Annotated Study Book for Study Design: SPI-1012

Study Design Version: 1.0

**Sponsor: Spectrum Pharmaceuticals** 

Protocol: SPI-1012

A Phase 3 International, Multicenter, Double-Blind, Placebo-Controlled, Randomized Trial Evaluating the Efficacy and Safety of Multiple Instillations of Intravesical Apaziquone vs. Placebo in Patients with Low-Intermediate Risk Non-Muscle Invasive Bladder Cancer (NMIBC)

Generated by Central Designer <sup>TM</sup>
December 19, 2011 10:56AM

SPI-1012: SYSTEM SCREENING (SYS SCR) [SYSSCR]			
SYSTEM SCREENING [SYSSCR]			
1.* Patient Initials [SSUBINIT]  Patient Initials [A3]			
2.* Date of Birth [Date of Birth]	[SBRTHDAT]   Req ▼ /   Req ▼ /   Req ▼ (1914-1995)		
3.* Date Informed Consent Signed [Date Informed Consent Signed]	[SICDAT]   Req ▼ /   Req ▼ /   Req ▼ (2012-2014)		
Key: [*] = Item is required [ ✓ ] = Source verification required			

RDE Analytics: RD_SYSSCR					
Data Variable RefName	RD Column Name	Column Data Type			
SSUBINIT	SSUBINIT	VARCHAR2			
	SSUBINIT_ND	VARCHAR2			
SBRTHDAT	SBRTHDAT	DATE			
	SBRTHDAT_DTS	VARCHAR2			
	SBRTHDAT_DTR	VARCHAR2			
	SBRTHDAT_ND	VARCHAR2			
SICDAT	SICDAT	DATE			
	SICDAT_DTS	VARCHAR2			
	SICDAT_ND	VARCHAR2			

SPI-1012: SYSTEM ENROLLMENT (SYS ENR) [SYSENR]			
SYSTEM ENROLLMENT [SYSENR]			
1.* Continue with system enrollment [Continue InForm Enrollment]	[SCONTE] [N:1]Yes		
Key: [*] = Item is required [ 🗸 ] = Source verification required			

Codelist Values and Tables: SYSTEM ENROLLMENT					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYES	Integer	Yes	1	CLIY	SCONTE

RDE Analytics: RD_SYSENR						
Data Variable RefName   RD Column Name   Column Data Type						
SCONTE	SCONTE_ND	VARCHAR2				
SCONTE - Yes	SCONTE_CLIY_C	NUMBER				
	SCONTE_CLIY	VARCHAR2				

SPI-1012: DATE OF VISIT (DOV) [DOV]		
DATE OF VISIT [DOV]		
	[VISDAT]  Req ☑ /   Req ☑ /   Req ☑ (2012-2017)	
Key: [*] = Item is required [ ✓ ] = Source verification required		

RDE Analytics: RD_DOV				
Data Variable RefName	RD Column Name	Column Data Type		
VISDAT	VISDAT	DATE		
	VISDAT_DTS	VARCHAR2		
	VISDAT_ND	VARCHAR2		

SPI-1012: DEMOGRAPHICS (DEM) [DM]	
INFORMED CONSENT [sctIC]	
	[ICDAT]   Req ♥ /   Req ♥ /   Req ♥ (2012-2014)
	[PROTVER] [N::1] ○ Original [N::99] ○ [PROTVERO] Other, specify: 0 < N2
DEMOGRAPHICS [sctDEM]	
	[SUBJINIT]
	[BRTHDAT]    Req ♥ /   Req/Unk ♥ /   Req ♥ (1914-1995)
	[ETHNIC] [N:1] OHispanic or Latino [N:2] ONot Hispanic or Latino
[Race]	RACE
[Gender]	[SEX] [N:1]
	[SUNCF] [N:1]
	[TOXEXP] [N:1]
Key: [*] = Item is required [✓] = Source verification required	

Stu	Study Object Descriptions: DEMOGRAPHICS				
Туре	RefName	Description			
Item	ICDAT	Value mapped from System Screening form and may be edited on this form			
Item	SUBJINIT	Value mapped from System Screening form and may be edited on this form			
Item	BRTHDAT	Value mapped from System Screening form and may be edited on this form			

Codelist Value	es and Tables: I	DEMOGRAPHICS			
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLPROTV	Integer	Original	1	ORIGINAL	PROTVER
		Other	99	OTHER	
CLETHNIC	Integer	Hispanic or Latino	1	HISP	ETHNIC
		Not Hispanic or Latino	2	NHISP	
CLRACE	Integer	American Indian or Alaska Native	1	INDALA	RACE
		Asian	2	ASIAN	
		Black or African American	3	BLACK	
		Native Hawaiian or Other Pacific Islander	4	HAWISL	
		White or Caucasian	5	WHITE	
		Other	99	OTHER	
CLSEX	Integer	Male	1	MALE	SEX
		Female	2	FEMALE	
CLYN	Integer	Yes	1	CLIY	SCTESTCB,
		No	0	CLIN	TOXEXP
CLSMOKST	Integer	Current	1	CURSMK	SUNCF
		Former	2	FORMSMK	
		Never	3	NEVERSMK	

Data Variable RefName	<b>RD Column Name</b>	Column Data Type
ICDAT	ICDAT	DATE
	ICDAT_DTS	VARCHAR2
	ICDAT_ND	VARCHAR2
PROTVER	PROTVER_C	NUMBER
	PROTVER	VARCHAR2
	PROTVER_ND	VARCHAR2
PROTVER - PROTVERO	PROTVERO	NUMBER
SUBJINIT	SUBJINIT	VARCHAR2
	SUBJINIT_ND	VARCHAR2
BRTHDAT	BRTHDAT	DATE
	BRTHDAT_DTS	VARCHAR2
	BRTHDAT_DTR	VARCHAR2
	BRTHDAT_ND	VARCHAR2
ETHNIC	ETHNIC_C	NUMBER
	ETHNIC	VARCHAR2
	ETHNIC_ND	VARCHAR2
RACE	RACE_ND	VARCHAR2
RACE - American Indian or Alaska Native	RACE_INDALA_C	NUMBER
	RACE_INDALA	VARCHAR2
RACE - Asian	RACE_ASIAN_C	NUMBER
	RACE_ASIAN	VARCHAR2
RACE - Black or African American	RACE_BLACK_C	NUMBER
	RACE_BLACK	VARCHAR2
RACE - Native Hawaiian or Other Pacific Islander	RACE_HAWISL_C	NUMBER
	RACE_HAWISL	VARCHAR2
RACE - White or Caucasian	RACE_WHITE_C	NUMBER
	RACE_WHITE	VARCHAR2
RACE - Other	RACE_RACEOTH_C	NUMBER
	RACE_RACEOTH	VARCHAR2
RACE - RACEOTH	RACEOTH	VARCHAR2
SEX	SEX_C	NUMBER
	SEX	VARCHAR2

	SEX_ND	VARCHAR2
SEX - SCTESTCB	SCTESTCB_C	NUMBER
	SCTESTCB	VARCHAR2
SUNCF	SUNCF_C	NUMBER
	SUNCF	VARCHAR2
	SUNCF_ND	VARCHAR2
TOXEXP	TOXEXP_C	NUMBER
	TOXEXP	VARCHAR2
	TOXEXP_ND	VARCHAR2

SF	PI-1012: INCLUSION/EXCLUSION CRITERIA (open-label) (INC/EXC (OL)) [IE]			
IN	CLUSION/EXCLUSION CRITERIA (open-label) [IE]			
1.*	the patient meet all inclusion and exclusion criteria? ', click the Add Entry button below to record details All Criteria?]		Yes  [IEWO]  No, Was a waiver obtained?  (N:1) OIEWODAT]  Yes, Date of Waiver:    Req v /   Req v /   Req v (2012-2017)  (N:0) No	
	Inclusion or Exclusion		Criterion Identifier	
2.				
Inc	clusion/Exclusion Criteria Not Met Entry [sctIENMET]			
2.1	* Inclusion or Exclusion? [Inclusion or Exclusion]	[IECAT] [N:1]	olnclusion [N:2] ○ Exclusion	
2.2	* Criterion Identifier [Criterion Identifier]	0 < N2	D)	
К	ey: [*] = Item is required [ ✓ ] = Source verification required			

Codelist Values and Tables: INCLUSION/EXCLUSION CRITERIA (open-label)					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLIY	IEYN,
		No	0	CLIN	IEWO
CLINCEXC	Integer	Inclusion	1	INCL	IECAT
		Exclusion	2	EXCL	

Data Variable RefName	RD Column Name	Column Data Type
IEYN	IEYN_C	NUMBER
	IEYN	VARCHAR2
	IEYN_ND	VARCHAR2
IEYN - IEWO	IEWO_C	**NUMBER
	IEWO	VARCHAR2
IEYN - IEWODAT	IEWODAT	DATE
	IEWODAT_DTS	VARCHAR2
RD_IE_SCTIENMET		
IECAT	IECAT_C	NUMBER
	IECAT	VARCHAR2
	IECAT_ND	VARCHAR2
IETESTCD	IETESTCD	NUMBER
	IETESTCD_ND	VARCHAR2

_								
SP	I-1012: GENER	AL MEDICAL HISTORY (MH) [M	IH]					
GEN	NERAL MEDICAL HIS	STORY [MH]						
	1.* Is there any significant medical history (other than bladder cancer) to report?  If 'Yes', click Add Entry button below to record details [Significant Medical History?]			[MHYN] [N:1]				
	Line #	Body System	Condition/Diagnosis		Start Date	End Date	Ongoing Meds?	
2.								
Me	dical History Entry [	MHA]						
Rec	Record any significant medical history (other than bladder cancer). Provide approximate dates.							
2.1	2.1 Line # [read-only] [Line #]			[MHSPID] N10				
2.2	* Body System [Body System]			[MHCAT] [CLMHBSYS]				
2.3	2.3° Condition/Diagnosis [Condition/Diagnosis]			[MHTERM] A200				
2.4"   Start Date   [Start Date]								
2.5* End Date [End Date]			[MHONGO] [N:0] ○ [MHENDAT]   Reg/Unk ♥ /   Reg/Unk ♥ /   Reg ♥ (1914-2017)					
2.6 Ongoing Meds?  * If 'Yes', please enter details on the Concomitant Medications form [Ongoing Meds?]			[MHONGM] [N:1]  Yes [N:0]	○ No				
Ke	Key: [*] = Item is required [ ▼ ] = Source verification required							

	Study Object Descriptions: GENERAL MEDICAL HISTORY				
Type RefName		RefName	Description		
Item MHSPID Calculated Record ID					

Codelist Values and Tables: GENERAL MEDICAL HISTORY						
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName	
CLYN	Integer	Yes	1	CLIY	MHYN,	
		No	0	CLIN	MHONGM	
CLMHBSYS	Integer	Head, Eyes, Ears, Nose, Throat	1	HEENT	MHCAT	
		Dermatologic	2	DERMA		
		Respiratory	3	RESP		
		Cardiovascular	4	CARDIO		
		Gastrointestinal	5	GASTRO		
		Hepatobiliary	6	HEPATO		
		Genitourinary	7	GENITO		
		Musculoskeletal	8	MUSCULO		
		Endocrine/Metabolic	9	ENDOMET		
		Neurological	10	NEURO		
		Psychological	11	PSYCHO		
		Allergy	12	ALLERGY		
		Other	99	OTHER		
CLMHXONG	Integer	Date	0	DATEP	MHONGO	
		Ongoing	1	ONGOING		

Data Variable RefName	RD Column Name	Column Data Type
MHYN	MHYN_C	NUMBER
	MHYN	VARCHAR2
	MHYN_ND	VARCHAR2
RD_MH_MHA		
MHSPID	MHSPID	NUMBER
	MHSPID_ND	VARCHAR2
MHCAT	MHCAT_C	NUMBER
	MHCAT	VARCHAR2
	MHCAT_ND	VARCHAR2
MHTERM	MHTERM	VARCHAR2
	MHTERM_ND	VARCHAR2
MHSTDAT	MHSTDAT	DATE
	MHSTDAT_DTS	VARCHAR2
	MHSTDAT_DTR	VARCHAR2
	MHSTDAT_ND	VARCHAR2
MHONGO	MHONGO_C	**NUMBER
	MHONGO	VARCHAR2
	MHONGO_ND	VARCHAR2
MHONGO - MHENDAT	MHENDAT	DATE
	MHENDAT_DTS	VARCHAR2
	MHENDAT_DTR	VARCHAR2
MHONGM	MHONGM_C	NUMBER
	MHONGM	VARCHAR2
	MHONGM_ND	VARCHAR2

SP	PI-1012: HISTORY OF BLADDER CANCER (CA HX) [CHX]						
HIS	STORY OF BLADDER	CANCER [CHX]					
1.*	Date of first patholog [Bladder Ca Diagnos	gic diagnosis of bladder cancer is Date]			[CHXDAT]     Reg/Unk   /   Req   (1914-2014)		
2.*	▼ [Disease Status at Study Entry]			[CHXDISST]  [N:3] ○ Primary  [N:2] ○ [CHXREGRP]  Recurrent,  [CHXCYDAT]  Date of last cystoscopy prior to the screening cystoscopy:    Req v   /   Req v   /   Req v   (1914-2014)  [CHXTUMR]  Were tumor(s) present? [N:1] ○ Yes [N:0] ○ No			
3.*		herapy for bladder cancer within 36 months prior to stud try button below to record details to Report?]	dy entry to report?		[CHXYN] [N:1] OYes [N:0] ONo		
	Line #	Surgery/Therapy	Agent/Site		Number of Courses	Date of Last Treatment	
4.							
Sui	urgery or Therapy for Bladder Cancer Entry [PTX]						
Red	ord the details for sur	gery or therapy for bladder cancer within 36 months pri	ior to study entry.				
4.1	Line # [read-only] [Line #]				[CHXSPID] N10		
4.2* Surgery/Therapy [Surgery/Therapy]				[CHXTYPE] [N::1]			
4.3	4.3* Agent(s)/Site(s) [Agent/Site]				[CHXAGSIT] A100		
4.4	4.4* Number of Courses [Number of Courses]				[CHXCOURS]		
4.5	* Date of Last Treatn [Date of Last Treat				[CHXTXDAT]   Reg/Unk ▼ / Reg/Unk ▼ /   Reg ▼ (1914-2014)		
K	ey: [*] = Item is require	ed [ ✔ ] = Source verification required					

	Study Object Descriptions: HISTORY OF BLADDER CANCER					
	Туре	RefName	Description			
ſ	Item	CHXSPID	Calculated Record ID			

Codelist Value	Codelist Values and Tables: HISTORY OF BLADDER CANCER					
Codelist RefName	Codelist RefName   Codelist Data Type		Code	Codelist Item RefName	Data Variable RefName	
CLDSTAT	Integer	Primary	1	DSPRIM	CHXDISST	
		Recurrent	2	DSRECUR		
CLYN	Integer	Yes	1	CLIY	CHXTUMR, CHXYN	
		No	0	CLIN		
CLBHXTYP	Integer	TURBT	1	TXTURBT	CHXTYPE	
		Immunotherapy	2	TXIMMUNO		
		Chemotherapy	3	TXCHEMO		
		Other	99	OTHER		

RDE Analytics: RD_CHX						
Data Variable RefName	RD Column Name	Column Data Type				
CHXDAT	CHXDAT	DATE				
	CHXDAT_DTS	VARCHAR2				
	CHXDAT_DTR	VARCHAR2				
	CHXDAT_ND	VARCHAR2				
CHXDISST	CHXDISST_C	NUMBER				
	CHXDISST	VARCHAR2				
	CHXDISST_ND	VARCHAR2				
CHXDISST - CHXCYDAT	CHXCYDAT	DATE				
	CHXCYDAT_DTS	VARCHAR2				
	CHXCYDAT_DTR	VARCHAR2				
CHXDISST - CHXTUMR	CHXTUMR_C	NUMBER				
	CHXTUMR	VARCHAR2				
CHXYN	CHXYN_C	NUMBER				
	CHXYN	VARCHAR2				
	CHXYN_ND	VARCHAR2				
RD_CHX_PTX						
CHXSPID	CHXSPID	NUMBER				
	CHXSPID_ND	VARCHAR2				
CHXTYPE	CHXTYPE_C	NUMBER				
	CHXTYPE	VARCHAR2				
	CHXTYPE_ND	VARCHAR2				
CHXTYPE - CHXTYPEO	CHXTYPEO	VARCHAR2				
CHXAGSIT	CHXAGSIT	VARCHAR2				
	CHXAGSIT_ND	VARCHAR2				
CHXCOURS	CHXCOURS	VARCHAR2				
	CHXCOURS_ND	VARCHAR2				
CHXTXDAT	CHXTXDAT	DATE				
	CHXTXDAT_DTS	VARCHAR2				
	CHXTXDAT DTR	VARCHAR2				
	CHXTXDAT ND	VARCHAR2				
		-				

SPI-1	SPI-1012: VITAL SIGNS (VS (BL)) [VSS]			
VITAL S	GIGNS [VSS]			
1.* Exar [Exa	mination Date amination Date]	[VSDAT]  Req ▼ /   Req ▼ /   Req ▼ (2012-2017)		
2.* Puls		[VSPULSE] N3 beats/min <sup>[b]</sup>		
3.* Bloo	ood Pressure]			
		VESTEMPU		
5.* Heig Hei	ght ght Group]	VSHTCRP   VSHTU		
6.* Weig		VESWTI		
Key: [*	*] = Item is required [ 🗸 ] = Source verification required [b] = Base Unit			

Study	Object D	escriptions: VITAL SIGNS
Туре	RefName	Description
Form	VSS	Vital Signs at Screening visit

Codelist Values and Tables: VITAL SIGNS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLTEMPU	Integer	°C	1	CELSIUS	VSTEMPU
		٥F	2	FAHREN	
CLHGTU	Integer	cm	1	CENT	VSHTU
		in	2	INCH	
CLWGTU	Integer	kg	1	KILO	VSWTU
		lb	2	POUND	

RDE Analytics: RD_VSS					
Data Variable RefName	RD Column Name	Column Data Type			
VSDAT	VSDAT	DATE			
	VSDAT_DTS	VARCHAR2			
	VSDAT_ND	VARCHAR2			
VSPULSE	VSPULSE	NUMBER			
	VSPULSE_U	VARCHAR2			
	VSPULSE_ND	VARCHAR2			
VSBPGRP	VSBPGRP_ND	VARCHAR2			
VSBPGRP - VSBPSYS	VSBPSYS	NUMBER			
VSBPGRP - VSBPDIA	VSBPDIA	NUMBER			
	VSBPDIA_U	VARCHAR2			
VSTMPGRP	VSTMPGRP_ND	VARCHAR2			
VSTMPGRP - VSTEMP	VSTEMP	FLOAT			
VSTMPGRP - VSTEMPU	VSTEMPU_C	NUMBER			
	VSTEMPU	VARCHAR2			
VSHTGRP	VSHTGRP_ND	VARCHAR2			
VSHTGRP - VSHT	VSHT	FLOAT			
VSHTGRP - VSHTU	VSHTU_C	NUMBER			
	VSHTU	VARCHAR2			
VSSWTGRP	VSSWTGRP_ND	VARCHAR2			
VSSWTGRP - VSWT	VSWT	FLOAT			
VSSWTGRP - VSWTU	VSWTU_C	NUMBER			
	VSWTU	VARCHAR2			

SPI-1012: PHYSICAL EXAMINATION (PE (BL)) [PE]					
PHYSICAL EXAMINATION [PE]					
1.* Was a physical examination performed?  **  **  **  **  **  **  **  **  **	[PEPER]				
Key: [*] = Item is required [ ✓ ] = Source verification required					

Codelist Values and Tables: PHYSICAL EXAMINATION					
<b>Codelist RefName</b>	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLIY	PEPERF
		No	0	CLIN	

Data Variable RefName	RD Column Name Column Data Type				
PEPERF	PEPERF_C	**NUMBER			
	PEPERF	VARCHAR2			
	PEPERF_ND	VARCHAR2			
PEPERF - PEDAT	PEDAT	DATE			
	PEDAT_DTS	VARCHAR2			
PEPERF - PENDRSN	PENDRSN	VARCHAR2			

SPI-1012: HEMATOLOGY/CHEMISTRY (HEM/CHEM) [LBHC]			
HEMATOLOGY/CHEMISTRY [LBHC]			
Specimen Collection for Central Laboratories			
1.* Hematology Blood Sample Collection Date [Hematology Collection Date]	[LBDATH]   Req   /   Req   /   Req   (2012-2017)		
2.* Chemistry Blood Sample Collection Date [Chemistry Collection Date]	[LEDATC]   Req ▼ /   Req ▼ /   Req ▼ (2012-2017)		
Key: [*] = Item is required [ v ] = Source verification required			

RDE Analytics: RD_LBHC				
Data Variable RefName	RD Column Name	e Column Data Type		
LBDATH	LBDATH	DATE		
	LBDATH_DTS	VARCHAR2		
	LBDATH_ND	VARCHAR2		
LBDATC	LBDATC	DATE		
	LBDATC_DTS	VARCHAR2		
	LBDATC_ND	VARCHAR2		

SI	PI-1012: URINE DIPSTICK (URIN) [LBU]					
	icroscopic examination may be performed as indicated by local standards of care. ny clinically significant abnormalities are to be reported on the MH form at baseline and on the AE form post baseline.					
1.	Collection Date [Collection Date]	[LBDATUD]   Req    /				
2.	Blood [Blood]	[BLOGRP] [LBORREB.] [CLNT1_3P]   Clinically Significant? [N:1] ○Yes [N:0] ○No				
3.	Protein [Protein]	[PROTGRP]       [LBCLSIPR]       [CLNT1_4P]     ✓ Clinically Significant? [N:1]     ○ Yes [N:0]     ○ No				
4.	Clucose [Glucose]	[GLUCGRP] [LBORREG] [CLINT1_4P] ✓ Clinically Significant? [N:1] ○Yes [N:0] ○No				
5.		[LUNCERP] [LBORRELE] [CLUTI_QP]   Clinically Significant? [N:1] ○Yes [N:0] ○No				
6.	Ketones [Ketones]	[KETOGRP] [LBORREKE] [LBCLSIKE] [CLNTSML]   Clinically Significant? [N:1] ○Yes [N:0] ○No				
ŀ	(ey: [*] = Item is required [ ✓ ] = Source verification required					

Codelist Value	s and Tables: l	JRINE D	DIPS	FICK	
<b>Codelist RefName</b>	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLNT1_3P	Integer	Negative	1	NEG	LBORREBL
		Trace	2	TRACEU	
		1+	3	ONEPL	
		2+	4	TWOPL	
		3+	5	THRPL	
CLYN	Integer	Yes	1	CLIY	LBCLSIBL, LBCLSIPR, LBCLSIGL, LBCLSILE, LBCLSIKE
		No	0	CLIN	
CLNT1_4P	Integer Negat Trace 1+ 2+ 3+	Negative	1	NEG	LBORREPR, LBORREGL, LBORRELE
		Trace	2	TRACEU	
		1+	3	ONEPL	
		2+	4	TWOPL	
		3+	5	THRPL	
		4+	6	FOURPL	
CLNTSML	Integer	Negative	1	NEG	LBORREKE
		Trace	2	TRACEU	
		Small	3	SMALL	
		Moderate	4	MOD	
		Large	5	LARGE	

Data Variable RefName   RD Column Name   Column Data Type						
LBDATUD	LBDATUD	DATE				
	LBDATUD_DTS	VARCHAR2				
	LBDATUD_ND	VARCHAR2				
BLDGRP	BLDGRP_ND	VARCHAR2				
BLDGRP - LBORREBL	LBORREBL_C	NUMBER				
	LBORREBL	VARCHAR2				
BLDGRP - LBCLSIBL	LBCLSIBL_C	NUMBER				
	LBCLSIBL	VARCHAR2				
PROTGRP	PROTGRP_ND	VARCHAR2				
PROTGRP - LBORREPR	LBORREPR_C	NUMBER				
	LBORREPR	VARCHAR2				
PROTGRP - LBCLSIPR	LBCLSIPR_C	NUMBER				
	LBCLSIPR	VARCHAR2				
GLUCGRP	GLUCGRP_ND	VARCHAR2				
GLUCGRP - LBORREGL	LBORREGL_C	NUMBER				
	LBORREGL	VARCHAR2				
GLUCGRP - LBCLSIGL	LBCLSIGL_C	NUMBER				
	LBCLSIGL	VARCHAR2				
LUKEGRP	LUKEGRP_ND	VARCHAR2				
LUKEGRP - LBORRELE	LBORRELE_C	NUMBER				
	LBORRELE	VARCHAR2				
LUKEGRP - LBCLSILE	LBCLSILE_C	NUMBER				
	LBCLSILE	VARCHAR2				
KETOGRP	KETOGRP_ND	VARCHAR2				
KETOGRP - LBORREKE	LBORREKE_C	NUMBER				
	LBORREKE	VARCHAR2				
KETOGRP - LBCLSIKE	LBCLSIKE_C	NUMBER				
	LBCLSIKE	VARCHAR2				

SPI-1012: SERUM PREGNANCY (SERUM PREG) [LBSP]			
SERUM PREGNANCY [LBSP]			
Specimen Collection for Central Laboratories			
1.* Serum Pregnancy Blood Sample Collection Date [Serum Preg Collection Date]	[LBDATSP]   Req   /   Req   (2012-2017)		
Key: [*] = Item is required [▼] = Source verification required			

RDE Analytics: RD_LBSP				
Data Variable RefName   RD Column Name   Column Data Type				
LBDATSP	LBDATSP	DATE		
	LBDATSP_DTS	VARCHAR2		
	LBDATSP_ND	VARCHAR2		

SPI-1012: PROSTATE SPECIFIC ANTIGEN (PSA) [LBPS]			
PROSTATE SPECIFIC ANTIGEN [LBPS]			
Specimen Collection for Central Laboratories			
1.* Prostate Specific Antigen Blood Sample Collection Date [LBDATPSA] [PSA Collection Date] Req v / Req v / Req v (2012-2017)			
Key: [*] = Item is required [ ✓ ] = Source verification required			

RDE Analytics: RD_LBPS				
Data Variable RefName	RD Column Name	Column Data Type		
LBDATPSA	LBDATPSA	DATE		
	LBDATPSA_DTS	VARCHAR2		
	LBDATPSA_ND	VARCHAR2		

SPI-1012: URINE CYTOLOGY (URIN CYTO) [LBUC]			
URINE CYTOLOGY [LBUC]			
Specimen Collection for Central Laboratories			
1.* Urine Cytology Sample Collection Date [Urine Cytology Collection Date]	[LBDATUC]        Req ▼ /   Req ▼ /   Req ▼ (2012-2017)		
2.* Was the specimen confirmed as <b>not</b> the first morning urine void? [Confirmed Not First Morning Void?]	[LBNFMVUC] [N:1]		
Key: [*] = Item is required [✓] = Source verification required			

Codelist Values and Tables: URINE CYTOLOGY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLIY	LBNFMVUC
		No	0	CLIN	

RDE Analytics: RD_LBUC				
Data Variable RefName   RD Column Name   Column Data Ty				
LBDATUC	LBDATUC	DATE		
	LBDATUC_DTS	VARCHAR2		
	LBDATUC_ND	VARCHAR2		
LBNFMVUC	LBNFMVUC_C	NUMBER		
	LBNFMVUC	VARCHAR2		
	LBNFMVUC_ND	VARCHAR2		

SPI-1012: UPPER URINARY TRACT EVALUATION (U	JTRACT EVAL) [UTE]				
UPPER URINARY TRACT EVALUATION [UTE]					
1.* Was an upper tract evaluation performed?  [Upper Tract Evaluation Performed?]	[UTEPERF] [N:1] \( \text{Yes}  [N:0] \( \text{Q} \)	io			
	Date of Procedure	Type of Evaluation	Result		
2.					
Evaluation Entry [UTE2]					
2.1 Line # [read-only] [Line #]	[UTESPID] N10				
2.2* Date of Procedure [Date of Procedure]	[UTEPRDAT]   Req	[UTEPRDAT]   Req   /   Req/Unk   /   Req   (2012-2017)			
2.3* Type of Evaluation [Type of Evaluation]	[UTEVTYP]   A200				
2.4* Result [Result]	[UTERSLT] [N:1]   Normal [N:2]   GUTEABNSP] Abnormal, Specify findin A200	js:			
Key: [*] = Item is required [ ✔ ] = Source verification required	·				

Study Object Descriptions: UPPER URINARY TRACT EVALUATION			
Type RefName		Description	
Item	UTESPID	Calculated Record ID	

Codelist Values and Tables: UPPER URINARY TRACT EVALUATION					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLIY	UTEPERF
		No	0	CLIN	
CLUTERST	Integer	Normal	1	UTENORM	UTERSLT
		Abnormal	2	UTEABNRM	

RDE Analytics: RD_UTE					
Data Variable RefName	RD Column Name	Column Data Type			
UTEPERF	UTEPERF_C	NUMBER			
	UTEPERF	VARCHAR2			
	UTEPERF_ND	VARCHAR2			
RD_UTE_UTE2					
UTESPID	UTESPID	NUMBER			
	UTESPID_ND	VARCHAR2			
UTEPRDAT	UTEPRDAT	DATE			
	UTEPRDAT_DTS	VARCHAR2			
	UTEPRDAT_DTR	VARCHAR2			
	UTEPRDAT_ND	VARCHAR2			
UTEEVTYP	UTEEVTYP	VARCHAR2			
	UTEEVTYP_ND	VARCHAR2			
UTERSLT	UTERSLT_C	NUMBER			
	UTERSLT	VARCHAR2			
	UTERSLT_ND	VARCHAR2			
UTERSLT - UTEABNSP	UTEABNSP	VARCHAR2			

SF	SPI-1012: CYSTOSCOPY (CYSTO (BL)) [CYSS]				
CY	CYSTOSCOPY [CYSS]				
1.*	Date of Cystoscopy [Date of Cystoscopy]	[CYSDAT]  Req ▼ /   Req ▼ /   Req ▼ (2012-2017)			
2.*	Method [Method]	[CYSMTHD] [N:1] ○White Light [N:2] ○ Blue Light			
3.*	Was Hexvix used? [Hexvix used?]	[CYSHEXV] [N:1] _OYES [N:0] _ONO			
4.*	Were any tumor(s) observed? [Tumor(s) Observed?]	[CYSLESOB] [N:1] ○ [CYSLOGRP] Yes,			
5.*	Were any visually apparent cancer seen in urethra? [Cancer in Urethra?]	[N:1] ○ [CYSCAURS]  N:1] ○ [CYSCAURS]  Yes, specify:   A200    N:0] ○ No			
6.*	Patient has clinically apparent primary or recurrent bladder cancer that is:  *Low grade, multiple (2-7 tumors), Ta, OR  *High grade, Single, Ta, with: No single tumor > 3 cm, and No history/evidence of Tis (carcinoma in situ) [Clinically Apparent Primary or Recurrent Cancer]	[CYSCABC] [N:1]			
к	Key: [*] = Item is required [v] = Source verification required				

Study Object Descriptions: CYSTOSCOPY				
Type RefName Description		Description		
Form	CYSS	Cystoscopy at Screening visit		

Codelist Values and Tables: CYSTOSCOPY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLCYSMTHD	Integer	White Light	1	WHITELT	CYSMTHD
		Blue Light	2	BLUELT	
CLYN	Integer	Yes	1	CLIY	CYSHEXV, CYSLESOB,
		No	0	CLIN	CYSCAUR, CYSCABC

Data Variable RefName	RD Column Name	Column Data Type
CYSDAT	CYSDAT	DATE
	CYSDAT_DTS	VARCHAR2
	CYSDAT_ND	VARCHAR2
CYSMTHD	CYSMTHD_C	NUMBER
	CYSMTHD	VARCHAR2
	CYSMTHD_ND	VARCHAR2
CYSHEXV	CYSHEXV_C	NUMBER
	CYSHEXV	VARCHAR2
	CYSHEXV_ND	VARCHAR2
CYSLESOB	CYSLESOB_C	**NUMBER
	CYSLESOB	VARCHAR2
	CYSLESOB_ND	VARCHAR2
CYSLESOB - CYSNUMT	CYSNUMT	NUMBER
CYSLESOB - CYSLDIAM	CYSLDIAM	FLOAT
CYSCAUR	CYSCAUR_C	**NUMBER
	CYSCAUR	VARCHAR2
	CYSCAUR_ND	VARCHAR2
CYSCAUR - CYSCAURS	CYSCAURS	VARCHAR2
CYSCABC	CYSCABC_C	NUMBER
	CYSCABC	VARCHAR2
	CYSCABC_ND	VARCHAR2

SPI-1012: NEX	SPI-1012: NEXT VISIT (NEXT VISIT) [CONTV]				
NEXT VISIT [CONT)	EXT VISIT [CONTV]				
	visit will become available for entry.	[CONT] [N:1] ○Yes [N:0] ○No			
Key: [*] = Item is re	Key: [*] = Item is required				

Study Object Descriptions: NEXT VISIT					
Туре	RefName	Description			
Item	CONT	If 'Yes' triggers next visit			

Codelist Value	Codelist Values and Tables: NEXT VISIT						
Codelist RefName   Codelist Data Type   Label   Code   Codelist Item RefName   Data Variable RefName							
CLYN	Integer	Yes	1	CLIY	CONT		
		No	0	CLIN			

RDE Analytics: RD_CONTV						
Data Variable RefName   RD Column Name   Column Data Typ						
CONT	CONT_C	NUMBER				
	CONT	VARCHAR2				
	CONT_ND	VARCHAR2				

SPI-101	12: VITAL SIGNS (VS) [VS]	
VITAL SIG	GNS [VS]	
1.* Examir Exami		[VSDAT]    Req    /     Req    /     Req    (2012-2017)
2.* Pulse Pulse		[VSPULSE]  N3 beats/min <sup>[b]</sup>
3.* Blood I	d Pressure]	[VSBPGRP]
4.* Tempe [Tempe	erature erature]	[VSTMPGRP]   WSTEMPI   WSTEMPU
5.* Weight		[VSWTNA] [N:1] ○ [VSWTGRP] [VSWT] [VSWT] [XXXX.] [N:1] ○ kg [N:2] ○ lb
Key: [*] =	= Item is required [ ✓ ] = Source verification required [b] = Base Unit	

Codelist Values and Tables: VITAL SIGNS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLTEMPU	Integer	°C	1	CELSIUS	VSTEMPU
		°F	2	FAHREN	
CLDORNA	Integer	Completed	1	COMP	VSWTNA
		Not Applicable	98	NOTAPP	
CLWGTU	Integer	kg	1	KILO	VSWTU
		lb	2	POUND	

Data Variable RefName	RD Column Name	Column Data Type
VSDAT	VSDAT	DATE
	VSDAT_DTS	VARCHAR2
	VSDAT_ND	VARCHAR2
/SPULSE	VSPULSE	NUMBER
	VSPULSE_U	VARCHAR2
	VSPULSE_ND	VARCHAR2
VSBPGRP	VSBPGRP_ND	VARCHAR2
VSBPGRP - VSBPSYS	VSBPSYS	NUMBER
VSBPGRP - VSBPDIA	VSBPDIA	NUMBER
	VSBPDIA_U	VARCHAR2
/STMPGRP	VSTMPGRP_ND	VARCHAR2
/STMPGRP - VSTEMP	VSTEMP	FLOAT
VSTMPGRP - VSTEMPU	VSTEMPU_C	NUMBER
	VSTEMPU	VARCHAR2
/SWTNA	VSWTNA_C	**NUMBER
	VSWTNA	VARCHAR2
	VSWTNA_ND	VARCHAR2
/SWTNA - VSWT	VSWT	FLOAT
/SWTNA - VSWTU	VSWTU_C	NUMBER
	VSWTU	VARCHAR2

SPI-1012: URINE PREGNANCY (URIN PREG) [LBUP]				
URINE PREGNANCY [LBUP]				
Specimen Collection for Central Laboratories				
1.* Urine Pregnancy Sample Collection Date [Urine Preg Collection Date]	[LBDATUP]   Req   /   Req   /   Req   (2012-2017)			
2.* Results [Results]	[LEORREUP] [N:1] Negative [N:2] Positive			
Key: [*] = Item is required [ v ] = Source verification required				

Codelist Values and Tables: URINE PREGNANCY					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLNEGPOS	Integer	Negative	1	NEG	LBORREUP
		Positive	2	POS	

RDE Analytics: RD_LBUP					
Data Variable RefName	RD Column Name	Column Data Type			
LBDATUP	LBDATUP	DATE			
	LBDATUP_DTS	VARCHAR2			
	LBDATUP_ND	VARCHAR2			
LBORREUP	LBORREUP_C	NUMBER			
	LBORREUP	VARCHAR2			
	LBORREUP_ND	VARCHAR2			

SF	SPI-1012: TRANSURETHRAL RESECTION (TURBT (V1)) [TURS]							
TR	TRANSURETHRAL RESECTION [TURS]							
1.*	Date of TURBT [Date of TURBT]		[TURDAT]   Reg   V   Reg   V   (2012-2017)					
2.*	TURBT End Time [TURBT End Time]			M]  Req ☑ 24-hour clock				
3.*	Method [Method]		[TURMTH	ID] White Light <i>[N:2]</i>				
4.*	Was Hexvix used? [Hexvix used?]		[N:1]	<b>v]</b> Yes <i>[N:0]</i>				
5.*	Were all visible tumors completely resected? [All Visible Tumors Completely Resected?]		[N:1] (N:0)					
	Tumor No	Location		Longest Diameter (cm)				
6.								
Re	sected Tumors Entry [RESTUM]							
6.1	Tumor No [read-only] [Tumor No]		[TURTNO] N10					
6.2			[A:NK] [A:TR] [A:BS] [A:BW] [A:LL]	-1				
6.3	Longest Diameter (cm)  [Longest Diameter (cm)]		TURLD xxx. cm					
•	.* Were tissues or slides sent for central pathology  [Sent for Central Pathology?]  Key: [*] = Item is required [✓] = Source verification required		[N:1] (N:0] (N:0)					

Study	Study Object Descriptions: TRANSURETHRAL RESECTION				
Туре	RefName	Description			
Form	TURS	TURBT at Visit 1 (OL)			
Item	TURTNO	Calculated Record ID			

Codelist Values and Tables: TRANSURETHRAL RESECTION					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLTURMTH	Integer	White Light	1	WHITELT	TURMTHD
		Blue Light	2	BLUELT	
CLYN	Integer	Yes	1	CLIY	TURHEXV,
		No	0	CLIN	TURLRES, TURPATH
CLTUMLOC	String	Dome	DO	DOME	TURLOC
		Bladder Neck	NK	BLADNECK	
		Trigone	TR	TRIGONE	
		Base Wall	BS	BASEWALL	
	Back V	Back Wall	BW	BACKWALL	
		Left Lateral Wall	LL	LFTLWALL	
		Right Lateral Wall	RL	RTLWALL	

RDE Analytics: RD_TURS							
Data Variable RefName   RD Column Name   Column Data Type							
TURDAT	TURDAT	DATE					
	TURDAT_DTS	VARCHAR2					
	TURDAT_ND	VARCHAR2					
TURENTM	TURENTM	DATE					
	TURENTM_TMS	VARCHAR2					
	TURENTM_ND	VARCHAR2					
TURMTHD	TURMTHD_C	NUMBER					
	TURMTHD	VARCHAR2					
	TURMTHD_ND	VARCHAR2					
TURHEXV	TURHEXV_C	NUMBER					
	TURHEXV	VARCHAR2					
	TURHEXV_ND	VARCHAR2					
TURLRES	TURLRES_C	NUMBER					
	TURLRES	VARCHAR2					
	TURLRES_ND	VARCHAR2					
TURLRES - TURRESRS	TURRESRS	VARCHAR2					
TURPATH	TURPATH_C	NUMBER					
	TURPATH	VARCHAR2					
	TURPATH_ND	VARCHAR2					
TURPATH - TURPATRS	TURPATRS	VARCHAR2					
RD_TURS_RESTUM							
TURTNO	TURTNO	NUMBER					
	TURTNO_ND	VARCHAR2					
TURLOC	TURLOC_C	VARCHAR2					
	TURLOC	VARCHAR2					
	TURLOC_ND	VARCHAR2					
TURLD	TURLD	FLOAT					
	TURLD_ND	VARCHAR2					

SPI-1012: LOCAL PATHOLOGY (LOCAL PATH) [LP]			
LOCAL PATHOLOGY [LP]			
Do <b>not</b> enter results from Bostwick.			
	[LPPERF] [N:1]		
✓ [Pathology Results Group]	CLPPATH6    CLPP		
Key: [*] = Item is required [ ✓ ] = Source verification required			

Codelist Value	Codelist Values and Tables: LOCAL PATHOLOGY						
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName		
CLYN	Integer	Yes	1	CLIY	LPPERF		
		No	0	CLIN			
CLPTSTAG	Integer	T0 - No evidence of primary tumor	1	то	LPTSTAG		
		Ta - Noninvasive papillary carcinoma	2	TA			
		Tis - Carcinoma in situ: "flat tumor"	3	TIS			
		T1 - Tumor invades subepithelial connective tissue	4	T1			
		T2 - Tumor invades muscularis propria	5	T2			
		T3 - Tumor invades perivesical tissue	6	T3			
		T4 - Tumor invades any of the following: prostatic stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall	7	T4			
		Not Applicable	98	NOTAPP			
CLWHOGR	Integer	Urothelial papilloma (benign)	1	UROPAP	LPWHOGR		
Papillary urothelial neoplasm of low malignant potential (PUNLMP)		Papillary urothelial neoplasm of low malignant potential (PUNLMP)	2	PUNLMP			
		Low-grade papillary urothelial carcinoma	3	LGPAPU			
		High-grade papillary urothelial carcinoma	4	HGPAPU			
		Not Applicable	98	NOTAPP			

RDE Analytics: RD_LP					
Data Variable RefName	RD Column Name	Column Data Type			
LPPERF	LPPERF_C	NUMBER			
	LPPERF	VARCHAR2			
	LPPERF_ND	VARCHAR2			
LPPATHG	LPPATHG_ND	VARCHAR2			
LPPATHG - LPPRDAT	LPPRDAT	DATE			
	LPPRDAT_DTS	VARCHAR2			
LPPATHG - LPTSTAG	LPTSTAG_C	NUMBER			
	LPTSTAG	VARCHAR2			
LPPATHG - LPWHOGR	LPWHOGR_C	NUMBER			
	LPWHOGR	VARCHAR2			

STUDY DRUG INSTILLATION [EX]	
1.* Date of Instillation [Date of Instillation]	[EXSTDAT]   Req ▼ /   Req ▼ (2012-2017)
2.* Time of Study Drug Reconstitution [Time of Study Drug Reconstitution]	[EXSDRTIM]       Req ☑: Req ☑ 24-hour clock
3,* Time Study Drug Instillation Started [Time Instillation Started]	[EXSTTIM]   Req ☑: Req ☑ 24-hour clock
4.* Time Study Drug Drained from Bladder [Time Drained from Bladder]	[EXENTIM]   Req ☑: Req ☑ 24-hour clock
5.* (Volume of Instillate [Volume of Instillate]	EXVOLT    (N:1)
6.* Was the study drug retained in bladder for 54-66 minutes? [Was Study Drug Retained in Bladder for 54-66 min?]	[EXDRET] [N:1] (∑Yes [N:0] (☐EXDURRS] No, reason:  A200
7. Was there any leakage? [Leakage?]	[EXLEAK]   N::1] ○[EXVOLL]  Yes, estimate the leaked volume:   xx.  mL <sup>(b)</sup>     N::0  ○No

Codelist Values and Tables: STUDY DRUG INSTILLATION						
Codelist RefName   Codelist Data Type   Label   Code   Codelist Item RefName   Data Variable RefName						
CLVOLINS	Integer	40 mL	1	FORTYML	EXVOLT	
		Other	99	OTHER		
CLYN	Integer	Yes	1	CLIY	EXDRET,	
		No	0	CLIN	EXLEAK	

Data Variable RefName	RD Column Name	Column Data Type
XSTDAT	EXSTDAT	DATE
	EXSTDAT_DTS	VARCHAR2
	EXSTDAT_ND	VARCHAR2
XSDRTIM	EXSDRTIM	DATE
	EXSDRTIM_TMS	VARCHAR2
	EXSDRTIM_ND	VARCHAR2
XSTTIM	EXSTTIM	DATE
	EXSTTIM_TMS	VARCHAR2
	EXSTTIM_ND	VARCHAR2
XENTIM	EXENTIM	DATE
	EXENTIM_TMS	VARCHAR2
	EXENTIM_ND	VARCHAR2
XVOLT	EXVOLT_C	NUMBER
	EXVOLT	VARCHAR2
	EXVOLT_ND	VARCHAR2
XVOLT - EXVOLTOT	EXVOLTOT	FLOAT
	EXVOLTOT_U	VARCHAR2
XVOLT - EXVOLTRS	EXVOLTRS	VARCHAR2
XDRET	EXDRET_C	NUMBER
	EXDRET	VARCHAR2
	EXDRET_ND	VARCHAR2
XDRET - EXDURRS	EXDURRS	VARCHAR2
XLEAK	EXLEAK_C	**NUMBER
	EXLEAK	VARCHAR2
	EXLEAK_ND	VARCHAR2
XLEAK - EXVOLL	EXVOLL	FLOAT
	EXVOLL_U	VARCHAR2

SPI-1012: RANDOMIZATION (RAND) [RAN]				
RANDOMIZATION [RAN]				
	[RANRES] [№:1] ○Yes [N:0] ○No			
[Was Patient Randomized?]	RANRAND    RANDORT    Date Randomized:   Req v   / Req v   / Req v   (2012-2017)   Study Drug Kit Number:   A5   A5     No, give reason:   A200			
Key: [*] = Item is required [ v ] = Source verification required				

Study Object Descriptions: RANDOMIZATION				
Туре	RefName	Description		
Item	RANRAND	If No, trigger START EOS form; If Yes, trigger V2 visit.		

Codelist Values and Tables: RANDOMIZATION							
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName		
CLYN	Integer	Yes	1	CLIY	RANRES,		
		No	0	CLIN	RANRAND		

Data Variable RefName	RD Column Name	Column Data Type
RANRES	RANRES_C	NUMBER
	RANRES	VARCHAR2
	RANRES_ND	VARCHAR2
RANRAND	RANRAND_C	**NUMBER
	RANRAND	VARCHAR2
	RANRAND_ND	VARCHAR2
RANRAND - RANDDAT	RANDDAT	DATE
	RANDDAT_DTS	VARCHAR2
RANRAND - RANDKITN	RANDKITN	VARCHAR2
RANRAND - RANNDRSN	RANNDRSN	VARCHAR2

s	SPI-1012: END OF STUDY (non-randomized patients) (START EOS) [EOS]				
EI	ND OF STUDY (non-randomized patients) [EOS]				
1.	* Did the patient come for the 90-day post apaziquone instillation visit? [Post-Apaziquone Instillation Visit?]				
	y: [*] = Item is required [ 🗸 ] = Source verification required				

Study Object Descriptions: END OF STUDY (non-randomized patients)					
Туре	RefName	Description			
Item	EOSINST	If 'Yes', triggers EOS visit			

Codelist Values and Tables: END OF STUDY (non-randomized patients)						
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName	
CLYN	Integer	Yes	1	CLIY	EOSINST	
		No	0	CLIN		

RDE Analytics: RD_EOS					
Data Variable RefName	RD Column Name	Column Data Type			
EOSINST	EOSINST_C	NUMBER			
	EOSINST	VARCHAR2			
	EOSINST_ND	VARCHAR2			
EOSINST - EOSVISND	EOSVISND	VARCHAR2			

-					
SPI-1012: PHYSICAL EXAMINATION (post baseline) (PE (POST BL)) [PE2]					
1	PHYSICAL EXAMINATION (post baseline) [PE2]				
	." Was a physical examination performed?  **Record any clinically significant post baseline abnormalities or baseline conditions that worsened post baseline on the AE from [PE Performed?]	[N:1] ○[PEDAT]         Yes, Examination Date:           Req ○   Re			
	Key: [*] = Item is required [ ✓ ] = Source verification required				

Codelist Values and Tables: PHYSICAL EXAMINATION (post baseline)						
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName	
CLYN	Integer	Yes	1	CLIY	PEPERF2	
		No	0	CLIN		

Data Variable RefName	RD Column Name	Column Data Type
PEPERF2	PEPERF2_C	**NUMBER
	PEPERF2	VARCHAR2
	PEPERF2_ND	VARCHAR2
PEPERF2 - PEDAT	PEDAT	DATE
	PEDAT_DTS	VARCHAR2
PEPERF2 - PENDRSN	PENDRSN	VARCHAR2

SP	PI-1012: CYSTOSCOPY (CYSTO) [CYS]		
CYS	STOSCOPY [CYS]		
~	Date of Cystoscopy [Date of Cystoscopy]		[CYSDAT]   Req ▼ /   Req ▼ /   Req ▼ (2012-2017)
2.* •	Method [Method]		[CYSMTHD] [N:1]  White Light  N:2]  Blue Light
3.* •	Was Hexvix used? [Hexvix used?]		[CYSHEXV] [N:1] OYES [N:0] ONO
4.*	Were any tumor(s) observed? [Tumor(s) Observed?]		CYSLESO1    (N:1)
	Tumor No.	Location	Longest Diameter (cm)
5.			
	served Tumors Entry [OBSTUM]		
5.1	Tumor No. [read-only] [Tumor No.]		[CYSTNO] N10
5.2	* Location [Location]		CVSLOC    (A:DO
5.3	* Longest Diameter (cm) [Longest Diameter (cm)]		CYSLD] xxx. cm
6.*	Were any visually apparent cancer seen in urethra? [Cancer in Urethra?]		[CYSCAUR] [N:1] ○[CYSCAURS] Yes, specify:   A200    [N:0] ○No
7.*	Were tissues or slides sent for central pathology?		[CYSCP]
•	[Sent for Central Pathology]		(N:1)
8.*	Were any other abnormalities seen? [Any Other Abnormalities]		CYSABNYN    (N:1)
Ke	ey: [*] = Item is required [ • ] = Source verification required		1

## Study Object Descriptions: CYSTOSCOPY Type RefName Description Form CYS Cystoscopy at visits except Screen and V8 Item CYSTNO Calculated Record ID

Codelist Value	Codelist Values and Tables: CYSTOSCOPY				
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLCYSMTHD	Integer	White Light	1	WHITELT	CYSMTHD
		Blue Light	2	BLUELT	
CLYN	CYSLESO		CYSHEXV, CYSLESO1, CYSCAUR,		
		No	0	CLIN	CYSCP, CYSABNYN
CLTUMACT	Integer	Biopsy	1	TUMBX	CYSACTT1
		TURBT planned	2	TUMTURBT	
		Other	99	OTHER	
CLTUMLOC	String	Dome	DO	DOME	CYSLOC
		Bladder Neck	NK	BLADNECK	
		Trigone	TR	TRIGONE	
		Base Wall	BS	BASEWALL	
		Back Wall	BW	BACKWALL	
		Left Lateral Wall	LL	LFTLWALL	
		Right Lateral Wall	RL	RTLWALL	
CLACTPL	Integer	Biopsy	1	BIOPSY	CYSACTN
		Other	99	OTHER	

RDE Analytics: RD_CYS					
Data Variable RefName	RD Column Name	Column Data Type			
CYSDAT	CYSDAT	DATE			
	CYSDAT_DTS	VARCHAR2			
	CYSDAT_ND	VARCHAR2			
CYSMTHD	CYSMTHD_C	NUMBER			
	CYSMTHD	VARCHAR2			
	CYSMTHD_ND	VARCHAR2			
CYSHEXV	CYSHEXV_C	NUMBER			

	CYSHEXV	VARCHAR2
	CYSHEXV_ND	VARCHAR2
CYSLESO1	CYSLESO1_C	**NUMBER
	CYSLESO1	VARCHAR2
	CYSLESO1_ND	VARCHAR2
CYSLESO1 - Biopsy	CYSACTT1_TUMBX_C	NUMBER
	CYSACTT1_TUMBX	VARCHAR2
CYSLESO1 - TURBT planned	CYSACTT1_TUMTURBT_C	NUMBER
	CYSACTT1_TUMTURBT	VARCHAR2
CYSLESO1 - Other	CYSACTT1_CYSACTTO_C	NUMBER
	CYSACTT1_CYSACTTO	VARCHAR2
CYSLESO1 - CYSACTTO	CYSACTTO	VARCHAR2
CYSCAUR	CYSCAUR_C	**NUMBER
	CYSCAUR	VARCHAR2
	CYSCAUR_ND	VARCHAR2
CYSCAUR - CYSCAURS	CYSCAURS	VARCHAR2
CYSCP	CYSCP_C	NUMBER
	CYSCP	VARCHAR2
	CYSCP_ND	VARCHAR2
CYSCP - CYSCPN	CYSCPN	VARCHAR2
CYSABNYN	CYSABNYN_C	**NUMBER
	CYSABNYN	VARCHAR2
	CYSABNYN_ND	VARCHAR2
CYSABNYN - CYSABN	CYSABN	VARCHAR2
CYSABNYN - CYSACTN	CYSACTN_C	NUMBER
	CYSACTN	VARCHAR2
CYSABNYN - CYSACTNO	CYSACTNO	VARCHAR2
RD_CYS_OBSTUM		
CYSTNO	CYSTNO	NUMBER
	CYSTNO_ND	VARCHAR2
CYSLOC	CYSLOC_C	VARCHAR2
	CYSLOC	VARCHAR2
	CYSLOC_ND	VARCHAR2
CYSLD	CYSLD	FLOAT
	CYSLD_ND	VARCHAR2

		SPI-1012: TRANSURETHRAL RESECTION (TURBT) [TUR]					
TRA	TRANSURETHRAL RESECTION [TUR]						
1.*	Date of TURBT [Date of TURBT]		[TURDAT]  Req ☑ /   Req ☑ /   Req ☑ (2012-2017)				
2.*	Reason TURBT Performed [Reason TURBT Performed]		[TURPRSN] A200				
3.*	Method [Method]		[TURMTHD] [N:1]  White Light [N:2]  Blue Light				
	Was Hexvix used? [Hexvix used?]		TURHEXV] N:1] ○Yes [N:0] ○No				
	Total Number of Tumors [Total Number of Tumors]		TURNUMLS) ) <= N3				
6.*	Were all Visible tumors completely resected? [All Visible Tumors Completely Resected?]	[P	TURLRES.]   No.				
П	Tumor No	Location	Longest Diameter (cm)				
7.							
Res	sected Tumors Entry [RESTUM2]						
7.1	Tumor No [read-only] [Tumor No]	I č	[TURTNO1] N10				
7.2*	* Location [Location]	1   1   1   1   1	TURLOC1     (A:DC)				
7.3	* Longest Diameter (cm) [Longest Diameter (cm)]		TURLD1] xxxx. cm				
•	Were tissues or slides sent for central pathology [Sent for Central Pathology?]  sy: [*] = Item is required [▼] = Source verification required	[[	TURPATH) N:1)				

Study Object Descriptions: TRANSURETHRAL RESECTION					
Type RefName Description					
Form	TUR	TURBT at visits except Screening			
Item TURTNO1 Calculated Record ID					

Codelist Values and Tables: TRANSURETHRAL RESECTION					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLTURMTH	Integer	White Light	1	WHITELT	TURMTHD
		Blue Light	2	BLUELT	
CLYN	Integer	Yes	1	CLIY	TURHEXV,
		No	0	CLIN	TURLRES1, TURPATH
CLTUMLOC	String	Dome	DO	DOME	TURLOC1
		Bladder Neck	NK	BLADNECK	
		Trigone	TR	TRIGONE	
		Base Wall	BS	BASEWALL	
		Back Wall	BW	BACKWALL	
		Left Lateral Wall	LL	LFTLWALL	
		Right Lateral Wall	RL	RTLWALL	

RDE Analytics: RD_TUR  Data Variable RefName RD Column Name Column Data Type						
Data Variable RefName	RD Column Name	Column Data Type				
TURDAT	TURDAT	DATE				
	TURDAT_DTS	VARCHAR2				
	TURDAT_ND	VARCHAR2				
TURPRSN	TURPRSN	VARCHAR2				
	TURPRSN_ND	VARCHAR2				
TURMTHD	TURMTHD_C	NUMBER				
	TURMTHD	VARCHAR2				
	TURMTHD_ND	VARCHAR2				
TURHEXV	TURHEXV_C	NUMBER				
	TURHEXV	VARCHAR2				
	TURHEXV_ND	VARCHAR2				
TURNUMLS	TURNUMLS	NUMBER				
	TURNUMLS_ND	VARCHAR2				
TURLRES1	TURLRES1_C	NUMBER				
	TURLRES1	VARCHAR2				
	TURLRES1_ND	VARCHAR2				
TURLRES1 - TURRESR1	TURRESR1	VARCHAR2				
TURPATH	TURPATH_C	NUMBER				
	TURPATH	VARCHAR2				
	TURPATH_ND	VARCHAR2				
TURPATH - TURPATRS	TURPATRS	VARCHAR2				
RD_TUR_RESTUM2						
TURTNO1	TURTNO1	NUMBER				
	TURTNO1_ND	VARCHAR2				
TURLOC1	TURLOC1_C	VARCHAR2				
	TURLOC1	VARCHAR2				
	TURLOC1_ND	VARCHAR2				
TURLD1	TURLD1	FLOAT				
	TURLD1 ND	VARCHAR2				

s	SPI-1012: START FOLLOW-UP (START FU) [STFUV]				
S	START FOLLOW-UP [STFUV]				
1.		[STFUVIS] [N::1]			
	Key: [*] = Item is required				

Study Object Descriptions: START FOLLOW-UP						
Туре	RefName	Description				
Item	STFUVIS	If 'Yes', triggers FU VISITS form				

C	Codelist Values and Tables: START FOLLOW-UP					
C	odelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CI	LYN	Integer	Yes	1	CLIY	STFUVIS
			No	0	CLIN	

RDE Analytics: RD_STFUV						
Data Variable RefName   RD Column Name   Column Data Type						
STFUVIS	STFUVIS_C	NUMBER				
	STFUVIS	VARCHAR2				
	STFUVIS_ND	VARCHAR2				

SPI-1012: FOLLOW-UP VISITS (FU VISITS) [FUV]			
Please answer 'Yes' or 'No' for each scheduled follow-up visit listed below to indicate if the visit was perform	ed or not (a response is required for each item below). If response is 'Yes', the associated follow-up visit will become available for entry.		
1.* Follow-Up Visit 8 (3 months) [V8 FU]	[STFUV8] [N:1] _OYES [N:0] _ONO		
2.* Follow-Up Visit 9 (6 months) [V9 FU]	[STFUV9] [N:1]		
3.* Follow-Up Visit 10 (9 months) [V10 FU]	[STFUV10] [N:1]		
4.* Follow-Up Visit 11 (12 months) [V11 FU]	[STFUV11] [N:1] _OYES [N:0] _No		
5.* Follow-Up Visit 12 (15 months) [V12 FU]	[STFUV12] [N:1] OYES [N:0] ONO		
6.* Follow-Up Visit 13 (18 months) [V13 FU]	[STFUV13] [N:1] _OYES [N:0] _ONO		
7.* Follow-Up Visit 14 (21 months) [V14 FU]	[STFUV14] [N:1]		
8.* Follow-Up Visit 15 (24 months) [V15 FU]	[STFUV15] [N:1] OYES [N:0] ONO		
Key: [*] = Item is required [ ✓ ] = Source verification required			

Study Object Descriptions: FOLLOW-UP VISITS							
Туре	Type RefName Description						
Form	FUV	If any Follow-Up Visit item question is 'Yes', the associated FU visit is triggered					

Codelist Values and Tables: FOLLOW-UP VISITS							
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName		
CLYN	Integer	Yes	1	CLIY	STFUV8, STFUV9, STFUV10, STFUV11,		
		No	0	CLIN	STFUV12, STFUV13, STFUV14, STFUV15		

RDE Analytics: RD_FUV								
Data Variable RefName	RD Column Name	Column Data Type						
STFUV8	STFUV8_C	NUMBER						
	STFUV8	VARCHAR2						
	STFUV8_ND	VARCHAR2						
STFUV9	STFUV9_C	NUMBER						
	STFUV9	VARCHAR2						
	STFUV9_ND	VARCHAR2						
STFUV10	STFUV10_C	NUMBER						
	STFUV10	VARCHAR2						
	STFUV10_ND	VARCHAR2						
STFUV11	STFUV11_C	NUMBER						
	STFUV11	VARCHAR2						
	STFUV11_ND	VARCHAR2						
STFUV12	STFUV12_C	NUMBER						
	STFUV12	VARCHAR2						
	STFUV12_ND	VARCHAR2						
STFUV13	STFUV13_C	NUMBER						
	STFUV13	VARCHAR2						
	STFUV13_ND	VARCHAR2						
STFUV14	STFUV14_C	NUMBER						
	STFUV14	VARCHAR2						
	STFUV14_ND	VARCHAR2						
STFUV15	STFUV15_C	NUMBER						
	STFUV15	VARCHAR2						
	STFUV15_ND	VARCHAR2						

SPI-1012: CYSTOSCOPY (CYSTO (V8)) [CYS8]										
STOSCOPY [CYS8]										
Date of Cystoscopy [Date of Cystoscopy]		[CYSDAT]   Req ♥ /   Req ♥ /   Req ♥ (2012-2017)								
Method [Method]		[CYSMTHD] [N:1]  White Light [N:2]  Blue Light								
Was Hexvix used? [Hexvix used?]		[CYSHEXY] [N:1]  \[Omega \text{[N:0]} \Qmathbb{No} \]  [N:1] \[Omega \text{[N:0]} \Qmathbb{No} \]								
[are Sites Re-Epitnelialized/]										
Were any tumor(s) observed? [Tumor(s) Observed?]		CYSLESO2    (N:1)   CYSACTT    Yes,								
Tumor No.	Location	Longest Diameter (cm)								
served Tumors Entry [OBSTUM2]										
Tumor No. [read-only] [Tumor No.]		[CYSTNO1] N10								
* Location [Location]		(CYSLOC1)								
* Longest Diameter (cm) [Longest Diameter (cm)]		[CYSLD1]   xxxx.								
Were any visually apparent cancer seen in urethra? [Cancer in Urethra?]		[CYSCAUR]								
		[N:0]								
Were tissues or slides sent for central pathology?  [Sent for Central Pathology]		[CYSCP]								
Were any other abnormalities seen? [Any Other Abnormalities]		CYSABNYN      N:1    CYSABGRP    Yes,   (CYSABN)     Specify the location and describe abnormality:   A200     CYSACTN      Action taken/planned:								
	Tumor No.  Tumor No.	Date of Cysacocy     Was Nervi used?     Herbid     Were and of the sites of initial TURST re-epithelialized?     Are Sites Re-Epithelialized?     Were any tumor(s) observed?     Tumor No.   Location     Locati								

Stud	Study Object Descriptions: CYSTOSCOPY								
Туре	RefName	Description							
Form	CYS8	Cystoscopy at V8 (3-mo only)							
Item	CYSTN01	Calculated Record ID							

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLCYSMTHD	Integer	White Light	1	WHITELT	CYSMTHD
		Blue Light	2	BLUELT	
CLYN	Integer	Yes	1	CLIY	CYSHEXV, CYSTURRE, CYSLESO2,
		No	0	CLIN	CYSCAUR, CYSCP, CYSABNYN
CLUHTLOC	String	Base Wall	BS	BASEWALL	CYSURLOC
		Back Wall	BW	BACKWALL	
		Left Wall	LW	LTWALL	
		Right Wall	RW	RTWALL	
		Dome	DO	DOME	
		Bladder Neck	NK	BLADNECK	
		Trigone	TR	TRIGONE	
CLTUMACT	Integer	Biopsy	1	TUMBX	CYSACTT
		TURBT planned	2	TUMTURBT	
		Other	99	OTHER	
CLTUMLOC	String	Dome	DO	DOME	CYSLOC1
		Bladder Neck	NK	BLADNECK	

		Trigone	TR	TRIGONE	
		Base Wall	BS	BASEWALL	
		Back Wall	BW	BACKWALL	
		Left Lateral Wall	LL	LFTLWALL	
		Right Lateral Wall	RL	RTLWALL	
CLACTPL	Integer	Biopsy	1	BIOPSY	CYSACTN
		Other	99	OTHER	

ata Variable RefName	RD Column Name	Column Data Type
YSDAT	CYSDAT	DATE
	CYSDAT_DTS	VARCHAR2
	CYSDAT_ND	VARCHAR2
YSMTHD	CYSMTHD_C	NUMBER
	CYSMTHD	VARCHAR2
	CYSMTHD_ND	VARCHAR2
YSHEXV	CYSHEXV_C	NUMBER
TOTIEXV	CYSHEXV	VARCHAR2
	CYSHEXV_ND	VARCHAR2
VCTURRE		NUMBER
YSTURRE	CYSTURRE_C	
	CYSTURRE	VARCHAR2
	CYSTURRE_ND	VARCHAR2
YSTURRE - Base Wall	CYSURLOC_BASEWALL_C	VARCHAR2
	CYSURLOC_BASEWALL	VARCHAR2
YSTURRE - Back Wall	CYSURLOC_BACKWALL_C	VARCHAR2
	CYSURLOC_BACKWALL	VARCHAR2
YSTURRE - Left Wall	CYSURLOC_LTWALL_C	VARCHAR2
	CYSURLOC_LTWALL	VARCHAR2
/STURRE - Right Wall	CYSURLOC_RTWALL_C	VARCHAR2
•	CYSURLOC_RTWALL	VARCHAR2
/STURRE - Dome	CYSURLOC_DOME_C	VARCHAR2
	CYSURLOC_DOME	VARCHAR2
YSTURRE - Bladder Neck	CYSURLOC_BLADNECK_C	VARCHAR2
1310KKL - Bladdel Neck		
	CYSURLOC_BLADNECK	VARCHAR2
/STURRE - Trigone	CYSURLOC_TRIGONE_C	VARCHAR2
	CYSURLOC_TRIGONE	VARCHAR2
SLES02	CYSLESO2_C	**NUMBER
	CYSLESO2	VARCHAR2
	CYSLESO2_ND	VARCHAR2
SLESO2 - Biopsy	CYSACTT_TUMBX_C	NUMBER
	CYSACTT_TUMBX	VARCHAR2
SLESO2 - TURBT planned	CYSACTT_TUMTURBT_C	NUMBER
	CYSACTT_TUMTURBT	VARCHAR2
/SLESO2 - Other	CYSACTT_CYSACTTO_C	NUMBER
	CYSACTT_CYSACTTO	VARCHAR2
/SLESO2 - CYSACTTO	CYSACTTO	VARCHAR2
/SCAUR	CYSCAUR_C	**NUMBER
. J. G. 1011		
	CYSCAUR	VARCHAR2
	CYSCAUR_ND	VARCHAR2
SCAUR - CYSCAURS	CYSCAURS	VARCHAR2
/SCP	CYSCP_C	NUMBER
	CYSCP	VARCHAR2
	CYSCP_ND	VARCHAR2
YSCP - CYSCPN	CYSCPN	VARCHAR2
'SABNYN	CYSABNYN_C	**NUMBER
	CYSABNYN	VARCHAR2
	CYSABNYN_ND	VARCHAR2
YSABNYN - CYSABN	CYSABN	VARCHAR2
SABNYN - CYSACTN	CYSACTN_C	NUMBER
	CYSACTN	VARCHAR2
YSABNYN - CYSACTNO	CYSACTNO	VARCHAR2
	CIONCINO	VANCIARZ
CYS8_OBSTUM2	GVGTN04	
	CYSTN01	NUMBER
SINO1	CYSTNO1_ND	VARCHAR2
	Lavarace c	VARCHAR2
	CYSLOC1_C	
YSLOC1	CYSLOC1_C	VARCHAR2
		VARCHAR2 VARCHAR2
	CYSLOC1	

SPI-1012: LABLOAD (LABLOAD) - Repeating Form [LBLOAD]  # Visit#,   Collection Collection Accession Test   Test   Department   US   US   US   US   SI (Standard																					
Ur	schedule	ed Date	n Collectio Time	n Accession #	n Test Code	Test D Name	epartment Name	(Conventional)	US Unit	Low High	SI (Standard International)	Unit	t Low F	SI Resu ligh Flag	It Toxicity Grade	Specific	Test Specific	Comments 1	Department Comments2	General/Receiving Comments1	General/Receiving Comments2
1	equence#	#						Result		Range Rang	e Result		Range R	ange		Comments1	Comments	2			
	OAD [LB																				
1.*	Visit#, U	nscheduled : Jnscheduled	Sequence# Sequence#	#]									A10	1]							
2.*	Collection [Collection	n Date on Date]											[LBDAT] A15								
3.*	Collection [Collection	n Time on Time]											A15	1							
4.*	Accession [Accession												(LBREFID) A14	1							
5.* •	Test Cod												A8	0]							
6.* •	Test Nam [Test Nam	ne me]											[LBTEST] A30								
7.* •	Departm [Departm	ent Name nent Name]											A30	м]							
8.*	US (Conv [US (Con	ventional) Re nventional) R	esult tesult]										A14	c]							
9.* •	US Unit [US Unit]	]											A14	T]							
10.*	US Low F	Range Range]											A10	/R]	]						
11.*	US High [US High												[LBUSHIR A10	1							
12.* •		dard Interna ndard Interna											A14	s]							
13.*	SI Unit [SI Unit]												A14	r]							
14.* •	SI Low R [SI Low F	ange Range]											A10	R]	]						
15.* •	SI High R [SI High	Range Range]											[LBSIHIR] A10	l	]						
16.*	Result Fla [Result F	ag [lag]											A2	]							
17.*	Toxicity ( [Toxicity	Grade Grade]											A2	1							
18.*	Test Spe [Test Spe	cific Comme ecific Comme	nts1 ents1]										A250	1]							
19.*	Test Sper	cific Comme	nts2									-	[LBTSTCM	21							
•	[Test Spe	ecific Comme	ents2]										A250								
20.*	Departm	ent Commer	nts1									$\dashv$	[LBDPTCM	1]							
-	[Departm	nent Comme	ents1]										A250								
21.*	Departm [Departm	ent Commer nent Comme	nts2 ents2]										A250	2]							
22.*	General/I	Receiving Co	omments1									-	[LBGRCM1	.]							
¥.	[General,	/Receiving C	comments1]	]									A250								
23.*	General/I	Receiving Co /Receiving C	omments2	1									LBGRCM2 A250	!]							
		,		•									AZJU								
Key	r: [*] = Ite	em is required	[ 🗸 ] = Sou	urce verificatio	on requir	red															

## 

RDE Analytics: RD_LBLOAD									
Data Variable RefName	RD Column Name	Column Data Type							
LBVISITN	LBVISITN	VARCHAR2							
	LBVISITN_ND	VARCHAR2							
LBDAT	LBDAT	VARCHAR2							
	LBDAT_ND	VARCHAR2							
LBDATTM	LBDATTM	VARCHAR2							
	LBDATTM_ND	VARCHAR2							
LBREFID	LBREFID	VARCHAR2							
	LBREFID_ND	VARCHAR2							
LBTESTCD	LBTESTCD	VARCHAR2							
	LBTESTCD_ND	VARCHAR2							
LBTEST	LBTEST	VARCHAR2							
	LBTEST_ND	VARCHAR2							
LBDEPTNM	LBDEPTNM	VARCHAR2							
	LBDEPTNM_ND	VARCHAR2							
LBORRESC	LBORRESC	VARCHAR2							
	LBORRESC_ND	VARCHAR2							

LBUSUNIT	LBUSUNIT	VARCHAR2
	LBUSUNIT_ND	VARCHAR2
LBUSLOWR	LBUSLOWR	VARCHAR2
	LBUSLOWR_ND	VARCHAR2
LBUSHIR	LBUSHIR	VARCHAR2
	LBUSHIR_ND	VARCHAR2
LBORRESS	LBORRESS	VARCHAR2
	LBORRESS_ND	VARCHAR2
LBSIUNIT	LBSIUNIT	VARCHAR2
	LBSIUNIT_ND	VARCHAR2
LBSILOWR	LBSILOWR	VARCHAR2
	LBSILOWR_ND	VARCHAR2
LBSIHIR	LBSIHIR	VARCHAR2
	LBSIHIR_ND	VARCHAR2
LBRFLAG	LBRFLAG	VARCHAR2
	LBRFLAG_ND	VARCHAR2
LBTOXGR	LBTOXGR	VARCHAR2
	LBTOXGR_ND	VARCHAR2
LBTSTCM1	LBTSTCM1	VARCHAR2
	LBTSTCM1_ND	VARCHAR2
LBTSTCM2	LBTSTCM2	VARCHAR2
	LBTSTCM2_ND	VARCHAR2
LBDPTCM1	LBDPTCM1	VARCHAR2
	LBDPTCM1_ND	VARCHAR2
LBDPTCM2	LBDPTCM2	VARCHAR2
	LBDPTCM2_ND	VARCHAR2
LBGRCM1	LBGRCM1	VARCHAR2
	LBGRCM1_ND	VARCHAR2
LBGRCM2	LBGRCM2	VARCHAR2
	LBGRCM2_ND	VARCHAR2

INSCHEDULED FORMS [UNSFRM]	
Please select the form(s) to complete for this unscheduled visit [Unscheduled Forms]	[UNSFRMS]  Check all that apply:  [IN:1]
	[N:2] PHYSICAL EXAMINATION [N:3] HEMATOLOGY/CHEMISTRY
	[N:4] URINE DIPSTICK [N:5] URINE PREGNANCY
	[N:6] URINE CYTOLOGY [N:7] UPPER URINARY TRACT EVALUATION [N:8] TRANSURETHRAL RESECTION
	[IN:0] CYSTOSCOPY [In:10] LOCAL PATHOLOGY

Stuc	Study Object Descriptions: UNSCHEDULED FORMS								
Type RefName Description									
Item	UNSFRMS	Chosen forms will be dynamically generated for the associated UNS visit							

Codelist Values and Tables: UNSCHEDULED FORMS											
Codelist RefName Codelist Data Type		Label		Codelist Item RefName	Data Variable RefName						
CLUNSFRM	Integer	VITAL SIGNS	1	F_VS	UNSFRMS						
		PHYSICAL EXAMINATION	2	F_PE							
		HEMATOLOGY/CHEMISTRY	3	F_HMCHM							
		URINE DIPSTICK	4	F_URIN							
		URINE PREGNANCY	5	F_UPREG							
		URINE CYTOLOGY	6	F_UCYT							
		UPPER URINARY TRACT EVALUATION	7	F_UTE							
		TRANSURETHRAL RESECTION	8	F_TURBT							
		CYSTOSCOPY	9	F_CYSTO							
		LOCAL PATHOLOGY	10	F_LPATH							

RDE Analytics: RD_UNSFRM		
Data Variable RefName	RD Column Name	Column Data Type
UNSFRMS	UNSFRMS_ND	VARCHAR2
UNSFRMS - VITAL SIGNS	UNSFRMS_F_VS_C	NUMBER
	UNSFRMS_F_VS	VARCHAR2
UNSFRMS - PHYSICAL EXAMINATION	UNSFRMS_F_PE_C	NUMBER
	UNSFRMS_F_PE	VARCHAR2
UNSFRMS - HEMATOLOGY/CHEMISTRY	UNSFRMS_F_HMCHM_C	NUMBER
	UNSFRMS_F_HMCHM	VARCHAR2
UNSFRMS - URINE DIPSTICK	UNSFRMS_F_URIN_C	NUMBER
	UNSFRMS_F_URIN	VARCHAR2
UNSFRMS - URINE PREGNANCY	UNSFRMS_F_UPREG_C	NUMBER
	UNSFRMS_F_UPREG	VARCHAR2
UNSFRMS - URINE CYTOLOGY	UNSFRMS_F_UCYT_C	NUMBER
	UNSFRMS_F_UCYT	VARCHAR2
UNSFRMS - UPPER URINARY TRACT EVALUATION	UNSFRMS_F_UTE_C	NUMBER
	UNSFRMS_F_UTE	VARCHAR2
UNSFRMS - TRANSURETHRAL RESECTION	UNSFRMS_F_TURBT_C	NUMBER
	UNSFRMS_F_TURBT	VARCHAR2
UNSFRMS - CYSTOSCOPY	UNSFRMS_F_CYSTO_C	NUMBER
	UNSFRMS_F_CYSTO	VARCHAR2
UNSFRMS - LOCAL PATHOLOGY	UNSFRMS_F_LPATH_C	NUMBER
	UNSFRMS_F_LPATH	VARCHAR2

<u>IEVN]</u> ::1] ○Yes [N:0] ○No
MYN] V:1] ○Yes [N:0] ○No
V:1]

Study C	bject Descriptions	: ADVERSE EVENTS OR CONMEDS TO REPORT?
Type RefName		Description
Form	ACTF	AE/CM trigger form

Codelist Values and Tables: ADVERSE EVENTS OR CONMEDS TO REPORT?							
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName		
CLYN	Integer	Yes	1	CLIY	AEYN,		
		No	0	CLIN	CMYN		

RDE Analytics: RD_ACTF								
Data Variable RefName   RD Column Name   Column Data Type								
AEYN	AEYN_C	NUMBER						
	AEYN	VARCHAR2						
	AEYN_ND	VARCHAR2						
CMYN	CMYN_C	NUMBER						
	CMYN	VARCHAR2						
	CMYN_ND	VARCHAR2						

SP	SPI-1012: ADVERSE EVENTS (AE) - Repeating Form [AE]								
	Line # Adverse Event Term	Start Date	End Date or Ongoing	Serious Adverse Event?	CTCAE Toxicity Grade	Relationship	Treatment Given?	Action Taken	Outcome
1									
_	/ERSE EVENTS [AE]								
1.	Line # [read-only] [Line #]			[AESPID] N10					
2.*	Adverse Event Term			[AETERM]					
4	[Adverse Event Term]			A100					
3.*	Start Date [Start Date]			Req / Req/Unk / Req	(2012-2017)				
4.*									
5.*	Serious Adverse Event? [Serious Adverse Event?]			[AESER] [N:1] ○[AESERY] Yes, mark all categor [N:2] [N:2] [N:3] [N:4] [N:5] [N:6] [N:0] ○No	ies that apply:    Fata    Fata    Initial or Prolonged   Congenital Anomaly,   Life Threatening   Disability or Perman   Other Important Med	Birth Defect			
6.* •	CTCAE Toxicity Grade [CTCAE Toxicity Grade]			[N:1] 01 [N:2] 02 [N:3] (	_3 [N:4] _4 [N:5] _5				
7.*	Relationship [Relationship]			[AEREL] [N:1] Ounrelated [N:2] OU	Inlikely [N:3] OPossible [N:4]	Probable [N:5] ODel	finite		
8.*	Treatment Given? [Treatment Given?]			[N:1] Yes (enter relevant in	nformation on CM form) [N:0] ON	lo			
9.*	Action Taken [Action Taken]			[AEACN] [N:1] None [N:2] Drug	Interrupted [N:3] ODose Delayed	d [N:4] ODrug Discon	tinued [N:5] Study Termin	ated	
10.	Outcome [Outcome]			[AEOUT] [N:1] Resolved [N:2] Re	esolved with Sequelae [N:3] Fa	tal [N:4] OUnknown			
	Sever (*) = Item is required [✓] = Source verification required [⑥] = Key item   Vote: Associated form = CONCOMITANT MEDICATIONS.								

	Study Object Descriptions: ADVERSE EVENTS							
	Type RefName		Description					
Item AESPID		AESPID	Calculated Record ID					

Keys (navigation)/Uniqueness: ADVERSE EVENT							
Item	Unique	Order #					
AE (Repeating f							
AETERM	None	1					
AESTDAT	None	2					

		ADVERSE EVENTS		I		
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefNam	
CLDTORONG	Integer	Date	0	DATEP	AEONGO	
		Ongoing	1	ONGOING		
CLYN Integer		Yes	1	CLIY	AESER	
		No	0	CLIN		
CLSAECAT	Integer	Fatal		AESDTH	AESERY	
		Initial or Prolonged Hospitalization	2	AESHOSP		
		Congenital Anomaly/Birth Defect	3	AESCONG		
		Life Threatening	4	AESLIFE		
		Disability or Permanent Damage	5	AESDISAB		
		Other Important Medical Events	6	AESMIE		
CLAETOX	Integer	1	1	GRADE1	AETOXGR	
		2	2	GRADE2		
		3	3	GRADE3		
		4	4	GRADE4		
		5	5	GRADE5		
CLAEREL	Integer	Unrelated	1	AERUNR	AEREL	
		Unlikely	2	AERUNL		
		Possible	3	AERPOSS		
		Probable	4	AERPROB		
		Definite	5	AERDEF		
CLAETRYN	Integer	Yes (enter relevant information on CM form)	1	AETRTYES	AETRT	
		No	0	CLIN		
CLAEACT	Integer	None	1	AEANONE	AEACN	
		Drug Interrupted	2	AEAINTER		
		Dose Delayed	3	AEADEL		
		Drug Discontinued	4	AEADIS		
		Study Terminated	5	AEASTERM		
CLAEOUT	Integer	Resolved	1	AEORES	AEOUT	
		Resolved with Sequelae	2	AEORESS		
		Fatal	3	AEOFATL	1	
		Unknown	4	AEOUNK	1	

RDE Analytics: RD_AE					
Data Variable RefName	RD Column Name	Column Data Type			
AESPID	AESPID	NUMBER			
	AESPID_ND	VARCHAR2			
AETERM	AETERM	VARCHAR2			
	AETERM_ND	VARCHAR2			
AESTDAT	AESTDAT	DATE			
	AESTDAT_DTS	VARCHAR2			
	AESTDAT_DTR	VARCHAR2			
	AESTDAT_ND	VARCHAR2			
AEONGO	AEONGO_C	**NUMBER			
	AEONGO	VARCHAR2			
	AEONGO_ND	VARCHAR2			

AEONGO - AEENDAT	AEENDAT	DATE
	AEENDAT_DTS	VARCHAR2
	AEENDAT_DTR	VARCHAR2
AESER	AESER_C	**NUMBER
	AESER	VARCHAR2
	AESER_ND	VARCHAR2
AESER - Fatal	AESERY_AESDTH_C	NUMBER
	AESERY_AESDTH	VARCHAR2
AESER - Initial or Prolonged Hospitalization	AESERY_AESHOSP_C	NUMBER
	AESERY_AESHOSP	VARCHAR2
AESER - Congenital Anomaly/Birth Defect	AESERY_AESCONG_C	NUMBER
	AESERY_AESCONG	VARCHAR2
AESER - Life Threatening	AESERY_AESLIFE_C	NUMBER
	AESERY_AESLIFE	VARCHAR2
AESER - Disability or Permanent Damage	AESERY_AESDISAB_C	NUMBER
	AESERY_AESDISAB	VARCHAR2
AESER - Other Important Medical Events	AESERY_AESMIE_C	NUMBER
	AESERY_AESMIE	VARCHAR2
AETOXGR	AETOXGR_C	NUMBER
	AETOXGR	VARCHAR2
	AETOXGR_ND	VARCHAR2
AEREL	AEREL_C	NUMBER
	AEREL	VARCHAR2
	AEREL_ND	VARCHAR2
AETRT	AETRT_C	NUMBER
	AETRT	VARCHAR2
	AETRT_ND	VARCHAR2
AEACN	AEACN_C	NUMBER
	AEACN	VARCHAR2
	AEACN_ND	VARCHAR2
AEOUT	AEOUT_C	NUMBER
	AEOUT	VARCHAR2
	AEOUT_ND	VARCHAR2
Key: [**] = In some versions of Inform and Rep	porting the data type will be	reported as VARCHAR2.

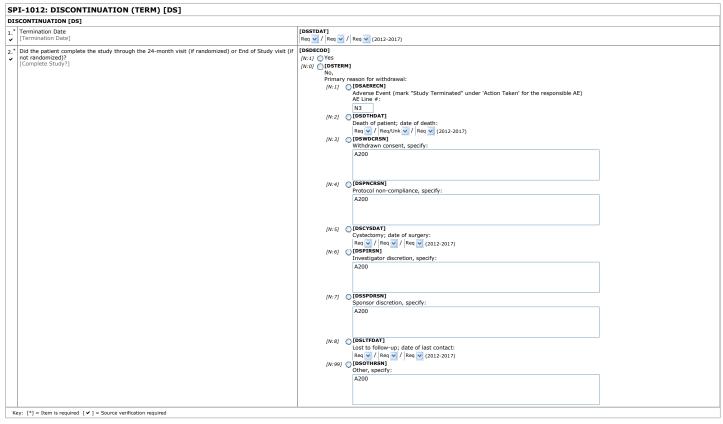
SI	SPI-1012: CONCOMITANT MEDICATIONS (CM) - Repeating Form [CM]									
#	Line #	Medication Name	Start Date	End Date or Ongoing	Dose/Unit	Route	Frequency	Indication		
1										
CC	NCOMITANT MED	ICATIONS [CM]								
1.	Line # [read-only] [Line #]	1		[CMSPID] N10						
2.*	Medication Name [Medication Name	1		[CMTRT] A100						
3.	3.* Start Date (CMSTDAT)   Start Date     Req/Unk v / Req v (1914-2017)									
4.* End Date [End Date or Ongoing]				[CMONGO] [N:0] [CMENDAT]   Req   /   Req/Unk   /   Req   (2012-20)						
5.*	Dose/Unit [Dose/Unit]			[CMDOSTOT] [CMDOSU]  Dose: A25 Unit: A25	[CMDOSTOT] [CMDOSU]					
6.	Route [Route]			[CMROUTE] A25						
7.*	Frequency [Frequency]			[CMDOSFRQ] A25						
8.*	[MINOC] [Indication] [Indication] [Indication] [Insert contains the second contains th									
	(ey: [*] = Item is required form :	uired [ $\checkmark$ ] = Source verification required [ $\ifmmode blue blue blue blue blue blue blue blu$	y item							
_										

Study Object Descriptions: CONCOMITANT MEDICATIONS		
Туре	RefName	Description
Item	CMSPID	Calculated Record ID

Keys (navigation)/Uniqueness: CONCOMITANT MEDICATIONS			
Item	Unique	Order #	
CM (Repeating form	)		
CMTRT	None	1	
CMSTDAT	None	2	

Codelist Values and Tables: CONCOMITANT MEDICATIONS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLDTORONG	Integer	Date	0	DATEP	CMONGO
		Ongoing	1	ONGOING	
CLCMIND	Integer	Adverse Event (enter relevant information on AE form)	1	ADVEVENT	CMINDC
		Other	99	OTHER	

Data Variable RefName	RD Column Name	Column Data Type
CMSPID	CMSPID	NUMBER
	CMSPID_ND	VARCHAR2
CMTRT	CMTRT	VARCHAR2
	CMTRT_ND	VARCHAR2
CMSTDAT	CMSTDAT	DATE
	CMSTDAT_DTS	VARCHAR2
	CMSTDAT_DTR	VARCHAR2
	CMSTDAT_ND	VARCHAR2
CMONGO	CMONGO_C	**NUMBER
	CMONGO	VARCHAR2
	CMONGO_ND	VARCHAR2
CMONGO - CMENDAT	CMENDAT	DATE
	CMENDAT_DTS	VARCHAR2
	CMENDAT_DTR	VARCHAR2
CMTDOSU	CMTDOSU_ND	VARCHAR2
CMTDOSU - CMDOSTOT	CMDOSTOT	VARCHAR2
CMTDOSU - CMDOSU	CMDOSU	VARCHAR2
CMROUTE	CMROUTE	VARCHAR2
	CMROUTE_ND	VARCHAR2
CMDOSFRQ	CMDOSFRQ	VARCHAR2
	CMDOSFRQ_ND	VARCHAR2
CMINDC	CMINDC_C	NUMBER
	CMINDC	VARCHAR2
	CMINDC_ND	VARCHAR2
CMINDC - CMINDCOT	CMINDCOT	VARCHAR2



Codelist Values and Tables: DISCONTINUATION					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLIY	DSDECOD
		No	0	CLIN	
CLWDRSN Int	Integer	Adverse event (mark "Study Terminated" under 'Action Taken' for the responsible AE)	1	TERMAE	DSTERM
		Death of patient	2	TERMDTH	
		Withdrawal of consent	3	TERMCONS	
		Protocol non-compliance	4	TERMPROT	
		Cystectomy	5	TERMCYST	
		Investigator discretion	6	TERMPI	
		Sponsor discretion	7	TERMSPON	
		Lost to follow-up	8	TERMLTFU	
		Other	99	OTHER	

RDE Analytics: RD_DS				
Data Variable RefName RD Column Name Column Data Type				
DSSTDAT	DSSTDAT	DATE		
	DSSTDAT_DTS	VARCHAR2		
	DSSTDAT_ND	VARCHAR2		
DSDECOD	DSDECOD_C	NUMBER		
	DSDECOD	VARCHAR2		
	DSDECOD_ND	VARCHAR2		
DSDECOD - DSTERM	DSTERM_C	**NUMBER		
	DSTERM	VARCHAR2		
DSDECOD - DSAERECN	DSAERECN	NUMBER		
DSDECOD - DSDTHDAT	DSDTHDAT	DATE		
	DSDTHDAT_DTS	VARCHAR2		
	DSDTHDAT_DTR	VARCHAR2		
DSDECOD - DSWDCRSN	DSWDCRSN	VARCHAR2		
DSDECOD - DSPNCRSN	DSPNCRSN	VARCHAR2		
DSDECOD - DSCYSDAT	DSCYSDAT	DATE		
	DSCYSDAT_DTS	VARCHAR2		
DSDECOD - DSPIRSN	DSPIRSN	VARCHAR2		
DSDECOD - DSSPDRSN	DSSPDRSN	VARCHAR2		
DSDECOD - DSLTFDAT	DSLTFDAT	DATE		
	DSLTFDAT_DTS	VARCHAR2		
		VARCHAR2		

Unit Conversions For Study Design: SPI-1012