROFRadio - Bladder	ITMRADT4_CITMT42_C	NUMBER
	ITMRADT4_CITMT42	VARCHAR2
itmMRincdnt	ITMMRINCIDNT_ND	VARCHAR2
itmMRincdnt - None	ITMMRINCIDNT_CITMINCFNON_C	VARCHAR2
	ITMMRINCIDNT_CITMINCFNON	VARCHAR2
itmMRincdnt - Bladder Tumour	ITMMRINCIDNT_CITMINCFBT_C	VARCHAR2
	ITMMRINCIDNT_CITMINCFBT	VARCHAR2
itmMRincdnt - Rectal Tumour	ITMMRINCIDNT_CITMINCFRT_C	VARCHAR2
	ITMMRINCIDNT_CITMINCFRT	VARCHAR2
itmMRincdnt - Other	*ITMMRINCIDNT_ITMINCDNTOTHR_C	VARCHAR2
	*ITMMRINCIDNT_ITMINCDNTOTHR	VARCHAR2
itmMRincdnt - citmIncdntOrPs	CITMINCDNTORPS	VARCHAR2
itmMRPrb	ITMMRPRB_ND	VARCHAR2

itmMRPrb - None	ITMMRPRB_CITMCAD0_C	NUMBER
	ITMMRPRB_CITMCAD0	VARCHAR2
itmMRPrb - Geometric distortion	ITMMRPRB_CITMCAD1_C	NUMBER
	ITMMRPRB_CITMCAD1	VARCHAR2
itmMRPrb - Susceptibility	ITMMRPRB_CITMCAD2_C	NUMBER
	ITMMRPRB_CITMCAD2	VARCHAR2
itmMRPrb - Internal motion	ITMMRPRB_CITMCAD3_C	NUMBER
	ITMMRPRB_CITMCAD3	VARCHAR2
itmMRPrb - Signal Graininess	ITMMRPRB_CITMCAD4_C	NUMBER
	ITMMRPRB_CITMCAD4	VARCHAR2
itmMRPrb - Blurring	ITMMRPRB_CITMCAD5_C	NUMBER
	ITMMRPRB_CITMCAD5	VARCHAR2
itmMRPrb - External motion	ITMMRPRB_CITMCAD6_C	NUMBER
	ITMMRPRB_CITMCAD6	VARCHAR2
itmMRPrb - Ghosting	ITMMRPRB_CITMCAD7_C	NUMBER
	ITMMRPRB_CITMCAD7	VARCHAR2
itmMRPrb - Other	ITMMRPRB_ITMMRPRBOTH_C	NUMBER
	ITMMRPRB_ITMMRPRBOTH	VARCHAR2
itmMRPrb - itmPrbOrPs	ITMPRBORPS	VARCHAR2
itmMRAdd	ITMMRADD_C	NUMBER
	ITMMRADD	VARCHAR2
	ITMMRADD_ND	VARCHAR2
itmMRDeclr	ITMMRDECLR_C	NUMBER
	ITMMRDECLR	VARCHAR2
	ITMMRDECLR_ND	VARCHAR2
itmMRDeclr - itmRadOrps	ITMRADORPS	VARCHAR2
RD_FRMMRIR_SECMRPLDETL		
itmMRILno	ITMMRILNO_C	NUMBER
	ITMMRILNO	VARCHAR2
	ITMMRILNO_ND	VARCHAR2
itmMRMxd	ITMMRMXD	NUMBER
	ITMMRMXD_U	VARCHAR2
	ITMMRMXD_ND	VARCHAR2
itmMRMod	ITMMRMOD_C	NUMBER
	ITMMRMOD	VARCHAR2
	ITMMRMOD_ND	VARCHAR2
cmpMRLikrt	CMPMRLIKRT_ND	VARCHAR2
cmpMRLikrt - itmMRLikert	ITMMRLIKERT_C	NUMBER
	ITMMRLIKERT	VARCHAR2
cmpMRLikrt - itmMRFD	ITMMRFD_C	NUMBER
	ITMMRFD	VARCHAR2

itmMRLocn	ITMMRLOCN_ND	VARCHAR2
itmMRLocn - 1	ITMMRLOCN_CITMLOC1_C	NUMBER
	ITMMRLOCN_CITMLOC1	VARCHAR2
itmMRLocn - 2	ITMMRLOCN_CITMLOC2_C	NUMBER
	ITMMRLOCN_CITMLOC2	VARCHAR2
itmMRLocn - 3	ITMMRLOCN_CITMLOC3_C	NUMBER
	ITMMRLOCN_CITMLOC3	VARCHAR2
itmMRLocn - 4	ITMMRLOCN_CITMLOC4_C	NUMBER
	ITMMRLOCN_CITMLOC4	VARCHAR2
itmMRLocn - 5	ITMMRLOCN_CITMLOC5_C	NUMBER
	ITMMRLOCN_CITMLOC5	VARCHAR2
itmMRLocn - 6	ITMMRLOCN_CITMLOC6_C	NUMBER
	ITMMRLOCN_CITMLOC6	VARCHAR2
itmMRLocn - 7	ITMMRLOCN_CITMLOC7_C	NUMBER
	ITMMRLOCN_CITMLOC7	VARCHAR2
itmMRLocn - 8	ITMMRLOCN_CITMLOC8_C	NUMBER
	ITMMRLOCN_CITMLOC8	VARCHAR2
itmMRLocn - 9	ITMMRLOCN_CITMLOC9_C	NUMBER
	ITMMRLOCN_CITMLOC9	VARCHAR2
itmMRLocn - 10	ITMMRLOCN_CITMLOC10_C	NUMBER
	ITMMRLOCN_CITMLOC10	VARCHAR2
itmMRLocn - 11	ITMMRLOCN_CITMLOC11_C	NUMBER
	ITMMRLOCN_CITMLOC11	VARCHAR2
itmMRLocn - 12	ITMMRLOCN_CITMLOC12_C	NUMBER
	ITMMRLOCN_CITMLOC12	VARCHAR2
itmMRLocn - 13	ITMMRLOCN_CITMLOC13_C	NUMBER
	ITMMRLOCN_CITMLOC13	VARCHAR2
itmMRLocn - 14	ITMMRLOCN_CITMLOC14_C	NUMBER
	ITMMRLOCN_CITMLOC14	VARCHAR2
itmMRLocn - 15	ITMMRLOCN_CITMLOC15_C	NUMBER
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	ITMMRLOCN_CITMLOC17	VARCHAR2
itmMRLocn - 18	ITMMRLOCN_CITMLOC18_C	NUMBER
	ITMMRLOCN_CITMLOC18	VARCHAR2
itmMRLocn - 19	ITMMRLOCN_CITMLOC19_C	NUMBER
	ITMMRLOCN_CITMLOC19	VARCHAR2
itmMRLocn - 20	ITMMRLOCN_CITMLOC20_C	NUMBER
	ITMMRLOCN_CITMLOC20	VARCHAR2

itmMRLocn - 21	ITMMRLOCN_CITMLOC21_C	NUMBER
	ITMMRLOCN_CITMLOC21	VARCHAR2
itmMRLocn - 22	ITMMRLOCN_CITMLOC22_C	NUMBER
	ITMMRLOCN_CITMLOC22	VARCHAR2
itmMRLocn - 23	ITMMRLOCN_CITMLOC23_C	NUMBER
	ITMMRLOCN_CITMLOC23	VARCHAR2
itmMRLocn - 24	ITMMRLOCN_CITMLOC24_C	NUMBER
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	ITMMRLOCN_CITMLOC25	VARCHAR2
itmMRLocn - 26	ITMMRLOCN_CITMLOC26_C	NUMBER
	ITMMRLOCN_CITMLOC26	VARCHAR2
itmMRLocn - 27	ITMMRLOCN_CITMLOC27_C	NUMBER
	ITMMRLOCN_CITMLOC27	VARCHAR2
itmMRLocn - 28	ITMMRLOCN_CITMLOC28_C	NUMBER
	ITMMRLOCN_CITMLOC28	VARCHAR2
itmMRLocn - 29	ITMMRLOCN_CITMLOC29_C	NUMBER
	ITMMRLOCN_CITMLOC29	VARCHAR2
itmMRLocn - 30	ITMMRLOCN_CITMLOC30_C	NUMBER
	ITMMRLOCN_CITMLOC30	VARCHAR2
itmMRLocn - 31	ITMMRLOCN_CITMLOC31_C	NUMBER
	ITMMRLOCN_CITMLOC31	VARCHAR2
itmMRLocn - 32	ITMMRLOCN_CITMLOC32_C	NUMBER
	ITMMRLOCN_CITMLOC32	VARCHAR2
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	ITMMRLOCN_CITMLOC33	VARCHAR2
itmMRLocn - 34	ITMMRLOCN_CITMLOC34_C	NUMBER
	ITMMRLOCN_CITMLOC34	VARCHAR2
itmMRLocn - 35	ITMMRLOCN_CITMLOC35_C	NUMBER
	ITMMRLOCN_CITMLOC35	VARCHAR2
itmMRLocn - 36	ITMMRLOCN_CITMLOC36_C	NUMBER
	ITMMRLOCN_CITMLOC36	VARCHAR2
itmMRLocn - 37	ITMMRLOCN_CITMLOC37_C	NUMBER
	ITMMRLOCN_CITMLOC37	VARCHAR2
itmMRLocn - 38	ITMMRLOCN_CITMLOC38_C	NUMBER
	ITMMRLOCN_CITMLOC38	VARCHAR2
itmMRLocn - 39	ITMMRLOCN_CITMLOC39_C	NUMBER
	ITMMRLOCN_CITMLOC39	VARCHAR2
itmMRLocn - 40	ITMMRLOCN_CITMLOC40_C	NUMBER
	ITMMRLOCN_CITMLOC40	VARCHAR2
itmMRLocn - 41	ITMMRLOCN_CITMLOC41_C	NUMBER

	ITMMRLOCN_CITMLOC41	VARCHAR2
itmMRCAD	ITMMRCAD_C	NUMBER
	ITMMRCAD	VARCHAR2
	ITMMRCAD_ND	VARCHAR2
itmMRCADScr	ITMMRCADSCR_C	NUMBER
	ITMMRCADSCR	VARCHAR2
	ITMMRCADSCR_ND	VARCHAR2
RD_FRMMRIR_SECCADDET		
itmMRTrgt	ITMMRTRGT_C	NUMBER
	ITMMRTRGT	VARCHAR2
	ITMMRTRGT_ND	VARCHAR2
itmMRmax	ITMMRMAX	NUMBER
	ITMMRMAX_U	VARCHAR2
	ITMMRMAX_ND	VARCHAR2
itmCADMod	ITMCADMOD_C	NUMBER
	ITMCADMOD	VARCHAR2
	ITMCADMOD_ND	VARCHAR2
itmCADLikert	ITMCADLIKERT_C	NUMBER
	ITMCADLIKERT	VARCHAR2
	ITMCADLIKERT_ND	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: CAD Report Form (CAD) [frmCAD]								
CAD Report Form [frmCAD]								
1.* ✓	Any problems with MRI quality which prevent CAD [Any problems with MRI quality which prevent CAD]			[itmCADPrb] [N:1] <input type="radio"/> None [N:2] <input type="radio"/> Susceptibility/Rectal Artifact [N:3] <input type="radio"/> Filtering issue				
2. ✓	Length of CAD analysis [Length of CAD analysis]			[itmCADLengh] NReq <input type="text"/> : NReq <input type="text"/>				
3. ✓	Are there any lesions scoring MAI ≥ 6 and Vol ≥ 0.5? [Are there any lesions scoring MAI]			[itmCADlesnsr] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No				
4. ✓	Are there any lesions scoring MAI ≥ 0.6 [Lesion Scoring]			[itmCADLesion] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No				
CAD Lesion Details [secCLD]								
# ✓	Number of CAD Lesions	Lesion Volume	Average ADC Value	Mean MAI	Median MAI	Highest MAI	Concordant on MRI	Location
5.a	CAD Lesion 1							
5.b	CAD Lesion 2							
5.c	CAD Lesion 3							
5.d	CAD Lesion 4							
5.e	CAD Lesion 5							
5.f	CAD Lesion 6							
CAD Lesion Details Entry [secCLD]								
5.1 ✓ 	Number of CAD Lesions [read-only] [Number of CAD Lesions]			[itmCADNo] [clCADLesion] <input type="text"/>				
5.2 ✓	Lesion Volume [Lesion Volume]			[itmCADLv] <input type="text"/> ml				
5.3 ✓	Average ADC Value [Average ADC Value]			[itmCADADC] <input type="text"/> 10 ⁻³ mm ² /s				
5.4 ✓	Mean MAI [Mean MAI]			[itmCADMMAI] <input type="text"/> 0.00 ≤ x.xx ≤ 1.00				
5.5 ✓	Median MAI [Median MAI]			[itmCADMDMAI] <input type="text"/> 0.00 ≤ x.xx ≤ 1.00				
5.6 ✓	Highest MAI [Highest MAI]			[itmCADHMAI] <input type="text"/> 0.00 ≤ x.xx ≤ 1.00				
5.7 ✓	Concordant on MRI [Concordant on MRI]			[itmCADCONCr] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No				
5.8 ✓	Location [Location]			[itmCADLcn] [N:1] <input type="checkbox"/> 1 [N:2] <input type="checkbox"/> 2 [N:3] <input type="checkbox"/> 3				

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0O28QNWE.8X6/orac...exe 137e31086639fb5d 0002.0000 c16... 03/05/2019

8.a	CAD Lesion 1						
8.b	CAD Lesion 2						
8.c	CAD Lesion 3						
8.d	CAD Lesion 4						
8.e	CAD Lesion 5						
8.f	CAD Lesion 6						

CAD Lesion Details Entry [secCLDs]	
8.1 ✓ [Number of CAD Lesions]	<div>Number of CAD Lesions <i>[read-only]</i></div> <div>[itmFSCADIs]</div> <div>[clCADLesion] ▼</div>
8.2 ✓ [Lesion Volume]	<div>Lesion Volume</div> <div>x.xx ml</div>
8.3 ✓ [Average ADC Value]	<div>Average ADC Value</div> <div>x.xx 10⁻³ mm²/s</div>
8.4 ✓ [Mean MAI]	<div>Mean MAI</div> <div>0.00 <= x.xx <= 1.00</div>
8.5 ✓ [Median MAI]	<div>Median MAI</div> <div>0.00 <= x.xx <= 1.00</div>
8.6 ✓ [Highest MAI]	<div>Highest MAI</div> <div>0.00 <= x.xx <= 1.00</div>
8.7 ✓ [Concordant on MRI]	<div>Concordant on MRI</div> <div>[N:1] <input type="radio"/> Yes</div> <div>[N:0] <input type="radio"/> No</div>
8.8 ✓ [Location]	<div>Location</div> <div>[itmFSLoc]</div> <div>[N:1] <input type="checkbox"/> 1</div> <div>[N:2] <input type="checkbox"/> 2</div> <div>[N:3] <input type="checkbox"/> 3</div> <div>[N:4] <input type="checkbox"/> 4</div> <div>[N:5] <input type="checkbox"/> 5</div> <div>[N:6] <input type="checkbox"/> 6</div> <div>[N:7] <input type="checkbox"/> 7</div> <div>[N:8] <input type="checkbox"/> 8</div> <div>[N:9] <input type="checkbox"/> 9</div> <div>[N:10] <input type="checkbox"/> 10</div> <div>[N:11] <input type="checkbox"/> 11</div> <div>[N:12] <input type="checkbox"/> 12</div> <div>[N:13] <input type="checkbox"/> 13</div> <div>[N:14] <input type="checkbox"/> 14</div> <div>[N:15] <input type="checkbox"/> 15</div> <div>[N:16] <input type="checkbox"/> 16</div> <div>[N:17] <input type="checkbox"/> 17</div> <div>[N:18] <input type="checkbox"/> 18</div> <div>[N:19] <input type="checkbox"/> 19</div> <div>[N:20] <input type="checkbox"/> 20</div> <div>[N:21] <input type="checkbox"/> 21</div> <div>[N:22] <input type="checkbox"/> 22</div>

		<div><div>[N:23] <input type="checkbox"/> 23</div><div>[N:24] <input type="checkbox"/> 24</div><div>[N:25] <input type="checkbox"/> 25</div><div>[N:26] <input type="checkbox"/> 26</div><div>[N:27] <input type="checkbox"/> 27</div><div>[N:28] <input type="checkbox"/> 28</div><div>[N:29] <input type="checkbox"/> 29</div><div>[N:30] <input type="checkbox"/> 30</div><div>[N:31] <input type="checkbox"/> 31</div><div>[N:32] <input type="checkbox"/> 32</div><div>[N:33] <input type="checkbox"/> 33</div><div>[N:34] <input type="checkbox"/> 34</div><div>[N:35] <input type="checkbox"/> 35</div><div>[N:36] <input type="checkbox"/> 36</div><div>[N:37] <input type="checkbox"/> 37</div><div>[N:38] <input type="checkbox"/> 38</div><div>[N:39] <input type="checkbox"/> 39</div><div>[N:40] <input type="checkbox"/> 40</div><div>[N:41] <input type="checkbox"/> 41</div></div>
Declaration [secCADDeclr]		
9. ✓	Radiologist [Radiologist]	<div><div>[itmCADDclrRad]</div><div>[N:1] <input type="radio"/> Mr D Eldred-Evans</div><div>[N:2] <input type="radio"/> Miss Emma Cullen</div><div>[N:3] <input type="radio"/> [itmCADRdOr] <input type="checkbox"/></div><div>Other</div><div>[itmCDRdOr]</div><div>Please specify</div><div>A50</div></div>
<div>Key: [*] = Item is required [✓] = Source verification required <input type="checkbox"/> = Item is collapsible <input checked="" type="checkbox"/> = Fixed item</div> <div>Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</div> <div>Note: Collapsible settings are only available to users who have the rights to edit the item.</div>		

Study Object Descriptions: CAD Report Form		
Type	RefName	Description
Form	frmCAD	CAD Report Form
Section	secCLD	CAD Lesion Details
Section	secFS25p	Filter settings (25%)
Section	secCLDs	CAD Lesion Details
Section	secCADDeclr	Declaration

Codelist Values Tables: CAD Report Form					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
cCADLesion	Integer	CAD Lesion 1	0	citmCADLsn0	itmCADNo, itmFSCADIs
		CAD Lesion 2	1	citmCADLsn1	
		CAD Lesion 3	2	citmCADLsn2	

		CAD Lesion 4	3	citmCADLsn3	
		CAD Lesion 5	4	citmCADLsn4	
		CAD Lesion 6	5	citmCADLsn5	

RDE Analytics: RD_FRMCAD		
Data Variable RefName	RD Column Name	Column Data Type
itmCADPrb	ITMCADPRB_C	NUMBER
	ITMCADPRB	VARCHAR2
	ITMCADPRB_ND	VARCHAR2
itmCADLengh	ITMCADLENGH_TMS	VARCHAR2
	ITMCADLENGH_TMR	VARCHAR2
	ITMCADLENGH_ND	VARCHAR2
itmCADlesnscr	ITMCADLESNSCR_C	NUMBER
	ITMCADLESNSCR	VARCHAR2
	ITMCADLESNSCR_ND	VARCHAR2
itmCADLesion	ITMCADLESION_C	NUMBER
	ITMCADLESION	VARCHAR2
	ITMCADLESION_ND	VARCHAR2
itmFSPrev	ITMFSPREV_C	NUMBER
	ITMFSPREV	VARCHAR2
	ITMFSPREV_ND	VARCHAR2
itmFSMAI	ITMFSMAI_C	NUMBER
	ITMFSMAI	VARCHAR2
	ITMFSMAI_ND	VARCHAR2
itmCADDclrRad	ITMCADDCLRRAD_C	NUMBER
	ITMCADDCLRRAD	VARCHAR2
	ITMCADDCLRRAD_ND	VARCHAR2
itmCADDclrRad - itmCDRdOr	ITMCDRDOR	VARCHAR2
RD_FRMCAD_SECCLD		
itmCADNo	ITMCADNO_C	NUMBER
	ITMCADNO	VARCHAR2
	ITMCADNO_ND	VARCHAR2
itmCADLv	ITMCADLV	FLOAT
	ITMCADLV_ND	VARCHAR2
itmCADADC	ITMCADADC	FLOAT
	ITMCADADC_ND	VARCHAR2
itmCADMMAI	ITMCADMMAI	FLOAT
	ITMCADMMAI_ND	VARCHAR2
itmCADMDMAI	ITMCADMDMAI	FLOAT
	ITMCADMDMAI_ND	VARCHAR2

itmCADHMAI	ITMCADHMAI	FLOAT
	ITMCADHMAI_ND	VARCHAR2
itmCADCONCr	ITMCADCONCR_C	NUMBER
	ITMCADCONCR	VARCHAR2
	ITMCADCONCR_ND	VARCHAR2
itmCADLcn	ITMCADLCN_ND	VARCHAR2
itmCADLcn - 1	ITMCADLCN_CITMLOC1_C	NUMBER
	ITMCADLCN_CITMLOC1	VARCHAR2
itmCADLcn - 2	ITMCADLCN_CITMLOC2_C	NUMBER
	ITMCADLCN_CITMLOC2	VARCHAR2
itmCADLcn - 3	ITMCADLCN_CITMLOC3_C	NUMBER
	ITMCADLCN_CITMLOC3	VARCHAR2
itmCADLcn - 4	ITMCADLCN_CITMLOC4_C	NUMBER
	ITMCADLCN_CITMLOC4	VARCHAR2
itmCADLcn - 5	ITMCADLCN_CITMLOC5_C	NUMBER
	ITMCADLCN_CITMLOC5	VARCHAR2
itmCADLcn - 6	ITMCADLCN_CITMLOC6_C	NUMBER
	ITMCADLCN_CITMLOC6	VARCHAR2
itmCADLcn - 7	ITMCADLCN_CITMLOC7_C	NUMBER
	ITMCADLCN_CITMLOC7	VARCHAR2
itmCADLcn - 8	ITMCADLCN_CITMLOC8_C	NUMBER
	ITMCADLCN_CITMLOC8	VARCHAR2
itmCADLcn - 9	ITMCADLCN_CITMLOC9_C	NUMBER
	ITMCADLCN_CITMLOC9	VARCHAR2
itmCADLcn - 10	ITMCADLCN_CITMLOC10_C	NUMBER
	ITMCADLCN_CITMLOC10	VARCHAR2
itmCADLcn - 11	ITMCADLCN_CITMLOC11_C	NUMBER
	ITMCADLCN_CITMLOC11	VARCHAR2
itmCADLcn - 12	ITMCADLCN_CITMLOC12_C	NUMBER
	ITMCADLCN_CITMLOC12	VARCHAR2
itmCADLcn - 13	ITMCADLCN_CITMLOC13_C	NUMBER
	ITMCADLCN_CITMLOC13	VARCHAR2
itmCADLcn - 14	ITMCADLCN_CITMLOC14_C	NUMBER
	ITMCADLCN_CITMLOC14	VARCHAR2
itmCADLcn - 15	ITMCADLCN_CITMLOC15_C	NUMBER
	ITMCADLCN_CITMLOC15	VARCHAR2
itmCADLcn - 16	ITMCADLCN_CITMLOC16_C	NUMBER
	ITMCADLCN_CITMLOC16	VARCHAR2
itmCADLcn - 17	ITMCADLCN_CITMLOC17_C	NUMBER
	ITMCADLCN_CITMLOC17	VARCHAR2
itmCADLcn - 18	ITMCADLCN_CITMLOC18_C	NUMBER

	ITMCADLCN_CITMLOC18	VARCHAR2
itmCADLcn - 19	ITMCADLCN_CITMLOC19_C	NUMBER
	ITMCADLCN_CITMLOC19	VARCHAR2
itmCADLcn - 20	ITMCADLCN_CITMLOC20_C	NUMBER
	ITMCADLCN_CITMLOC20	VARCHAR2
itmCADLcn - 21	ITMCADLCN_CITMLOC21_C	NUMBER
	ITMCADLCN_CITMLOC21	VARCHAR2
itmCADLcn - 22	ITMCADLCN_CITMLOC22_C	NUMBER
	ITMCADLCN_CITMLOC22	VARCHAR2
itmCADLcn - 23	ITMCADLCN_CITMLOC23_C	NUMBER
	ITMCADLCN_CITMLOC23	VARCHAR2
itmCADLcn - 24	ITMCADLCN_CITMLOC24_C	NUMBER
	ITMCADLCN_CITMLOC24	VARCHAR2
itmCADLcn - 25	ITMCADLCN_CITMLOC25_C	NUMBER
	ITMCADLCN_CITMLOC25	VARCHAR2
itmCADLcn - 26	ITMCADLCN_CITMLOC26_C	NUMBER
	ITMCADLCN_CITMLOC26	VARCHAR2
itmCADLcn - 27	ITMCADLCN_CITMLOC27_C	NUMBER
	ITMCADLCN_CITMLOC27	VARCHAR2
itmCADLcn - 28	ITMCADLCN_CITMLOC28_C	NUMBER
	ITMCADLCN_CITMLOC28	VARCHAR2
itmCADLcn - 29	ITMCADLCN_CITMLOC29_C	NUMBER
	ITMCADLCN_CITMLOC29	VARCHAR2
itmCADLcn - 30	ITMCADLCN_CITMLOC30_C	NUMBER
	ITMCADLCN_CITMLOC30	VARCHAR2
itmCADLcn - 31	ITMCADLCN_CITMLOC31_C	NUMBER
	ITMCADLCN_CITMLOC31	VARCHAR2
itmCADLcn - 32	ITMCADLCN_CITMLOC32_C	NUMBER
	ITMCADLCN_CITMLOC32	VARCHAR2
itmCADLcn - 33	ITMCADLCN_CITMLOC33_C	NUMBER
	ITMCADLCN_CITMLOC33	VARCHAR2
itmCADLcn - 34	ITMCADLCN_CITMLOC34_C	NUMBER
	ITMCADLCN_CITMLOC34	VARCHAR2
itmCADLcn - 35	ITMCADLCN_CITMLOC35_C	NUMBER
	ITMCADLCN_CITMLOC35	VARCHAR2
itmCADLcn - 36	ITMCADLCN_CITMLOC36_C	NUMBER
	ITMCADLCN_CITMLOC36	VARCHAR2
itmCADLcn - 37	ITMCADLCN_CITMLOC37_C	NUMBER
	ITMCADLCN_CITMLOC37	VARCHAR2
itmCADLcn - 38	ITMCADLCN_CITMLOC38_C	NUMBER
	ITMCADLCN_CITMLOC38	VARCHAR2

itmCADLcn - 39	ITMCADLCN_CITMLOC39_C	NUMBER
	ITMCADLCN_CITMLOC39	VARCHAR2
itmCADLcn - 40	ITMCADLCN_CITMLOC40_C	NUMBER
	ITMCADLCN_CITMLOC40	VARCHAR2
itmCADLcn - 41	ITMCADLCN_CITMLOC41_C	NUMBER
	ITMCADLCN_CITMLOC41	VARCHAR2
RD_FRMCAD_SECCLDS		
itmFSCADIs	ITMFSCADLS_C	NUMBER
	ITMFSCADLS	VARCHAR2
	ITMFSCADLS_ND	VARCHAR2
itmFSLv	ITMFSLV	FLOAT
	ITMFSLV_ND	VARCHAR2
itmFSAdc	ITMFSADC	FLOAT
	ITMFSADC_ND	VARCHAR2
itmFSMn	ITMFSMN	FLOAT
	ITMFSMN_ND	VARCHAR2
itmFSMed	ITMFSMED	FLOAT
	ITMFSMED_ND	VARCHAR2
itmFSHM	ITMFSHM	FLOAT
	ITMFSHM_ND	VARCHAR2
itmFSCncrdnt	ITMFSCNCRDNT_C	NUMBER
	ITMFSCNCRDNT	VARCHAR2
	ITMFSCNCRDNT_ND	VARCHAR2
itmFSLoc	ITMFSLOC_ND	VARCHAR2
itmFSLoc - 1	ITMFSLOC_CITMLOC1_C	NUMBER
	ITMFSLOC_CITMLOC1	VARCHAR2
itmFSLoc - 2	ITMFSLOC_CITMLOC2_C	NUMBER
	ITMFSLOC_CITMLOC2	VARCHAR2
itmFSLoc - 3	ITMFSLOC_CITMLOC3_C	NUMBER
	ITMFSLOC_CITMLOC3	VARCHAR2
itmFSLoc - 4	ITMFSLOC_CITMLOC4_C	NUMBER
	ITMFSLOC_CITMLOC4	VARCHAR2
itmFSLoc - 5	ITMFSLOC_CITMLOC5_C	NUMBER
	ITMFSLOC_CITMLOC5	VARCHAR2
itmFSLoc - 6	ITMFSLOC_CITMLOC6_C	NUMBER
	ITMFSLOC_CITMLOC6	VARCHAR2
itmFSLoc - 7	ITMFSLOC_CITMLOC7_C	NUMBER
	ITMFSLOC_CITMLOC7	VARCHAR2
itmFSLoc - 8	ITMFSLOC_CITMLOC8_C	NUMBER
	ITMFSLOC_CITMLOC8	VARCHAR2
itmFSLoc - 9	ITMFSLOC_CITMLOC9_C	NUMBER

	ITMFSLOC_CITMLOC9	VARCHAR2
itmFSLoc - 10	ITMFSLOC_CITMLOC10_C	NUMBER
	ITMFSLOC_CITMLOC10	VARCHAR2
itmFSLoc - 11	ITMFSLOC_CITMLOC11_C	NUMBER
	ITMFSLOC_CITMLOC11	VARCHAR2
itmFSLoc - 12	ITMFSLOC_CITMLOC12_C	NUMBER
	ITMFSLOC_CITMLOC12	VARCHAR2
itmFSLoc - 13	ITMFSLOC_CITMLOC13_C	NUMBER
	ITMFSLOC_CITMLOC13	VARCHAR2
itmFSLoc - 14	ITMFSLOC_CITMLOC14_C	NUMBER
	ITMFSLOC_CITMLOC14	VARCHAR2
itmFSLoc - 15	ITMFSLOC_CITMLOC15_C	NUMBER
	ITMFSLOC_CITMLOC15	VARCHAR2
itmFSLoc - 16	ITMFSLOC_CITMLOC16_C	NUMBER
	ITMFSLOC_CITMLOC16	VARCHAR2
itmFSLoc - 17	ITMFSLOC_CITMLOC17_C	NUMBER
	ITMFSLOC_CITMLOC17	VARCHAR2
itmFSLoc - 18	ITMFSLOC_CITMLOC18_C	NUMBER
	ITMFSLOC_CITMLOC18	VARCHAR2
itmFSLoc - 19	ITMFSLOC_CITMLOC19_C	NUMBER
	ITMFSLOC_CITMLOC19	VARCHAR2
itmFSLoc - 20	ITMFSLOC_CITMLOC20_C	NUMBER
	ITMFSLOC_CITMLOC20	VARCHAR2
itmFSLoc - 21	ITMFSLOC_CITMLOC21_C	NUMBER
	ITMFSLOC_CITMLOC21	VARCHAR2
itmFSLoc - 22	ITMFSLOC_CITMLOC22_C	NUMBER
	ITMFSLOC_CITMLOC22	VARCHAR2
itmFSLoc - 23	ITMFSLOC_CITMLOC23_C	NUMBER
	ITMFSLOC_CITMLOC23	VARCHAR2
itmFSLoc - 24	ITMFSLOC_CITMLOC24_C	NUMBER
	ITMFSLOC_CITMLOC24	VARCHAR2
itmFSLoc - 25	ITMFSLOC_CITMLOC25_C	NUMBER
	ITMFSLOC_CITMLOC25	VARCHAR2
itmFSLoc - 26	ITMFSLOC_CITMLOC26_C	NUMBER
	ITMFSLOC_CITMLOC26	VARCHAR2
itmFSLoc - 27	ITMFSLOC_CITMLOC27_C	NUMBER
	ITMFSLOC_CITMLOC27	VARCHAR2
itmFSLoc - 28	ITMFSLOC_CITMLOC28_C	NUMBER
	ITMFSLOC_CITMLOC28	VARCHAR2
itmFSLoc - 29	ITMFSLOC_CITMLOC29_C	NUMBER
	ITMFSLOC_CITMLOC29	VARCHAR2


itmFSLoc - 30	ITMFSLOC_CITMLOC30_C	NUMBER
	ITMFSLOC_CITMLOC30	VARCHAR2
itmFSLoc - 31	ITMFSLOC_CITMLOC31_C	NUMBER
	ITMFSLOC_CITMLOC31	VARCHAR2
itmFSLoc - 32	ITMFSLOC_CITMLOC32_C	NUMBER
	ITMFSLOC_CITMLOC32	VARCHAR2
itmFSLoc - 33	ITMFSLOC_CITMLOC33_C	NUMBER
	ITMFSLOC_CITMLOC33	VARCHAR2
itmFSLoc - 34	ITMFSLOC_CITMLOC34_C	NUMBER
	ITMFSLOC_CITMLOC34	VARCHAR2
itmFSLoc - 35	ITMFSLOC_CITMLOC35_C	NUMBER
	ITMFSLOC_CITMLOC35	VARCHAR2
itmFSLoc - 36	ITMFSLOC_CITMLOC36_C	NUMBER
	ITMFSLOC_CITMLOC36	VARCHAR2
itmFSLoc - 37	ITMFSLOC_CITMLOC37_C	NUMBER
	ITMFSLOC_CITMLOC37	VARCHAR2
itmFSLoc - 38	ITMFSLOC_CITMLOC38_C	NUMBER
	ITMFSLOC_CITMLOC38	VARCHAR2
itmFSLoc - 39	ITMFSLOC_CITMLOC39_C	NUMBER
	ITMFSLOC_CITMLOC39	VARCHAR2
itmFSLoc - 40	ITMFSLOC_CITMLOC40_C	NUMBER
	ITMFSLOC_CITMLOC40	VARCHAR2
itmFSLoc - 41	ITMFSLOC_CITMLOC41_C	NUMBER
	ITMFSLOC_CITMLOC41	VARCHAR2

PROSTAGRAM: Ultrasound Reporting Form (US-R) [frmUSR]		
Ultrasound Reporting Form [frmUSR]		
1.* ✓	Is there an US report? [US report]	<div><div>[itmURReprt]</div><div>[N:1] <input type="radio"/> [itmUSrptYs] </div><div>Yes</div><div>[itmUSRScndt]</div><div>Scan date</div><div>Req / Req / Req (2018-2030)</div><div>[itmUSRTs]</div><div>Transverse size</div><div><input type="text"/> xx.x <input type="text"/> cm^[b]</div><div>[itmUSRAP]</div><div>AP size</div><div><input type="text"/> xx.x <input type="text"/> cm^[b]</div><div>[itmUSRCCs]</div><div>Cranio-caudal size</div><div><input type="text"/> xx.x <input type="text"/> cm^[b]</div><div>[N:0] <input type="radio"/> No</div></div>
2. ✓	Volume <i>[read-only]</i> [Volume]	<div><div>[itmULTVol]</div><div><input type="text"/> xxxxxx.x <input type="text"/> cm³</div></div>
3.* ✓	Is there significant calcification present causing an acoustic shadow? [Causing an acoustic shadow]	<div><div>[itmURAcoustc]</div><div>[N:1] <input type="radio"/> [itmURAcousYs] </div><div>Yes</div><div>[itmURLocn]</div><div>Location of the calcification</div><div><div>[N:1] <input type="checkbox"/> 1</div><div>[N:2] <input type="checkbox"/> 2</div><div>[N:3] <input type="checkbox"/> 3</div><div>[N:4] <input type="checkbox"/> 4</div><div>[N:5] <input type="checkbox"/> 5</div><div>[N:6] <input type="checkbox"/> 6</div><div>[N:7] <input type="checkbox"/> 7</div><div>[N:8] <input type="checkbox"/> 8</div><div>[N:9] <input type="checkbox"/> 9</div><div>[N:10] <input type="checkbox"/> 10</div><div>[N:11] <input type="checkbox"/> 11</div><div>[N:12] <input type="checkbox"/> 12</div><div>[N:13] <input type="checkbox"/> 13</div><div>[N:14] <input type="checkbox"/> 14</div><div>[N:15] <input type="checkbox"/> 15</div><div>[N:16] <input type="checkbox"/> 16</div><div>[N:17] <input type="checkbox"/> 17</div><div>[N:18] <input type="checkbox"/> 18</div><div>[N:19] <input type="checkbox"/> 19</div><div>[N:20] <input type="checkbox"/> 20</div><div>[N:21] <input type="checkbox"/> 21</div><div>[N:22] <input type="checkbox"/> 22</div><div>[N:23] <input type="checkbox"/> 23</div><div>[N:24] <input type="checkbox"/> 24</div><div>[N:25] <input type="checkbox"/> 25</div></div></div>

```
file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe 137e31086639fb5d 0002.0000 c16... 03/05/2019
```


6.7 ✓	Depth [Depth]	[itmULDDpth] x.x cm ^[b]
6.8 ✓	US score [US score]	[itmULDScr] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5
6.9 ✓	If score = 3 Doppler [If score = 3 Doppler]	[itmULDScr3] [N:1] <input type="radio"/> Positive [N:2] <input type="radio"/> Negative
6.10 ✓	Doppler score [Doppler score]	[itmULDDplrScr] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5
6.11 ✓	Location [Location]	[itmULDLoc] [N:1] <input type="checkbox"/> 1 [N:2] <input type="checkbox"/> 2 [N:3] <input type="checkbox"/> 3 [N:4] <input type="checkbox"/> 4 [N:5] <input type="checkbox"/> 5 [N:6] <input type="checkbox"/> 6 [N:7] <input type="checkbox"/> 7 [N:8] <input type="checkbox"/> 8 [N:9] <input type="checkbox"/> 9 [N:10] <input type="checkbox"/> 10 [N:11] <input type="checkbox"/> 11 [N:12] <input type="checkbox"/> 12 [N:13] <input type="checkbox"/> 13 [N:14] <input type="checkbox"/> 14 [N:15] <input type="checkbox"/> 15 [N:16] <input type="checkbox"/> 16 [N:17] <input type="checkbox"/> 17 [N:18] <input type="checkbox"/> 18 [N:19] <input type="checkbox"/> 19 [N:20] <input type="checkbox"/> 20 [N:21] <input type="checkbox"/> 21 [N:22] <input type="checkbox"/> 22 [N:23] <input type="checkbox"/> 23 [N:24] <input type="checkbox"/> 24 [N:25] <input type="checkbox"/> 25 [N:26] <input type="checkbox"/> 26 [N:27] <input type="checkbox"/> 27 [N:28] <input type="checkbox"/> 28 [N:29] <input type="checkbox"/> 29 [N:30] <input type="checkbox"/> 30 [N:31] <input type="checkbox"/> 31

								<div><div>[N:32]</div><div><input type="checkbox"/></div>32</div> <div><div>[N:33]</div><div><input type="checkbox"/></div>33</div> <div><div>[N:34]</div><div><input type="checkbox"/></div>34</div> <div><div>[N:35]</div><div><input type="checkbox"/></div>35</div> <div><div>[N:36]</div><div><input type="checkbox"/></div>36</div> <div><div>[N:37]</div><div><input type="checkbox"/></div>37</div> <div><div>[N:38]</div><div><input type="checkbox"/></div>38</div> <div><div>[N:39]</div><div><input type="checkbox"/></div>39</div> <div><div>[N:40]</div><div><input type="checkbox"/></div>40</div> <div><div>[N:41]</div><div><input type="checkbox"/></div>41</div>
--	--	--	--	--	--	--	--	---

10.c	US Lesion 3					
10.d	US Lesion 4					
INDIVIDUAL SCORES Entry [secIVS]						
10.1 ✓ 	US Lesions <i>[read-only]</i> [US Lesions]	[itmIVSLes] [N:0] <input type="radio"/> US Lesion 1 [N:1] <input type="radio"/> US Lesion 2 [N:2] <input type="radio"/> US Lesion 3 [N:3] <input type="radio"/> US Lesion 4				
10.2 ✓	B mode score [B mode score]	[itmIVSBmod] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5				
10.3 ✓	B mode Location [B mode Location]	[itmIVSBloc] [N:1] <input type="checkbox"/> 1 [N:2] <input type="checkbox"/> 2 [N:3] <input type="checkbox"/> 3 [N:4] <input type="checkbox"/> 4 [N:5] <input type="checkbox"/> 5 [N:6] <input type="checkbox"/> 6 [N:7] <input type="checkbox"/> 7 [N:8] <input type="checkbox"/> 8 [N:9] <input type="checkbox"/> 9 [N:10] <input type="checkbox"/> 10 [N:11] <input type="checkbox"/> 11 [N:12] <input type="checkbox"/> 12 [N:13] <input type="checkbox"/> 13 [N:14] <input type="checkbox"/> 14 [N:15] <input type="checkbox"/> 15 [N:16] <input type="checkbox"/> 16 [N:17] <input type="checkbox"/> 17 [N:18] <input type="checkbox"/> 18 [N:19] <input type="checkbox"/> 19 [N:20] <input type="checkbox"/> 20 [N:21] <input type="checkbox"/> 21 [N:22] <input type="checkbox"/> 22 [N:23] <input type="checkbox"/> 23 [N:24] <input type="checkbox"/> 24 [N:25] <input type="checkbox"/> 25 [N:26] <input type="checkbox"/> 26 [N:27] <input type="checkbox"/> 27 [N:28] <input type="checkbox"/> 28 [N:29] <input type="checkbox"/> 29 [N:30] <input type="checkbox"/> 30 [N:31] <input type="checkbox"/> 31 [N:32] <input type="checkbox"/> 32 [N:33] <input type="checkbox"/> 33 [N:34] <input type="checkbox"/> 34				



		<div><div>[N:35]</div><div><input type="checkbox"/></div>35</div> <div><div>[N:36]</div><div><input type="checkbox"/></div>36</div> <div><div>[N:37]</div><div><input type="checkbox"/></div>37</div> <div><div>[N:38]</div><div><input type="checkbox"/></div>38</div> <div><div>[N:39]</div><div><input type="checkbox"/></div>39</div> <div><div>[N:40]</div><div><input type="checkbox"/></div>40</div> <div><div>[N:41]</div><div><input type="checkbox"/></div>41</div>
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		<div><div>[N:36]</div><div><input type="checkbox"/></div>36</div> <div><div>[N:37]</div><div><input type="checkbox"/></div>37</div> <div><div>[N:38]</div><div><input type="checkbox"/></div>38</div> <div><div>[N:39]</div><div><input type="checkbox"/></div>39</div> <div><div>[N:40]</div><div><input type="checkbox"/></div>40</div> <div><div>[N:41]</div><div><input type="checkbox"/></div>41</div>
10.6 ✓	Doppler score [Doppler score]	<div><div>[itmIVSDoplrScr]</div><div><div>[N:1]</div><div><input checked="" type="radio"/></div>1</div><div><div>[N:2]</div><div><input type="radio"/></div>2</div><div><div>[N:3]</div><div><input type="radio"/></div>3</div><div><div>[N:4]</div><div><input type="radio"/></div>4</div><div><div>[N:5]</div><div><input type="radio"/></div>5</div></div>
10.7 ✓	Doppler location [Doppler location]	<div><div>[itmIVSDoplrLoc]</div><div><div>[N:1]</div><div><input type="checkbox"/></div>1</div><div><div>[N:2]</div><div><input type="checkbox"/></div>2</div><div><div>[N:3]</div><div><input type="checkbox"/></div>3</div><div><div>[N:4]</div><div><input type="checkbox"/></div>4</div><div><div>[N:5]</div><div><input type="checkbox"/></div>5</div><div><div>[N:6]</div><div><input type="checkbox"/></div>6</div><div><div>[N:7]</div><div><input type="checkbox"/></div>7</div><div><div>[N:8]</div><div><input type="checkbox"/></div>8</div><div><div>[N:9]</div><div><input type="checkbox"/></div>9</div><div><div>[N:10]</div><div><input type="checkbox"/></div>10</div><div><div>[N:11]</div><div><input type="checkbox"/></div>11</div><div><div>[N:12]</div><div><input type="checkbox"/></div>12</div><div><div>[N:13]</div><div><input type="checkbox"/></div>13</div><div><div>[N:14]</div><div><input type="checkbox"/></div>14</div><div><div>[N:15]</div><div><input type="checkbox"/></div>15</div><div><div>[N:16]</div><div><input type="checkbox"/></div>16</div><div><div>[N:17]</div><div><input type="checkbox"/></div>17</div><div><div>[N:18]</div><div><input type="checkbox"/></div>18</div><div><div>[N:19]</div><div><input type="checkbox"/></div>19</div><div><div>[N:20]</div><div><input type="checkbox"/></div>20</div><div><div>[N:21]</div><div><input type="checkbox"/></div>21</div><div><div>[N:22]</div><div><input type="checkbox"/></div>22</div><div><div>[N:23]</div><div><input type="checkbox"/></div>23</div><div><div>[N:24]</div><div><input type="checkbox"/></div>24</div><div><div>[N:25]</div><div><input type="checkbox"/></div>25</div><div><div>[N:26]</div><div><input type="checkbox"/></div>26</div><div><div>[N:27]</div><div><input type="checkbox"/></div>27</div><div><div>[N:28]</div><div><input type="checkbox"/></div>28</div><div><div>[N:29]</div><div><input type="checkbox"/></div>29</div><div><div>[N:30]</div><div><input type="checkbox"/></div>30</div><div><div>[N:31]</div><div><input type="checkbox"/></div>31</div><div><div>[N:32]</div><div><input type="checkbox"/></div>32</div><div><div>[N:33]</div><div><input type="checkbox"/></div>33</div><div><div>[N:34]</div><div><input type="checkbox"/></div>34</div><div><div>[N:35]</div><div><input type="checkbox"/></div>35</div><div><div>[N:36]</div><div><input type="checkbox"/></div>36</div></div>

		<div><div>[N:37]</div><div><div></div></div>37</div> <div><div>[N:38]</div><div><div></div></div>38</div> <div><div>[N:39]</div><div><div></div></div>39</div> <div><div>[N:40]</div><div><div></div></div>40</div> <div><div>[N:41]</div><div><div></div></div>41</div>				
SWE Scores [secSWE]						
# ✓	Regions	Visible	Emean	Emin	Emax	SD
11.a	Region 1					
11.b	Region 2					
11.c	Region 3					
11.d	Region 4					
11.e	Region 5					
11.f	Region 6					
11.g	Region 7					
11.h	Region 8					
11.i	Region 9					
11.j	Region 10					
11.k	Region 11					
11.l	Region 12					
11.m	Region 13					
11.n	Region 14					
11.o	Region 15					
11.p	Region 16					
11.q	Region 17					
11.r	Region 18					
11.s	Region 19					
11.t	Region 20					
11.u	Region 21					
11.v	Region 22					
11.w	Region 23					
11.x	Region 24					
11.y	Region 25					
11.z	Region 26					
11.aa	Region 27					
11.ab	Region 28					
11.ac	Region 29					
11.ad	Region 30					
11.ae	Region 31					
11.af	Region 32					
11.ag	Region 33					

11.ah	Region 34				
11.ai	Region 35				
11.aj	Region 36				
11.ak	Region 37				
11.al	Region 38				
11.am	Region 39				
11.an	Region 40				
11.ao	Region 41				

SWE Scores Entry [secSWE]

11.1 ✓ 	Regions <i>[read-only]</i> [Regions]	[itmUSRSWERgn] [clRegion] 
11.2 ✓	Visible [Visible]	[itmUSRvisbl] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
11.3 ✓	Emean [Emean]	[itmUSREmn] <input type="text"/> xxx.x kPA
11.4 ✓	Emin [Emin]	[itmUSREmin] <input type="text"/> xxx.x kPA
11.5 ✓	Emax [Emax]	[itmUSREmx] <input type="text"/> xxx.x kPA
11.6 ✓	SD [SD]	[itmUSRSD] <input type="text"/> xx.x

Key: [✓] = Source verification required [b] = Base Unit  = Item is collapsible  = Fixed item
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Ultrasound Reporting Form		
Type	RefName	Description
Form	frmUSR	Ultrasound report
Section	secULD	US Lesion Details
Section	secUSROF	Other Findings
Section	secDeclrtn	Declaration
Section	secIVS	US Lesion Details
Section	secSWE	SWE Scores

Codelist Values Tables: Ultrasound Reporting Form					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clRegion	Integer	Region 1	1	cltmRgn1	itmUSRSWERgn
		Region 2	2	cltmRgn2	
		Region 3	3	cltmRgn3	
		Region 4	4	cltmRgn4	

	Region 5	5	citmRgn5
	Region 6	6	citmRgn6
	Region 7	7	citmRgn7
	Region 8	8	citmRgn8
	Region 9	9	citmRgn9
	Region 10	10	citmRgn10
	Region 11	11	citmRgn11
	Region 12	12	citmRgn12
	Region 13	13	citmRgn13
	Region 14	14	citmRgn14
	Region 15	15	citmRgn15
	Region 16	16	citmRgn16
	Region 17	17	citmRgn17
	Region 18	18	citmRgn18
	Region 19	19	citmRgn19
	Region 20	20	citmRgn20
	Region 21	21	citmRgn21
	Region 22	22	citmRgn22
	Region 23	23	citmRgn23
	Region 24	24	citmRgn24
	Region 25	25	citmRgn25
	Region 26	26	citmRgn26
	Region 27	27	citmRgn27
	Region 28	28	citmRgn28
	Region 29	29	citmRgn29
	Region 30	30	citmRgn30
	Region 31	31	citmRgn31
	Region 32	32	citmRgn32
	Region 33	33	citmRgn33
	Region 34	34	citmRgn34
	Region 35	35	citmRgn35
	Region 36	36	citmRgn36
	Region 37	37	citmRgn37
	Region 38	38	citmRgn38
	Region 39	39	citmRgn39
	Region 40	40	citmRgn40
	Region 41	41	citmRgn41

RDE Analytics: RD_FRMUSR		
Data Variable RefName	RD Column Name	Column Data Type

itmURReprt	ITMURREPRT_C	**NUMBER
	ITMURREPRT	VARCHAR2
	ITMURREPRT_ND	VARCHAR2
itmURReprt - itmUSRScndt	ITMUSRSCNDT	DATE
	ITMUSRSCNDT_DTS	VARCHAR2
itmURReprt - itmUSRTs	ITMUSRTS	FLOAT
	ITMUSRTS_U	VARCHAR2
itmURReprt - itmUSRAP	ITMUSRAP	FLOAT
	ITMUSRAP_U	VARCHAR2
itmURReprt - itmUSRCCs	ITMUSRCCS	FLOAT
	ITMUSRCCS_U	VARCHAR2
itmULTVol	ITMULTVOL	FLOAT
	ITMULTVOL_ND	VARCHAR2
itmURAcoustc	ITMURACOUSTC_C	**NUMBER
	ITMURACOUSTC	VARCHAR2
	ITMURACOUSTC_ND	VARCHAR2
itmURAcoustc - 1	ITMURLOCN_CITMLOC1_C	NUMBER
	ITMURLOCN_CITMLOC1	VARCHAR2
itmURAcoustc - 2	ITMURLOCN_CITMLOC2_C	NUMBER
	ITMURLOCN_CITMLOC2	VARCHAR2
itmURAcoustc - 3	ITMURLOCN_CITMLOC3_C	NUMBER
	ITMURLOCN_CITMLOC3	VARCHAR2
itmURAcoustc - 4	ITMURLOCN_CITMLOC4_C	NUMBER
	ITMURLOCN_CITMLOC4	VARCHAR2
itmURAcoustc - 5	ITMURLOCN_CITMLOC5_C	NUMBER
	ITMURLOCN_CITMLOC5	VARCHAR2
itmURAcoustc - 6	ITMURLOCN_CITMLOC6_C	NUMBER
	ITMURLOCN_CITMLOC6	VARCHAR2
itmURAcoustc - 7	ITMURLOCN_CITMLOC7_C	NUMBER
	ITMURLOCN_CITMLOC7	VARCHAR2
itmURAcoustc - 8	ITMURLOCN_CITMLOC8_C	NUMBER
	ITMURLOCN_CITMLOC8	VARCHAR2
itmURAcoustc - 9	ITMURLOCN_CITMLOC9_C	NUMBER
	ITMURLOCN_CITMLOC9	VARCHAR2
itmURAcoustc - 10	ITMURLOCN_CITMLOC10_C	NUMBER
	ITMURLOCN_CITMLOC10	VARCHAR2
itmURAcoustc - 11	ITMURLOCN_CITMLOC11_C	NUMBER
	ITMURLOCN_CITMLOC11	VARCHAR2
itmURAcoustc - 12	ITMURLOCN_CITMLOC12_C	NUMBER
	ITMURLOCN_CITMLOC12	VARCHAR2
itmURAcoustc - 13	ITMURLOCN_CITMLOC13_C	NUMBER

	ITMURLOCN_CITMLOC13	VARCHAR2
itmURAcoustc - 14	ITMURLOCN_CITMLOC14_C	NUMBER
	ITMURLOCN_CITMLOC14	VARCHAR2
itmURAcoustc - 15	ITMURLOCN_CITMLOC15_C	NUMBER
	ITMURLOCN_CITMLOC15	VARCHAR2
itmURAcoustc - 16	ITMURLOCN_CITMLOC16_C	NUMBER
	ITMURLOCN_CITMLOC16	VARCHAR2
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itmURAcoustc - 18	ITMURLOCN_CITMLOC18_C	NUMBER
	ITMURLOCN_CITMLOC18	VARCHAR2
itmURAcoustc - 19	ITMURLOCN_CITMLOC19_C	NUMBER
	ITMURLOCN_CITMLOC19	VARCHAR2
itmURAcoustc - 20	ITMURLOCN_CITMLOC20_C	NUMBER
	ITMURLOCN_CITMLOC20	VARCHAR2
itmURAcoustc - 21	ITMURLOCN_CITMLOC21_C	NUMBER
	ITMURLOCN_CITMLOC21	VARCHAR2
itmURAcoustc - 22	ITMURLOCN_CITMLOC22_C	NUMBER
	ITMURLOCN_CITMLOC22	VARCHAR2
itmURAcoustc - 23	ITMURLOCN_CITMLOC23_C	NUMBER
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itmURAcoustc - 24	ITMURLOCN_CITMLOC24_C	NUMBER
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itmURAcoustc - 25	ITMURLOCN_CITMLOC25_C	NUMBER
	ITMURLOCN_CITMLOC25	VARCHAR2
itmURAcoustc - 26	ITMURLOCN_CITMLOC26_C	NUMBER
	ITMURLOCN_CITMLOC26	VARCHAR2
itmURAcoustc - 27	ITMURLOCN_CITMLOC27_C	NUMBER
	ITMURLOCN_CITMLOC27	VARCHAR2
itmURAcoustc - 28	ITMURLOCN_CITMLOC28_C	NUMBER
	ITMURLOCN_CITMLOC28	VARCHAR2
itmURAcoustc - 29	ITMURLOCN_CITMLOC29_C	NUMBER
	ITMURLOCN_CITMLOC29	VARCHAR2
itmURAcoustc - 30	ITMURLOCN_CITMLOC30_C	NUMBER
	ITMURLOCN_CITMLOC30	VARCHAR2
itmURAcoustc - 31	ITMURLOCN_CITMLOC31_C	NUMBER
	ITMURLOCN_CITMLOC31	VARCHAR2
itmURAcoustc - 32	ITMURLOCN_CITMLOC32_C	NUMBER
	ITMURLOCN_CITMLOC32	VARCHAR2
itmURAcoustc - 33	ITMURLOCN_CITMLOC33_C	NUMBER
	ITMURLOCN_CITMLOC33	VARCHAR2

itmURAcoustc - 34	ITMURLOCN_CITMLOC34_C	NUMBER
	ITMURLOCN_CITMLOC34	VARCHAR2
itmURAcoustc - 35	ITMURLOCN_CITMLOC35_C	NUMBER
	ITMURLOCN_CITMLOC35	VARCHAR2
itmURAcoustc - 36	ITMURLOCN_CITMLOC36_C	NUMBER
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itmURAcoustc - 37	ITMURLOCN_CITMLOC37_C	NUMBER
	ITMURLOCN_CITMLOC37	VARCHAR2
itmURAcoustc - 38	ITMURLOCN_CITMLOC38_C	NUMBER
	ITMURLOCN_CITMLOC38	VARCHAR2
itmURAcoustc - 39	ITMURLOCN_CITMLOC39_C	NUMBER
	ITMURLOCN_CITMLOC39	VARCHAR2
itmURAcoustc - 40	ITMURLOCN_CITMLOC40_C	NUMBER
	ITMURLOCN_CITMLOC40	VARCHAR2
itmURAcoustc - 41	ITMURLOCN_CITMLOC41_C	NUMBER
	ITMURLOCN_CITMLOC41	VARCHAR2
itmURAnter	ITMURANTER_C	NUMBER
	ITMURANTER	VARCHAR2
	ITMURANTER_ND	VARCHAR2
itmURLesin	ITMURLESIN_C	NUMBER
	ITMURLESIN	VARCHAR2
	ITMURLESIN_ND	VARCHAR2
itmUSRRad	ITMUSRRAD_C	NUMBER
	ITMUSRRAD	VARCHAR2
	ITMUSRRAD_ND	VARCHAR2
itmUSRRad - Sphincter	ITMUSRT4_CITMT40_C	NUMBER
	ITMUSRT4_CITMT40	VARCHAR2
itmUSRRad - Rectum	ITMUSRT4_CITMT41_C	NUMBER
	ITMUSRT4_CITMT41	VARCHAR2
itmUSRRad - Bladder	ITMUSRT4_CITMT42_C	NUMBER
	ITMUSRT4_CITMT42	VARCHAR2
itmUSRfndgs	ITMUSRFNDGS_ND	VARCHAR2
itmUSRfndgs - None	ITMUSRFNDGS_CITMINCFNON_C	VARCHAR2
	ITMUSRFNDGS_CITMINCFNON	VARCHAR2
itmUSRfndgs - Bladder Tumour	ITMUSRFNDGS_CITMINCFBT_C	VARCHAR2
	ITMUSRFNDGS_CITMINCFBT	VARCHAR2
itmUSRfndgs - Rectal Tumour	ITMUSRFNDGS_CITMINCFRT_C	VARCHAR2
	ITMUSRFNDGS_CITMINCFRT	VARCHAR2
itmUSRfndgs - Other	ITMUSRFNDGS_ITMUSRFNDGSOR_C	VARCHAR2
	ITMUSRFNDGS_ITMUSRFNDGSOR	VARCHAR2
itmUSRfndgs - itmFndgsOr	ITMFNDGSOR	VARCHAR2

itmDeclrReprr	ITMDECLRREPRTR_C	NUMBER
	ITMDECLRREPRTR	VARCHAR2
	ITMDECLRREPRTR_ND	VARCHAR2
itmDeclrReprr - itmDclrOrPs	ITMDCLRORPS	VARCHAR2
RD_FRMUSR_SECULD		
itmULDLesn	ITMULDLESN_C	NUMBER
	ITMULDLESN	VARCHAR2
	ITMULDLESN_ND	VARCHAR2
itmULDErat	ITMULDERAT	FLOAT
	ITMULDERAT_ND	VARCHAR2
itmULDEmn	ITMULDEMNI	FLOAT
	ITMULDEMNI_ND	VARCHAR2
itmULDEmx	ITMULDEMX	FLOAT
	ITMULDEMX_ND	VARCHAR2
itmULDSD	ITMULDSD	FLOAT
	ITMULDSD_ND	VARCHAR2
itmULDDia	ITMULDDIA	FLOAT
	ITMULDDIA_U	VARCHAR2
	ITMULDDIA_ND	VARCHAR2
itmULDDpth	ITMULDDPTH	FLOAT
	ITMULDDPTH_U	VARCHAR2
	ITMULDDPTH_ND	VARCHAR2
itmULDScr	ITMULDSCR_C	NUMBER
	ITMULDSCR	VARCHAR2
	ITMULDSCR_ND	VARCHAR2
itmULDScr3	ITMULDSCR3_C	NUMBER
	ITMULDSCR3	VARCHAR2
	ITMULDSCR3_ND	VARCHAR2
itmULDDplrScr	ITMULDDPLRSCR_C	NUMBER
	ITMULDDPLRSCR	VARCHAR2
	ITMULDDPLRSCR_ND	VARCHAR2
itmULDLoc	ITMULDLOC_ND	VARCHAR2
itmULDLoc - 1	ITMULDLOC_CITMLOC1_C	NUMBER
	ITMULDLOC_CITMLOC1	VARCHAR2
itmULDLoc - 2	ITMULDLOC_CITMLOC2_C	NUMBER
	ITMULDLOC_CITMLOC2	VARCHAR2
itmULDLoc - 3	ITMULDLOC_CITMLOC3_C	NUMBER
	ITMULDLOC_CITMLOC3	VARCHAR2
itmULDLoc - 4	ITMULDLOC_CITMLOC4_C	NUMBER
	ITMULDLOC_CITMLOC4	VARCHAR2
itmULDLoc - 5	ITMULDLOC_CITMLOC5_C	NUMBER

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itmULDLoc - 6	ITMULDLOC_CITMLOC6_C	NUMBER
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	ITMULDLOC_CITMLOC8	VARCHAR2
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	ITMULDLOC_CITMLOC21	VARCHAR2
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itmULDLoc - 24	ITMULDLOC_CITMLOC24_C	NUMBER
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itmULDLoc - 25	ITMULDLOC_CITMLOC25_C	NUMBER
	ITMULDLOC_CITMLOC25	VARCHAR2

itmULDLoc - 26	ITMULDLOC_CITMLOC26_C	NUMBER
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itmULDLoc - 27	ITMULDLOC_CITMLOC27_C	NUMBER
	ITMULDLOC_CITMLOC27	VARCHAR2
itmULDLoc - 28	ITMULDLOC_CITMLOC28_C	NUMBER
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itmULDLoc - 30	ITMULDLOC_CITMLOC30_C	NUMBER
	ITMULDLOC_CITMLOC30	VARCHAR2
itmULDLoc - 31	ITMULDLOC_CITMLOC31_C	NUMBER
	ITMULDLOC_CITMLOC31	VARCHAR2
itmULDLoc - 32	ITMULDLOC_CITMLOC32_C	NUMBER
	ITMULDLOC_CITMLOC32	VARCHAR2
itmULDLoc - 33	ITMULDLOC_CITMLOC33_C	NUMBER
	ITMULDLOC_CITMLOC33	VARCHAR2
itmULDLoc - 34	ITMULDLOC_CITMLOC34_C	NUMBER
	ITMULDLOC_CITMLOC34	VARCHAR2
itmULDLoc - 35	ITMULDLOC_CITMLOC35_C	NUMBER
	ITMULDLOC_CITMLOC35	VARCHAR2
itmULDLoc - 36	ITMULDLOC_CITMLOC36_C	NUMBER
	ITMULDLOC_CITMLOC36	VARCHAR2
itmULDLoc - 37	ITMULDLOC_CITMLOC37_C	NUMBER
	ITMULDLOC_CITMLOC37	VARCHAR2
itmULDLoc - 38	ITMULDLOC_CITMLOC38_C	NUMBER
	ITMULDLOC_CITMLOC38	VARCHAR2
itmULDLoc - 39	ITMULDLOC_CITMLOC39_C	NUMBER
	ITMULDLOC_CITMLOC39	VARCHAR2
itmULDLoc - 40	ITMULDLOC_CITMLOC40_C	NUMBER
	ITMULDLOC_CITMLOC40	VARCHAR2
itmULDLoc - 41	ITMULDLOC_CITMLOC41_C	NUMBER
	ITMULDLOC_CITMLOC41	VARCHAR2
RD_FRMUSR_SECIVS		
itmIVSLes	ITMIVSLES_C	NUMBER
	ITMIVSLES	VARCHAR2
	ITMIVSLES_ND	VARCHAR2
itmIVSBmod	ITMIVSBMOD_C	NUMBER
	ITMIVSBMOD	VARCHAR2
	ITMIVSBMOD_ND	VARCHAR2
itmIVSBloc	ITMIVSBLOC_ND	VARCHAR2
itmIVSBloc - 1	ITMIVSBLOC_CITMLOC1_C	NUMBER

	ITMIVSBLOC_CITMLOC1	VARCHAR2
itmIVSBloc - 2	ITMIVSBLOC_CITMLOC2_C	NUMBER
	ITMIVSBLOC_CITMLOC2	VARCHAR2
itmIVSBloc - 3	ITMIVSBLOC_CITMLOC3_C	NUMBER
	ITMIVSBLOC_CITMLOC3	VARCHAR2
itmIVSBloc - 4	ITMIVSBLOC_CITMLOC4_C	NUMBER
	ITMIVSBLOC_CITMLOC4	VARCHAR2
itmIVSBloc - 5	ITMIVSBLOC_CITMLOC5_C	NUMBER
	ITMIVSBLOC_CITMLOC5	VARCHAR2
itmIVSBloc - 6	ITMIVSBLOC_CITMLOC6_C	NUMBER
	ITMIVSBLOC_CITMLOC6	VARCHAR2
itmIVSBloc - 7	ITMIVSBLOC_CITMLOC7_C	NUMBER
	ITMIVSBLOC_CITMLOC7	VARCHAR2
itmIVSBloc - 8	ITMIVSBLOC_CITMLOC8_C	NUMBER
	ITMIVSBLOC_CITMLOC8	VARCHAR2
itmIVSBloc - 9	ITMIVSBLOC_CITMLOC9_C	NUMBER
	ITMIVSBLOC_CITMLOC9	VARCHAR2
itmIVSBloc - 10	ITMIVSBLOC_CITMLOC10_C	NUMBER
	ITMIVSBLOC_CITMLOC10	VARCHAR2
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	ITMIVSBLOC_CITMLOC11	VARCHAR2
itmIVSBloc - 12	ITMIVSBLOC_CITMLOC12_C	NUMBER
	ITMIVSBLOC_CITMLOC12	VARCHAR2
itmIVSBloc - 13	ITMIVSBLOC_CITMLOC13_C	NUMBER
	ITMIVSBLOC_CITMLOC13	VARCHAR2
itmIVSBloc - 14	ITMIVSBLOC_CITMLOC14_C	NUMBER
	ITMIVSBLOC_CITMLOC14	VARCHAR2
itmIVSBloc - 15	ITMIVSBLOC_CITMLOC15_C	NUMBER
	ITMIVSBLOC_CITMLOC15	VARCHAR2
itmIVSBloc - 16	ITMIVSBLOC_CITMLOC16_C	NUMBER
	ITMIVSBLOC_CITMLOC16	VARCHAR2
itmIVSBloc - 17	ITMIVSBLOC_CITMLOC17_C	NUMBER
	ITMIVSBLOC_CITMLOC17	VARCHAR2
itmIVSBloc - 18	ITMIVSBLOC_CITMLOC18_C	NUMBER
	ITMIVSBLOC_CITMLOC18	VARCHAR2
itmIVSBloc - 19	ITMIVSBLOC_CITMLOC19_C	NUMBER
	ITMIVSBLOC_CITMLOC19	VARCHAR2
itmIVSBloc - 20	ITMIVSBLOC_CITMLOC20_C	NUMBER
	ITMIVSBLOC_CITMLOC20	VARCHAR2
itmIVSBloc - 21	ITMIVSBLOC_CITMLOC21_C	NUMBER
	ITMIVSBLOC_CITMLOC21	VARCHAR2

itmIVSBloc - 22	ITMIVSBLOC_CITMLOC22_C	NUMBER
	ITMIVSBLOC_CITMLOC22	VARCHAR2
itmIVSBloc - 23	ITMIVSBLOC_CITMLOC23_C	NUMBER
	ITMIVSBLOC_CITMLOC23	VARCHAR2
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	ITMIVSBLOC_CITMLOC25	VARCHAR2
itmIVSBloc - 26	ITMIVSBLOC_CITMLOC26_C	NUMBER
	ITMIVSBLOC_CITMLOC26	VARCHAR2
itmIVSBloc - 27	ITMIVSBLOC_CITMLOC27_C	NUMBER
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itmIVSBloc - 29	ITMIVSBLOC_CITMLOC29_C	NUMBER
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itmIVSBloc - 30	ITMIVSBLOC_CITMLOC30_C	NUMBER
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itmIVSBloc - 37	ITMIVSBLOC_CITMLOC37_C	NUMBER
	ITMIVSBLOC_CITMLOC37	VARCHAR2
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itmIVSSweloc - 2	ITMIVSSWELOC_CITMLOC2_C	NUMBER
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itmIVSSweloc - 3	ITMIVSSWELOC_CITMLOC3_C	NUMBER
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itmIVSSweloc - 4	ITMIVSSWELOC_CITMLOC4_C	NUMBER
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itmIVSSweloc - 22	ITMIVSSWELOC_CITMLOC22_C	NUMBER
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itmIVSSweloc - 26	ITMIVSSWELOC_CITMLOC26_C	NUMBER
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itmIVSSweloc - 27	ITMIVSSWELOC_CITMLOC27_C	NUMBER
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itmIVSSweloc - 37	ITMIVSSWELOC_CITMLOC37_C	NUMBER
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	ITMIVSDOPLRSCR	VARCHAR2
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itmIVSDoplrLoc - 2	ITMIVSDOPLRLOC_CITMLOC2_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC2	VARCHAR2
itmIVSDoplrLoc - 3	ITMIVSDOPLRLOC_CITMLOC3_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC3	VARCHAR2
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	ITMIVSDOPLRLOC_CITMLOC4	VARCHAR2
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	ITMIVSDOPLRLOC_CITMLOC5	VARCHAR2
itmIVSDoplrLoc - 6	ITMIVSDOPLRLOC_CITMLOC6_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC6	VARCHAR2
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	ITMIVSDOPLRLOC_CITMLOC7	VARCHAR2
itmIVSDoplrLoc - 8	ITMIVSDOPLRLOC_CITMLOC8_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC8	VARCHAR2
itmIVSDoplrLoc - 9	ITMIVSDOPLRLOC_CITMLOC9_C	NUMBER
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itmIVSDoplrLoc - 13	ITMIVSDOPLRLOC_CITMLOC13_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC13	VARCHAR2
itmIVSDoplrLoc - 14	ITMIVSDOPLRLOC_CITMLOC14_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC14	VARCHAR2
itmIVSDoplrLoc - 15	ITMIVSDOPLRLOC_CITMLOC15_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC15	VARCHAR2
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	ITMIVSDOPLRLOC_CITMLOC17	VARCHAR2

itmIVSDoplrLoc - 18	ITMIVSDOPLRLOC_CITMLOC18_C	NUMBER
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itmIVSDoplrLoc - 33	ITMIVSDOPLRLOC_CITMLOC33_C	NUMBER
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itmIVSDoplrLoc - 34	ITMIVSDOPLRLOC_CITMLOC34_C	NUMBER
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	ITMIVSDOPLRLOC_CITMLOC35	VARCHAR2
itmIVSDoplrLoc - 36	ITMIVSDOPLRLOC_CITMLOC36_C	NUMBER
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itmIVSDoplrLoc - 37	ITMIVSDOPLRLOC_CITMLOC37_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC37	VARCHAR2
itmIVSDoplrLoc - 38	ITMIVSDOPLRLOC_CITMLOC38_C	NUMBER

	ITMIVSDOPLRLOC_CITMLOC38	VARCHAR2
itmIVSDoplrLoc - 39	ITMIVSDOPLRLOC_CITMLOC39_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC39	VARCHAR2
itmIVSDoplrLoc - 40	ITMIVSDOPLRLOC_CITMLOC40_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC40	VARCHAR2
itmIVSDoplrLoc - 41	ITMIVSDOPLRLOC_CITMLOC41_C	NUMBER
	ITMIVSDOPLRLOC_CITMLOC41	VARCHAR2
RD_FRMUSR_SECSWE		
itmUSRSWERgn	ITMUSRSWERN_C	NUMBER
	ITMUSRSWERN	VARCHAR2
	ITMUSRSWERN_ND	VARCHAR2
itmUSRvisbl	ITMUSRVISBL_C	NUMBER
	ITMUSRVISBL	VARCHAR2
	ITMUSRVISBL_ND	VARCHAR2
itmUSREmn	ITMUSREMN	FLOAT
	ITMUSREMN_ND	VARCHAR2
itmUSREmin	ITMUSREMIN	FLOAT
	ITMUSREMIN_ND	VARCHAR2
itmUSREmx	ITMUSREMX	FLOAT
	ITMUSREMX_ND	VARCHAR2
itmUSRSD	ITMUSRSD	FLOAT
	ITMUSRSD_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

Study Object Descriptions: Randomisation		
Type	RefName	Description
Form	frmRND	Randomisation

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe 137e31086639fb5d 0002.0000 c16... 03/05/2019

PROSTAGRAM: Second MRI Report Form (SECOND MRI) [frmScndMRI]							
Second MRI Report Form [frmScndMRI]							
1. ✓	MRI report completed? [MRI report completed?]	<div>[itmSecMRIcomp] [N:1] <input type="radio"/> [itmSecMRIYs] </div> <div>Yes</div> <div>[itmSecMRITrans] Transverse size <input type="text" value="xx.x"/> cm^[b]</div> <div>[itmSecMRIsize] AP size <input type="text" value="xx.x"/> cm^[b]</div> <div>[itmSecMRIcranio] Cranio-caudal size <input type="text" value="xx.x"/> cm^[b]</div> <div>[itmSecMRIIdt] Scan date Req <input type="text" value=""/> / Req <input type="text" value=""/> / Req <input type="text" value=""/> (2018-2030)</div> <div>[N:0] <input type="radio"/> No</div>					
2. ✓	Volume <i>[read-only]</i> [Volume]	<div>[itmSecMRIVol] <input type="text" value="xxxxxx.x"/> cm³</div>					
3. ✓	Are there any lesions with an MRI score ≥ 3? [lesions with an MRI]	<div>[itmSecMRIlesn] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No</div>					
MRI Lesion Details [secSecMRIIdt]							
# ✓	Number of MRI Lesions	Maximum Diameter	Modified PIRADS Score	LIKERT Score	Location	Visible on CAD	CAD score
4.a	MRI Lesion 1						
4.b	MRI Lesion 2						
4.c	MRI Lesion 3						
4.d	MRI Lesion 4						
MRI Lesion Details Entry [secSecMRIIdt]							
4.1 ✓ 	Number of MRI Lesions <i>[read-only]</i> [Number of MRI Lesions]	<div>[itmSecMRIIdt] [N:0] <input type="radio"/> MRI Lesion 1 [N:1] <input type="radio"/> MRI Lesion 2 [N:2] <input type="radio"/> MRI Lesion 3 [N:3] <input type="radio"/> MRI Lesion 4</div>					
4.2 ✓	Maximum Diameter [Maximum Diameter]	<div>[itmSecMRIIdtmax] <input type="text" value="N3"/> mm^[b]</div>					
4.3 ✓	Modified PIRADS Score [Modified PIRADS Score]	<div>[itmSecMRIIdtmod] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5</div>					
4.4 ✓	LIKERT Score [LIKERT Score]	<div>[itmSecMRIIdtlikrt] [itmLickert] LIKERT Score</div>					

		<div><div>[N:1] <input type="radio"/> 1</div><div>[N:2] <input type="radio"/> 2</div><div>[N:3] <input type="radio"/> 3</div><div>[N:4] <input type="radio"/> 4</div><div>[N:5] <input type="radio"/> 5</div><div>[itmSecMRILF]</div><div>Focal or Diffuse (if score = 3)</div><div>[N:0] <input type="radio"/> Focal</div><div>[N:1] <input type="radio"/> Diffuse</div><div>[N:2] <input type="radio"/> Not Applicable</div></div>
4.5 ✓	Location [Location]	<div><div>[itmSecMRILoc]</div><div>[N:1] <input type="checkbox"/> 1</div><div>[N:2] <input type="checkbox"/> 2</div><div>[N:3] <input type="checkbox"/> 3</div><div>[N:4] <input type="checkbox"/> 4</div><div>[N:5] <input type="checkbox"/> 5</div><div>[N:6] <input type="checkbox"/> 6</div><div>[N:7] <input type="checkbox"/> 7</div><div>[N:8] <input type="checkbox"/> 8</div><div>[N:9] <input type="checkbox"/> 9</div><div>[N:10] <input type="checkbox"/> 10</div><div>[N:11] <input type="checkbox"/> 11</div><div>[N:12] <input type="checkbox"/> 12</div><div>[N:13] <input type="checkbox"/> 13</div><div>[N:14] <input type="checkbox"/> 14</div><div>[N:15] <input type="checkbox"/> 15</div><div>[N:16] <input type="checkbox"/> 16</div><div>[N:17] <input type="checkbox"/> 17</div><div>[N:18] <input type="checkbox"/> 18</div><div>[N:19] <input type="checkbox"/> 19</div><div>[N:20] <input type="checkbox"/> 20</div><div>[N:21] <input type="checkbox"/> 21</div><div>[N:22] <input type="checkbox"/> 22</div><div>[N:23] <input type="checkbox"/> 23</div><div>[N:24] <input type="checkbox"/> 24</div><div>[N:25] <input type="checkbox"/> 25</div><div>[N:26] <input type="checkbox"/> 26</div><div>[N:27] <input type="checkbox"/> 27</div><div>[N:28] <input type="checkbox"/> 28</div><div>[N:29] <input type="checkbox"/> 29</div><div>[N:30] <input type="checkbox"/> 30</div><div>[N:31] <input type="checkbox"/> 31</div><div>[N:32] <input type="checkbox"/> 32</div><div>[N:33] <input type="checkbox"/> 33</div><div>[N:34] <input type="checkbox"/> 34</div><div>[N:35] <input type="checkbox"/> 35</div><div>[N:36] <input type="checkbox"/> 36</div><div>[N:37] <input type="checkbox"/> 37</div><div>[N:38] <input type="checkbox"/> 38</div><div>[N:39] <input type="checkbox"/> 39</div></div>

		[N:40] <input type="checkbox"/> 40 [N:41] <input type="checkbox"/> 41
4.6 ✓	Visible on CAD [Visible on CAD]	[itmSecMRICAD] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
4.7 ✓	CAD score [CAD score]	[itmSecMRIScr] [N:1] <input type="radio"/> 1 [N:2] <input type="radio"/> 2 [N:3] <input type="radio"/> 3 [N:4] <input type="radio"/> 4 [N:5] <input type="radio"/> 5
Other Findings [secSecMRIOf]		
5. ✓	Radiological stage if subsequently found to have cancer [Radiological stage]	[itmSecOFRadio] [N:0] <input type="radio"/> ≤T2 [N:1] <input type="radio"/> T2a [N:2] <input type="radio"/> T2b [N:3] <input type="radio"/> T2c [N:4] <input type="radio"/> T3a [N:5] <input type="radio"/> T3b [N:6] <input type="radio"/> [itmSecRdioT4] <input type="checkbox"/> T4 [itmSecT4] [N:0] <input type="checkbox"/> Sphincter [N:1] <input type="checkbox"/> Rectum [N:2] <input type="checkbox"/> Bladder
6. ✓	Any incidental findings [Any incidental findings]	[itmSecIF] [A:A] <input type="checkbox"/> None [A:B] <input type="checkbox"/> Bladder Tumour [A:C] <input type="checkbox"/> Rectal Tumour [A:D] <input type="checkbox"/> [itmSecIncndnt] <input type="checkbox"/> Other [itmIncOrSpc] Please specify A80
7. ✓	Is there quality reasons why the MRI needs to be repeated [Quality reasons]	[itmSecPrvnt] [N:0] <input type="radio"/> None [N:1] <input type="radio"/> Geometric distortion [N:2] <input type="radio"/> Susceptibility [N:3] <input type="radio"/> Internal motion [N:4] <input type="radio"/> Signal Graininess [N:5] <input type="radio"/> Blurring [N:6] <input type="radio"/> External motion [N:7] <input type="radio"/> Ghosting [N:8] <input type="radio"/> [itmSecPrevOr] <input type="checkbox"/> Other [itmPrevOr] Please specify A80

Declaration [secDeclrn]

8.

✓

Radiologist
[Radiologist]

[itmSecMRIRad]

[N:1] ☐ Prof A Padhani
[N:2] ☐ Dr H Sokhi
[N:3] ☐ Dr H Tam
[N:4] ☐ [itmSecMRIOr]

Other

[itmRadOr]

Please specify

9.*

✓

Date Reported
[Date Reported]

[itmSecMRIDat]

Req / Req / Req (2018-2030)

Key: [*] = Item is required [✓] = Source verification required [✓] = Source verification critical [b] = Base Unit [] = Item is collapsible [] = Fixed item

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Second MRI Report Form		
Type	RefName	Description
Form	frmScndMRI	Second MRI Report Form
Section	secSecMRIDet	MRI Lesion Details
Section	secSecMRIOF	Other Findings
Section	secDeclrn	Declaration

RDE Analytics: RD_FRMSCNDMRI		
Data Variable RefName	RD Column Name	Column Data Type
itmSecMRIcomp	ITMSECMRICOMP_C	**NUMBER
	ITMSECMRICOMP	VARCHAR2
	ITMSECMRICOMP_ND	VARCHAR2
itmSecMRIcomp - itmSecMRITrans	ITMSECMRITRANS	FLOAT
	ITMSECMRITRANS_U	VARCHAR2
itmSecMRIcomp - itmSecMRIsize	ITMSECMRISIZE	FLOAT
	ITMSECMRISIZE_U	VARCHAR2
itmSecMRIcomp - itmSecMRICranio	ITMSECMRICRANIO	FLOAT
	ITMSECMRICRANIO_U	VARCHAR2
itmSecMRIcomp - itmSecMRIDt	ITMSECMRIDT	DATE
	ITMSECMRIDT_DTS	VARCHAR2
itmSecMRIVol	ITMSECMRIVOL	FLOAT
	ITMSECMRIVOL_ND	VARCHAR2
itmSecMRIlesn	ITMSECMRILESN_C	NUMBER
	ITMSECMRILESN	VARCHAR2
	ITMSECMRILESN_ND	VARCHAR2
itmSecOFRadio	ITMSECOFRADIO_C	NUMBER
	ITMSECOFRADIO	VARCHAR2
	ITMSECOFRADIO_ND	VARCHAR2

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe_137e31086639fb5d_0002.0000_c16... 03/05/2019

itmSecOFRadio - Sphincter	ITMSECT4_CITMT40_C	NUMBER
	ITMSECT4_CITMT40	VARCHAR2
itmSecOFRadio - Rectum	ITMSECT4_CITMT41_C	NUMBER
	ITMSECT4_CITMT41	VARCHAR2
itmSecOFRadio - Bladder	ITMSECT4_CITMT42_C	NUMBER
	ITMSECT4_CITMT42	VARCHAR2
itmSecIF	ITMSECIF_ND	VARCHAR2
itmSecIF - None	ITMSECIF_CITMINCFNON_C	VARCHAR2
	ITMSECIF_CITMINCFNON	VARCHAR2
itmSecIF - Bladder Tumour	ITMSECIF_CITMINCFBT_C	VARCHAR2
	ITMSECIF_CITMINCFBT	VARCHAR2
itmSecIF - Rectal Tumour	ITMSECIF_CITMINCFRT_C	VARCHAR2
	ITMSECIF_CITMINCFRT	VARCHAR2
itmSecIF - Other	ITMSECIF_ITMSECINCDNT_C	VARCHAR2
	ITMSECIF_ITMSECINCDNT	VARCHAR2
itmSecIF - itmIncOrSpc	ITMINCORSPC	VARCHAR2
itmSecPrvnt	ITMSECPRVNT_C	NUMBER
	ITMSECPRVNT	VARCHAR2
	ITMSECPRVNT_ND	VARCHAR2
itmSecPrvnt - itmPrevOr	ITMPREVOR	VARCHAR2
itmSecMRIRad	ITMSECMRIRAD_C	NUMBER
	ITMSECMRIRAD	VARCHAR2
	ITMSECMRIRAD_ND	VARCHAR2
itmSecMRIRad - itmRadOr	ITMRADOR	VARCHAR2
itmSecMRIDat	ITMSECMRIDAT	DATE
	ITMSECMRIDAT_DTS	VARCHAR2
	ITMSECMRIDAT_ND	VARCHAR2
*RD_FRMSCNDMRI_SECSECMRIDE		
itmSecMRINo	ITMSECMRINO_C	NUMBER
	ITMSECMRINO	VARCHAR2
	ITMSECMRINO_ND	VARCHAR2
itmSecMRImax	ITMSECMRIMAX	NUMBER
	ITMSECMRIMAX_U	VARCHAR2
	ITMSECMRIMAX_ND	VARCHAR2
itmSecMRIMod	ITMSECMRIMOD_C	NUMBER
	ITMSECMRIMOD	VARCHAR2
	ITMSECMRIMOD_ND	VARCHAR2
itmSecMRILickrt	ITMSECMRILICKRT_ND	VARCHAR2
itmSecMRILickrt - itmLickert	ITMLICKERT_C	NUMBER
	ITMLICKERT	VARCHAR2
itmSecMRILickrt - itmSecMRILF	ITMSECMRILF_C	NUMBER

	ITMSECMRILF	VARCHAR2
itmSecMRIloc	ITMSECMRILOC_ND	VARCHAR2
itmSecMRIloc - 1	ITMSECMRILOC_CITMLOC1_C	NUMBER
	ITMSECMRILOC_CITMLOC1	VARCHAR2
itmSecMRIloc - 2	ITMSECMRILOC_CITMLOC2_C	NUMBER
	ITMSECMRILOC_CITMLOC2	VARCHAR2
itmSecMRIloc - 3	ITMSECMRILOC_CITMLOC3_C	NUMBER
	ITMSECMRILOC_CITMLOC3	VARCHAR2
itmSecMRIloc - 4	ITMSECMRILOC_CITMLOC4_C	NUMBER
	ITMSECMRILOC_CITMLOC4	VARCHAR2
itmSecMRIloc - 5	ITMSECMRILOC_CITMLOC5_C	NUMBER
	ITMSECMRILOC_CITMLOC5	VARCHAR2
itmSecMRIloc - 6	ITMSECMRILOC_CITMLOC6_C	NUMBER
	ITMSECMRILOC_CITMLOC6	VARCHAR2
itmSecMRIloc - 7	ITMSECMRILOC_CITMLOC7_C	NUMBER
	ITMSECMRILOC_CITMLOC7	VARCHAR2
itmSecMRIloc - 8	ITMSECMRILOC_CITMLOC8_C	NUMBER
	ITMSECMRILOC_CITMLOC8	VARCHAR2
itmSecMRIloc - 9	ITMSECMRILOC_CITMLOC9_C	NUMBER
	ITMSECMRILOC_CITMLOC9	VARCHAR2
itmSecMRIloc - 10	ITMSECMRILOC_CITMLOC10_C	NUMBER
	ITMSECMRILOC_CITMLOC10	VARCHAR2
itmSecMRIloc - 11	ITMSECMRILOC_CITMLOC11_C	NUMBER
	ITMSECMRILOC_CITMLOC11	VARCHAR2
itmSecMRIloc - 12	ITMSECMRILOC_CITMLOC12_C	NUMBER
	ITMSECMRILOC_CITMLOC12	VARCHAR2
itmSecMRIloc - 13	ITMSECMRILOC_CITMLOC13_C	NUMBER
	ITMSECMRILOC_CITMLOC13	VARCHAR2
itmSecMRIloc - 14	ITMSECMRILOC_CITMLOC14_C	NUMBER
	ITMSECMRILOC_CITMLOC14	VARCHAR2
itmSecMRIloc - 15	ITMSECMRILOC_CITMLOC15_C	NUMBER
	ITMSECMRILOC_CITMLOC15	VARCHAR2
itmSecMRIloc - 16	ITMSECMRILOC_CITMLOC16_C	NUMBER
	ITMSECMRILOC_CITMLOC16	VARCHAR2
itmSecMRIloc - 17	ITMSECMRILOC_CITMLOC17_C	NUMBER
	ITMSECMRILOC_CITMLOC17	VARCHAR2
itmSecMRIloc - 18	ITMSECMRILOC_CITMLOC18_C	NUMBER
	ITMSECMRILOC_CITMLOC18	VARCHAR2
itmSecMRIloc - 19	ITMSECMRILOC_CITMLOC19_C	NUMBER
	ITMSECMRILOC_CITMLOC19	VARCHAR2
itmSecMRIloc - 20	ITMSECMRILOC_CITMLOC20_C	NUMBER

	ITMSECMRILOC_CITMLOC20	VARCHAR2
itmSecMRIloc - 21	ITMSECMRILOC_CITMLOC21_C	NUMBER
	ITMSECMRILOC_CITMLOC21	VARCHAR2
itmSecMRIloc - 22	ITMSECMRILOC_CITMLOC22_C	NUMBER
	ITMSECMRILOC_CITMLOC22	VARCHAR2
itmSecMRIloc - 23	ITMSECMRILOC_CITMLOC23_C	NUMBER
	ITMSECMRILOC_CITMLOC23	VARCHAR2
itmSecMRIloc - 24	ITMSECMRILOC_CITMLOC24_C	NUMBER
	ITMSECMRILOC_CITMLOC24	VARCHAR2
itmSecMRIloc - 25	ITMSECMRILOC_CITMLOC25_C	NUMBER
	ITMSECMRILOC_CITMLOC25	VARCHAR2
itmSecMRIloc - 26	ITMSECMRILOC_CITMLOC26_C	NUMBER
	ITMSECMRILOC_CITMLOC26	VARCHAR2
itmSecMRIloc - 27	ITMSECMRILOC_CITMLOC27_C	NUMBER
	ITMSECMRILOC_CITMLOC27	VARCHAR2
itmSecMRIloc - 28	ITMSECMRILOC_CITMLOC28_C	NUMBER
	ITMSECMRILOC_CITMLOC28	VARCHAR2
itmSecMRIloc - 29	ITMSECMRILOC_CITMLOC29_C	NUMBER
	ITMSECMRILOC_CITMLOC29	VARCHAR2
itmSecMRIloc - 30	ITMSECMRILOC_CITMLOC30_C	NUMBER
	ITMSECMRILOC_CITMLOC30	VARCHAR2
itmSecMRIloc - 31	ITMSECMRILOC_CITMLOC31_C	NUMBER
	ITMSECMRILOC_CITMLOC31	VARCHAR2
itmSecMRIloc - 32	ITMSECMRILOC_CITMLOC32_C	NUMBER
	ITMSECMRILOC_CITMLOC32	VARCHAR2
itmSecMRIloc - 33	ITMSECMRILOC_CITMLOC33_C	NUMBER
	ITMSECMRILOC_CITMLOC33	VARCHAR2
itmSecMRIloc - 34	ITMSECMRILOC_CITMLOC34_C	NUMBER
	ITMSECMRILOC_CITMLOC34	VARCHAR2
itmSecMRIloc - 35	ITMSECMRILOC_CITMLOC35_C	NUMBER
	ITMSECMRILOC_CITMLOC35	VARCHAR2
itmSecMRIloc - 36	ITMSECMRILOC_CITMLOC36_C	NUMBER
	ITMSECMRILOC_CITMLOC36	VARCHAR2
itmSecMRIloc - 37	ITMSECMRILOC_CITMLOC37_C	NUMBER
	ITMSECMRILOC_CITMLOC37	VARCHAR2
itmSecMRIloc - 38	ITMSECMRILOC_CITMLOC38_C	NUMBER
	ITMSECMRILOC_CITMLOC38	VARCHAR2
itmSecMRIloc - 39	ITMSECMRILOC_CITMLOC39_C	NUMBER
	ITMSECMRILOC_CITMLOC39	VARCHAR2
itmSecMRIloc - 40	ITMSECMRILOC_CITMLOC40_C	NUMBER
	ITMSECMRILOC_CITMLOC40	VARCHAR2

itmSecMRIloc - 41	ITMSECMRILOC_CITMLOC41_C	NUMBER
	ITMSECMRILOC_CITMLOC41	VARCHAR2
itmSecMRICAD	ITMSECMRICAD_C	NUMBER
	ITMSECMRICAD	VARCHAR2
	ITMSECMRICAD_ND	VARCHAR2
itmSecMRIScr	ITMSECMRISCR_C	NUMBER
	ITMSECMRISCR	VARCHAR2
	ITMSECMRISCR_ND	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: Episwitch result (Optional) (EPIS) [frmEPSR]

Episwitch result (Optional) [frmEPSR]

1.*
✓

Episwitch result available?
[Episwitch result available]

[itmEPSRAvbl]

[N:1] ☐ [cmpEpisYs]

Yes

[itmEpisdt]

Date of Episwitch sample

Req / Req / Req (2018-2030)

[N:2] ☐ No

[N:3] ☐ Not consented

Episwitch Result Details [secEPSRDtl]

# ✓	Marker	Loci	Cq.value	Sq. value	Classifier probability score
2.a	PCa119.245.247	DAPK1			
2.b	PCa119.129.131	HSD3B2			
2.c	PCa119.165.167	DAPK1			
2.d	PCa119.154.155	SRD5A3			
2.e	PCa119.65.67	ERG			
2.f	MMP1.4.12	MMP1			

Episwitch Result Details Entry [secEPSRDtl]

2.1
✓

Marker [read-only]
[Marker]

[itmEPSRMrkr]

[clMarker]

2.2
✓

Loci [read-only]
[Loci]

[itmEPSRLoci]

[clLoci]

2.3
✓

Cq.value
[Cq.value]

[itmEPSRCq]

cq

2.4
✓

Sq. value
[Sq. value]

[itmEPSRSq]

sq

2.5
✓

Classifier probability score
[Classifier probability score]

[itmEPSRCps]

Key: [✓] = Source verification required [] = Item is collapsible [] = Fixed item

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Episwitch result (Optional)		
Type	RefName	Description
Form	frmEPSR	Episwitch result
Section	secEPSRDtl	Episwitch Result Details

Codelist Values Tables: Episwitch result (Optional)					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clMarker	Integer	PCa119.245.247	0	citmMrkr0	itmEPSRMrkr

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe_137e31086639fb5d_0002.0000_c16... 03/05/2019

		PCa119.129.131	1	citmMrkr1	
		PCa119.165.167	2	citmMrkr2	
		PCa119.154.155	3	citmMrkr3	
		PCa119.65.67	4	citmMrkr4	
		MMP1.4.12	5	citmMarhr5	
clLoci	Integer	DAPK1	0	citmLoci0	itmEPSRLoci
		HSD3B2	1	citmLoci1	
		DAPK1	2	citmLoci2	
		SRD5A3	3	citmLoci3	
		ERG	4	citmLoci4	
		MMP1	5	citmLoci5	

RDE Analytics: RD_FRMEPSR		
Data Variable RefName	RD Column Name	Column Data Type
itmEPSRAVlbl	ITMEPSRAVLBL_C	**NUMBER
	ITMEPSRAVLBL	VARCHAR2
	ITMEPSRAVLBL_ND	VARCHAR2
itmEPSRAVlbl - itmEpisdt	ITMEPISDT	DATE
	ITMEPISDT_DTS	VARCHAR2
RD_FRMEPSR_SECEPSRDTL		
itmEPSRMrkr	ITMEPSRMRKR_C	NUMBER
	ITMEPSRMRKR	VARCHAR2
	ITMEPSRMRKR_ND	VARCHAR2
itmEPSRLoci	ITMEPSRLOCI_C	NUMBER
	ITMEPSRLOCI	VARCHAR2
	ITMEPSRLOCI_ND	VARCHAR2
itmEPSRCq	ITMEPSRCQ	FLOAT
	ITMEPSRCQ_ND	VARCHAR2
itmEPSRSq	ITMEPSRSQ	FLOAT
	ITMEPSRSQ_ND	VARCHAR2
itmEPSRCps	ITMEPSRCPS	FLOAT
	ITMEPSRCPS_ND	VARCHAR2
Key: [*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: Targeted biopsy form (TBR) [frmTBF]

Targeted biopsy form [frmTBF]

1.*
✓

Was a prostate biopsy done?
[Prostate biopsy]

[itmTBRBiop]
[N:1] ☐ [itmTBRBiopYs]

Yes

[itmBiopDt]
Date of biopsy
Req / Req / Req (2018-2030)

[itmTBRTyp]
Type of anaesthetic
[N:0] ☐ Local
[N:1] ☐ Local & Sedation
[N:2] ☐ General anaesthetic
[N:0] ☐ No

Key: [✓] = Source verification required [] = Item is collapsible


Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Targeted biopsy form		
Type	RefName	Description
Form	frmTBF	Targeted biopsy form

RDE Analytics: RD_FRMTBF		
Data Variable RefName	RD Column Name	Column Data Type
itmTBRBiop	ITMTBRBIOP_C	**NUMBER
	ITMTBRBIOP	VARCHAR2
	ITMTBRBIOP_ND	VARCHAR2
itmTBRBiop - itmBiopDt	ITMBIOPDT	DATE
	ITMBIOPDT_DTS	VARCHAR2
itmTBRBiop - itmTBRTyp	ITMTBRTYP_C	NUMBER
	ITMTBRTYP	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

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PROSTAGRAM: Pathology Result (PATH) [frmPath]							
Pathology Result [frmPath]							
1.	Is pathology data available? ✓ [Pathology data]	[itmPATHdata] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No					
Non-Targeted biopsy Details [secOPNTB]							
# ✓	Details	Total number of cores taken	Number of cores containing cancer	Pathology Grade	Maximum cancer core length in any core	Additional findings	
2.a	Non-Targeted biopsy: Ipsilateral						
2.b	Non-Targeted biopsy: Contralateral						
Non-Targeted biopsy Details Entry [secOPNTB]							
2.1	Details <i>[read-only]</i> ✓ [Details] 	[itmPATHDet] [N:0] <input type="radio"/> Non-Targeted biopsy: Ipsilateral [N:1] <input type="radio"/> Non-Targeted biopsy: Contralateral					
2.2	Total number of cores taken ✓ [Total number of cores taken]	[itmPATHCores] N2					
2.3	Number of cores containing cancer ✓ [Number of cores containing cancer]	[itmPATHcncr] N2					
2.4	Pathology Grade ✓ [Pathology Grade]	[itmPATHGrd] [N:0] <input type="radio"/> Benign [N:1] <input type="radio"/> 3+3 [N:2] <input type="radio"/> 3+4 [N:3] <input type="radio"/> 3+5 [N:4] <input type="radio"/> 4+3 [N:5] <input type="radio"/> 4+4 [N:6] <input type="radio"/> 4+5 [N:7] <input type="radio"/> 5+3 [N:8] <input type="radio"/> 5+4 [N:9] <input type="radio"/> 5+5					
2.5	Maximum cancer core length in any core ✓ [Maximum cancer core length in any core]	[itmPATHMax] N2 mm ^[b]					
2.6	Additional findings ✓ [Additional findings]	[itmPATHAdd] [N:1] <input type="checkbox"/> Inflammation [N:2] <input type="checkbox"/> Atrophy [N:3] <input type="checkbox"/> Prostatitis [N:4] <input type="checkbox"/> Fibrosis [N:5] <input type="checkbox"/> HGPIN [N:6] <input type="checkbox"/> ASAP					
Targets(MRI,CAD,US) [secPATHTrgt]							
# ✓	Target Details	Is this concordant with any other targets	Total number of cores taken	Number of cores containing cancer	Pathology Grade	Maximum cancer core length in non targeted cores	Additional findings
3.a	MRI Target 1						
3.b	MRI Target 2						
3.c	CAD Target 1						
3.d	CAD Target 2						

3.e	US Target 1				
3.f	US Target 2				
Targets(MRI,CAD,US) Entry [secPATHTrgt]					
3.1	Target Details <i>[read-only]</i> ✓ [Target Details]	[itmTrgtDtIs] [clPATHTarget]			
3.2	Is this concordant with any other targets ✓ [Is this concordant with any other targets]	[itmTrgtConcr] [N:0] <input type="checkbox"/> CAD Target 1 [N:1] <input type="checkbox"/> CAD Target 2 [N:2] <input type="checkbox"/> MRI Target 1 [N:3] <input type="checkbox"/> MRI Target 2 [N:4] <input type="checkbox"/> US Target 1 [N:5] <input type="checkbox"/> US Target 2			
3.3	Total number of cores taken ✓ [Total number of cores taken]	[itmTrgtTcor] N2			
3.4	Number of cores containing cancer ✓ [Number of cores containing cancer]	[itmTrgtNcor] N2			
3.5	Pathology Grade ✓ [Pathology Grade]	[itmTrgtPth] [N:0] <input type="radio"/> Benign [N:1] <input type="radio"/> 3+3 [N:2] <input type="radio"/> 3+4 [N:3] <input type="radio"/> 3+5 [N:4] <input type="radio"/> 4+3 [N:5] <input type="radio"/> 4+4 [N:6] <input type="radio"/> 4+5 [N:7] <input type="radio"/> 5+3 [N:8] <input type="radio"/> 5+4 [N:9] <input type="radio"/> 5+5			
3.6	Maximum cancer core length in non targeted cores ✓ [Maximum cancer core length in non targeted cores]	[itmTrgtMax] N2 mm ^[b]			
3.7	Additional findings ✓ [Additional findings]	[itmTrgAdd] [N:1] <input type="checkbox"/> Inflammation [N:2] <input type="checkbox"/> Atrophy [N:3] <input type="checkbox"/> Prostatitis [N:4] <input type="checkbox"/> Fibrosis [N:5] <input type="checkbox"/> HGPIN [N:6] <input type="checkbox"/> ASAP			
Key: [✓] = Source verification required [b] = Base Unit = Fixed item Note: Source verification critical settings made in InForm will override any settings made in Central Designer.					

Study Object Descriptions: Pathology Result		
Type	RefName	Description
Form	frmPath	Pathology form
Section	secOPNTB	Non-Targeted biopsy
Section	secPATHTrgt	Targets(MRI,CAD,US)

Codelist Values Tables: Pathology Result					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
clPATHTarget	Integer	MRI Target 1	0	citmTgt0	itmTrgtdtls
		MRI Target 2	1	citmTgt1	
		CAD Target 1	2	citmTgt2	
		CAD Target 2	3	citmTgt3	
		US Target 1	4	citmTgt4	
		US Target 2	5	citmTgt5	

RDE Analytics: RD_FRMPATH		
Data Variable RefName	RD Column Name	Column Data Type
itmPATHdata	ITMPATHDATA_C	NUMBER
	ITMPATHDATA	VARCHAR2
	ITMPATHDATA_ND	VARCHAR2
RD_FRMPATH_SECOPNTB		
itmPATHDet	ITMPATHDET_C	NUMBER
	ITMPATHDET	VARCHAR2
	ITMPATHDET_ND	VARCHAR2
itmPATHCores	ITMPATHCORES	NUMBER
	ITMPATHCORES_ND	VARCHAR2
itmPATHcncr	ITMPATHCNCR	NUMBER
	ITMPATHCNCR_ND	VARCHAR2
itmPATHGrd	ITMPATHGRD_C	NUMBER
	ITMPATHGRD	VARCHAR2
	ITMPATHGRD_ND	VARCHAR2
itmPATHMax	ITMPATHMAX	NUMBER
	ITMPATHMAX_U	VARCHAR2
	ITMPATHMAX_ND	VARCHAR2
itmPATHAdd	ITMPATHADD_ND	VARCHAR2
itmPATHAdd - Inflammation	ITMPATHADD_CITMADDINFLM_C	NUMBER
	ITMPATHADD_CITMADDINFLM	VARCHAR2
itmPATHAdd - Atrophy	ITMPATHADD_CITMADDATR_C	NUMBER
	ITMPATHADD_CITMADDATR	VARCHAR2
itmPATHAdd - Prostatitis	ITMPATHADD_CITMADDPROST_C	NUMBER
	ITMPATHADD_CITMADDPROST	VARCHAR2
itmPATHAdd - Fibrosis	ITMPATHADD_CITMADDFIBR_C	NUMBER
	ITMPATHADD_CITMADDFIBR	VARCHAR2
itmPATHAdd - HGPIN	ITMPATHADD_CITMADDHGPN_C	NUMBER
	ITMPATHADD_CITMADDHGPN	VARCHAR2
itmPATHAdd - ASAP	ITMPATHADD_CITMADDASAP_C	NUMBER

	ITMPATHADD_CITMADDASAP	VARCHAR2
RD_FRMPATH_SECPATHTRGT		
itmTrgtDtls	ITMTRGDTLS_C	NUMBER
	ITMTRGDTLS	VARCHAR2
	ITMTRGDTLS_ND	VARCHAR2
itmTrgtconcr	ITMTRGTCONCR_ND	VARCHAR2
itmTrgtconcr - CAD Target 1	ITMTRGTCONCR_CITMCNCR0_C	NUMBER
	ITMTRGTCONCR_CITMCNCR0	VARCHAR2
itmTrgtconcr - CAD Target 2	ITMTRGTCONCR_CITMCNCR1_C	NUMBER
	ITMTRGTCONCR_CITMCNCR1	VARCHAR2
itmTrgtconcr - MRI Target 1	ITMTRGTCONCR_CITMCNCR2_C	NUMBER
	ITMTRGTCONCR_CITMCNCR2	VARCHAR2
itmTrgtconcr - MRI Target 2	ITMTRGTCONCR_CITMCNCR3_C	NUMBER
	ITMTRGTCONCR_CITMCNCR3	VARCHAR2
itmTrgtconcr - US Target 1	ITMTRGTCONCR_CITMCNCR4_C	NUMBER
	ITMTRGTCONCR_CITMCNCR4	VARCHAR2
itmTrgtconcr - US Target 2	ITMTRGTCONCR_CITMCNCR5_C	NUMBER
	ITMTRGTCONCR_CITMCNCR5	VARCHAR2
itmTrgtTcor	ITMTRGTTCOR	NUMBER
	ITMTRGTTCOR_ND	VARCHAR2
itmTrgtNcor	ITMTRGTNCOR	NUMBER
	ITMTRGTNCOR_ND	VARCHAR2
itmTrgtPth	ITMTRGTPTH_C	NUMBER
	ITMTRGTPTH	VARCHAR2
	ITMTRGTPTH_ND	VARCHAR2
itmTrgtMax	ITMTRGTMAX	NUMBER
	ITMTRGTMAX_U	VARCHAR2
	ITMTRGTMAX_ND	VARCHAR2
itmTrgAdd	ITMTRGADD_ND	VARCHAR2
itmTrgAdd - Inflammation	ITMTRGADD_CITMADDINFLM_C	NUMBER
	ITMTRGADD_CITMADDINFLM	VARCHAR2
itmTrgAdd - Atrophy	ITMTRGADD_CITMADDATR_C	NUMBER
	ITMTRGADD_CITMADDATR	VARCHAR2
itmTrgAdd - Prostatitis	ITMTRGADD_CITMADDPROST_C	NUMBER
	ITMTRGADD_CITMADDPROST	VARCHAR2
itmTrgAdd - Fibrosis	ITMTRGADD_CITMADDFIBR_C	NUMBER
	ITMTRGADD_CITMADDFIBR	VARCHAR2
itmTrgAdd - HGPIN	ITMTRGADD_CITMADDHGPIN_C	NUMBER
	ITMTRGADD_CITMADDHGPIN	VARCHAR2
itmTrgAdd - ASAP	ITMTRGADD_CITMADDASAP_C	NUMBER
	ITMTRGADD_CITMADDASAP	VARCHAR2

PROSTAGRAM: Treatment Form (TRTMNT) [frmTrtmnt]

Treatment Form [frmTrtmnt]

1.*
✓

Did this patient have prostate cancer
[Did this patient have prostate cancer]

[itmTrtmntcncr]
[N:1] ☐ [itmTrtmntcncrYs]

Yes

[itmTrtmntoptn]
What treatment did the patient have?

[N:0] ☐

Active surveillance

[N:1] ☐

Watchful Waiting

[N:2] ☐

Focal Treatment

[N:3] ☐

[itmTrtmntRad]
Radical Prostatectomy

[itmTrtPthGrd]
Pathology Grade on Radical prostatectomy

[N:0] ☐ Benign

[N:1] ☐ ASAP

[N:2] ☐ HGPIN

[N:3] ☐ 3+3

[N:4] ☐ 3+4

[N:5] ☐ 3+5

[N:6] ☐ 4+3

[N:7] ☐ 4+4

[N:8] ☐ 4+5

[N:9] ☐ 5+3

[N:10] ☐ 5+4

[N:11] ☐ 5+5

[itmTrtTstg]
T stage on Radical prostatectomy

[N:1] ☐ <T1c

[N:2] ☐ T2a

[N:3] ☐ T2b

[N:4] ☐ T2c

[N:5] ☐ T3a

[N:6] ☐ T3b

[N:7] ☐ T3

[N:4] ☐

Radiotherapy

[N:5] ☐

ADT

[N:0] ☐ No

Key: [*] = Item is required [✓] = Source verification required [] = Item is collapsible

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Treatment Form		
Type	RefName	Description
Form	frmTrtmnt	Treatment Form

RDE Analytics: RD_FRMTRTMNT		
Data Variable RefName	RD Column Name	Column Data Type

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe_137e31086639fb5d_0002.0000_c16... 03/05/2019

itmTrtmntcncr	ITMTRTMNTCNCR_C	**NUMBER
	ITMTRTMNTCNCR	VARCHAR2
	ITMTRTMNTCNCR_ND	VARCHAR2
itmTrtmntcncr - Active surveillance	ITMTRTMNTOPTN_CITMTRTMNT0_C	NUMBER
	ITMTRTMNTOPTN_CITMTRTMNT0	VARCHAR2
itmTrtmntcncr - Watchful Waiting	*ITMTRTMNTOPTN_CITMTRTMNTWTCH_C	NUMBER
	*ITMTRTMNTOPTN_CITMTRTMNTWTCH	VARCHAR2
itmTrtmntcncr - Focal Treatment	*ITMTRTMNTOPTN_CITMTRTMNTFOOD_C	NUMBER
	*ITMTRTMNTOPTN_CITMTRTMNTFOOD	VARCHAR2
itmTrtmntcncr - Radical Prostatectomy	*ITMTRTMNTOPTN_ITMTRTMNTRAD_C	NUMBER
	*ITMTRTMNTOPTN_ITMTRTMNTRAD	VARCHAR2
itmTrtmntcncr - itmTrtPthGrd	ITMTRTPTHGRD_C	NUMBER
	ITMTRTPTHGRD	VARCHAR2
itmTrtmntcncr - itmTrtTstg	ITMTRTTSTG_C	NUMBER
	ITMTRTTSTG	VARCHAR2
itmTrtmntcncr - Radiotherapy	*ITMTRTMNTOPTN_CITMTRTMNTRADIO_C	NUMBER
	*ITMTRTMNTOPTN_CITMTRTMNTRADIO	VARCHAR2
itmTrtmntcncr - ADT	*ITMTRTMNTOPTN_CITMTRTMNTADT_C	NUMBER
	*ITMTRTMNTOPTN_CITMTRTMNTADT	VARCHAR2
Key: [*] = The column and/or table name in the actual RDE extract may be different. [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: Protocol Deviations/Violations (PROT DEV) - Repeating Form [frmPDV]											
#	Protocol Dev/Vio Number	Date dev/vio reported	Protocol Deviation or Violation	How was Deviation / Violation Identified?	Classification	Description of Deviation/Violation	Date of Deviation/Violation	Response to Deviation / Violation	Serious breach?	Study Manager Comments	Principal Investigator Comments
1											
Protocol Deviations/Violations [frmPDV]											
1.	Protocol Deviation/Violation Number <i>[read-only]</i> [Protocol Dev/Vio Number]				[itmPDPDNo] N3						
2.*	Date Deviation/Violation reported [Date dev/vio reported]				[itmPDDatRep] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)						
3.*	Protocol Deviation or Violation [Protocol Deviation or Violation]				[itmPDPDPV] [N:1] <input type="radio"/> Protocol Deviation [N:2] <input type="radio"/> Protocol Violation						
4.*	How was Deviation / Violation Identified? [How was Deviation / Violation Identified?]				[itmPDVIden] [N:1] <input type="radio"/> Monitoring visit [N:2] <input type="radio"/> By Coordinating centre [N:3] <input type="radio"/> By site [N:4] <input type="radio"/> [itmPDVIdenOth] <input type="text"/> Other [itmPDVIdenOth] Please Specify A200						
5.*	Classification of Protocol Deviation/Violation [Classification]				[itmPDTypPD] [N:1] <input type="radio"/> Inclusion/exclusion criteria [N:2] <input type="radio"/> Study drug administration [N:3] <input type="radio"/> Sampling / laboratory measurements [N:4] <input type="radio"/> Consent issue [N:5] <input type="radio"/> Study visit windows [N:6] <input type="radio"/> NIMP administration [N:7] <input type="radio"/> Study drug prescription [N:8] <input type="radio"/> Dispensing [N:9] <input type="radio"/> Accountability [N:10] <input type="radio"/> Compliance [N:11] <input type="radio"/> Missed study visit [N:12] <input type="radio"/> [itmPDSMea] <input type="text"/> Study measurements/assessments [N:1] <input type="radio"/> Primary outcome measure [N:2] <input type="radio"/> Secondary outcome measure [N:3] <input type="radio"/> Safety outcome [N:13] <input type="radio"/> Device [N:14] <input type="radio"/> Equipment [N:15] <input type="radio"/> Prohibited medication/substance(s) [N:16] <input type="radio"/> AE/SAE reporting [N:17] <input type="radio"/> Blinding/unblinding [N:18] <input type="radio"/> Randomisation [N:19] <input type="radio"/> Implementation of document prior to research approval [N:20] <input type="radio"/> License/certification/calibration/servicing (labs and equipment) [N:21] <input type="radio"/> Delegation log/authorisation [N:22] <input type="radio"/> Dose interruptions / modifications not specified in the protocol						

		<p>[N:23] <input type="radio"/> Variation in clinical management of participant</p> <p>[N:24] <input type="radio"/> Withdrawal issue</p> <p>[N:25] <input type="radio"/> Falsifying research or medical records</p> <p>[N:26] <input type="radio"/> Repeated protocol deviations (of same type)</p> <p>[N:27] <input type="radio"/> [itmPDClassOC] <input type="checkbox"/></p> <p>Other</p> <p>[itmPDTypOth]</p> <p>Please give details</p> <p>A200</p>
6.* <input checked="" type="checkbox"/>	Description of Deviation/Violation [Description of Deviation/Violation]	<p>[itmPDDets]</p> <p>A400</p>
7.* <input checked="" type="checkbox"/>	Date of Deviation/Violation [Date of Deviation/Violation]	<p>[itmPDDatDev]</p> <p>Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)</p>
8.* <input checked="" type="checkbox"/>	Response to Deviation / Violation (e.g. CAPA) [Response to Deviation / Violation]	<p>[itmPDStpRec]</p> <p>A600</p>
9.* <input checked="" type="checkbox"/>	Is this a serious breach? <i>[read-only]</i> [Serious breach?]	<p>[itmPDVSerBr]</p> <p>[N:1] <input type="radio"/> [itmPDVCAC] <input type="checkbox"/></p> <p>Yes</p> <p>[itmPDVCA]</p> <p>Was Deviation/Violation reported to CA (Competent Authority) as a serious breach? [N:1] <input type="radio"/> Yes</p> <p>[N:0] <input type="radio"/> No</p> <p>[N:0] <input type="radio"/> No</p>
10. <input checked="" type="checkbox"/>	Study Manager Comments <i>[read-only]</i> [Study Manager Comments]	<p>[itmPDSMCom]</p> <p>A400</p>
11. <input checked="" type="checkbox"/>	Principal Investigator Comments <i>[read-only]</i> [Principal Investigator Comments]	<p>[itmPDPICom]</p> <p>A400</p>
<p>Key: [<input checked="" type="checkbox"/>] = Source verification required [<input checked="" type="checkbox"/>] = Source verification critical [<input type="checkbox"/>] = Item is collapsible</p> <p>Note: Source verification critical settings made in InForm will override any settings made in Central Designer.</p> <p>Note: Collapsible settings are only available to users who have the rights to edit the item.</p>		

Study Object Descriptions: Protocol Deviations/Violations

Type	RefName	Description
Form	frmPDV	Protocol Deviations

RDE Analytics: RD_FRMPDV

Data Variable RefName	RD Column Name	Column Data Type
itmPDPDNo	ITMPDPDNO	NUMBER
	ITMPDPDNO_ND	VARCHAR2
itmPDDatRep	ITMPDDATREP	DATE
	ITMPDDATREP_DTS	VARCHAR2
	ITMPDDATREP_ND	VARCHAR2

itmPDPDPV	ITMPDPPDV_C	NUMBER
	ITMPDPPDV	VARCHAR2
	ITMPDPPDV_ND	VARCHAR2
itmPDVIden	ITMPDVIDEN_C	NUMBER
	ITMPDVIDEN	VARCHAR2
	ITMPDVIDEN_ND	VARCHAR2
itmPDVIden - itmPDVIdOth	ITMPDVIDEOTH	VARCHAR2
itmPDTypPD	ITMPDTPPD_C	NUMBER
	ITMPDTPPD	VARCHAR2
	ITMPDTPPD_ND	VARCHAR2
itmPDTypPD - itmPDSMea	ITMPDSMEA_C	NUMBER
	ITMPDSMEA	VARCHAR2
itmPDTypPD - itmPDTypOth	ITMPDTPOTH	VARCHAR2
itmPDDets	ITMPDDETS	VARCHAR2
	ITMPDDETS_ND	VARCHAR2
itmPDDatDev	ITMPDDATDEV	DATE
	ITMPDDATDEV_DTS	VARCHAR2
	ITMPDDATDEV_ND	VARCHAR2
itmPDStpRec	ITMPDSTPREC	VARCHAR2
	ITMPDSTPREC_ND	VARCHAR2
itmPDVSerBr	ITMPDVSERBR_C	**NUMBER
	ITMPDVSERBR	VARCHAR2
	ITMPDVSERBR_ND	VARCHAR2
itmPDVSerBr - itmPDVCA	ITMPDVCA_C	NUMBER
	ITMPDVCA	VARCHAR2
itmPDSMCom	ITMPDSMCOM	VARCHAR2
	ITMPDSMCOM_ND	VARCHAR2
itmPDPICom	ITMPDPICOM	VARCHAR2
	ITMPDPICOM_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: Adverse Events (AE) - Repeating Form [frmPAE]							
#	Adverse Event Description (select an option that applies)	Date Event Started	Date of site knowledge	Date Sponsor/ Representative notified	Seriousness: The Adverse Event	The reported adverse event related to	Outcome
1							
Adverse Events [frmPAE]							
1.* <input checked="" type="checkbox"/>	Adverse Event Description (select an option that applies) [Adverse Event Description (select an option that applies)]	<div> <div>[itmPAEDesc]</div> <div>[N:1] <input type="radio"/> [itmPAEVeni] </div> <div>Expected Adverse Events Associated with Venipuncture Procedure</div> <div>[itmPAEVp]</div> <div>[N:1] <input type="radio"/> Haematomas and ecchymoses around venipuncture site</div> <div>[N:2] <input type="radio"/> Minor discomfort</div> <div>[N:3] <input type="radio"/> Infection</div> <div>[N:2] <input type="radio"/> [itmPAEMri] </div> <div>Expected Adverse Events Associated with MRI</div> <div>[itmPAEMri]</div> <div>[N:1] <input type="radio"/> Claustrophobia</div> <div>[N:2] <input type="radio"/> Anxiety/Stress</div> <div>[N:3] <input type="radio"/> Discomfort</div> <div>[N:3] <input type="radio"/> [itmPAEPtu] </div> <div>Expected Adverse Events Associated with Prostate Transrectal Ultrasound</div> <div>[itmPAEPUS]</div> <div>[N:1] <input type="radio"/> Rectal discomfort during the procedure</div> <div>[N:4] <input type="radio"/> [itmPAEPb] </div> <div>Expected Adverse Events Associated with Prostate Biopsy</div> <div>[itmPrb]</div> <div>[N:0] <input type="radio"/> Blood in the urine (Haematuria)</div> <div>[N:1] <input type="radio"/> Pain passing urine (Dysuria)</div> <div>[N:2] <input type="radio"/> Blood in the semen is common (Haemospermia)</div> <div>[N:3] <input type="radio"/> Temporary pain/discomfort in the perineal area</div> <div>[N:4] <input type="radio"/> Temporary problems with erection</div> <div>[N:5] <input type="radio"/> Retention of urine requiring a temporary catheter</div> <div>[N:6] <input type="radio"/> Prostatitis (inflammation or infection of the prostate)</div> <div>[N:7] <input type="radio"/> Infection requiring admission and intravenous antibiotics</div> <div>[N:5] <input type="radio"/> [itmPAESp] </div> <div>Expected Adverse Events Associated with local anaesthetic and conscious sedation procedure (if applicable)</div> <div>[itmPAECsp]</div> <div>[N:1] <input type="radio"/> Nausea and vomiting</div> <div>[N:2] <input type="radio"/> Minor bruises from intravenous catheters</div> <div>[N:3] <input type="radio"/> Extensive bruising</div> <div>[N:4] <input type="radio"/> Temporary hardening of the vein (phlebitis)</div> <div>[N:5] <input type="radio"/> Infection can occur from intravenous catheters</div> <div>[N:6] <input type="radio"/> Dizziness/Vertigo</div> <div>[N:7] <input type="radio"/> Confusion/Disorientation</div> <div>[N:8] <input type="radio"/> Respiratory depression and apnoea</div> <div>[N:9] <input type="radio"/> Anaphylaxis to Local Anaesthetic</div> <div>[N:6] <input type="radio"/> [itmPAEGa] </div> <div>Expected Adverse Events Associated the procedure under general anaesthetic (if applicable)</div> <div>[itmPAEGAnsth]</div> <div>[N:1] <input type="radio"/> Nausea and vomiting</div> <div>[N:2] <input type="radio"/> Dry cough for an hour or a sore throat</div> <div>[N:3] <input type="radio"/> Minor bruises from intravenous catheters</div> <div>[N:4] <input type="radio"/> Extensive bruising</div> </div>					

		<p>[N:5] <input type="radio"/> Temporary hardening of the vein (phlebitis)</p> <p>[N:6] <input type="radio"/> Infection can occur from intravenous catheters</p> <p>[N:7] <input type="radio"/> Death</p> <p>[N:7] <input type="radio"/> [itmPAEOthr] <input type="checkbox"/></p> <p>Other</p> <p>[itmPAEOtrs]</p> <p>Please specify</p> <p>A200</p>
2.* <input checked="" type="checkbox"/>	Date Event Started [Date Event Started]	[itmPAEEvtdt] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
3.* <input checked="" type="checkbox"/>	Date of site knowledge [Date of site knowledge]	[itmPAEEvtsit] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
4.* <input checked="" type="checkbox"/>	Date Sponsor/ Representative notified [Date Sponsor/ Representative notified]	[itmPAESpnsrDt] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
5.* <input checked="" type="checkbox"/>	Seriousness: The Adverse Event [Seriousness: The Adverse Event]	<p>[itmPAESerious]</p> <p>[N:1] <input type="radio"/> 1 = Resulted in Death</p> <p>[N:2] <input type="radio"/> 2 = Life-threatening</p> <p>[N:5] <input type="radio"/> 3 = Required inpatient hospitalisation or prolongation of existing hospitalisation</p> <p>[N:4] <input type="radio"/> 4 = Resulted in persistent or significant disability/incapacity</p> <p>[N:3] <input type="radio"/> 5 = Resulted in congenital anomaly/birth defect</p> <p>[N:6] <input type="radio"/> [itmAEledSer] <input type="checkbox"/></p> <p>6 = Other medically important event</p> <p>[itmAESrOthrdtl]</p> <p>Please provide details</p> <p>A200</p> <p>[N:7] <input type="radio"/> 7= None of the above</p>
6.* <input checked="" type="checkbox"/>	The reported adverse event related to [The reported adverse event related to]	<p>[itmPAERel]</p> <p>[N:1] <input type="radio"/> Venipuncture Procedure</p> <p>[N:2] <input type="radio"/> Magnetic Resonance Imaging</p> <p>[N:3] <input type="radio"/> Digital Transrectal Ultrasound</p> <p>[N:4] <input type="radio"/> Prostate Biopsy</p> <p>[N:5] <input type="radio"/> Local Anaesthetic</p> <p>[N:6] <input type="radio"/> Conscious Sedation</p> <p>[N:7] <input type="radio"/> General Anaesthetic</p> <p>[N:8] <input type="radio"/> Not related to study procedure</p> <p>[N:9] <input type="radio"/> [itmPAERepOr] <input type="checkbox"/></p> <p>Other</p> <p>[itmRltdOr]</p> <p>Please specify</p> <p>A200</p>
7.* <input checked="" type="checkbox"/>	Outcome [Outcome]	[itmPAEOtcom] [N:1] <input type="radio"/> [itmPAERSlvd] <input type="checkbox"/>

Resolved

[itmRsItmDt]

Date of resolution

Req / Req / Req (2018-2030)

[N:2] Unresolved at the time of study exit closure

[N:3] Records not available to determine resolution at the time of study exit/closure

8. ✓	Low Level Term - Code [hidden] [Low Level Term - Code]	[itmAELLTCod] N8
9. ✓	Low Level Term - Term [hidden] [Low Level Term - Term]	[itmAELLTTrm] A100
10. ✓	Preferred Term - Code [hidden] [Preferred Term - Code]	[itmAEPrfTCod] N8
11. ✓	Preferred Term - Term [hidden] [Preferred Term - Term]	[itmAEPrfTTrm] A100
12. ✓	High Level Group Term - Code [hidden] [High Level Group Term - Code]	[itmAEHLGTCod] N8
13. ✓	High Level Group Term - Term [hidden] [High Level Group Term - Term]	[itmAEHLGTTTrm] A100
14. ✓	High Level Term - Code [hidden] [High Level Term - Code]	[itmAEHLTCod] N8
15. ✓	High Level Term - Term [hidden] [High Level Term - Term]	[itmAEHLTTrm] A100
16. ✓	System Organ Class - Code [hidden] [System Organ Class - Code]	[itmAESOCCod] N8
17. ✓	System Organ Class - Term [hidden] [System Organ Class - Term]	[itmAESOCTrm] A100
18. ✓	Dictionary Version [hidden] [Dictionary Version]	[itmAEDicVer] A10

Key: [✓] = Source verification required [🔍] = Source verification critical [⌵] = Item is collapsible

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Adverse Events		
Type	RefName	Description
Form	frmPAE	Adverse Events

RDE Analytics: RD_FRMPAE		
Data Variable RefName	RD Column Name	Column Data Type
itmPAEDesc	ITMPAEDESC_C	**NUMBER

	ITMPAEDESC	VARCHAR2
	ITMPAEDESC_ND	VARCHAR2
itmPAEDesc - itmPAEVp	ITMPAEVP_C	NUMBER
	ITMPAEVP	VARCHAR2
itmPAEDesc - itmPAEAMri	ITMPAEAMRI_C	NUMBER
	ITMPAEAMRI	VARCHAR2
itmPAEDesc - itmPAEPUS	ITMPAEPUS_C	NUMBER
	ITMPAEPUS	VARCHAR2
itmPAEDesc - itmPrb	ITMPRB_C	NUMBER
	ITMPRB	VARCHAR2
itmPAEDesc - itmPAECsp	ITMPAECSP_C	NUMBER
	ITMPAECSP	VARCHAR2
itmPAEDesc - itmPAEGAnsth	ITMPAEGANSTH_C	NUMBER
	ITMPAEGANSTH	VARCHAR2
itmPAEDesc - itmPAEOtrs	ITMPAEOTRS	VARCHAR2
itmPAEEvtdt	ITMPAEEVTDt	DATE
	ITMPAEEVTDt_DTS	VARCHAR2
	ITMPAEEVTDt_ND	VARCHAR2
itmPAEEvtsit	ITMPAEEVTSIT	DATE
	ITMPAEEVTSIT_DTS	VARCHAR2
	ITMPAEEVTSIT_ND	VARCHAR2
itmPAESpnsrDt	ITMPAESPNsRDT	DATE
	ITMPAESPNsRDT_DTS	VARCHAR2
	ITMPAESPNsRDT_ND	VARCHAR2
itmPAESerious	ITMPAESERIOUS_C	NUMBER
	ITMPAESERIOUS	VARCHAR2
	ITMPAESERIOUS_ND	VARCHAR2
itmPAESerious - itmAESrOthrdtl	ITMAESROTHRDTL	VARCHAR2
itmPAERel	ITMPAEREL_C	NUMBER
	ITMPAEREL	VARCHAR2
	ITMPAEREL_ND	VARCHAR2
itmPAERel - itmRltdOr	ITMRLTDOR	VARCHAR2
itmPAEOtcom	ITMPAEOTCOM_C	**NUMBER
	ITMPAEOTCOM	VARCHAR2
	ITMPAEOTCOM_ND	VARCHAR2
itmPAEOtcom - itmRsItndt	ITMRSLTNDT	DATE
	ITMRSLTNDT_DTS	VARCHAR2
itmAELLTCod	ITMAELLTCOD	NUMBER
	ITMAELLTCOD_ND	VARCHAR2
itmAELLTTRm	ITMAELLTTRM	VARCHAR2
	ITMAELLTTRM_ND	VARCHAR2

itmAEPrfTCod	ITMAEPRFTCOD	NUMBER
	ITMAEPRFTCOD_ND	VARCHAR2
itmAEPrfTTrm	ITMAEPRFTTRM	VARCHAR2
	ITMAEPRFTTRM_ND	VARCHAR2
itmAEHLGTCod	ITMAEHLGTCOD	NUMBER
	ITMAEHLGTCOD_ND	VARCHAR2
itmAEHLGTTrm	ITMAEHLGTTRM	VARCHAR2
	ITMAEHLGTTRM_ND	VARCHAR2
itmAEHLTCod	ITMAEHLTCOD	NUMBER
	ITMAEHLTCOD_ND	VARCHAR2
itmAEHLTTrm	ITMAEHLTTRM	VARCHAR2
	ITMAEHLTTRM_ND	VARCHAR2
itmAESOCCod	ITMAESOCCOD	NUMBER
	ITMAESOCCOD_ND	VARCHAR2
itmAESOCTrm	ITMAESOCTRM	VARCHAR2
	ITMAESOCTRM_ND	VARCHAR2
itmAEDicVer	ITMAEDICVER	VARCHAR2
	ITMAEDICVER_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: SAE Report Form (SAE REP) - Repeating Form [frmSAER]																
#	SAE Number	Related to AE Number	Date of notification	Why was the event serious?	Where did the SAE take place?	Date of onset	Severity	Outcome	Date of outcome	Causal Relationship to event	Expectedness	Action taken	Serious Adverse Event Term	Briefly describe SAE	Assessment of the implications, if any, for the safety of study participants	How will these be addressed
1																
SAE Report Form [frmSAER]																
1.* <input checked="" type="checkbox"/>	SAE Number <i>[read-only]</i> [SAE Number]						[itmSAENo] N3									
2.* <input checked="" type="checkbox"/>	Related to AE Number [Related to AE Number]						[itmSAEAENo] N3									
Serious Adverse Event Information [secSAEInfo]																
3.* <input checked="" type="checkbox"/>	Date of notification [Date of notification]						[itmSAEDatNot] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)									
4.* <input checked="" type="checkbox"/>	Why was the event serious? [Why was the event serious?]						[itmSAEWhySer] [N:1] <input type="radio"/> 1 = Resulted in Death [N:2] <input type="radio"/> 2 = Life-threatening [N:5] <input type="radio"/> 3 = Required inpatient hospitalisation or prolongation of existing hospitalisation [N:4] <input type="radio"/> 4 = Resulted in persistent or significant disability/incapacity [N:3] <input type="radio"/> 5 = Resulted in congenital anomaly/birth defect [N:6] <input type="radio"/> [itmSAESerOthC] <input type="checkbox"/> 6 = Other medically important event [itmSAESerOth] Please provide details A200 [N:7] <input type="radio"/> 7 = None of the above									
5.* <input checked="" type="checkbox"/>	Where did the SAE take place? [Where did the SAE take place?]						[itmSAETakPlac] [N:1] <input type="radio"/> 1=Hospital [N:2] <input type="radio"/> 2=Out-patient clinic [N:3] <input type="radio"/> 3=Home [N:4] <input type="radio"/> 4=Nursing Home [N:5] <input type="radio"/> 5=Hospice [N:6] <input type="radio"/> [itmSAETakPlcC] <input type="checkbox"/> 6=Other [itmSAEOTkPlc] Please provide details A200									
6.* <input checked="" type="checkbox"/>	Date of onset [Date of onset]						[itmSAEDatOnset] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)									
7.* <input checked="" type="checkbox"/>	Severity [Severity]						[itmSAESev] [N:1] <input type="radio"/> 1=Mild [N:2] <input type="radio"/> 2=Moderate [N:3] <input type="radio"/> 3=Severe [N:4] <input type="radio"/> 4=Life threatening or disabling [N:5] <input type="radio"/> 5=Fatal									
8.* <input checked="" type="checkbox"/>	Outcome [Outcome]						[itmSAEOut] [N:1] <input type="radio"/> Resolved									

		[N:2] <input type="radio"/> Resolved with sequelae [N:3] <input type="radio"/> Persisting [N:4] <input type="radio"/> Worsened [N:5] <input type="radio"/> Fatal [N:6] <input type="radio"/> Not assessable
9. <input checked="" type="checkbox"/>	Date of outcome [Date of outcome]	[itmSAEDatOut] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
10.* <input checked="" type="checkbox"/>	Causal Relationship to event <i>[read-only]</i> [Causal Relationship to event]	[itmSAECasRel] [N:1] <input type="radio"/> Definitely [N:2] <input type="radio"/> Probably [N:3] <input type="radio"/> Possibly [N:4] <input type="radio"/> Unlikely [N:5] <input type="radio"/> Not related [N:6] <input type="radio"/> Not assessable
11.* <input checked="" type="checkbox"/>	Expectedness <i>[read-only]</i> [Expectedness]	[itmSAEExp] [N:1] <input type="radio"/> Expected [N:2] <input type="radio"/> Unexpected
12.* <input checked="" type="checkbox"/>	Action taken <i>[read-only]</i> [Action taken]	[itmSAEAct] [N:0] <input type="radio"/> 0=None [N:1] <input type="radio"/> 1=Dose reduction [N:2] <input type="radio"/> 2=Dose increase [N:3] <input type="radio"/> 3=Treatment delayed [N:4] <input type="radio"/> 4=Treatment delayed and reduced [N:5] <input type="radio"/> 5=Treatment permanently stopped
13.* <input checked="" type="checkbox"/>	Serious Adverse Event Term [Serious Adverse Event Term]	[itmSAESAETerm] <input type="text" value="A40"/>
14.* <input checked="" type="checkbox"/>	Briefly describe SAE (include relevant symptoms, body site, relevant lab tests and treatments received for management of the SAE) [Briefly describe SAE]	[itmSAEDesc] <input type="text" value="A2000"/>
15. <input checked="" type="checkbox"/>	Low Level Term - Code <i>[hidden]</i> [Low Level Term - Code]	[itmSAELLTCod] <input type="text" value="N8"/>
16. <input checked="" type="checkbox"/>	Low Level Term - Term <i>[hidden]</i> [Low Level Term - Term]	[itmSAELLTTrm] <input type="text" value="A100"/>
17. <input checked="" type="checkbox"/>	Preferred Term - Code <i>[hidden]</i> [Preferred Term - Code]	[itmSAEPFTCod] <input type="text" value="N8"/>
18. <input checked="" type="checkbox"/>	Preferred Term - Term <i>[hidden]</i> [Preferred Term - Term]	[itmSAEPFTTrm] <input type="text" value="A100"/>
19. <input checked="" type="checkbox"/>	High Level Group Term - Code <i>[hidden]</i> [High Level Group Term - Code]	[itmSAEHLGTCod] <input type="text" value="N8"/>
20. <input checked="" type="checkbox"/>	High Level Group Term - Term <i>[hidden]</i> [High Level Group Term - Term]	[itmSAEHLGTTTrm] <input type="text" value="A100"/>
21. <input checked="" type="checkbox"/>	High Level Term - Code <i>[hidden]</i> [High Level Term - Code]	[itmSAEHLTCod] <input type="text" value="N8"/>

22. ✓	High Level Term - Term <i>[hidden]</i> [High Level Term - Term]	[itmSAEHLTTrm] A100
23. ✓	System Organ Class - Code <i>[hidden]</i> [System Organ Class - Code]	[itmSAESOCod] N8
24. ✓	System Organ Class - Term <i>[hidden]</i> [System Organ Class - Term]	[itmSAESOCTrm] A100
25. ✓	Dictionary Version <i>[hidden]</i> [Dictionary Version]	[itmSAEDictVer] A10
PI Assessment [secOthInfor]		
26.* ☑	Assessment of the implications, if any, for the safety of study participants <i>[read-only]</i> [Assessment of the implications, if any, for the safety of study participants]	[itmSAEOthInfo] A500
27.* ☑	How will these be addressed <i>[read-only]</i> [How will these be addressed]	[itmSAEExpClin] A500

Key: [*] = Item is required [✓] = Source verification required [☑] = Source verification critical [⌵] = Item is collapsible
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.
Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: SAE Report Form		
Type	RefName	Description
Form	frmSAER	Serious Adverse Event Report Form
Section	secSAEInfo	Serious Adverse Event Information
Section	secOthInfor	Other Information

RDE Analytics: RD_FRMSAER		
Data Variable RefName	RD Column Name	Column Data Type
itmSAENo	ITMSAENO	NUMBER
	ITMSAENO_ND	VARCHAR2
itmSAEAENO	ITMSAEAENO	NUMBER

	ITMSAEAEENO_ND	VARCHAR2
itmSAEDatNot	ITMSAEDATNOT	DATE
	ITMSAEDATNOT_DTS	VARCHAR2
	ITMSAEDATNOT_ND	VARCHAR2
itmSAEWhySer	ITMSAEWHYSER_C	NUMBER
	ITMSAEWHYSER	VARCHAR2
	ITMSAEWHYSER_ND	VARCHAR2
itmSAEWhySer - itmSAESerOth	ITMSAESEROTH	VARCHAR2
itmSAETakPlac	ITMSAETAKPLAC_C	NUMBER
	ITMSAETAKPLAC	VARCHAR2
	ITMSAETAKPLAC_ND	VARCHAR2
itmSAETakPlac - itmSAEOTkPlc	ITMSAEOTKPLC	VARCHAR2
itmSAEDatOnset	ITMSAEDATONSET	DATE
	ITMSAEDATONSET_DTS	VARCHAR2
	ITMSAEDATONSET_ND	VARCHAR2
itmSAESev	ITMSAESEV_C	NUMBER
	ITMSAESEV	VARCHAR2
	ITMSAESEV_ND	VARCHAR2
itmSAEOut	ITMSAEOUT_C	NUMBER
	ITMSAEOUT	VARCHAR2
	ITMSAEOUT_ND	VARCHAR2
itmSAEDatOut	ITMSAEDATOUT	DATE
	ITMSAEDATOUT_DTS	VARCHAR2
	ITMSAEDATOUT_ND	VARCHAR2
itmSAECasRel	ITMSAECASREL_C	NUMBER
	ITMSAECASREL	VARCHAR2
	ITMSAECASREL_ND	VARCHAR2
itmSAEExp	ITMSAEEXP_C	NUMBER
	ITMSAEEXP	VARCHAR2
	ITMSAEEXP_ND	VARCHAR2
itmSAEAct	ITMSAEACT_C	NUMBER
	ITMSAEACT	VARCHAR2
	ITMSAEACT_ND	VARCHAR2
itmSAESAETerm	ITMSAESAETERM	VARCHAR2
	ITMSAESAETERM_ND	VARCHAR2
itmSAEDesc	ITMSAEDESC	VARCHAR2
	ITMSAEDESC_ND	VARCHAR2
itmSAELLTCod	ITMSAELLTCOD	NUMBER
	ITMSAELLTCOD_ND	VARCHAR2
itmSAELLTTrm	ITMSAELLTTRM	VARCHAR2
	ITMSAELLTTRM_ND	VARCHAR2

itmSAEPFTCod	ITMSAEPFTCOD	NUMBER
	ITMSAEPFTCOD_ND	VARCHAR2
itmSAEPFTTrm	ITMSAEPFTTRM	VARCHAR2
	ITMSAEPFTTRM_ND	VARCHAR2
itmSAEHLGTCod	ITMSAEHLGTCOD	NUMBER
	ITMSAEHLGTCOD_ND	VARCHAR2
itmSAEHLGTTrm	ITMSAEHLGTTRM	VARCHAR2
	ITMSAEHLGTTRM_ND	VARCHAR2
itmSAEHLTCod	ITMSAEHLTCOD	NUMBER
	ITMSAEHLTCOD_ND	VARCHAR2
itmSAEHLTTrm	ITMSAEHLTTRM	VARCHAR2
	ITMSAEHLTTRM_ND	VARCHAR2
itmSAESOCCod	ITMSAESOCCOD	NUMBER
	ITMSAESOCCOD_ND	VARCHAR2
itmSAESOCTrm	ITMSAESOCTRM	VARCHAR2
	ITMSAESOCTRM_ND	VARCHAR2
itmSAEDictVer	ITMSAEDICTVER	VARCHAR2
	ITMSAEDICTVER_ND	VARCHAR2
itmSAEOthInfo	ITMSAEOTHINFO	VARCHAR2
	ITMSAEOTHINFO_ND	VARCHAR2
itmSAEExpClin	ITMSAEEXPCLIN	VARCHAR2
	ITMSAEEXPCLIN_ND	VARCHAR2

PROSTAGRAM: CI Review Form (CI REVIEW) - Repeating Form [frmCIR]

#	SAE Number	Serious Adverse Event Term	Study Treatment
1			

CI Review Form [frmCIR]

1 *

SAE Number [read-only]
[SAE Number]

[itmCISAENo]
N3

2 *

Serious Adverse Event Term [read-only]
[Serious Adverse Event Term]

[itmCISAErm]
A40

Study Treatment [secCIIMP]

#	Study Treatment Name*	Was the SAE related to treatment*	Causal Relationship to event*	Expectedness*	Comments
3.a	Prostate biopsy				
3.b	Other treatment				

Study Treatment Entry [secCIIMP]

3.1 *

Study Treatment Name [read-only]
[Study Treatment Name]

[itmCIIMPnam]
[N:1] ☐ Prostate biopsy
[N:2] ☐ Other treatment

3.2 *

Was the SAE related to treatment [read-only]
[Was the SAE related to treatment]

[itmCISAERel]
[N:1] ☐ Yes
[N:0] ☐ No

3.3 *

Causal Relationship to event [read-only]
[Causal Relationship to event]

[itmCIReL]
[N:1] ☐ Definitely
[N:2] ☐ Probably
[N:3] ☐ Possibly
[N:4] ☐ Unlikely
[N:5] ☐ Not related
[N:6] ☐ Not assessable

3.4 *

Expectedness [read-only]
[Expectedness]

[itmCISAEExp]
[N:1] ☐ Expected
[N:2] ☐ Unexpected

3.5

Comments [read-only]
[Comments]

[itmCICom]
A200

Key: ☒ = Source verification critical ☐ = Fixed item

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

Study Object Descriptions: CI Review Form		
Type	RefName	Description
Form	frmCIR	CI Review
Section	secCIIMP	CIIMP

RDE Analytics: RD_FRMCIR		
Data Variable	RefName	RD Column Name
itmCISAENo		ITMCISAENO
		NUMBER

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe_137e31086639fb5d_0002.0000_c16... 03/05/2019

	ITMCISAENO_ND	VARCHAR2
itmCISAEterm	ITMCISAETERM	VARCHAR2
	ITMCISAETERM_ND	VARCHAR2
RD_FRMCIR_SECCIIMP		
itmCIIMPnam	ITMCIIMPnam_C	NUMBER
	ITMCIIMPnam	VARCHAR2
	ITMCIIMPnam_ND	VARCHAR2
itmCISAErel	ITMCISAEREL_C	NUMBER
	ITMCISAEREL	VARCHAR2
	ITMCISAEREL_ND	VARCHAR2
itmCIrel	ITMCIREL_C	NUMBER
	ITMCIREL	VARCHAR2
	ITMCIREL_ND	VARCHAR2
itmCISAEexp	ITMCISAEEXP_C	NUMBER
	ITMCISAEEXP	VARCHAR2
	ITMCISAEEXP_ND	VARCHAR2
itmCICom	ITMCICOM	VARCHAR2
	ITMCICOM_ND	VARCHAR2

PROSTAGRAM: Device Deficiency Worksheet (DEV DEF) [frmDD]		
Device Deficiency Worksheet [frmDD]		
1.* ✔	Date Device Deficiency occurred [Date Device Deficiency occurred]	[itmDDDevicDt] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
2.* ✔	Site/Sponsor Aware Date [Site/Sponsor Aware Date]	[itmDDSiteDt] Req <input type="text"/> / Req <input type="text"/> / Req <input type="text"/> (2018-2030)
3.* ✔	Visit associated with this Event [Visit associated with this Event]	[itmDDEvt] [N:0] <input type="radio"/> Visit 1: Screening Visit [N:1] <input type="radio"/> Visit 2: Prostate Biopsy [N:2] <input type="radio"/> Visit 3: Follow up [N:3] <input type="radio"/> [itmDDOthr] <input type="text"/> Other [itmEvtOtr] Please give details A100
4.* ✔	Event Description: Select component the device deficiency was observed in [Event Description]	[itmDDEvtDesc] [N:0] <input type="radio"/> Magnetic Resonance Scanner [N:1] <input type="radio"/> Aixplorer Ultrasound System [N:2] <input type="radio"/> Watson Elementary (CAD/AI) [N:3] <input type="radio"/> [itmDDDescOthr] <input type="text"/> Other [itmDesOtr] Please give details A100
5. ✔	Component Model Number (if applicable) [Component Model Number (if applicable)]	[itmDDCompMN] A30
6. ✔	Component Serial Number (if applicable) [Component Serial Number (if applicable)]	[itmDDCompSN] A30
7. ✔	Component Lot Number (if applicable) [Component Lot Number]	[itmDDCompLN] A30
8.* ✔	Device Deficiency [Device Deficiency]	[itmDDDef] [N:0] <input type="radio"/> Malfunction [N:1] <input type="radio"/> User Error [N:2] <input type="radio"/> [itmDDDefOthr] <input type="text"/> Other [itmDevDOtr] Please give details A100
9. ✔	Narrative: Please provide details of Device Deficiency, relevant circumstances, outcome, etc. [Narrative]	[itmDDNarratv] A100
10.* ✔	Was the Device Deficiency associated with an Adverse Event? [Associated with an Adverse Event]	[itmDDAsst] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
11.*	Could the device deficiency have led to a Serious Adverse Event (SAE) if:	[itmDDLed]

a) suitable action had not been taken or
b) intervention had not been made or
c) if circumstances had been less fortunate?
[Led to a Serious Adverse Event]

[N:1]

Yes

[N:0]

No

Key: [*] = Item is required [✓] = Source verification required [🔍] = Source verification critical [⊞] = Item is collapsible

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Study Object Descriptions: Device Deficiency Worksheet

Type	RefName	Description
Form	frmDD	Device Deficiency Worksheet

RDE Analytics: RD_FRMDD		
Data Variable RefName	RD Column Name	Column Data Type
itmDDDevicDt	ITMDDDEVICDT	DATE
	ITMDDDEVICDT_DTS	VARCHAR2
	ITMDDDEVICDT_ND	VARCHAR2
itmDDSiteDt	ITMDDSITEDT	DATE
	ITMDDSITEDT_DTS	VARCHAR2
	ITMDDSITEDT_ND	VARCHAR2
itmDDEvnt	ITMDDEVNT_C	NUMBER
	ITMDDEVNT	VARCHAR2
	ITMDDEVNT_ND	VARCHAR2
itmDDEvnt - itmEvtOtr	ITMEVTOTR	VARCHAR2
itmDDEvtDesc	ITMDDEVTDESC_C	NUMBER
	ITMDDEVTDESC	VARCHAR2
	ITMDDEVTDESC_ND	VARCHAR2
itmDDEvtDesc - itmDesOtr	ITMDESOTR	VARCHAR2
itmDDCompMN	ITMDDCOMPMN	VARCHAR2
	ITMDDCOMPMN_ND	VARCHAR2
itmDDCompSN	ITMDDCOMPSN	VARCHAR2
	ITMDDCOMPSN_ND	VARCHAR2
itmDDCompLN	ITMDDCOMPLN	VARCHAR2
	ITMDDCOMPLN_ND	VARCHAR2
itmDDDef	ITMDDDEF_C	NUMBER
	ITMDDDEF	VARCHAR2
	ITMDDDEF_ND	VARCHAR2
itmDDDef - itmDevDOtr	ITMDEVDOTR	VARCHAR2
itmDDNarratv	ITMDDNARRATV	VARCHAR2
	ITMDDNARRATV_ND	VARCHAR2
itmDDAsst	ITMDDASST_C	NUMBER
	ITMDDASST	VARCHAR2

	ITMDDASST_ND	VARCHAR2
itmDDLed	ITMDDLED_C	NUMBER
	ITMDDLED	VARCHAR2
	ITMDDLED_ND	VARCHAR2

PROSTAGRAM: Study Exit (EOS) [frmEOS]

Study Exit [frmEOS]

1.*

Did the subject complete the study?

[Subject complete the study?]

[itmEOSCompYN]

[N:1] [itmEOSDATC]

Yes

[itmEOSComDt]

Date of completion

Req / Req / Req (2018-2030)

[N:2] [itmEOSNo]

No

[itmEOSRsn]

Reason for Exit

[N:0] Screening Failure

[N:1] Patient withdrew consent

[N:2] Investigator withdrew subject consent

[N:3] Death

[N:4] [itmEOSOthRsn]

Other reason

A200

[itmEOSDatDis]

Date of Exit

Req / Req / Req (2018-2030)

2.*

Adverse Events: Were there any adverse events between the last visit and the study exit?

[Adverse Events]

[itmEOSAdv]

[N:1] Yes

[N:0] No

3.*

Are there any unresolved AEs that need to be updated?

[Unresolved AEs]

[itmEOSUAEs]

[N:1] Yes

[N:0] No

Key: [*] = Item is required [✓] = Source verification required [✔] = Source verification critical [⌵] = Item is collapsible

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.



Note: Collapsible settings are only available to users who have the rights to edit the item.

Study Object Descriptions: Study Exit		
Type	RefName	Description
Form	frmEOS	End of study
Item	itmEOSComDt	Termination Date

RDE Analytics: RD_FRMEOS		
Data Variable RefName	RD Column Name	Column Data Type
itmEOSCompYN	ITMEOSCOMPYN_C	**NUMBER
	ITMEOSCOMPYN	VARCHAR2
	ITMEOSCOMPYN_ND	VARCHAR2
itmEOSCompYN - itmEOSComDt	ITMEOSCOMDT	DATE
	ITMEOSCOMDT_DTS	VARCHAR2

file:///C:/Users/smitadas/AppData/Local/Apps/2.0/OW9HQXMA.3PX/0028QNWE.8X6/orac...exe_137e31086639fb5d_0002.0000_c16... 03/05/2019

itmEOSCompYN - itmEOSRsn	ITMEOSRSN_C	NUMBER
	ITMEOSRSN	VARCHAR2
itmEOSCompYN - itmEOSOthRsn	ITMEOSOTHRSN	VARCHAR2
itmEOSCompYN - itmEOSDatDis	ITMEOSDATDIS	DATE
	ITMEOSDATDIS_DTS	VARCHAR2
itmEOSAdv	ITMEOSADV_C	NUMBER
	ITMEOSADV	VARCHAR2
	ITMEOSADV_ND	VARCHAR2
itmEOSUAES	ITMEOSUAES_C	NUMBER
	ITMEOSUAES	VARCHAR2
	ITMEOSUAES_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

PROSTAGRAM: Study Sign Off (SIGN OFF) [frmSIGNOFF]		
Study Sign Off [frmSIGNOFF]		
1.* 	Is the case book ready for sign off? [Case book ready for sign off?]	[itmSIGNOFF] [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No
Key: [*] = Item is required [] = Source verification critical Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

Study Object Descriptions: Study Sign Off		
Type	RefName	Description
Form	frmSIGNOFF	Study Sign Off

RDE Analytics: RD_FRMSIGNOFF			
Data Variable	RefName	RD Column Name	Column Data Type
itmSIGNOFF		ITMSIGNOFF_C	NUMBER
		ITMSIGNOFF	VARCHAR2
		ITMSIGNOFF_ND	VARCHAR2

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 SCR.V.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 SCR.V.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 SCR.V.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

	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