

**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™**

**December 19, 2011 10:56AM**

<b>SPI-1012: SYSTEM SCREENING (SYS SCR) [SYSSCR]</b>	
<b>SYSTEM SCREENING [SYSSCR]</b>	
1.* ✓ Patient Initials [Patient Initials]	<b>[SSUBINIT]</b> A3
2.* ✓ Date of Birth [Date of Birth]	<b>[SBRTHDAT]</b> Req <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input type="checkbox"/> (1914-1995)
3.* ✓ Date Informed Consent Signed [Date Informed Consent Signed]	<b>[SICDAT]</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (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

<b>SPI-1012: SYSTEM ENROLLMENT (SYS ENR) [SYSENK]</b>	
<b>SYSTEM ENROLLMENT [SYSENK]</b>	
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	CLYI	SCONTE

RDE Analytics: RD_SYSENK		
Data Variable RefName	RD Column Name	Column Data Type
SCONTE	SCONTE_ND	VARCHAR2
SCONTE - Yes	SCONTE_CLYI_C	NUMBER
	SCONTE_CLYI	VARCHAR2

<b>SPI-1012: DATE OF VISIT (DOV) [DOV]</b>		
<b>DATE OF VISIT [DOV]</b>		
1.* ✓	Date of Visit [Date of Visit]	<b>[VISDAT]</b> Req <input type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (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

Study Object Descriptions: DEMOGRAPHICS		
Type	RefName	Description
Item	ICDAT	Value mapped from System Screening form and may be edited on this form
Item	SUBJINT	Value mapped from System Screening form and may be edited on this form
Item	BIRTHDAT	Value mapped from System Screening form and may be edited on this form

CodeList RefName	CodeList Data Type	Label	Code	CodeList Item RefName	Data Variable RefName
CLPROTV	Integer	Original	1	ORIGINAL	PROTVR
		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	HAWIISL	
		White or Caucasian	5	WHITE	
			99	OTHER	
CLSEX	Integer	Male	1	MALE	SEX
		Female	2	FEMALE	
CLYN	Integer	Yes	1	CL1Y	SCTESTCB, TOXEXP
		No	0	CL1N	
CLSMOKST	Integer	Current	1	CURSMK	SUNCF
		Former	2	FORMSMK	
		Never	3	NEVERSMK	

RDE Analytics: RD_DM		
Data Variable RefName	RD Column Name	Column Data Type
ICDAT	ICDAT	DATE
	ICDAT_DTS	VARCHAR2
	ICDAT_ND	VARCHAR2
PROTVR	PROTVR_C	NUMBER
	PROTVR	VARCHAR2
	PROTVR_ND	VARCHAR2
PROTVR - 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

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	CL1Y	IEYN, IEWO
		No	0	CL1N	
CLINCEXC	Integer	Inclusion	1	INCL	IECAT
		Exclusion	2	EXCL	

Key: **[\*\*]** = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

Study Object Descriptions: GENERAL MEDICAL HISTORY		
Type	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	CLYI	MHYN, MHONGM
		No	0	CLIN	
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	
Ongoing	1			ONGOING	

RDE Analytics: RD_MH		
Data Variable RefName	RD Column Name	Column Data Type
MHYN	MHYN_C	NUMBER
	MHYN	VARCHAR2
	MHYN_ND	VARCHAR2
<b>RD_MH_MHA</b>		
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

Key: [\*\*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.



SPI-1012: HISTORY OF BLADDER CANCER (CA HX) [CHX]

HISTORY OF BLADDER CANCER [CHX]

1.\*

Date of first pathologic diagnosis of bladder cancer

[Bladder Ca Diagnosis Date]

2.\*

Disease Status at Study Entry

[Disease Status at Study Entry]

3.\*

Is there surgery or therapy for bladder cancer within 36 months prior to study entry to report?

If 'Yes', click Add Entry button below to record details  
[Surgery or Therapy to Report?]

[CHXDAT]

Req/Unk / / Req/Unk / / Req (1914-2014)

[CHXDISST]

[N:1] Primary

[N:2] [CHXREGRP] Recurrent,

[CHXCYPDAT]

Date of last cystoscopy prior to the screening cystoscopy:

Req / / Req/Unk / / Req (1914-2014)

[CHXTUMR]

Were tumor(s) present? [N:1] Yes [N:0] No

[CHXYN]

[N:1] Yes [N:0] No

4.

Line #

Surgery/Therapy

Agent/Site

Number of Courses

Date of Last Treatment

Surgery or Therapy for Bladder Cancer Entry [PTX]

Record the details for surgery or therapy for bladder cancer within 36 months prior to study entry.

4.1

Line # [read-only]

[Line #]

4.2\*

Surgery/Therapy

[Surgery/Therapy]

4.3\*

Agent(s)/Site(s)

[Agent/Site]

4.4\*

Number of Courses

[Number of Courses]

4.5\*

Date of Last Treatment

[Date of Last Treatment]

[CHXSPID]

N10

[CHXTYPE]

[N:1] TURBT

[N:2] Immunotherapy

[N:3] Chemotherapy

[N:99] [CHXTYPEO] Other, specify:

A200

[CHXAGSIT]

A100

[CHXCOURS]

A40

[CHXTXDAT]

Req/Unk / / Req/Unk / / Req (1914-2014)

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

Study Object Descriptions: HISTORY OF BLADDER CANCER

Type	RefName	Description
Item	CHXSPID	Calculated Record ID

Codelist Values and Tables: HISTORY OF BLADDER CANCER

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLDSTAT	Integer	Primary	1	DSPRIM	CHXDISST
		Recurrent	2	DSRECUR	
CLYN	Integer	Yes	1	CL1Y	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 - CHXCYPDAT	CHXCYPDAT	DATE
	CHXCYPDAT_DTS	VARCHAR2
	CHXCYPDAT_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

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12/19/2011

<b>SPI-1012: VITAL SIGNS (VS (BL)) [VSS]</b>	
<b>VITAL SIGNS [VSS]</b>	
1.* ✓ Examination Date [Examination Date]	<b>[VSDAT]</b> Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2012-2017)
2.* ✓ Pulse [Pulse]	<b>[VSPULSE]</b> N3 <input type="text"/> beats/min <sup>[b]</sup>
3.* ✓ Blood Pressure [Blood Pressure]	<b>[VSBPGRP]</b> <b>[VSBPSYS]</b> <b>[VSBPDIA]</b> N3 <input type="text"/> N3 <input type="text"/> mmHg <sup>[b]</sup> Systolic Diastolic
4.* ✓ Temperature [Temperature]	<b>[VSTMPGRP]</b> <b>[VSTEMPU]</b> xxxx. <input type="text"/> [N:1] <input type="radio"/> °C [N:2] <input type="radio"/> °F
5.* ✓ Height [Height Group]	<b>[VSHTGRP]</b> <b>[VSHTU]</b> xxxx. <input type="text"/> [N:1] <input type="radio"/> cm [N:2] <input type="radio"/> in
6.* ✓ Weight [Weight]	<b>[VSSWTGRP]</b> <b>[VSWTU]</b> xxxx. <input type="text"/> [N:1] <input type="radio"/> kg [N:2] <input type="radio"/> lb
Key: [*] = Item is required [ ✓ ] = Source verification required [b] = Base Unit	

Study Object Descriptions: VITAL SIGNS

Type	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
		°F	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

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

**Codelist Values and Tables: PHYSICAL EXAMINATION**

RDE Analytics: RD PE

Key: **[\*\*]** = In some versions of Inform and Reporting the data type will be reported as 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 <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2012-2017)
2.* ✓	Chemistry Blood Sample Collection Date [Chemistry Collection Date]	[LBDATC] Req <input checked="" type="checkbox"/> / Req <input type="checkbox"/> / Req <input type="checkbox"/> (2012-2017)
Key: [*] = Item is required [ ✓ ] = Source verification required		

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

RDE Analytics: RD_LBU		
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 - LBCLSI BL	LBCLSI BL_C	NUMBER
	LBCLSI BL	VARCHAR2
PROTGRP	PROTGRP_ND	VARCHAR2
PROTGRP - LBORREPR	LBORREPR_C	NUMBER
	LBORREPR	VARCHAR2
PROTGRP - LBCLSI PR	LBCLSI PR_C	NUMBER
	LBCLSI PR	VARCHAR2
	GLUCGRP_ND	VARCHAR2
GLUCGRP - LBORREGL	LBORREGL_C	NUMBER
	LBORREGL	VARCHAR2
GLUCGRP - LBCLSI GL	LBCLSI GL_C	NUMBER
	LBCLSI GL	VARCHAR2
LUKEGRP	LUKEGRP_ND	VARCHAR2
	LBORRELE_C	NUMBER
	LBORRELE	VARCHAR2
LUKEGRP - LBCLSI LE	LBCLSI LE_C	NUMBER
	LBCLSI LE	VARCHAR2
KETOGRP	KETOGRP_ND	VARCHAR2
KETOGRP - LBORREKE	LBORREKE_C	NUMBER
	LBORREKE	VARCHAR2
KETOGRP - LBCLSI KE	LBCLSI KE_C	NUMBER
	LBCLSI KE	VARCHAR2

<b>SPI-1012: SERUM PREGNANCY (SERUM PREG) [LBSP]</b>				
<b>SERUM PREGNANCY [LBSP]</b>				
Specimen Collection for Central Laboratories				
1.*	Serum Pregnancy Blood Sample Collection Date	<b>[LBDATSP]</b> Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2012-2017)		
✓	[Serum Preg Collection Date]			
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

<b>SPI-1012: PROSTATE SPECIFIC ANTIGEN (PSA) [LBPS]</b>		
<b>PROSTATE SPECIFIC ANTIGEN [LBPS]</b>		
Specimen Collection for Central Laboratories		
1.* ✓	Prostate Specific Antigen Blood Sample Collection Date [PSA Collection Date]	<b>[LBDATPSA]</b> Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (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

<b>SPI-1012: URINE CYTOLOGY (URIN CYTO) [LBUC]</b>	
<b>URINE CYTOLOGY [LBUC]</b>	
Specimen Collection for Central Laboratories	
1.* ✓ Urine Cytology Sample Collection Date [Urine Cytology Collection Date]	<b>[LBDATUC]</b> Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2012-2017)
2.* ✓ Was the specimen confirmed as <b>not</b> the first morning urine void? [Confirmed Not First Morning Void?]	<b>[LBNFMVUC]</b> [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No
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	CLYI	LBNFMVUC
		No	0	CLIN	

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



SPI-1012: UPPER URINARY TRACT EVALUATION (UTRACT EVAL) [UTE]

UPPER URINARY TRACT EVALUATION [UTE]

1.\*  
✓

Was an upper tract evaluation performed?  
[Upper Tract Evaluation Performed?]

[UTEPERF]

[N:1] ☐ Yes [N:0] ☐ No

2.

Line #

Date of Procedure

Type of Evaluation

Result

Evaluation Entry [UTE2]

2.1  
Line # [read-only]  
[Line #]

[UTESPID]

N10

2.2\*  
✓

Date of Procedure  
[Date of Procedure]

[UTEPRDAT]

Req ☒ / Req/Unk ☒ / Req ☒ (2012-2017)

2.3\*  
✓

Type of Evaluation  
[Type of Evaluation]

[UTEEVTYP]

A200

2.4\*  
✓

Result  
[Result]

[UTERSLT]

[N:1] ☐ Normal  
[N:2] ☐ [UTEABNSP]  
Abnormal,  
Specify findings:  
A200

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	CLIIY	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

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12/19/2011

RDE Analytics: RD_CYSS		
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
CYLESOB	CYLESOB_C	**NUMBER
	CYLESOB	VARCHAR2
	CYLESOB_ND	VARCHAR2
	CYLSOBT	VARCHAR2
CYLESOB - CYSNUMT	CYSNUMT	NUMBER
CYLESOB - 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

Key: [\*\*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

<b>SPI-1012: NEXT VISIT (NEXT VISIT) [CONTV]</b>	
<b>NEXT VISIT [CONTV]</b>	
1.* Continue to next protocol-defined visit?  <i>If 'Yes', the next visit will become available for entry.</i> [Continue to Next Visit?]	<b>[CONTV]</b> [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No
Key: [*] = Item is required	

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

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

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

RDE Analytics: RD_VS		
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
VSTMGRP	VSTMGRP_ND	VARCHAR2
VSTMGRP - VSTEMP	VSTEMP	FLOAT
VSTMGRP - VSTEMPU	VSTEMPU_C	NUMBER
	VSTEMPU	VARCHAR2
	VSWTNA_C	**NUMBER
VSWTNA	VSWTNA	VARCHAR2
	VSWTNA_ND	VARCHAR2
	VSWT	FLOAT
VSWTNA - VSWTU	VSWTU_C	NUMBER
	VSWTU	VARCHAR2

Key: [\*\*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

<b>SPI-1012: URINE PREGNANCY (URIN PREG) [LBUP]</b>	
<b>URINE PREGNANCY [LBUP]</b>	
Specimen Collection for Central Laboratories	
1.* ✓ Urine Pregnancy Sample Collection Date [Urine Preg Collection Date]	<b>[LBDATUP]</b> Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2012-2017)
2.* ✓ Results [Results]	<b>[LBORREUP]</b> [N:1] <input checked="" type="radio"/> Negative [N:2] <input checked="" type="radio"/> Positive
Key: [*] = Item is required [✓] = 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

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

CodeList RefName	CodeList Data Type	Label	Code	CodeList Item RefName	Data Variable RefName
CLTRMTH	Integer	White Light	1	WHITELT	TURMTHD
		Blue Light	2	BLUELT	
CLYN	Integer	Yes	1	CLYI	TURHEXV, TURLRES, TURPATH
		No	0	CLIN	
CLTUMLOC	String	Dome	DO	DOME	TURLOC
		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_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

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

<b>SPI-1012: STUDY DRUG INSTILLATION (STUDY DRUG) [EX]</b>		
<b>STUDY DRUG INSTILLATION [EX]</b>		
1.* ✓ Date of Instillation [Date of Instillation]	<b>[EXSTDAT]</b> Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> / Req <input checked="" type="checkbox"/> (2012-2017)	
2.* ✓ Time of Study Drug Reconstitution [Time of Study Drug Reconstitution]	<b>[EXSDRTIM]</b> Req <input checked="" type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock	
3.* ✓ Time Study Drug Instillation Started [Time Instillation Started]	<b>[EXSTTIM]</b> Req <input checked="" type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock	
4.* ✓ Time Study Drug Drained from Bladder [Time Drained from Bladder]	<b>[EXENTIM]</b> Req <input checked="" type="checkbox"/> : Req <input checked="" type="checkbox"/> 24-hour clock	
5.* ✓ Volume of Instillate [Volume of Instillate]	<b>[EXVOLT]</b> [N:1] <input checked="" type="radio"/> 40 mL [N:99] <input checked="" type="radio"/> <b>[EXVOLGRP]</b> Other, <b>[EXVOLTOT]</b> specify the volume: xx. <input type="text"/> mL <sup>[b]</sup> <b>[EXVOLTRS]</b> and give reason: A200 <input type="text"/>	
6.* ✓ Was the study drug retained in bladder for 54-66 minutes? [Was Study Drug Retained in Bladder for 54-66 min?]	<b>[EXDRET]</b> [N:1] <input checked="" type="radio"/> Yes [N:0] <input checked="" type="radio"/> <b>[EXDURRS]</b> No, reason: A200 <input type="text"/>	
7.* ✓ Was there any leakage? [Leakage?]	<b>[EXLEAK]</b> [N:1] <input checked="" type="radio"/> <b>[EXVOLL]</b> Yes, estimate the leaked volume: xx. <input type="text"/> mL <sup>[b]</sup> [N:0] <input checked="" type="radio"/> No	
Key: [*] = Item is required [✓] = Source verification required [b] = Base Unit		

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	CLIIY	EXDRET, EXLEAK
		No	0	CLIN	

RDE Analytics: RD_EX		
Data Variable RefName	RD Column Name	Column Data Type
EXSTDAT	EXSTDAT	DATE
	EXSTDAT_DTS	VARCHAR2
	EXSTDAT_ND	VARCHAR2
EXSDRTIM	EXSDRTIM	DATE
	EXSDRTIM_TMS	VARCHAR2
	EXSDRTIM_ND	VARCHAR2
EXSTTIM	EXSTTIM	DATE
	EXSTTIM_TMS	VARCHAR2
	EXSTTIM_ND	VARCHAR2
EXENTIM	EXENTIM	DATE
	EXENTIM_TMS	VARCHAR2
	EXENTIM_ND	VARCHAR2
EXVOLT	EXVOLT_C	NUMBER
	EXVOLT	VARCHAR2
	EXVOLT_ND	VARCHAR2
EXVOLT - EXVOLTOT	EXVOLTOT	FLOAT
	EXVOLTOT_U	VARCHAR2
EXVOLT - EXVOLTRS	EXVOLTRS	VARCHAR2
EXDRET	EXDRET_C	NUMBER
	EXDRET	VARCHAR2
	EXDRET_ND	VARCHAR2
EXDRET - EXDURRS	EXDURRS	VARCHAR2
EXLEAK	EXLEAK_C	**NUMBER
	EXLEAK	VARCHAR2
	EXLEAK_ND	VARCHAR2
EXLEAK - EXVOLL	EXVOLL	FLOAT
	EXVOLL_U	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		



SPI-1012: RANDOMIZATION (RAND) [RAN]

RANDOMIZATION [RAN]

1.\* Was the patient eligible for the double blind phase of study?  
[Patient Eligible for Double Blind Phase?]

2.\* Was the patient randomized?  
[Was Patient Randomized?]

[RANRES]  
[N:1] ☒ Yes [N:0] ☐ No

[RANRAND]  
[N:1] ☒ [RANDGRP]  
Yes,  
[RANDDAT]  
Date Randomized:  
Req ☒ / Req ☒ / Req ☒ (2012-2017)  
[RANDKITN]  
Study Drug Kit Number:  
A5  
[N:0] ☐ [RANNDRSN]  
No, give reason:  
A200

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

Study Object Descriptions: RANDOMIZATION		
Type	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	CLII	RANRES,
		No	0	CLIN	RANRAND

RDE Analytics: RD_RAN		
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
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

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12/19/2011

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

Type	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	CLYI	EOSINST
		No	0	CLIN	

Data Variable RefName	RD Column Name	Column Data Type
EOSINST	EOSINST_C	NUMBER
	EOSINST	VARCHAR2
	EOSINST_ND	VARCHAR2
EOSINST - EOSVISND	EOSVISND	VARCHAR2

RDE Analytics: RD_PE2		
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

Key: [\*]= In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

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

CodeList RefName	CodeList Data Type	Label	Code	CodeList Item RefName	Data Variable RefName
CLCYSMTMD	Integer	White Light	1	WHITELT	CYSMTMD
		Blue Light	2	BLUELT	
CLYN	Integer	Yes	1	CLYI	CYSHEXV, CYSLESO1, CYSCAUR, CYS CP, CYSABNYN
		No	0	CLIN	
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
CYSLES01	CYSLES01_C	**NUMBER
	CYSLES01	VARCHAR2
	CYSLES01_ND	VARCHAR2
CYSLES01 - Biopsy	CYSACTT1_TUMBX_C	NUMBER
	CYSACTT1_TUMBX	VARCHAR2
CYSLES01 - TURBT planned	CYSACTT1_TUMTURBT_C	NUMBER
	CYSACTT1_TUMTURBT	VARCHAR2
CYSLES01 - Other	CYSACTT1_CYSACTTO_C	NUMBER
	CYSACTT1_CYSACTTO	VARCHAR2
CYSLES01 - 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
<b>RD_CYS_OBSTUM</b>		
CYSTNO	CYSTNO	NUMBER
	CYSTNO_ND	VARCHAR2
CYSLOC	CYSLOC_C	VARCHAR2
	CYSLOC	VARCHAR2
	CYSLOC_ND	VARCHAR2
CYSLD	CYSLD	FLOAT
	CYSLD_ND	VARCHAR2
Key: [**] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.		

### Study Object Descriptions: TRANSURETHRAL RESECTION

**Codelist Values and Tables: TRANSURETHRAL RESECTION**RDE Analytics: RD\_TUR

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<b>SPI-1012: START FOLLOW-UP (START FU) [STFUV]</b>	
<b>START FOLLOW-UP [STFUV]</b>	
1.* Will subject enter follow-up period? [Start Follow-Up Visits?]	<b>[STFUVIS]</b> [N:1] <input checked="" type="radio"/> Yes [N:0] <input type="radio"/> No
Key: [*] = Item is required	

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

Codelist Values and Tables: START FOLLOW-UP					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLYI	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

Please answer 'Yes' or 'No' for each scheduled follow-up visit listed below to indicate if the visit was performed 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] <input type="radio"/> Yes [N:0] <input type="radio"/> No
2.* Follow-Up Visit 9 (6 months) [V9 FU]	[STFUV9] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
3.* Follow-Up Visit 10 (9 months) [V10 FU]	[STFUV10] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
4.* Follow-Up Visit 11 (12 months) [V11 FU]	[STFUV11] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
5.* Follow-Up Visit 12 (15 months) [V12 FU]	[STFUV12] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
6.* Follow-Up Visit 13 (18 months) [V13 FU]	[STFUV13] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
7.* Follow-Up Visit 14 (21 months) [V14 FU]	[STFUV14] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
8.* Follow-Up Visit 15 (24 months) [V15 FU]	[STFUV15] [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
Key: [*] = Item is required [✓] = Source verification required	

Type	RefName	Description
Form	FUV	If any Follow-Up Visit item question is 'Yes', the associated FU visit is triggered

Columnist RefName	Columnist Data Type	Label	Code	Columnist Item RefName	Data Variable RefName
CLYN	Integer	Yes	1	CLYI	STFUV8, STFUV9, STFUV10, STFUV11, STFUV12, STFUV13, STFUV14, STFUV15
		No	0	CLIN	

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



Study Object Descriptions: CYSTOSCOPY		
Type	RefName	Description
Form	CYS8	Cystoscopy at V8 (3-mo only)
Item	CYSTNO1	Calculated Record ID

CodeList RefName	CodeList Data Type	Label	Code	CodeList Item RefName	Data Variable RefName
CLCSYMTMD	Integer	White Light	1	WHITELT	CYSMTMD
		Blue Light	2	BLUFLT	
CLYN	Integer	Yes	1	CLYI	CYSHEXV, CYSTURRE, CYSLESO2, CYSCAUR, CYS CP, CYSABNYN
		No	0	CLIN	
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	

**RDE Analytics: RD\_CYS8**

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
CYSTURRE	CYSTURRE_C	NUMBER
	CYSTURRE	VARCHAR2
	CYSTURRE_ND	VARCHAR2
CYSTURRE - Base Wall	CYSURLOC_BASEWALL_C	VARCHAR2
	CYSURLOC_BASEWALL	VARCHAR2
CYSTURRE - Back Wall	CYSURLOC_BACKWALL_C	VARCHAR2
	CYSURLOC_BACKWALL	VARCHAR2
CYSTURRE - Left Wall	CYSURLOC_LTWALL_C	VARCHAR2
	CYSURLOC_LTWALL	VARCHAR2
CYSTURRE - Right Wall	CYSURLOC_RTWALL_C	VARCHAR2
	CYSURLOC_RTWALL	VARCHAR2
CYSTURRE - Dome	CYSURLOC_DOME_C	VARCHAR2
	CYSURLOC_DOME	VARCHAR2
CYSTURRE - Bladder Neck	CYSURLOC_BLADNECK_C	VARCHAR2
	CYSURLOC_BLADNECK	VARCHAR2
CYSTURRE - Trigone	CYSURLOC_TRIGONE_C	VARCHAR2
	CYSURLOC_TRIGONE	VARCHAR2
CYSLESO2	CYSLESO2_C	**NUMBER
	CYSLESO2	VARCHAR2
	CYSLESO2_ND	VARCHAR2
CYSLESO2 - Biopsy	CYSACTT_TUMBX_C	NUMBER
	CYSACTT_TUMBX	VARCHAR2
CYSLESO2 - TURBT planned	CYSACTT_TUMTURBT_C	NUMBER
	CYSACTT_TUMTURBT	VARCHAR2
CYSLESO2 - Other	CYSACTT_CYSACTTO_C	NUMBER
	CYSACTT_CYSACTTO	VARCHAR2
CYSLESO2 - CYSACTTO	CYSACTTO	VARCHAR2
	CYSACTTO	VARCHAR2
	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
<b>RD_CYS8_OBSTUM2</b>		
CYSTNO1	CYSTNO1	NUMBER
	CYSTNO1_ND	VARCHAR2
CYSLOC1	CYSLOC1_C	VARCHAR2
	CYSLOC1	VARCHAR2
	CYSLOC1_ND	VARCHAR2
CYSLD1	CYSLD1	FLOAT
	CYSLD1_ND	VARCHAR2

Key: [\*\*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

**SPI-1012: LABLOAD (LABLOAD) - Repeating Form [LBLOAD]**

#	Visit#, Unscheduled Sequence#	Collection Date	Collection Time	Accession #	Test Code	Test Name	Department Name	US (Conventional) Result	US Unit	US Low Range	US High Range	SI (Standard International) Result	SI Unit	SI Low Range	SI High Range	Result Flag	Toxicity Grade	Test Specific Comments1	Test Specific Comments2	Department Comments1	Department Comments2	General/Receiving Comments1	General/Receiving Comments2		
1																									
<b>LABLOAD [LBLOAD]</b>																									
1.*	Visit#, Unscheduled Sequence# [Visit#, Unscheduled Sequence#]																[LBVISITN] A10								
2.*	Collection Date [Collection Date]																[LBDAT] A15								
3.*	Collection Time [Collection Time]																[LBDATTM] A15								
4.*	Accession # [Accession #]																[LBREFID] A14								
5.*	Test Code [Test Code]																[LBTESTCD] A8								
6.*	Test Name [Test Name]																[LBTEST] A30								
7.*	Department Name [Department Name]																[LBDEPTNM] A30								
8.*	US (Conventional) Result [US (Conventional) Result]																[LBORRESC] A14								
9.*	US Unit [US Unit]																[LBUSUNIT] A14								
10.*	US Low Range [US Low Range]																[LBUSLOWR] A10								
11.*	US High Range [US High Range]																[LBUSHIR] A10								
12.*	SI (Standard International) Result [SI (Standard International) Result]																[LBORRESS] A14								
13.*	SI Unit [SI Unit]																[LBSIUNIT] A14								
14.*	SI Low Range [SI Low Range]																[LBSILOWR] A10								
15.*	SI High Range [SI High Range]																[LBSIHIR] A10								
16.*	Result Flag [Result Flag]																[LBFLAG] A2								
17.*	Toxicity Grade [Toxicity Grade]																[LBTOXGR] A2								
18.*	Test Specific Comments1 [Test Specific Comments1]																[LBSTTCM1] A250								
19.*	Test Specific Comments2 [Test Specific Comments2]																[LBSTTCM2] A250								
20.*	Department Comments1 [Department Comments1]																[LBPTCM1] A250								
21.*	Department Comments2 [Department Comments2]																[LBPTCM2] A250								
22.*	General/Receiving Comments1 [General/Receiving Comments1]																[LBGRCM1] A250								
23.*	General/Receiving Comments2 [General/Receiving Comments2]																[LBGRCM2] A250								
Key: [*] = Item is required [✓] = Source verification required																									

**Study Object Descriptions: LABLOAD**

Type	RefName	Description
Form	LBLOAD	This form is a target form for external data to be loaded via Direct Data Loader and that it should be dynamic without a triggering condition

**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

LBSUNIT	LBSUNIT	VARCHAR2
	LBSUNIT_ND	VARCHAR2
LBSLOWR	LBSLOWR	VARCHAR2
	LBSLOWR_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

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

Codelist Values and Tables: UNSCHEDULED FORMS					
Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLUNSRM	Integer	VITAL SIGNS	1	F_VS	UNSRMS
		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_UNSRM		
Data Variable RefName	RD Column Name	Column Data Type
UNSRFMS	UNSRFMS_ND	VARCHAR2
UNSRFMS - VITAL SIGNS	UNSRFMS_F_VS_C	NUMBER
	UNSRFMS_F_VS	VARCHAR2
UNSRFMS - PHYSICAL EXAMINATION	UNSRFMS_F_PE_C	NUMBER
	UNSRFMS_F_PE	VARCHAR2
UNSRFMS - HEMATOLOGY/CHEMISTRY	UNSRFMS_F_HMCHM_C	NUMBER
	UNSRFMS_F_HMCHM	VARCHAR2
UNSRFMS - URINE DIPSTICK	UNSRFMS_F_URIN_C	NUMBER
	UNSRFMS_F_URIN	VARCHAR2
UNSRFMS - URINE PREGNANCY	UNSRFMS_F_UPREG_C	NUMBER
	UNSRFMS_F_UPREG	VARCHAR2
UNSRFMS - URINE CYTOLOGY	UNSRFMS_F_UCYT_C	NUMBER
	UNSRFMS_F_UCYT	VARCHAR2
UNSRFMS - UPPER URINARY TRACT EVALUATION	UNSRFMS_F_UTE_C	NUMBER
	UNSRFMS_F_UTE	VARCHAR2
UNSRFMS - TRANSURETHRAL RESECTION	UNSRFMS_F_TURBT_C	NUMBER
	UNSRFMS_F_TURBT	VARCHAR2
UNSRFMS - CYSTOSCOPY	UNSRFMS_F_CYSTO_C	NUMBER
	UNSRFMS_F_CYSTO	VARCHAR2
UNSRFMS - LOCAL PATHOLOGY	UNSRFMS_F_LPATH_C	NUMBER
	UNSRFMS_F_LPATH	VARCHAR2

<b>SPI-1012: ADVERSE EVENTS OR CONMEDS TO REPORT? (AE/CM?) [ACTF]</b>	
<b>ADVERSE EVENTS OR CONMEDS TO REPORT? [ACTF]</b>	
1.* ✓ Are there any adverse events to report? [Adverse Events to Report?]	<b>[AEYN]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
2.* ✓ Are there any concomitant medications to report? [Concomitant Medications to Report?]	<b>[CMYN]</b> [N:1] <input type="radio"/> Yes [N:0] <input type="radio"/> No
Key: [*] = Item is required    [✓] = Source verification required	

Study Object 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	CL1Y	AEYN, CMYN
		No	0	CL1N	

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

**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	
<b>ADVERSE EVENTS [AE]</b>											
1.	Line # [read-only] [Line #]										
						<b>[AESPID]</b> N10					
2.*	Adverse Event Term [Adverse Event Term]					<b>[AETERM]</b> A100					
3.*	Start Date [Start Date]					<b>[AESTDAT]</b> Req <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2012-2017)					
4.*	End Date [End Date or Ongoing]					<b>[AEONGO]</b> [N:0] <input type="radio"/> <b>[AEENDAT]</b> Req <input checked="" type="checkbox"/> / Req/Unk <input type="checkbox"/> / Req <input checked="" type="checkbox"/> (2012-2017) [N:1] <input type="radio"/> Ongoing					
5.*	Serious Adverse Event? [Serious Adverse Event?]					<b>[AESER]</b> [N:1] <input type="radio"/> <b>[AESERY]</b> Yes, mark all categories that apply: [N:1] <input type="checkbox"/> Fatal [N:2] <input type="checkbox"/> Initial or Prolonged Hospitalization [N:3] <input type="checkbox"/> Congenital Anomaly/Birth Defect [N:4] <input type="checkbox"/> Life Threatening [N:5] <input type="checkbox"/> Disability or Permanent Damage [N:6] <input type="checkbox"/> Other Important Medical Events [N:0] <input type="radio"/> No					
6.*	CTCAE Toxicity Grade [CTCAE Toxicity Grade]					<b>[AETOXGR]</b> [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					
7.*	Relationship [Relationship]					<b>[AEREL]</b> [N:1] <input type="radio"/> Unrelated [N:2] <input type="radio"/> Unlikely [N:3] <input type="radio"/> Possible [N:4] <input type="radio"/> Probable [N:5] <input type="radio"/> Definite					
8.*	Treatment Given? [Treatment Given?]					<b>[AETRT]</b> [N:1] <input type="radio"/> Yes (enter relevant information on CM form) [N:0] <input type="radio"/> No					
9.*	Action Taken [Action Taken]					<b>[AEACN]</b> [N:1] <input type="radio"/> None [N:2] <input type="radio"/> Drug Interrupted [N:3] <input type="radio"/> Dose Delayed [N:4] <input type="radio"/> Drug Discontinued [N:5] <input type="radio"/> Study Terminated					
10.	Outcome [Outcome]					<b>[AEOUT]</b> [N:1] <input type="radio"/> Resolved [N:2] <input type="radio"/> Resolved with Sequelae [N:3] <input type="radio"/> Fatal [N:4] <input type="radio"/> Unknown					
Key: [*] = Item is required [✓] = Source verification required [K] = Key item Note: Associated form = CONCOMITANT MEDICATIONS.											

**Study Object Descriptions: ADVERSE EVENTS**

Type	RefName	Description
Item	AESPID	Calculated Record ID

**Keys (navigation)/Uniqueness: ADVERSE EVENTS**

Item	Unique	Order #
<b>AE (Repeating form)</b>		
AETERM	None	1
AESTDAT	None	2

**Codelist Values and Tables: ADVERSE EVENTS**

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
CLDTORONG	Integer	Date	0	DATEP	AEONGO
		Ongoing	1	ONGOING	
CLYN	Integer	Yes	1	CLYI	AESER
		No	0	CLIN	
CLSAECAT	Integer	Fatal	1	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	
		Unknown	4	AEOUNK	

**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
	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 Reporting the data type will be reported as VARCHAR2.		



SPI-1012: CONCOMITANT MEDICATIONS (CM) - Repeating Form [CM]

#	Line #	Medication Name	Start Date	End Date or Ongoing	Dose/Unit	Route	Frequency	Indication
1								

CONCOMITANT MEDICATIONS [CM]

1. Line # [read-only]  
[Line #]

[CMSPID]  
N10

2.\* Medication Name  
[Medication Name]

[CMTRT]  
A100

3.\* Start Date  
[Start Date]

[CMSTDAT]  
Req/Unk / Req/Unk / Req (1914-2017)

4.\* End Date  
[End Date or Ongoing]

[CMONGO]  
[N:0] [CMENDAT]  
Req / Req/Unk / Req (2012-2017) [N:1] Ongoing

5.\* Dose/Unit  
[Dose/Unit]

[CMTDOSU]  
[CMDOSTOT]  
Dose: A25 Unit: A25

6.\* Route  
[Route]

[CMROUTE]  
A25

7.\* Frequency  
[Frequency]

[CMDOSFRQ]  
A25

8.\* Indication  
[Indication]

[CMINDC]  
[N:1] Adverse Event (enter relevant information on AE form)  
[N:99] [CMINDCOT]  
Other:  
A100

Key: [\*] = Item is required [✓] = Source verification required [K] = Key item  
Note: Associated form = ADVERSE EVENTS.

Study Object Descriptions: CONCOMITANT MEDICATIONS

Type	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	

RDE Analytics: RD\_CM

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
	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

Key: [\*\*] = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

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

Key: **[\*\*]** = In some versions of Inform and Reporting the data type will be reported as VARCHAR2.

<b>Unit Conversions For Study Design: SPI-1012</b>
No unit conversion data.