SPI-611 #025 Informed Consent / Inclusion Criteria #001

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 0 1

Visit Date: DD MMM YYYY

INFORMED CONSENT

Date Informed Consent Signed: DD MMM YYYY

Screening ID:

INCLUSION CRITERIA

All of the following questions must be answered "YES" or "N/A" in order for the patient to participate in the study.

		YES	NO	N/A
1.	Has the patient given written informed consent?	☐	☐	
2.	Is the patient at least 18 years old?	☐	☐	
3.	Does the patient have transitional cell carcinoma of the bladder with clinically apparent stage Ta, grade G1-G2?	☐	☐	
4.	If the patient is a female of childbearing potential, is she using an acceptable/effective method of contraception?	☐	☐	☐
5.	If the patient is a female of childbearing potential, has she had a negative serum pregnancy test within the past 14 days?	☐	☐	☐
6.	Is the patient willing and able to abide by the protocol?	☐	☐	

SPI-611 #025 Exclusion Criteria #002

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 01

EXCLUSION CRITERIA

All of the following questions must be answered "NO" in order for the patient to participate in the study.

	YES	NO
1. Does the patient have more than 4 bladder tumors?	☐	☐
2. Does any single bladder tumor exceed 3.5 cm in diameter?	☐	☐
3. Does the patient have a single, primary (no previous diagnosis of TCC) bladder tumor <0.5 cm?	☐	☐
4. Has the patient ever received EOquin®?	☐	☐
5. Does the patient have, or has the patient ever had, any bladder tumor known to be other than stage Ta or grade G1 or G2 (low grade [WHO/ISUP classification])?	☐	☐
6. Does the patient have, or has the patient ever had, any bladder tumor with histology other than transitional cell carcinoma?	☐	☐
7. Does the patient have, or has the patient ever had, CIS?	☐	☐
8. Does the patient have an active urinary tract infection?	☐	☐
9. Does the patient have a bleeding disorder or a screening platelet count <100 x 10^9/L?	☐	☐
10. Does the patient have any unstable medical condition that would make it unsafe for him/her to undergo TUR-BT under general or spinal anesthesia?	☐	☐
11. Does the patient have a screening hemoglobin <10 mg/dL, a screening absolute neutrophil count <1.5 x 10^9/L or a screening creatinine >2 mg/dL?	☐	☐
12. Does the patient have a known immunodeficiency disorder?	☐	☐
13. Has the patient received any investigational treatment within the past 30 days?	☐	☐
14. Is the patient breast feeding?	☐	☐
15. Does the patient have a history of interstitial cystitis?	☐	☐
16. Does the patient have a history of allergy to red color food dye?	☐	☐
17. Has the patient had transitional cell carcinoma of the bladder within the past 4 months?	☐	☐

SPI-611 #025 Demographics / Smoking Status #003

Site No. | Randomization No. | Patient Initials

SCREENING

DF Code: 01

DEMOGRAPHICS

Date of Birth: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Sex: ☐ Male ☐ Female

Ethnicity: *(Mark "X" one)*
- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

Race: *(Mark "X" all that apply)*
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

SMOKING STATUS

Smoking Status: *(Mark "X" one)*
- ☐ Current
- ☐ Former
- ☐ Never

SPI-611 #025 Medical History #004

Site No. | Randomization No. | Patient Initials

SCREENING

DF Code: 01

MH Page #: 01

Mark "X" if Last MH Page: ☐

MEDICAL HISTORY

Please record any previous illnesses, surgery or medical conditions in the space provided below. Please provide an approximate date of onset (month and year).

Body System Code	Body System	Normal	Abnormal	If ABNORMAL, Specify
01	EYES	☐	☐	
02	EARS, NOSE, THROAT	☐	☐	
03	RESPIRATORY	☐	☐	
04	CARDIOVASCULAR	☐	☐	
05	GASTROINTESTINAL	☐	☐	
06	MUSCULOSKELETAL	☐	☐	
07	SKIN	☐	☐	
08	CNS/PSYCHIATRIC	☐	☐	
09	ENDOCRINE	☐	☐	
			☐	
			☐	
			☐	

System Codes:

01 = Eyes
02 = Ears, Nose, Throat
03 = Respiratory
04 = Cardiovascular
05 = Gastrointestinal
06 = Musculoskeletal
07 = Skin
08 = CNS/Psychiatric
09 = Endocrine
93 = Other

SPI-611 #025 Bladder Cancer History #005

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 01

BLADDER CANCER HISTORY

Is the current tumor primary or recurrent bladder cancer?

- ☐ Primary
- ☐ Recurrent, complete below:

If RECURRENT, complete the following:

Date of First Pathological Diagnosis of Bladder Cancer: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Number of Previous Cystoscopies Positive for Bladder Cancer: ☐☐

Date of Last Occurrence: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Were any prior intravesical therapies administered? *(Mark all that apply)*

- ☐ BCG
- ☐ Mitomycin C
- ☐ Other, specify: _____

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 01

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg (Systolic / Diastolic)

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

Weight: ___.___ kg

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

SCREENING

DF Code: 01

PHYSICAL EXAMINATION

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Body System Code	Body System	Normal	Abnormal	Not Done	If ABNORMAL, Specify
01	SKIN	☐	☐	☐	
02	EARS, NOSE, THROAT	☐	☐	☐	
03	NECK/THYROID	☐	☐	☐	
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
07	UROGENITAL	☐	☐	☐	
08	LYMPH NODES	☐	☐	☐	
09	NERVOUS SYSTEM	☐	☐	☐	
☐☐			☐		

Body System Codes:

01 = Skin
02 = Ears, Nose, Throat
03 = Neck/Thyroid
04 = Lungs
05 = Heart
06 = Abdomen
07 = Urogenital
08 = Lymph Nodes
09 = Nervous System
93 = Other

SPI-611 #025 Laboratory Tests / Pregnancy Test #008

Site No. | Randomization No. | Patient Initials

SCREENING

DF Code: 01

LABORATORY TESTS

Hematology ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Chemistry ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

PREGNANCY TEST

☐ Not Done, specify reason →
- ☐ Patient is male
- ☐ Patient is not of childbearing potential
- ☐ Other, specify: _____

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 01

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	**Result**
Specific Gravity	☐.☐☐☐
pH	☐.☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+
	Non-Hemolyzed / Hemolyzed
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+
Nitrite	☐ Negative ☐ Positive

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

URINE CYTOLOGY ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

SPI-611 #025 Vital Signs #006

VISIT 1: WEEK 0

Site No. | Randomization No. | Patient Initials

DF Code: 02

Visit Date: ___ ___ ___ ___ ___ ___ ___ ___ ___

DD *MMM* *YYYY*

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: ___ ___ ___ ___ ___ ___ ___ ___ ___

DD *MMM* *YYYY*

Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg

Systolic *Diastolic*

Pulse: ___ ___ ___ beats/minute (bpm)

Temperature: ___ ___ . ___ °C

SPI-611 #025 Laboratory Tests / Pregnancy Test #008

Site No. Randomization No. Patient Initials

VISIT 1: WEEK 0

DF Code: 02

LABORATORY TESTS

Hematology ☐ Mark “X” if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Chemistry ☐ Mark “X” if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. | Randomization No. | Patient Initials

VISIT 1: WEEK 0

DF Code: 02

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Transurethral Resection #010

Site No. Randomization No. Patient Initials

VISIT 1: WEEK 0

DF Code: 02

TRANSURETHRAL RESECTION

Date of Surgery: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

TUR Start Time: ☐☐:☐☐ *(00:00-23:59)*

TUR End Time: ☐☐:☐☐ *(00:00-23:59)*

Total Number of Lesions: ☐☐ ***If more than 4 lesions, patient is ineligible (do not instill study drug)***

Lesion #	Location Code	Size *(Largest Diameter)*
1.	☐	☐☐.☐ cm
2.	☐	☐☐.☐ cm
3.	☐	☐☐.☐ cm
4.	☐	☐☐.☐ cm

Location Codes:

A = Anterior Wall
D = Dome
L = Left Wall
N = Neck of Bladder
P = Posterior Wall
R = Right Wall
T = Trigone

SPI-611 #025 Study Drug Instillation #012

Site No. Randomization No. Patient Initials

VISIT 1: WEEK 0

DF Code: 02

STUDY DRUG INSTILLATION

Instillation Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Time Study Drug Instillation Began: ☐☐:☐☐
(00:00-23:59)

Time Study Drug Drained from Bladder: ☐☐:☐☐
(00:00-23:59)

Was the start of instillation within 6 hours from end of TUR?

☐ Yes _____

☐ No If NO, Give Reason: _____

Volume of Instillate:

☐ 40 mL

☐ Other, specify: ☐☐☐ mL

If other than 40 mL, give reason: _____

_____

Was the study drug retained in bladder for 60 minutes?

☐ Yes

☐ No If NO, Give Reason: _____

_____

If NO, Duration of Retention: ☐☐ Minutes

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 2: WEEK 3

DF Code: 0 3

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg (*Systolic* / *Diastolic*)

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

VISIT 2: WEEK 3

DF Code: 03

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Laboratory Tests / Pregnancy Test #008

Site No. Randomization No. Patient Initials

VISIT 2: WEEK 3

DF Code: 0 3

LABORATORY TESTS

Hematology ☐ Mark “X” if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Chemistry ☐ Mark “X” if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 2: WEEK 3

DF Code: 03

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Pathology #011

Site No. Randomization No. Patient Initials

VISIT 2: WEEK 3

DF Code: 0 3

PATHOLOGY

Report Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Pathology Report Source: *(Mark One)*
☐ Central Lab (Bostwick)
☐ Local Lab

Highest pT Stage[A]: ☐

Highest Histologic Grade[B]: ☐

Will patient receive additional intravesical therapy (e.g. BCG, Mitomycin) for bladder cancer based on this report?

☐ Yes *(Report therapy on Concomitant Medication CRF)*

☐ No

A - pT Stage Codes:		**B - Histologic Grade Codes:**	
1 = Ta	3 = T2	1 = G1	3 = G3
2 = T1	4 = Cis	2 = G2	4 = Low Grade - WHO/ISUP
			5 = High Grade - WHO/ISUP

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 3: MONTH 3

DF Code: 04

Visit Date: *DD* *MMM* *YYYY*

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: *DD* *MMM* *YYYY*

Blood Pressure: ___ / ___ mmHg
Systolic *Diastolic*

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

VISIT 3: MONTH 3

DF Code: 04

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Laboratory Tests / Pregnancy Test #008

Site No. Randomization No. Patient Initials

VISIT 3: MONTH 3

DF Code: 04

LABORATORY TESTS

Hematology ☐ Mark “X” if Not Done

Collection Date: DD MMM YYYY

Chemistry ☐ Mark “X” if Not Done

Collection Date: DD MMM YYYY

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. | Randomization No. | Patient Initials

VISIT 3: MONTH 3

DF Code: 04

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 3: MONTH 3

DF Code: 04

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Is the site of initial TUR re-epithelialized? ☐ Yes ☐ No

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

VISIT 4: MONTH 6

Site No. | Randomization No. | Patient Initials

DF Code: 05

Visit Date: ___ ___ ___ (*DD MMM YYYY*)

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: ___ ___ ___ (*DD MMM YYYY*)

Blood Pressure: ___ / ___ mmHg (*Systolic / Diastolic*)

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

VISIT 4: MONTH 6

DF Code: 05

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 4: MONTH 6

DF Code: 05

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

URINE CYTOLOGY ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 4: MONTH 6

DF Code: 05

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

VISIT 5: MONTH 9

Site No. | Randomization No. | Patient Initials

DF Code: 06

Visit Date: ___ ___ ___ ___ ___ ___ ___ ___ ___

DD *MMM* *YYYY*

VITAL SIGNS ☐ Mark "X" if Not Done

Exam Date: ___ ___ ___ ___ ___ ___ ___ ___ ___

DD *MMM* *YYYY*

Blood Pressure: ___ ___ ___ / ___ ___ ___ mmHg

Systolic *Diastolic*

Pulse: ___ ___ ___ beats/minute (bpm)

Temperature: ___ ___ . ___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

VISIT 5: MONTH 9

DF Code: 06

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 5: MONTH 9

DF Code: 06

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 5: MONTH 9

DF Code: 06

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg

Systolic *Diastolic*

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin
02 = Ears, Nose, Throat
03 = Neck/Thyroid
04 = Lungs
05 = Heart
06 = Abdomen
07 = Urogenital
08 = Lymph Nodes
09 = Nervous System
93 = Other

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

URINE CYTOLOGY ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 7: MONTH 15

DF Code: 08

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg (*Systolic* / *Diastolic*)

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. Randomization No. Patient Initials

VISIT 7: MONTH 15

DF Code: 08

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 7: MONTH 15

DF Code: 08

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 7: MONTH 15

DF Code: 08

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 8: MONTH 18

DF Code: 09

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg (*Systolic* / *Diastolic*)

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. Randomization No. Patient Initials

VISIT 8: MONTH 18

DF Code: 09

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. | Randomization No. | Patient Initials

VISIT 8: MONTH 18

DF Code: 09

URINE DIPSTICK

☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

URINE CYTOLOGY

☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 8: MONTH 18

DF Code: 09

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 9: MONTH 21

DF Code: 1 0

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg

Systolic *Diastolic*

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

VISIT 9: MONTH 21

DF Code: 10

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 9: MONTH 21

DF Code: 10

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 9: MONTH 21

DF Code: 10

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Vital Signs #006

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg
Systolic *Diastolic*

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

VISIT 10: MONTH 24

DF Code: 11

PHYSICAL EXAMINATION (Brief)

PE Page #: 01

Mark "X" if Last PE Page: ☐

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

URINE CYTOLOGY ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

CYSTOSCOPY

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below: ☐ ☐ ☐ ☐

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 End of Study #099

Site No. Randomization No. Patient Initials

END OF STUDY

Date of Termination: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Did the patient complete the study through Year 2? ☐ Yes ☐ No

If NO, did the patient experience an AE that caused them to discontinue the study? ☐ Yes ☐ No

If YES, AE primarily responsible for discontinuing the study:

AE Page #: ☐☐ AE #: ☐

If NO, mark one of the following:

- ☐ Patient Withdrew Consent
- ☐ Patient Refuses Follow-up Cystoscopy
- ☐ Patient Lost to Follow-up or does not Comply with Protocol
- ☐ Sponsor Decision
- ☐ Investigator Decision
- ☐ Other, specify: _____

SPI-611 #025 Investigator Signature #100

Site No. Randomization No. Patient Initials

INVESTIGATOR SIGNATURE

To be completed only after the data in this CRF have been reviewed, corrected and accepted.

I have reviewed the forms and the data collected are, to the best of my knowledge, correct.

Principal Investigator's Signature

Date: *DD* *MMM* *YYYY*

Printed Name of Principal Investigator

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 01

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

☐ Mark "X" if No Adverse Events

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 0 2

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 0 3

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 04

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 05

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 06

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 07

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 0 8

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 09

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #: 10

Mark "X" if Last AE Page: ☐

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

2. Adverse Event Term: _____

Start Date: ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Stop Date:** ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Serious?	**Toxicity Grade**	**Relationship to Study Drug**	**Outcome**
☐ Yes *(Notify Sponsor)*	☐ 1-Mild	☐ Unrelated	☐ Persisted at end of study
☐ No	☐ 2-Moderate	☐ Unlikely	☐ Resolved with sequelae
	☐ 3-Severe	☐ Possible	☐ Resolved without sequelae
	☐ 4-Life threatening	☐ Probable	☐ Death (If caused by this AE)
	☐ 5-Fatal	☐ Definite	

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 1

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

☐ Mark "X" if No Concomitant Medications

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 2

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 3

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 4

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 5

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 6

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 7

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. | Randomization No. | Patient Initials

CM Page: 0 8

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 0 9

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page: 1 0

Mark "X" if Last CM Page: ☐

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

FORMS BEHIND EXTRA FORMS TAB

- Medical History (Additional)
- Physical Examination (Additional)
- Transurethral Resection
- Pathology
- Death Report

SPI-611 #025 Medical History #004

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 0 1

MH Page #:

Mark "X" if Last MH Page: ☐

MEDICAL HISTORY (Additional)

Please record any previous illnesses, surgery or medical conditions in the space provided below. Please provide an approximate date of onset (month and year).

Body System Code	Body System	Abnormal	If ABNORMAL, Specify
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	
☐☐		☐	

System Codes:

01 = Eyes	05 = Gastrointestinal	08 = CNS/Psychiatric
02 = Ears, Nose, Throat	06 = Musculoskeletal	09 = Endocrine
03 = Respiratory	07 = Skin	93 = Other
04 = Cardiovascular		

SPI-611 #025 Physical Exam #007

Site No. Randomization No. Patient Initials

DF Code:

PHYSICAL EXAMINATION (Additional)

PE Page #:

Mark "X" if Last PE Page:

Exam Date: *DD* *MMM* *YYYY*

Body System Code	Body System	Abnormal*	If ABNORMAL, Specify

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Transurethral Resection #010

Site No. Randomization No. Patient Initials

DF Code:

TRANSURETHRAL RESECTION

Date of Surgery:

DD *MMM* *YYYY*

TUR Start Time: : *(00:00-23:59)*

TUR End Time: : *(00:00-23:59)*

Total Number of Lesions:

Lesion #	Location Code	Size *(Largest Diameter)*
1.		. cm
2.		. cm
3.		. cm
4.		. cm

Location Codes:

A = Anterior Wall
D = Dome
L = Left Wall
N = Neck of Bladder
P = Posterior Wall
R = Right Wall
T = Trigone

SPI-611 #025 Pathology #011

Site No. Randomization No. Patient Initials

DF Code:

PATHOLOGY

Report Date: *DD* *MMM* *YYYY*

Pathology Report Source: *(Mark One)*
- ☐ Central Lab (Bostwick)
- ☐ Local Lab

Highest pT Stage[A]:

Highest Histologic Grade[B]:

Will patient receive additional intravesical therapy (e.g. BCG, Mitomycin) for bladder cancer based on this report?

- ☐ Yes *(Report therapy on Concomitant Medication CRF)*
- ☐ No

A - pT Stage Codes:		**B - Histologic Grade Codes:**	
1 = Ta	3 = T2	1 = G1	3 = G3
2 = T1	4 = Cis	2 = G2	4 = Low Grade - WHO/ISUP
			5 = High Grade - WHO/ISUP

SPI-611 #025 Death Report #101

Site No. Randomization No. Patient Initials

DEATH REPORT

Date of Death: ☐☐ ☐☐☐ ☐☐☐☐

DD MMM YYYY

Primary Cause of Death: _____

SAE Report required if death occurs within 28 days of last dose of study drug.

INTERIM VISIT

- Vital Signs
- Physical Examination (Brief)
- Urine Dipstick
- Cystoscopy
- Transurethral Resection
- Pathology

SPI-611 #025 Vital Signs #006

INTERIM VISIT

Site No. | Randomization No. | Patient Initials

DF Code: 9 9

Interim Visit #:

Visit Date: DD MMM YYYY

VITAL SIGNS

☐ Mark "X" if Not Done

Exam Date: DD MMM YYYY

Blood Pressure: ___ / ___ mmHg (*Systolic* / *Diastolic*)

Pulse: ___ beats/minute (bpm)

Temperature: ___.___ °C

SPI-611 #025 Physical Exam #007

Site No. | Randomization No. | Patient Initials

INTERIM VISIT

DF Code: 99

Interim Visit #:

PE Page #:

Mark "X" if Last PE Page: ☐

PHYSICAL EXAMINATION (Brief)

Exam Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Body System Code	Body System	Normal	Abnormal*	Not Done	If ABNORMAL, Specify
04	LUNGS	☐	☐	☐	
05	HEART	☐	☐	☐	
06	ABDOMEN	☐	☐	☐	
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		
☐☐			☐		

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

Body System Codes:

01 = Skin	05 = Heart	08 = Lymph Nodes
02 = Ears, Nose, Throat	06 = Abdomen	09 = Nervous System
03 = Neck/Thyroid	07 = Urogenital	93 = Other
04 = Lungs		

SPI-611 #025 Urine Dipstick / Urine Cytology #009

Site No. | Randomization No. | Patient Initials

INTERIM VISIT

DF Code: 9 9

Interim Visit #:

URINE DIPSTICK ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Test	Result	Mark "X" if Abnormal and Clinically Significant*
Specific Gravity	☐.☐☐☐	☐
pH	☐.☐	☐
Protein	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+ ☐ 4+	☐
	Non-Hemolyzed / Hemolyzed	
Blood	☐ Negative ☐ Trace ☐ Moderate / ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Glucose	☐ Negative ☐ 100 ☐ 250 ☐ 500 ☐ 1000 ☐ 2000 or more	☐
Leukocyte Esterase	☐ Negative ☐ Trace ☐ 1+ ☐ 2+ ☐ 3+	☐
Nitrite	☐ Negative ☐ Positive	☐

If patient is leukocyte esterase or nitrite positive by urine dipstick, send urine sample to central lab for microscopic analysis. Otherwise, do not send urine sample to central lab.

Microscopic Exam ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

URINE CYTOLOGY ☐ Mark "X" if Not Done

Collection Date: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

**** If Clinically Significant (change from Baseline), document relevant event on the Adverse Events CRF.***

SPI-611 #025 Cystoscopy #013

Site No. Randomization No. Patient Initials

INTERIM VISIT

DF Code: 9 9

Interim Visit #:

CYSTOSCOPY

Exam Date: *DD* *MMM* *YYYY*

Is the site of initial TUR re-epithelialized? ☐ Yes ☐ No

Were any tumors seen? ☐ Yes ☐ No

If YES, were any biopsies performed?

Location:

☐ Yes If YES, enter location from code list below:

☐ No If NO, explain: _____

Were any other abnormalities seen?

☐ Yes If YES, explain: _____

☐ No _____

Location Codes:

A = Anterior Wall	N = Neck of Bladder	R = Right Wall
D = Dome	P = Posterior Wall	T = Trigone
L = Left Wall		

SPI-611 #025 Transurethral Resection #010

Site No. Randomization No. Patient Initials

INTERIM VISIT

DF Code: 9 9

Interim Visit #:

TRANSURETHRAL RESECTION

Date of Surgery: DD MMM YYYY

TUR Start Time: : *(00:00-23:59)*

TUR End Time: : *(00:00-23:59)*

Total Number of Lesions:

Lesion #	Location Code	Size *(Largest Diameter)*
1.		. cm
2.		. cm
3.		. cm
4.		. cm

Location Codes:

A = Anterior Wall
D = Dome
L = Left Wall
N = Neck of Bladder
P = Posterior Wall
R = Right Wall
T = Trigone

SPI-611 #025 Pathology #011

Site No. Randomization No. Patient Initials

INTERIM VISIT

DF Code: 9 9

Interim Visit #:

PATHOLOGY

Report Date: *DD* *MMM* *YYYY*

Pathology Report Source: *(Mark One)*
- ☐ Central Lab (Bostwick)
- ☐ Local Lab

Highest pT Stage[A]:

Highest Histologic Grade[B]:

Will patient receive additional intravesical therapy (e.g. BCG, Mitomycin) for bladder cancer based on this report?

- ☐ Yes *(Report therapy on Concomitant Medication CRF)*
- ☐ No

A - pT Stage Codes:		**B - Histologic Grade Codes:**	
1 = Ta	3 = T2	1 = G1	3 = G3
2 = T1	4 = Cis	2 = G2	4 = Low Grade - WHO/ISUP
			5 = High Grade - WHO/ISUP

SITE SPECIFIC ASSESSMENT PACKET

Wrap for Subjects at Selected Sites Only

- Screening Visit (4 Pages)
  Insert behind page 9

- Visit 6 Month 12 (4 Pages)
  Insert behind page 36

- Visit 10 Month 24 (4 Pages)
  Insert behind page 52

SPI-611 #025 Bladder Capacity / Postvoid Residual Measurement #014

Site No. | Randomization No. | Patient Initials

SCREENING

DF Code: 01

BLADDER CAPACITY

Date of Measurement: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Voided Volume: ☐☐☐ mL

POSTVOID RESIDUAL MEASUREMENT (ULTRASOUND)

Date of Ultrasound: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Postvoid Residual Volume: ☐☐☐ mL

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 0 1

DAY: 1

PATIENT VOIDING DIARY - DAY 1

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 0 1

DAY: 2

PATIENT VOIDING DIARY - DAY 2

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

SCREENING

DF Code: 0 1

DAY: 3

PATIENT VOIDING DIARY - DAY 3

Date: ___ ___ (*DD*) ___ ___ ___ (*MMM*) ___ ___ ___ ___ (*YYYY*)

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**11.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
2.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**12.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
3.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**13.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
4.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**14.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
5.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**15.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
6.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**16.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
7.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**17.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
8.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**18.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
9.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**19.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___
10.	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___	**20.**	___ ___ : ___ ___	☐ AM ☐ PM	___ ___ ___

SPI-611 #025 Bladder Capacity / Postvoid Residual Measurement #014

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

BLADDER CAPACITY

Date of Measurement: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Voided Volume: ☐☐☐ mL

POSTVOID RESIDUAL MEASUREMENT (ULTRASOUND)

Date of Ultrasound: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

Postvoid Residual Volume: ☐☐☐ mL

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

DAY: 1

PATIENT VOIDING DIARY - DAY 1

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

DAY: 2

PATIENT VOIDING DIARY - DAY 2

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

VISIT 6: MONTH 12

DF Code: 07

DAY: 3

PATIENT VOIDING DIARY - DAY 3

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Bladder Capacity / Postvoid Residual Measurement #014

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

BLADDER CAPACITY

Date of Measurement: DD MMM YYYY

Voided Volume: mL

POSTVOID RESIDUAL MEASUREMENT (ULTRASOUND)

Date of Ultrasound: DD MMM YYYY

Postvoid Residual Volume: mL

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

DAY: 1

PATIENT VOIDING DIARY - DAY 1

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

DAY: 2

PATIENT VOIDING DIARY - DAY 2

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SPI-611 #025 Patient Voiding Diary #015

Site No. Randomization No. Patient Initials

VISIT 10: MONTH 24

DF Code: 1 1

DAY: 3

PATIENT VOIDING DIARY - DAY 3

Date: DD MMM YYYY

	TIME *(12 Hour Clock)*		VOLUME *(oz)*		TIME *(12 Hour Clock)*		VOLUME *(oz)*
1.	:	☐ AM ☐ PM		**11.**	:	☐ AM ☐ PM	
2.	:	☐ AM ☐ PM		**12.**	:	☐ AM ☐ PM	
3.	:	☐ AM ☐ PM		**13.**	:	☐ AM ☐ PM	
4.	:	☐ AM ☐ PM		**14.**	:	☐ AM ☐ PM	
5.	:	☐ AM ☐ PM		**15.**	:	☐ AM ☐ PM	
6.	:	☐ AM ☐ PM		**16.**	:	☐ AM ☐ PM	
7.	:	☐ AM ☐ PM		**17.**	:	☐ AM ☐ PM	
8.	:	☐ AM ☐ PM		**18.**	:	☐ AM ☐ PM	
9.	:	☐ AM ☐ PM		**19.**	:	☐ AM ☐ PM	
10.	:	☐ AM ☐ PM		**20.**	:	☐ AM ☐ PM	

SHRINK WRAP PACKETS TO SPONSOR

Site Screening Log
Documentation of Protocol Violations
Adverse Events
Concomitant Medications

SPI-611 #025 Site Screening Log #254

Site No. ☐☐☐

Page: ☐☐

Mark “X” if Last Page: ☐

SITE SCREENING LOG

Please refer to CRF Completion Instructions to correctly complete this form.

Please fax to Synteract weekly by 4:00 pm (PST) on Friday.

Patient Initials: ☐☐☐ Screening No.: ☐☐☐ Randomization No.: ☐☐☐☐

Date Consented: ☐☐ ☐☐☐ ☐☐☐☐ (*DD* *MMM* *YYYY*)

Screen Fail? ☐ Yes, Reason for Screen Failure:* ☐☐ If “04” or “05”, specify criterion #: ☐☐
☐ No

Patient Initials: ☐☐☐ Screening No.: ☐☐☐ Randomization No.: ☐☐☐☐

Date Consented: ☐☐ ☐☐☐ ☐☐☐☐ (*DD* *MMM* *YYYY*)

Screen Fail? ☐ Yes, Reason for Screen Failure:* ☐☐ If “04” or “05”, specify criterion #: ☐☐
☐ No

Patient Initials: ☐☐☐ Screening No.: ☐☐☐ Randomization No.: ☐☐☐☐

Date Consented: ☐☐ ☐☐☐ ☐☐☐☐ (*DD* *MMM* *YYYY*)

Screen Fail? ☐ Yes, Reason for Screen Failure:* ☐☐ If “04” or “05”, specify criterion #: ☐☐
☐ No

***Reason for Screen Failure Codes:**

01 = Withdrew Consent or HIPAA
02 = Lost to Follow-up
03 = Investigator/Sponsor Decision
04 = Inclusion Criteria
05 = Exclusion Criteria

SPI-611 #025 Documentation of Protocol Violations #251

Site No. Randomization No. Patient Initials

Page:

Mark "X" if Last Page:

DOCUMENTATION OF PROTOCOL VIOLATIONS

To be completed by the Spectrum CRA only.

☐ None

1. Inclusion/Exclusion Criteria violation without exception granted by medical director.

(Note: CRA to ensure that appropriate boxes on CRF are checked).

Violation Code[A]	Criteria #	Specify	IRB Reported? Yes	IRB Reported? No	CRA Initials
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

2. Other Violations (Please include dates)

Violation Code[A]	Start Date (DD/MMM/YYYY)	Specify	IRB Reported? Yes	IRB Reported? No	CRA Initials
			☐	☐	
			☐	☐	
			☐	☐	
			☐	☐	

A - Violation Codes:

01 = Informed Consent
02 = Inclusion Criteria (Specify criteria #)
03 = Exclusion Criteria (Specify criteria #)
04 = Concomitant Medication
05 = Laboratory
06 = SAE Reporting
07 = Regulatory
08 = Drug Storage/Preparation
09 = Drug Administration
10 = Visit Schedule
11 = Noncompliance (i.e., trends, missed measures)
93 = Other, specify

SPI-611 #025 Adverse Events #097

Site No. Randomization No. Patient Initials

AE Page #:

Mark "X" if Last AE Page:

ADVERSE EVENTS

Collect all Adverse Events through Visit 4 (6 Months). Collect genitourinary Adverse Events for the patient's entire participation in the study.

1. Adverse Event Term: _____

Start Date: DD MMM YYYY **Stop Date:** DD MMM YYYY

Serious?	Toxicity Grade	Relationship to Study Drug	Outcome
Yes *(Notify Sponsor)*	1-Mild	Unrelated	Persisted at end of study
No	2-Moderate	Unlikely	Resolved with sequelae
	3-Severe	Possible	Resolved without sequelae
	4-Life threatening	Probable	Death (If caused by this AE)
	5-Fatal	Definite	

2. Adverse Event Term: _____

Start Date: DD MMM YYYY **Stop Date:** DD MMM YYYY

Serious?	Toxicity Grade	Relationship to Study Drug	Outcome
Yes *(Notify Sponsor)*	1-Mild	Unrelated	Persisted at end of study
No	2-Moderate	Unlikely	Resolved with sequelae
	3-Severe	Possible	Resolved without sequelae
	4-Life threatening	Probable	Death (If caused by this AE)
	5-Fatal	Definite	

SPI-611 #025 Concomitant Medications #098

Site No. Randomization No. Patient Initials

CM Page:

Mark "X" if Last CM Page:

CONCOMITANT MEDICATIONS

List all medications taken at Week 0 and through Visit 4 (Month 6). List medications taken for GU Adverse Events and Serious Adverse Events throughout the study.

1. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

2. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

3. Name of Drug: _____

Total Daily Dose: _____ **Units:** _____

Was medication taken for AE? ☐ Yes ☐ No

If YES, primary AE Page #: ☐☐ AE #: ☐

If NO, record indication: _____

Start Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*)

Stop Date ☐☐ ☐☐☐ ☐☐☐☐ (*DD MMM YYYY*) **Continuing** ☐

INTERNAL FORMS
(Printer does not print)

DCF

SPI-611 #025 Data Clarification Form #250

Site No. Randomization No. Patient Initials

Query Page #:

DATA CLARIFICATION FORM

CRF Page(s): _____

Visit: _____

Clarification/Change Required:

Resolution:

By signing in the space provided below, the investigator acknowledges his/her approval of the clarifications/changes noted above.

_____

Principal Investigator Signature

Date: DD MMM YYYY

SPI-611 #025 Original CRF Retrieval Approval Form #255

Site No. Randomization No. Patient Initials

ORIGINAL CRF RETRIEVAL APPROVAL FORM

1. ☐ All Documentation of Protocol Violations CRFs have been faxed into DataFax.

2. ☐ All visits for this subject have been fully monitored.

I confirm that all required original Case Report Forms for this subject are ready to be sent to Synteract:

_____ Date: ☐☐ ☐☐☐ ☐☐☐☐

CRA *DD MMM YYYY*