A Multi Center Randomized Trial to Study Tamsulosin for Urolithiasis in the Emergency Department (STONE)

Database Reference

Sponsored by:

National Institute of Diabetes and Digestive and Kidney Diseases

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1 Database Reference Notes

1.1 Introduction

The Multi-Center Randomized Trial to Study Tamsulosin for Urolithiasis in the Emergency Department (STONE study) is designed to investigate the effect of tamsulosin in the treatment of acute urolithiasis in the Emergency Department. A full description of this randomized trial may be found in the protocol and manual of operations, which accompany the data. (See table below for a listing of all documents and files.)

1.1.1 General

The study is a multi-center randomized, placebo-controlled, double-blind clinical trial. Patients are randomized to one of two treatment groups, placebo or active tamsulosin. The primary research question is to determine if the administration of tamsulosin after the clinical and radiographic diagnosis of acute urolithiasis produces an increase in the proportion of patients passing their stone within 28 days as reported by the participant.

A vanguard or pilot phase (phase 1) of this study was undertaken in the Emergency Department (ED) at George Washington University Medical Center (GWU) to examine the ability to recruit patients, as well as assess the adherence of study patients to the protocol and the passage rate in the placebo group. The multi-center phase (phase 2) was initially performed in the Emergency Departments at GWU, the Thomas Jefferson University Hospital (formerly at HUP) and the University of Pittsburgh Medical Center – Presbyterian Hospital. Two new centers began recruitment in July of 2015: the University of Alabama at Birmingham and a satellite center at the University of Pittsburgh Medical Center – Mercy Hospital.

Randomization for vanguard/pilot phase (phase 1) of the study began in February 2008 and completed in September 2009, enrolling 109 patients. Randomization for the multi-center phase (phase 2) began in August 2013 and completed in October 2016, enrolling 403 patients.

1.1.2 Screening and Randomization

All patients diagnosed with kidney stones via radiographic imaging were approached for screening. Patients who satisfied the eligibility criteria and consented to randomization were centrally randomized to one of the following two medical regimens, each implemented a tablet each day: an active group who received 30 tablets of 0.4 mg tamsulosin and a placebo group who received 30 similar inactive tablets.

The randomization sequence was prepared and maintained centrally by the DCC. The active and placebo study medications were packaged according to the randomization sequence, so that each patient was randomized when he or she was assigned to the next available individual supply of study medication. Randomization was stratified by clinical site to assure balance between the two treatment groups with respect to anticipated differences within the clinic populations and possible differences in patient management. The study was double masked; neither the patients nor the clinical staffs were aware of the treatment assignment.

1.1.3 Study Procedures

Following screening and randomization, a comprehensive baseline assessment was completed for each patient that included: medical history review, physical exam, dipstick urinalysis, pregnancy test (female patients), hematology and/or serum chemistry (if clinically indicated), CT scan.

After randomization, patients were contacted on days 2, 7, 15, 20, 29 (to capture status through Day 28), and 90. At all contacts, the patients were asked if the stone was seen/captured, if the patient had any surgical interventions for the stone, if the patient was hospitalized, if the patient had any physician, urologist, or ED visits, and if the patient had returned to work. At all contacts through post randomization

day 29, the patients were asked if they had taken the study drug and any analgesics. Follow–up data was collected in one of three ways: telephone follow-up was the preferred method, but email communication or texting were also used in cases that a telephone call was not feasible.

In the multi-center phase (phase 2), a follow-up low dose CT scan of the abdomen and pelvis was performed at day 29 (with a window to day 36). A central committee of three study urologists used this scan in conjunction with the follow-up data to evaluate stone passage.

2 Release Information

2.1 General Information

- No patient identifying information is included.
- A randomly generated ID_NO uniquely identifies each patient.
- Clinic and other location identifiers have been removed.
- No dates are included; all time points are given as days from randomization (or before randomization in the case of history).

In accordance with HIPAA regulations and to protect the identification of patients, the data has been modified to ensure that no patient is identifiable. For example, data was sorted into small clearly-identifiable groups (age, race, etc.) and collapsed if the sample size was small.

Only research data is included in the released dataset. Non-research data, including tracking forms, are not included. This includes data from the Eligibility & Randomization Form (ST04) and the Violation/Deviation Form (ST13). Adverse event and serious adverse event data were collected on the Adverse Event Form (ST12), but are also not included in the data release. This data was not adjudicated and is not considered research data.

All available data from each form is included. Missing data was caused by a variety of reasons: the contact form was not completed in its entirety; the variable was accidentally not collected or measured; the variable was completed incorrectly; the contact was missed, etc.

2.2 Modifications to the Data

2.2.1 ID Variable

In accordance with HIPAA guidelines, no patient identifiers are present on this dataset. Patients are identified by an ID number (variable: ID_NO), with no reference to recruitment center or original patient number.

2.2.2 Date Variables

All dates are expressed as the number of days before or since the screening date, depending on the variable, for each patient. The day numbers on each record will bear the same relationship to each other as did the original dates. Note that all date variables converted in this fashion will keep the same variable name as shown on the CRFs, *except the subscript '_DAYN' will be replace the 'DT' or 'DATE' subscripts of the original variable names*. This will signify that the original date variable has been converted to day numbers (e.g. FFUPDATE on Form ST10 will appear in the release data set as 'FFUP_DAYN'.)

2.2.3 Derived Variables

Variables created for analysis are included, as well as variables which summarize and replace original variables from the CRFs (e.g. CROSSOVER_DAYN in the Phase 2 Analysis Dataset is derived using the data from FOPENLAB and FOLDOS in conjunction with dates from LSCRDT and FDATE). See the Reference Dictionary for details/code showing their derivation.

2.2.4 Dropped Variables

Apart from those described above, some variables shown on CRFs are not included in the release dataset due to their largely administrative nature (e.g. related to patient identification, sample collection, etc.) or their potential to identify subjects. Those with low numbers have been re-categorized with new derived variables when possible, as explained above. Those that could not be re-categorized have been removed from the datasets. These are identified as having been dropped in the Reference Dictionary.

In the listings of the variables from the CRFs/datasets, the following abbreviations apply to the original variables that have been removed from the datasets:

- D = Variable deleted (not present on the released data set)
- R/D = Recoded and then deleted (derived variable exists)

2.3 Data Location

Data are released from the Biostatistical Coordinating Center at the George Washington University Biostatistics Center to the Data Repository at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health.

2.3.1 Structure of the SAS Data Files

Multiple SAS datasets are available in transport files, under the library STN_REL. One dataset exists for each STONE form or dataset.

The files are included as SAS datasets within transport files with the same name as the embedded form or dataset name and the extension XPT, in the format **<<DATASET>>.xpt**. All data points are stored in a single SAS export file (see contents listing) for each form/dataset. Note that since some variables are coded, a format listing, "STONE Formats.sas", is provided for convenience.

The SAS export data file was created in SAS using UTF-8 encoding. Information about reading this file is below.

2.3.2 Reading a SAS Transport File with UTF-8 Encoding

In order to read a transport file with UTF-8 encoding via PROC CIMPORT, the SAS session must use UTF-8 encoding. The default SAS session encoding in the U.S. is wLatin1. Please follow the steps below to enable SAS to use UTF-8 encoding.

Changing the SAS Session Encoding to UTF-8

1) Make a copy of the SAS icon on your desktop by right clicking on it, then select 'copy' then right-click on the desktop and select 'paste'.

2) Now you have a second icon for SAS. Right click this new icon, then select 'Rename'. Now type UTF8 for the new name.

3) Now right click the new 'UTF8' icon and select 'Properties' and carefully, put your cursor in the 'Target' field. The text in the field should be similar to:

"C:\Program Files\SAS\x86\SASFoundation\9.4\sas.exe" -CONFIG "C:\Program Files\SAS\x86\SASFoundation\9.4\nls\en\sasv9.cfg"

Edit to:

"C:\Program Files\SAS\x86\SASFoundation\9.4\sas.exe" -CONFIG "C:\Program Files\SAS\x86\SASFoundation\9.4\nls\u8\sasv9.cfg"

The only change is replacing "en" with "u8" since the "u8" directory has a config file that defines ENCODING=utf-8

4) Now click OK and then start a SAS session using this new icon. To check the encoding, run:

```
proc options option=encoding;
run;
```

NOTE: If you wish to save the imported dataset as a "regular" SAS dataset, i.e., with the default encoding, use the code below. Replace **<<DATA_PATH>>** in the libname statement below so that it

points to the location on your computer, network, or SAS Share library where you wish to save the dataset.

```
libname SaveLib '<<DATA_PATH>>';
data SaveLib.<<DATASET>> (encoding=wLatin1);
set <<DATASET>>;
run;
```

2.3.3 SAS Program to Import Datasets

The code below will import a specific SAS dataset to your SAS library. Replace **<<DATA_PATH>>** in the libname statement below so that it points to the location on your computer, network, or SAS Share library where you wish to save the dataset. Replace **<<TRAN_PATH>>** in libname statement so that it points to the location where the transport file is stored on your computer.

Please note, this SAS program must be run using UTF-8 encoding, as the transport file was created as UTF-8.

```
libname STN_REL '<<DATA_PATH>>';
libname TAGIN xport '<<TRAN_PATH>>/<<DATASET>>_UTF8.XPT';

proc cimport library=STN_REL infile=TAGIN;
run;
```

For example, to import STN_REL.ST01 from your SAS files library:

```
libname STN_REL 'c:\mysasfiles';
libname TAGIN xport 'c:\myxptfiles\ST01_UTF8.XPT';

proc cimport library=STN_REL infile=TAGIN;
run;
```

The code below will put a note in the SAS log about the encoding used in your SAS session:

```
proc options option=encoding;
run;
```

To verify the dataset:

```
proc contents data = STN_REL.<<DATASET>>;
title "STONE Study Release Dataset for <<DATASET>>, In UTF-8 Encoding";
run;
```

2.4 De-identified Data

The datasets were de-identified in the following manner. All personal identifiers were removed, including patient ID and other personal identifiers, clinical center, and all dates. In addition, variables that might identify a particular individual were collapsed into wider groupings where possible and removed where not. For example, race was re-coded as White and Non-white/Not reported/Unknown, while age at baseline was collapsed into 10-year age groups, with the youngest group including patients age 18 to 29, and the oldest group including all patients aged 50 and older.

2.5 Structure of the Datasets

For the Screening Log (ST01), Clinical Screening Form (ST02), Radiological Screening Form (ST03), Radiological Follow-up Form (ST11), and derived variable datasets, one record exists in each file for

each patient for which that particular form was completed or data was collected. For the Follow-up Form (ST10), all completed contacts in which the patient was reached are included as separate records. Variable ID_NO is used to identify a particular patient for all datasets, and variable FDAY is used to identify a specific contact for that patient in the follow-up datasets.

2.6 Documentation Listing for Electronic Data Release

Documents	**Notes/formats**	**Filename**
Final Protocol	pdf	STONE Protocol.pdf
Final Manual of Operations	pdf	STONE Manual of Operations.pdf
Phase 1 CRFs with Variable Names	pdf	STONE Phase 1 CRFs.pdf
Phase 2 CRFs with Variable Names	pdf	STONE Phase 2 CRFs.pdf
Variable Dictionary	pdf	STONE Release Reference Dictionary.pdf
SAS Datasets / Files	**Notes/formats**	**Filename**
Dataset Contents Listing	pdf	STONE Dataset Contents.pdf
Dataset Variable Distributions	pdf	STONE Dataset Info.pdf
Phase 1:		
Scrn Dataset	SAS transport file	Scrn_UTF8.xpt
Cl Dataset	SAS transport file	Cl_UTF8.xpt
Tfu Dataset	SAS transport file	Tfu_UTF8.xpt
Phase 1 Analysis Dataset	SAS transport file	Phase1_UTF8.xpt
Phase 2:		
ST01 Dataset	SAS transport file	ST01_UTF8.xpt
ST02 Dataset	SAS transport file	ST02_UTF8.xpt
ST03 Dataset	SAS transport file	ST03_UTF8.xpt
ST10 Dataset	SAS transport file	ST10_UTF8.xpt
ST11 Dataset	SAS transport file	ST11_UTF8.xpt
Phase 2 Analysis Dataset	SAS transport file	Phase2_UTF8.xpt

3 Statistical Considerations

3.1 Definition of the Primary Outcome

The primary research question asks if the administration of tamsulosin in patients with evidence of ureterolithiasis (i.e. stone is located in ureter), as demonstrated on CT with confident diagnosis, produces an increase in the proportion of patients passing their stone within 28 days. This does not include stones located in the bladder (for phase 2) or solely in the kidney.

In cases in which there is more than one stone noted on the screening CT scan, the physician treating the patient determined the likely location and dimensions of the stone causing symptoms by reviewing the patient's ED record and the CT report.

For the multi-center phase (phase 2), if the physician believed that the symptomatic stone had not yet reached the bladder, the patient was eligible to be enrolled. Regardless of the number of stones, if the stone causing symptoms reached the bladder, the patient was not eligible for enrollment.

Stone expulsion was defined as patient report that the stone was visualized or captured after urination. In the multi-center phase (phase 2), a follow-up low dose CT scan of the abdomen and pelvis was performed at day 29 (with a window to day 36) and used in conjunction with the follow-up data to evaluate stone passage by a central committee.

If a patient reported having surgical intervention for the stone prior to the first reported stone passage (or 28 days post randomization), the intervention was defined as a failure, and the stone expulsion was not considered as attaining the primary outcome.

4 Publications and Presentations

4.1 Design Paper

Burrows PK, Hollander JE, Wolfson AB, Kurz MC, Richards L, DiFiore S, Watts P, Patkar N, Brown J, Jackman S, et al. Design and challenges of a randomized clinical trial of medical expulsive therapy (tamsulosin) for urolithiasis in the emergency department. Contemp Clin Trials. 2017 Jan;52:91-94. doi: 10.1016/j.cct.2016.11.010. Epub 2016 Nov 23. PubMed PMID: 27890522; PubMed Central PMCID: PMC5167651.

4.2 Results

Results manuscript is pending publication at JAMA Internal Medicine in June 2018.

Results have been presented at the following meetings:

- American Urological Association, annual meeting in Boston, MA from May 12-16, 2017
- Society for Academic Emergency Medicine Annual Meeting in Indianapolis, IN from May 15-18

5 Phase 1 – Screening Log (Scrn)

5.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
LAGE	D	Age	years	
LENROLL	D	Was patient enrolled?	0 = No 1 = Yes	
LPATID	D	STONE Patient ID		
LREASON	D	Main reason patient not enrolled		01 = Age < 18 02 = No evidence of ureterolithiasis 03 = No phone 04 = Concurrent UTI 05 = Prior kidney/ureter surgery 06 = Pregnant 07 = Anatomical GU abnormality 08 = Ipsilateral/solitary kidney 09 = Prior renal transplant or donation 10 = History of renal insufficiency 11 = Fever 12 = History of hypersensitivity to tamsulosin 13 = Taking α-blockers or Ca++blockers 14 = Taking vardenafil 15 = Floppy iris syndrome 16 = Cataract surgery within 60 days 17 = Stone expulsion in the ED 18 = Largest stone diameter ≥ 9mm 19 = Admitted to the hospital 20 = Prisoner or ward of state 21 = Breastfeeding mother 22 = Prior enrollment 23 = Bladder stone 24 = Taking steroids

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
				25 = Non-English speaker 99 = Other
LSCRNDT	R/D	Date of screening		
LSEX	D	Gender		1 = Female 2 = Male
SCREEN	D	Screening ID		

*** Note: The dataset released for the Screening Log (Scrn) only contains data for the randomly assigned patient ID number. Data for all other variables on this form were either collected elsewhere (e.g., LAGE and LSEX), were identifiable (e.g., LSCRNDT), or were not of importance for the randomized patients (e.g., LENROLL and LREASON).

6 Phase 1 – Clinical Screening Form (Cl)

6.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
RBILAT		CT: Bilateral stones?		0 = No 1 = Yes
RCTABDO		Abdominal mass		0 = No 1 = Yes
RCTAORT		Aortic aneurysm		0 = No 1 = Yes
RCTAPPEN		Appendicitis		0 = No 1 = Yes
RCTDIVER		Diverticulitis		0 = No 1 = Yes
RCTFIBR		Fibroids		0 = No 1 = Yes
RCTINFLA		Inflammatory bowel disease		0 = No 1 = Yes
RCTOTHER	D	Other CT findings		
RCTPELMS		Pelvic mass		0 = No 1 = Yes
RCTPHLEB		CT: Phlebolith?		0 = No 1 = Yes
RCTPOSS		CT: Possible stone?		0 = No 1 = Yes
RCTSINGL		Solitary kidney		0 = No 1 = Yes
RCTSTONE		CT: Was a stone noted?		0 = No stone noted 1 = Yes, one stone 2 = Yes, multiple stones
RHYDRON		Hydronephrosis?		0 = No 1 = Yes
RKBILAT		KUB: Bilateral stones?		0 = No 1 = Yes
RKLARGST		KUB: Largest dimension	mm	
RKPHLEB		KUB: Phlebolith?		0 = No 1 = Yes
RKPOSS		KUB: Possible stone?		0 = No 1 = Yes

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
RKSTONE		KUB: Was a stone noted?		0 = No stone noted 1 = Yes, one stone 2 = Yes, multiple stones
RKUB		Was a KUB done?		0 = No 1 = Yes
RLARGEST		CT: Largest dimension	mm	
RLBLAD		Stone location: Bladder		0 = No 1 = Yes
RLDISTUR		Stone location: Distal ureter		0 = No 1 = Yes
RLMIDUR		Stone location: Mid ureter		0 = No 1 = Yes
RLNOTSPC		Stone location: Not specified		0 = No 1 = Yes
RLOCASYM		Location of symptomatic stone		1 = Renal pelvis 2 = Proximal ureter 3 = Mid ureter 4 = Distal ureter 5 = UVJ
RLPROXUR		Stone location: Proximal ureter		0 = No 1 = Yes
RLRENPEL		Stone location: Renal pelvis		0 = No 1 = Yes
RLUVJ		Stone location: UVJ		0 = No 1 = Yes
RSIDELOC		Side of additional stones		1 = Left 2 = Right 3 = Bilateral
RSIDESYM		Side of symptomatic stone		1 = Left 2 = Right
RSIZESYM		Size of stone causing symptoms	mm	
RSTRAND		Stranding noted?		0 = No 1 = Yes
SADMIT		Was the patient admitted		0 = No 1 = Yes
SADMSERV	D	To which service was the patient admitted?		1 = Urology 2 = Surgery 3 = Medicine 4 = Other
SADMSRVX	D	Other service to which the patient was admitted		

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SAGE	R/D	Age	years	
SALLTAM		Allergic to tamsulosin?		0 = No (or unknown) 1 = Yes
SBUNABN		Blood chemistry abnormalities: BUN		0 = No 1 = Raised 2 = Low
SCBC		Was A CBC obtained?		0 = No 1 = Yes
SCBCABN		CBC: Were there any abnormalities?		0 = No 1 = Yes
SCHEM		Blood chemistry obtained?		0 = No 1 = Yes
SCHEMABN		Blood chemistry: Were there any abnormalities?		0 = No 1 = Yes
SCHPAIN	D	Symptom: Chest pain		0 = No 1 = Yes
SCO2ABN		Blood chemistry abnormalities: CO2		0 = No 1 = Raised 2 = Low
SCRTABN		Blood chemistry abnormalities: Creatinine		0 = No 1 = Raised 2 = Low
SDATE	D	Visit date		
SDBPDIA		Diastolic blood pressure (Discharge)	mmHg	
SDBPSYS		Systolic blood pressure (Discharge)	mmHg	
SDHR		Heart rate (Discharge)	bpm	
SDIPBLD	R/D	Urine dipstick: Blood		0 = None 1 = Trace 2 = 1+ 3 = 2+ 4 = 3+ 5 = 4+
SDIPGLUC	R/D	Urine dipstick: Glucose		0 = None 1 = Trace 2 = 1+ 3 = 2+ 4 = 3+ 5 = 4+

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SDIPWBC	R/D	Urine dipstick: White cells		0 = None 1 = Trace 2 = 1+ 3 = 2+ 4 = 3+ 5 = 4+
SDIZZY		Symptom: Dizzy		0 = No 1 = Yes
SDRR		Respiratory rate (Discharge)		
SDTEMP		Temperature (Discharge)	°F	
SDTSTN	R/D	Date of most recent episode of kidney stones		
SETHN	D	Do you consider yourself Hispanic or Latino?		0 = No 1 = Yes 2 = Unknown
SEXPEL	D	Stone expelled in the ED?		0 = No 1 = Yes
SFAMHX		Family history of kidney stones?		0 = No 1 = Yes
SFEVER		Symptom: Fever		0 = No 1 = Yes
SFINDX	D	Final primary ED diagnosis		1 = Renal colic 2 = Nephrolithiasis 3 = Other
SFINDXX	D	Other ED diagnosis		
SGLUCABN		Blood chemistry abnormalities: Glucose		0 = No 1 = Raised 2 = Low
SHCG		Was an HCG done?		0 = No or not indicated 1 = Yes
SHCGRES		HCG result		0 = Negative 1 = Positive
SHCTABN		CBC abnormalities: HCT		0 = No 1 = Raised 2 = Low
SHXKSTN		Past history of kidney stones?		0 = No 1 = Yes
SIBPDIA		Diastolic blood pressure	mmHg	
SIBPSYS		Systolic blood pressure	mmHg	
SIHR		Heart rate	bpm	

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SIRR		Respiratory rate		
SITEMP		Temperature	°F	
SKABN		Blood chemistry abnormalities: K		0 = No 1 = Raised 2 = Low
SMEDS		Do you take any medication on a regular basis?		0 = No 1 = Yes
SMEDSX	D	List of medications taken on a regular basis		
SMICBACT	R/D	Urinalysis microscopy: Bacteria		0 = None, negative, WNL 1 = 1-5, trace, present, slight, rare 2 = 6-15, moderate 3 = 16-30, many, frequent 4 = >30, innumerable, TNTC
SMICBLD	D	Urinalysis microscopy: Blood		0 = None, negative, WNL 1 = 1-5, trace, present, slight, rare 2 = 6-15, moderate 3 = 16-30, many, frequent 4 = >30, innumerable, TNTC
SMICRO		Was urinalysis microscopy done?		0 = No 1 = Yes
SMICWBC	R/D	Urinalysis microscopy: White cells		0 = None, negative, WNL 1 = 1-5, trace, present, slight, rare 2 = 6-15, moderate 3 = 16-30, many, frequent 4 = >30, innumerable, TNTC
SNAABN		Blood chemistry abnormalities: Na		0 = No 1 = Raised 2 = Low
SNAUSEA		Nausea		0 = No 1 = Yes
SNOTEMP		Symptom: Feeling of not emptying bladder?		0 = No 1 = Yes

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SNUMSTN	R/D	How many past episodes of kidney stones?		
SPAINUR		Symptom: Pain when urinating		0 = No 1 = Yes
SPLATABN	D	CBC abnormalities: Platelets		0 = No 1 = Raised 2 = Low
SRACE	R/D	Race		1 = American Indian / Alaskan Native 2 = Asian 3 = Native Hawaiian / Pacific Islander 4 = Black / African American 5 = White 6 = Unknown or Not Reported
SSEX		Gender		1 = Female 2 = Male
SSIDEP		Symptom: Side pain (Flank pain)		0 = No 1 = Yes
SSURG	D	Have you had surgery for stones in the kidney or renal system?		
STRANSP		Have you had a kidney transplant or donated a kidney?		0 = No 1 = Yes
SURIN		Symptom: Increased need to urinate		0 = No 1 = Yes
SURNGHT		Symptom: Urinating more often at night		0 = No 1 = Yes
SVOMIT		Symptom: Vomiting		0 = No 1 = Yes
SWBCABN		CBC abnormalities: WBC		0 = No 1 = Raised 2 = Low

6.2 Derived Variables

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
AGE_CAT	Age category		1 = 18 – 30 2 = 31 – 40 3 = 41 – 50 4 = > 50	Calculated using SAGE and ranges given in format

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
DIPBLD_CAT	Urine dipstick: Blood category		0 = Negative 1 = Trace and above	If SDIPBLD = 0, then category is “Negative.” If SDIPBLD ≥ 1, then category is “Trace and above.”
DIPGLUC_CAT	Urine dipstick: Glucose category		0 = Normal 1 = 50 and above	If SDIPGLUC = 0, then category is “Normal.” If SDIPGLUC ≥ 1, then category is “50 and above.”
DIPWBC_CAT	Urine dipstick: WBC category		0 = Negative 1 = Trace and above	If SDIPWBC = 0, then category is “Negative.” If SDIPWBC ≥ 1, then category is “Trace and above.”
ETHN_CAT	Ethnicity category		0 = Not Hispanic / Latino or Unknown 1 = Hispanic / Latino	If SETHN=0 or 2, then category is “Not Hispanic / Latino or Unknown.’ If SETHN=1, then category is “Hispanic / Latino.”
MICBACT_CAT	Urinalysis microscopy: Bacteria category		0 = 0, none, negative, WNL 1 = ≥ 1, trace or greater	If SMICBACT = 0, then category is “0, none, negative, WNL.” If SMICBACT = 1, then category is “≥ 1, trace or greater.”
MICWBC_CAT	Urinalysis microscopy: WBC category		0 = 0, none, negative, WNL 1 = ≥ 1, trace or greater	If SMICWBC = 0, then category is “0, none, negative, WNL.” If SMICWBC = 1, then category is “≥ 1, trace or greater.”
NUMSTN_CAT	Past episodes of kidney stones category		1 = 1 2 = 2 or more	If SNUMSTN=1 then category is “1.” If SNUMSTN ≥ 2, then category is “2 or more.”
RACE_CAT	Race category		0 = Non-white 1 = White	If SRACE=5 then category is “White.” If SRACE is 1, 2, 3, 4 or 6, then category is “Non-white.”
SDTSTN_DAYN	Days since most recent episode of kidney stones			Number of days between date of SDTSTN and date of LSCRNDT

7 Phase 1– Follow-up Form (Tfu)

7.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
DAY		Post ED Visit day NUMBER		
FABNEJAC		Abnormalities of ejaculation?		0 = No 1 = Yes 2 = Female
FANALG		Are you taking another analgesic?		0 = No 1 = Yes
FANALGX	D	Specify other analgesic		
FANDOS	D	Other analgesic dose	mg	
FANNUM	D	How many other analgesic pills have you taken since the last phone contact?		
FDATE	D	Date of contact		
FDIZSTND		Feeling dizzy on standing up?		0 = No 1 = Yes
FDIZZY		Feeling dizzy at any time?		0 = No 1 = Yes
FEMPLOYD		Are you employed?		0 = No 1 = Yes
FERCT		CT performed performed in the ER for the stone(s)?		0 = No 1 = Yes
FERDATE	R/D	Date of most recent visit to the ER because of the stone		
FERXRAY		X-ray performed in the ER for the stone(s)?		0 = No 1 = Yes
FEXPDATE	R/D	Date expelled stone was seen or passed		
FEXPEL		Have you expelled the stone?		0 = No 1 = Seen 2 = Captured
FFUPDATE	R/D	Date of follow-up visit with a doctor for the stone		
FFUPSPCX	D	Other specialty for follow-up visit for the stone		

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
FFUPSPEC		Specialty for follow-up visit for the stone		1 = PCP 2 = Urologist 3 = Other
FFUPVST		Have you had a follow-up visit with a doctor for the stone?		0 = No 1 = Yes
FRETER		Have you been hospitalized because of the stone?		0 = No 1 = Yes
FHSPDATE	R/D	Date of hospitalization for the stone		
FHSPNITE		How many nights did you spend in the hospital because of the stone		
FNSAID		Are you taking a NSAID?		
FNSDOS		NSAID dose	mg	
FNSNUM		How many other NSAID pills have you taken since the last phone contact?		
FPERC		Are you taking Percocet		0 = No 1 = Yes
FPERCDOS		Percocet dose	mg	
FPERCNUM		How many Percocet pills have you taken since the last phone contact?		
FREACH	D	Patient Unable To Be Reached		0 = No 1 = Yes
FRETER		Have you returned to the ER because of the stone?		0 = No 1 = Yes
FRETWORK		Have you returned to work?		0 = No 1 = Yes
FSMEDDOS		How many study medication doses since the last interview?		
FSRGTYPX		Other type of surgical intervention procedure for stone		
FSTDYMED		Have you taken the study medication?		0 = No 1 = Yes
FSURG		Have you had or been scheduled for surgical intervention for stone?		0 = No 1 = Yes

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
FSURGTYP		Type of surgical intervention procedure for stone		1 = Lithotripsy 2 = Ureteral stent 3 = Ureteroscopy (no stent) 4 = Other
FURINATE		Burning, stinging when urinating or needing to urinate more often?		0 = No 1 = Yes
F_DAYN	N	Date of contact		

7.2 Derived Variables

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
FER_DAYN	Days after screening of most recent visit to the ER because of the stone			Number of days between date of LSCRNDT and date of FERDATE
FEXP_DAYN	Days after screening expelled stone was seen or passed			Number of days between date of LSCRNDT and date of FEXPDATE
FFUP_DAYN	Days after screening of follow-up visit with a doctor for the stone			Number of days between date of LSCRNDT and date of FFUPDATE
FHSP_DAYN	Days after screening of hospitalization for the stone			Number of days between date of LSCRNDT and date of FHSPDATE

8 Phase 1– Analysis Dataset Variables (PILOT)

8.1 ID_NO

Label — Randomly assigned patient ID number

8.2 GROUP

Label — Treatment group (0/1)

Description — Patient's numeric treatment group assignment. This value comes directly from the randomization database.

Formats — 0 = Placebo
1 = Active Tamsulosin

8.3 GROUP_LABEL

Label — Treatment group

Description — Patient's treatment group assignment. This value comes directly from the randomization database.

Formats — Placebo
Active Tamsulosin

8.4 OUTCOME

Label — Expelled stone within 28 days of screening?

Source Variables — Scrn: LSCRNDT
Tfu: DAY, FREACH, FEXPEL, FEXPDATE

Description — If a patient reported seeing or capturing a stone (FEXPEL=1 or FEXPEL=2) at any follow-up visit, and the number of days between the date of screening (LSCRNDT) and the earliest date an expelled stone seen or captured (FEXPDATE) for that patient is < 29 days, then OUTCOME = 1.

Otherwise, if a patient reported seeing or capturing a stone (FEXPEL=1 or FEXPEL=2) at any follow-up visit, and the number of days between the date of screening (LSCRNDT) and the earliest date an expelled stone seen or captured (FEXPDATE) for that patient is ≥ 29 days, then OUTCOME = 0.

Likewise, if a patient did not report seeing or capturing a stone (FEXPEL ≠ 1 and FEXPEL ≠ 2) at any follow-up visit, and the patient was able to be reached (FREACH=0) at any follow-up visit (DAY) ≥ 29, then OUTCOME = 0.

Formats — 0 = No
1 = Yes

Notes — Comments accompanying the data entry for 7 patients indicated that the stone expulsion entered was a result of surgical intervention for the stone. Those cases were coded as OUTCOME=0.

Sample Code

```
DATA TFU;
SET TFU;
BY ID_NO;
RETAIN EXPEL EXPELDT REACH29;
IF FIRST.ID_NO THEN DO;
EXPEL = 0;
EXPELDT = .;
REACH29 = 0;
END;
IF FEXPEL IN (1,2) THEN EXPEL = 1;
IF FREACH=0 AND DAY>=29 THEN REACH29=1;
EXPELDT = MIN(EXPELDT, FEXPDATE);
IF LAST.ID_NO;
KEEP ID_NO EXPEL EXPELDT REACH29;
RUN;

DATA BUILD;
MERGE SCRN TFU;
BY ID_NO;
DAYS_TO_EXPEL = EXPELDT - LSCRNDT;
IF EXPEL = 0 AND REACH29=1 THEN OUTCOME = 0;
IF DAYS_TO_EXPEL >= 29 THEN OUTCOME = 0;
IF 0 <= DAYS_TO_EXPEL < 29 THEN OUTCOME = 1;
*Hardcode OUTCOME=0 after review of comments because expel
at same time as surgery and no expel without surgery;
IF ID_NO IN (106,246,259,385,442,477,508) THEN DO;
```

```
OUTCOME=0;
END;
```

8.5 SURG_DONE29

Label — Had surgical intervention for stone? (specified on any follow-up day up to day 36)

Source Variables — Tfu: DAY, FSURG

Description — If a patient reported having a surgical intervention for stone (FSURG=2) at any follow-up visit (DAY) ≤ 36 days, then SURG_DONE29 = 1.

Formats — 0 = No
1 = Yes

Sample Code

```
DATA TFU;
SET TFU;
BY ID_NO;
RETAIN SURG_DONE29;
IF FIRST.ID_NO THEN SURG_DONE29=0;
IF FSURG = 2 AND DAY <=36 THEN SURG_DONE29 = 1;
IF LAST.ID_NO;
KEEP ID_NO SURG_DONE29;
RUN;
```

8.6 HOSP29

Label — Hospitalized because of the stone (specified on any follow-up day up to day 36)?

Source Variables — Tfu: DAY, FHOSP

Description — If a patient reported being hospitalized because of the stone (FHOSP=1) at any follow-up visit (DAY) ≤ 36 days, then HOSP29 = 1.

Formats — 0 = No
1 = Yes

Sample Code

```
DATA TFU;
SET TFU;
BY ID_NO;
RETAIN HOSP29;
IF FIRST.ID_NO THEN HOSP29=0;
IF FRETER = 1 AND DAY <=36 THEN HOSP29 = 1;
IF LAST.ID_NO;
KEEP ID_NO HOSP29;
RUN;
```

8.7 RETER29

Label — Returned to the ER for the stone(s) (specified on any follow-up day up to day 36)?

Source Variables — Tfu: DAY, FRETER

Description — If a patient returned to the ER because of the stone (FRETER=1) at any follow-up visit (DAY) ≤ 36 days, then RETER29 = 1.

Formats
0 = No
1 = Yes

Sample Code

```
DATA TFU;
SET TFU;
BY ID_NO;
RETAIN RETER29;
IF FIRST.ID_NO THEN RETER29=0;
IF FRETER = 1 AND DAY <=36 THEN RETER29 = 1;
IF LAST.ID_NO;
KEEP ID_NO RETER29;
RUN;
```

8.8 RETWORK29

Label — Returned to work (specified on any follow-up day up to day 36)

Source Variables — Tfu: DAY, FRETWORK, FEMPLOYD

Description — If a patient returned to work (FRETWORK=1) and was employed (FEMPLOYD=1) at any follow-up visits (DAY) ≤ 36 days, then RETWORK29 = 1.

Formats
0 = No
1 = Yes

Sample Code

```
DATA TFU;
SET TFU;
BY ID_NO;
RETAIN RETWORK29;
IF FIRST.ID_NO THEN RETWORK29=0;
IF FRETWORK = 1 AND DAY <=36 THEN RETWORK29 = 1;
IF FEMPLOYD=1 AND DAY<=36 THEN EMPLOYD29 = 1;
IF LAST.ID_NO;
IF EMPLOYD29 NE 1 THEN RETWORK29 = .;
KEEP ID_NO RETWORK29;
RUN;
```

9 Phase 2 – Clinical Screening Form (ST01)

9.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
LETHNIC		Ethnicity		0 = No, Not Hispanic / Latino 1 = Yes, Hispanic / Latino
LGEN		Gender		1 = Female 2 = Male
LINELIG	D	Reason for ineligibility		01 = Age < 18 02 = No evidence of ureterolithiasis 03 = No phone 04 = Concurrent UTI 05 = Prior kidney/ureter surgery 06 = Pregnant 07 = Anatomical GU abnormality 08 = Ipsilateral/solitary kidney 09 = Prior renal transplant or donation 10 = History of renal insufficiency 11 = Fever 12 = History of hypersensitivity to tamsulosin 13 = Taking α-blockers or Ca++blockers 14 = Taking vardenafil 15 = Floppy iris syndrome 16 = Cataract surgery within 60 days 17 = Stone expulsion in the ED 18 = Largest stone diameter ≥ 9mm 19 = Admitted to the hospital 20 = Prisoner or ward of state 21 = Breastfeeding mother 22 = Prior enrollment 23 = Bladder stone

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
				24 = Taking steroids 25 = Non-English speaker 99 = Other
LOTHREAS	D	Explain other reason for ineligibility		
LPATID	D	STONE Patient ID		
LPRVSCR	D	Previous Screen?		
LPRVSCRN	D	Previous Screening Number		
LRACE	R/D	Race		1 = American Indian / Alaskan Native 2 = Asian 3 = Native Hawaiian / Pacific Islander 4 = Black / African American 5 = White 6 = Unknown or Not Reported
LSCRDT	D	Date screened		
LSTATUS	D	Screen Status		1 = Patient declined consent 2 = Ineligible 3 = Randomized
SCREEN	D	Screening Number		

9.2 Derived Variables

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
RACE_CAT	Race category		0 = Non-white 1 = White	If LRACE=5 then category is “White.” If LRACE is 1, 2, 3, 4 or 6, then category is “Non-white.”

10 Phase 2 – Clinical Screening Form (ST02)

10.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SADMIT	D	Patient Admitted		0 = No 1 = Yes
SADMSERV	D	To which service?		1 = Urology 2 = Surgery 3 = Medicine 4 = Other
SAGE	R/D	Age	years	
SALLTAM		Known allergy to tamsulosin?		0 = No 1 = Yes
SALPHAB		Currently taking calcium channel blockers?		0 = No 1 = Yes
SCHPAIN		Chest Pain		0 = No 1 = Yes
SDATE	D	Date of screening		
SDIPBLD	R/D	Urine dipstick: Blood		0 = Negative 1 = Trace 2 = Abt 50 3 = Abt 250
SDIPGLUC	R/D	Urine dipstick: Glucose		0 = Normal 1 = 50 2 = 100 3 = 250 4 = 500 5 = 1000
SDIPWBC	R/D	Urine dipstick: White cells		0 = Negative 1 = Trace 2 = + 3 = ++
SDIZZY		Dizziness		0 = No 1 = Yes
SEXPEL	D	Stone expelled in the ED? (NOTE: Not eligible if expelled)		0 = No 1 = Yes
SFAMHX		Family history of kidney stones?		0 = No 1 = Yes
SFEVER		Fever		0 = No 1 = Yes

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SFINDX		Final primary ED diagnosis		1 = Renal colic 2 = Stone 3 = Other
SGROINP		Scrotum or groin pain		0 = No 1 = Yes
SHCG		Was an HCG done?		0 = No 1 = Yes 2 = N/A
SHCGRES		HCG results positive?		0 = No 1 = Yes
SHXKSTN		Past history of kidney stones?		0 = No 1 = Yes
SIBPDIA		Diastolic blood pressure	mmHg	
SIBPSYS		Systolic blood pressure	mmHg	
SIHR		Heart rate	bpm	
SITEMP		Temperature	°F	
SLEVITRA		Currently taking vardenafil?		0 = No 1 = Yes
SLOWABDP		Lower abdomen pain		0 = No 1 = Yes
SMEDS		Currently taking OTHER medication on a regular basis?		0 = No 1 = Yes
SMEDSB	D	List current other medication		
SMEDSC	D	List current other medication		
SMEDSD	D	List current other medication		
SMEDSX	D	List current other medication		
SMICBACT	R/D	Urinalysis microscopy: Bacteria		0 = 0, none, negative, WNL 1 = 1-5, trace, rare, present, slight 2 = 6-15, moderate 3 = 16-30, many, frequent 4 = > 30, innumerable, TNTC

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
SMICBLD	R/D	Urinalysis microscopy: Blood		0 = 0, none, negative, WNL 1 = 1-5, trace, rare, present, slight 2 = 6-15, moderate 3 = 16-30, many, frequent 4 = > 30, innumerable, TNTC
SMICRO		Urinalysis microscopy done?		0 = No 1 = Yes
SMICWBC	R/D	Urinalysis microscopy: White cells		0 = 0, none, negative, WNL 1 = 1-5, trace, rare, present, slight 2 = 6-15, moderate 3 = 16-30, many, frequent 4 = > 30, innumerable, TNTC
SMONSTN	R/D	Month of most recent episode of kidney stones		
SNAUSEA		Nausea		0 = No 1 = Yes
SNOTEMP		Feeling of not emptying bladder completely		0 = No 1 = Yes
SNUMSTN	R/D	How many past episodes of kidney stones?		
SPAINUR		Pain when urinating		0 = No 1 = Yes
SSCREEN	D	Screening Number		
SSIDEP		Side pain ("Flank" pain)		0 = No 1 = Yes
SSTEROID		Currently taking steroids?		0 = No 1 = Yes
SURIN		Increased need to urinate		0 = No 1 = Yes
SURNGHT		Urinating more often at night		0 = No 1 = Yes
SVOMIT		Vomiting		0 = No 1 = Yes
SYRSTN	R/D	Year of most recent episode of kidney stones		

10.2 Derived Variables

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
AGE_CAT	Age category		1 = 18 – 30 2 = 31 – 40 3 = 41 – 50 4 = > 50	Calculated using SAGE and ranges given in format
DIPBLD_CAT	Urine dipstick: Blood category		0 = Negative 1 = Trace and above	If SDIPBLD = 0, then category is "Negative." If SDIPBLD ≥ 1, then category is "Trace and above."
DIPGLUC_CAT	Urine dipstick: Glucose category		0 = Normal 1 = 50 and above	If SDIPGLUC = 0, then category is "Normal." If SDIPGLUC ≥ 1, then category is "50 and above."
DIPWBC_CAT	Urine dipstick: WBC category		0 = Negative 1 = Trace and above	If SDIPWBC = 0, then category is "Negative." If SDIPWBC ≥ 1, then category is "Trace and above."
MICBACT_CAT	Urinalysis microscopy: Bacteria category		0 = 0, none, negative, WNL 1 = 1-5, trace, rare, present, slight 2 = ≥6, moderate or greater	If SMICBACT = 0, then category is "0, none, negative, WNL." If SMICBACT = 1, then category is "1-5, trace, rare, present, slight." If SMICBACT>1, then category is "≥6, moderate or greater."
MICBLD_CAT	Urinalysis microscopy: Blood category		0 = 0, none, negative, WNL 1 = 1-5, trace, rare, present, slight 2 = ≥6, moderate or greater	If SMICBLD = 0, then category is "0, none, negative, WNL." If SMICBLD = 1, then category is "1-5, trace, rare, present, slight." If SMICBLD>1, then category is "≥6, moderate or greater."

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
MICWBC_CAT	Urinalysis microscopy: WBC category		0 = 0, none, negative, WNL 1 = 1-5, trace, rare, present, slight 2 = ≥6, moderate or greater	If SMICWBC = 0, then category is "0, none, negative, WNL." If SMICWBC = 1, then category is "1-5, trace, rare, present, slight." If SMICWBC>1, then category is "≥6, moderate or greater."
NUMSTN_CAT	Past episodes of kidney stones category		1 = 1 2 = 2 or more	If SNUMSTN=1 then category is "1." If SNUMSTN ≥ 2, then category is "2 or more."
STN_MON	Months since most recent episode of kidney stones			Number of months between date of SMONSTN/SYRSTN and month and year of LSCRDT

11 Phase 2 – Radiological Screening Form (ST03)

11.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
RCTSTONE		CT Result		0 = No stones 1 = Single stone 2 =Multiple stones 3 = Bladder stone(s)
RDATE	D	Date of screening		
RDIALAR		Diameter of largest stone (If not symptomatic stone)	mm	
RHYDRON		Hydronephrosis?		0 = No 1 = Yes
RLARGEST		Is the symptomatic stone the largest stone?		0 = No 1 = Yes
RLDISTUR		Location of additional stones: Distal ureter		0 = No 1 = Yes
RLKIDNEY		Location of additional stones: Kidney		0 = No 1 = Yes
RLMIDUR		Location of additional stones: Mid ureter		0 = No 1 = Yes
RLOCASYM		Location of symptomatic stone		1 = Renal pelvis 2 = Proximal ureter 3 = Mid ureter 4 = Distal ureter 5 = UVJ
RLPROXUR		Location of additional stones: Proximal ureter		0 = No 1 = Yes
RLRENPEL		Location of additional stones: Renal pelvis		0 = No 1 = Yes
RLUVJ		Location of additional stones: UVJ		0 = No 1 = Yes
RNUMSTN		Number of stones		
RSIDELOC		Side of additional stone(s)		1 = Left 2 = Right 3 = Bilateral
RSIDESYM		Side of symptomatic stone		1 = Left 2 = Right
RSIZESYM		Diameter of symptomatic stone	mm	

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
RSTRAND		Stranding?		0 = No 1 = Yes

12 Phase 2 – Follow-up Form (ST10)

12.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
FABNEJAC		Abnormalities of ejaculation?		0 = No 1 = Yes 2 = Female
FAE		Have you experienced any adverse events not mentioned above?		0 = No 1 = Yes
FANALG		Are you currently taking any other analgesic?		0 = No 1 = Yes
FANALGT		Type of analgesic?		1 = Acetaminophen 2 = Demerol 3 = Other
FANALGX	D	Specify other analgesic		
FANDOS	D	Other analgesic dose	mg	
FANNUM	D	How many other analgesic pills have you taken since the last phone contact?		
FCONTRA		Have you taken a contraindicated medication since the last contact?		0 = No 1 = Yes
FDATE	D	Date of Contact		
FDAY		Post ED Day		
FDIZRST		Dizziness at rest?		0 = No 1 = Yes
FDIZSTND		Dizziness when standing up?		0 = No 1 = Yes
FEMPLOYD		Are you employed?		0 = No 1 = Yes
FERCT		CT performed performed in the ER for the stone(s)?		0 = No 1 = Yes
FERDATE	D	Date of most recent visit to the ER because of the stone		
FERNUMV		How many visits to the ER for the stone(s)?		
FERUS		Ultrasound performed in the ER for the stone(s)?		0 = No 1 = Yes
FEXPDATE	D	Date expelled stone seen or captured		

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
FEXPEL		Have you expelled a stone?		0 = No 1 = Seen 2 = Captured
FEXPMULT		Have you expelled multiple stones?		0 = No 1 = Yes
FFACFLSH		Facial flushing?		0 = No 1 = Yes
FFUPDATE	R/D	Date of follow-up visit with a doctor for the stone		
FFUPSPCX	D	Other specialty for follow-up visit for the stone		
FFUPSPEC		Specialty for follow-up visit for the stone		1 = PCP 2 = Urologist 3 = Nephrologist 4 = Other
FFUPVST		Have you had a follow-up visit with any doctor for the stone?		0 = No 1 = Yes
FGASTRO		Stomach upset, nausea or vomiting (gastrointestinal disorder)?		0 = No 1 = Yes
FGBLEED		Bloody/ black stool or bloody vomiting (gastrointestinal bleeding)?		0 = No 1 = Yes
FHEADACH		Headache(s)?		0 = No 1 = Yes
FRETER		Have you been hospitalized because of the stone?		0 = No 1 = Yes
FHSPCT		CT performed performed during hospitalization for the stone(s)?		0 = No 1 = Yes
FHSPDATE	D	Date of hospitalization for the stone(s)		
FHSPNITE		How many nights did you spend in the hospital for the stone?		
FHSPNUM		How many hospitalizations for the stone?		
FHSPUS		Ultrasound performed during hospitalization for the stone(s)?		0 = No 1 = Yes
FMULTNUM	D	How many stones were expelled?		
FNSAID		Are you currently taking an NSAID?		0 = No 1 = Yes
FNSDOS		NSAID dose	mg	

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
FNSNUM		How many other NSAID pills have you taken since the last phone contact?		
FOLDOS		How many open label tamsulosin doses since the last contact?		
FOPENLAB		Have you taken any open label tamsulosin/Flomax since the last contact?		0 = No 1 = Yes
FPERC		Are you currently taking Percocet?		0 = No 1 = Yes
FPERCDOS		Percocet dose per day?		1 = 1 tablet 2 = 2 tablets 3 = 3 tablets 4 = Other
FREACH	D	Patient Reached?		0 = No 1 = Yes
FRETER		Have you returned to the ER for the stone(s)?		0 = No 1 = Yes
FRETWORK		Have you returned to work?		0 = No 1 = Yes
FSMEDDOS		How many study medication doses since the last contact?		
FSRGDATE	D	Date of surgical intervention procedure for stone		
FSTDYMED		Have you taken the study medication since the last contact?		0 = No 1 = Yes
FSTEROID		Have you taken a steroid medication since the last contact?		0 = No 1 = Yes
FSURG		Have you had or been scheduled for surgical intervention for stone?		0 = No 1 = Yes, scheduled 2 = Yes, already done
FSURGTYP		Type of surgical intervention procedure for stone		1 = Lithotripsy 2 = Ureteral stent 3 = Ureteroscopy 4 = Laser Blast 5 = Other
FTACHY		Tachycardia or fast heart rate?		0 = No 1 = Yes
FULCER		Abdominal pain or a stomach ulcer?		0 = No 1 = Yes

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
FUTI		Urinary tract infection(s)?		0 = No 1 = Yes

12.2 Derived Variables

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
FER_DAYN	Days after screening of most recent visit to the ER because of the stone			Number of days between date of LSCRDT and date of FERDATE
FEXP_DAYN	Days after screening expelled stone seen or captured			Number of days between date of LSCRDT and date of FEXPDATE
FFUP_DAYN	Days after screening of follow-up visit with a doctor for the stone			Number of days between date of LSCRDT and date of FFUPDATE
FHSP_DAYN	Days after screening of hospitalization for the stone(s)			Number of days between date of LSCRDT and date of FHSPDATE
FSRG_DAYN	Days after screening of surgical intervention procedure for stone			Number of days between date of LSCRDT and date of FSRGDATE

13 Phase 2 – Radiological Follow-up Form (ST11)

13.1 Form Variables

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
DCTPERF		Follow-up CT performed?		0 = No 1 = Yes
DCTSTONE		CT result:		0 = No stones 1 = Single stone 2 =Multiple stones
DDATE	D	Date of scan (mm/dd/yyyy):		
DDAY28CT	D	Performed as Day 28 CT for study?		0 = No 1 = Yes
DHYDRON		Hydronephrosis?		0 = No 1 = Yes
DKIDNEY		Location of additional stones: Kidney		0 = No 1 = Yes
DLDISTUR		Location of additional stones: Distal ureter		0 = No 1 = Yes
DLMIDUR		Location of additional stones: Mid ureter		0 = No 1 = Yes
DLPROXUR		Location of additional stones: Proximal ureter		0 = No 1 = Yes
DLRENPEL		Location of additional stones: Renal Pelvis		0 = No 1 = Yes
DLUVJ		Location of additional stones: UVJ		0 = No 1 = Yes
DNOCTRSN		Reason follow-up CT not performed		1 = Refused 2 = Captured/seen stone 3 = CT or scan already done 4 = Urologist recommendation 5 = Radiation exposure 6 = Surgical intervention 9 = Other
DNUMSTN		Number of stones:		
DSIDESTN		Side of stone(s):		1 = Left 2 = Right 3 = Bilateral
DSIZELG		Diameter of largest stone	mm	

NAME	RELEASE STATUS	LABEL	UNITS	FORMAT
DSTRAND		Stranding?		0 = No 1 = Yes

13.2 Derived Variables

NAME	LABEL	UNITS	FORMAT	DESCRIPTION
D_DAYN	Days after screening of CT scan			Number of days between date of LSCRDT and date of DDATE

14 Phase 2– Analysis Dataset Variables (MC)

14.1 ID_NO

Label — Randomly assigned patient ID number

14.2 GROUP

Label — Treatment group (0/1)

Description — Patient's numeric treatment group assignment. This value comes directly from the randomization database.

Formats — 0 = Placebo
1 = Active Tamsulosin

14.3 GROUP_LABEL

Label — Treatment group

Description — Patient's treatment group assignment. This value comes directly from the randomization database.

Formats — Placebo
Active Tamsulosin

14.4 OUTCOME

Label — Expelled stone within 28 days of screening?

Source Variables — ST01: LSCRDT
ST10: FDAY, FREACH, FEXPEL, FEXPDATE, FSURG, FSRGDATE

Description — If a patient reported seeing or capturing a stone (FEXPEL=1 or FEXPEL=2) at any follow-up visit, and the number of days between the date of screening (LSCRDT) and the earliest date an expelled stone seen or captured (FEXPDATE) for that patient is < 29 days, then OUTCOME = 1.

Otherwise, if a patient reported seeing or capturing a stone (FEXPEL=1 or FEXPEL=2) at any follow-up visit, and the number of days between the date of screening (LSCRDT) and the earliest date an expelled stone seen or captured (FEXPDATE) for that patient is ≥ 29 days, then OUTCOME = 0.

Likewise, if a patient did not report seeing or capturing a stone (FEXPEL ≠ 1 and FEXPEL ≠ 2) at any follow-up visit, and the patient was able to be reached (FREACH=1) at any follow-up visit (FDAY) ≥ 29, then OUTCOME = 0.

If a patient reported having a surgical intervention for stone (FSURG=2) and the earliest date of surgical intervention procedure for stone (FSRGDATE) is ≤ the

earliest date an expelled stone was seen or captured (FEXPDATE) for that patient, then OUTCOME = 0.

Formats

0 = No
1 = Yes

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN EXPEL EXPELDT REACH29;
IF FIRST.ID_NO THEN DO;
EXPEL = 0;
EXPELDT = .;
REACH29 = 0;
END;
IF FEXPEL IN (1,2) THEN EXPEL = 1;
IF FREACH=0 AND DAY>=29 THEN REACH29=1;
EXPELDT = MIN(EXPELDT, FEXPDATE);
IF LAST.ID_NO;
KEEP ID_NO EXPEL EXPELDT REACH29;
RUN;

DATA SURG;
SET ST10;
WHERE FSURG = 2;
KEEP ID_NO FDAY FSURGTYP FSRGDATE;
RUN;
PROC SORT;
BY ID_NO FDAY;
RUN;

DATA SURG;
SET SURG;
BY ID_NO;
IF FIRST.ID_NO THEN N=0;
N+1;
RUN;

PROC SQL;
SELECT MAX(N) INTO :MAX_SURG FROM SURG;
QUIT;

DATA BUILD;
MERGE ST01 ST10;
BY ID_NO;
DAYS_TO_EXPEL = EXPELDT - LSCRNDT;
IF EXPEL = 0 AND REACH29=1 THEN OUTCOME = 0;
IF DAYS_TO_EXPEL >= 29 THEN OUTCOME = 0;
IF 0 <= DAYS_TO_EXPEL < 29 THEN OUTCOME = 1;

*Additional recoding of primary outcome for surgeries;
ARRAY SURGDT(&MAX_SURG);
IF . < MIN(OF SURGDT(*)) <= EXPELDT THEN RECODE_OUTCOME =
0;
IF RECODE_OUTCOME = 0 THEN OUTCOME = 0;
```

14.5 SURG_DONE29

Label — Had surgical intervention for stone? (specified on any follow-up day up to day 36)

Source Variables — ST10: FDAY, FSURG

Description — If a patient reported having a surgical intervention for stone (FSURG=2) at any follow-up visit (FDAY) ≤ 36 days, then SURG_DONE29 = 1.

Formats — 0 = No
1 = Yes

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN SURG_DONE29;
IF FIRST.ID_NO THEN SURG_DONE29=0;
IF FSURG = 2 AND 0 <= FDAY <=36 THEN SURG_DONE29 = 1;
IF LAST.ID_NO;
KEEP ID_NO SURG_DONE29;
RUN;
```

14.6 HOSP29

Label — Hospitalized because of the stone (specified on any follow-up day up to day 36)?

Source Variables — ST10: FDAY, FHOSP

Description — If a patient reported being hospitalized because of the stone (FHOSP=1) at any follow-up visit (FDAY) ≤ 36 days, then HOSP29 = 1.

Formats — 0 = No
1 = Yes

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN HOSP29;
IF FIRST.ID_NO THEN HOSP29=0;
IF FRETER = 1 AND 0 <= FDAY <=36 THEN HOSP29 = 1;
IF LAST.ID_NO;
KEEP ID_NO HOSP29;
RUN;
```

14.7 RETER29

Label — Returned to the ER for the stone(s) (specified on any follow-up day up to day 36)?

Source Variables — ST10: FDAY, FRETER

Description — If a patient returned to the ER because of the stone (FRETER=1) at any follow-up visit(FDAY) ≤ 36 days, then RETER29 = 1.

Formats
0 = No
1 = Yes

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN RETER29;
IF FIRST.ID_NO THEN RETER29=0;
IF FRETER = 1 AND 0 <= FDAY <=36 THEN RETER29 = 1;
IF LAST.ID_NO;
KEEP ID_NO RETER29;
RUN;
```

14.8 RETWORK29

Label — Returned to work (specified on any follow-up day up to day 36)

Source Variables — ST10: FDAY, FRETWORK, FEMPLOYD

Description — If a patient returned to work (FRETWORK=1) and was employed (FEMPLOYD=1) at any follow-up visits (FDAY) ≤ 36 days, then RETWORK29 = 1.

Formats
0 = No
1 = Yes

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN RETWORK29;
IF FIRST.ID_NO THEN RETWORK29=0;
IF FRETWORK = 1 AND 0 <= FDAY <=36 THEN RETWORK29 = 1;
IF FEMPLOYD=1 AND 0 <= FDAY<=36 THEN EMPLOYD29 = 1;
IF LAST.ID_NO;
IF EMPLOYD29 NE 1 THEN RETWORK29 = .;
KEEP ID_NO RETWORK29;
RUN;
```

14.9 OPENLAB29

Label — Open label tamsulosin/Flomax taken (specified on any follow-up day up to day 36)?

Source Variables — ST10: FDAY, FOPENLAB

Description — If a patient took any open label tamsulosin/Flomax since the last contact (FOPENLAB=1) at any follow-up visit (FDAY) ≤ 36 days, then OPENLAB29 = 1.

Formats — 0 = No
1 = Yes

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN OPENLAB29;
IF FIRST.ID_NO THEN OPENLAB29=0;
IF FOPENLAB = 1 AND 0<=FDAY <=36 THEN OPENLAB29 = 1;
IF LAST.ID_NO;
KEEP ID_NO OPENLAB29;
RUN;
```

14.10 CROSSOVER_DAYN

Label — Estimated days after screening of crossover to open label Flomax/tamsulosin

Source Variables — ST01: LSCRDT
ST10: FDATE, FOPENLAB

Description — The crossover date to open label Flomax / tamsulosin (CROSSOVERDT) is the earliest date of follow-up contact (FDATE) when the patient took any open label tamsulosin/Flomax (FOPENLAB=1) minus a number of days equal to the number of open label Flomax/tamsulosin doses since last contact (FOLDOS).

The number of days after screening of crossover to open label Flomax/tamsulosin (CROSSOVER_DAYN) is the number of days between the screening date (LSCRDT) and the crossover date to open label Flomax / tamsulosin (CROSSOVERDT).

Sample Code

```
DATA ST10;
SET ST10;
BY ID_NO;
RETAIN OPENLAB1STDT CROSSOVERDT OPENLAB29;
IF FIRST.ID_NO THEN DO;
OPENLAB1STDT = .;
CROSSOVERDT = .;
OPENLAB29=0;
END;
IF FOPENLAB=1 THEN OPENLAB1STDT = MIN(OPENLAB1STDT, FDATE);
IF FDATE=OPENLAB1STDT AND FOPENLAB=1 THEN CROSSOVERDT =
FDATE-FOLDOS;
```

```
IF LAST.ID_NO;
KEEP ID_NO CROSSOVERDT;
RUN;

DATA BUILD;
MERGE ST01 ST10;
BY ID_NO;
IF CROSSOVERDT NE .;
CROSSOVER_DAYN=CROSSOVERDT - LSCRDT;
KEEP ID_NO CROSSOVER_DAYN;
RUN;
```

14.11 CTPASS

Label — Passage by follow-up CT per Review Committee

Source Variables — ST03: RCTSTONE, RSIDESYM, RLOCASYM, RSIDELOV, RLRENPEL, RLPROXUR, RLMIDUR, RLDISTUR, RLUVJ, RLKIDNEY
ST11: DCTPERF, DCTSTONE DNUMSTN, DSIDESTN, DLRENPEL, DLPROXUR, DLMIDUR, DLDISTUR, DLUVJ, DKIDNEY

Description — If CT review falls into the following categories, then CTPASS = 1:

- STATUS 2 = No stones at follow-up but CT performed
- STATUS 3 = No stones on same side at follow-up
- STATUS 5 = Single stone at screening and follow-up and follow-up stone higher
- STATUS 7 = Multiple stones at screening, symptomatic stone in ureter (proximal, mid, distal or UVJ) at screening and rest in kidney, follow-up stone(s) higher than symptomatic stone and not in ureter
- STATUS 9.2 = Multiple stones at screening, other, symptomatic lower than renal pelvis, follow-up in kidney on same side
- STATUS 10.1 = Single stone at screening, only stones in kidney or bladder at follow-up

If CT review falls into the following categories, then CTPASS = 0:

- STATUS 4 = Single stone at screening and follow-up and follow-up stone in same place or lower
- STATUS 6 = Multiple stones at screening, symptomatic stone in ureter (proximal, mid, distal or UVJ) at screening and rest in kidney, follow-up stone(s) not higher than symptomatic stone
- STATUS 8 = Multiple stones at screening, symptomatic stone in ureter (proximal, mid, distal or UVJ) at screening and rest in kidney, follow-up stone(s) higher than symptomatic stone and in ureter
- STATUS 9 = Multiple stones at screening, other
- STATUS 10 = Single stone at screening, other
- STATUS 11 = Reviewed by CT Review Committee;

Formats — 0 = No
1 = Yes

Sample Code

```
PROC SORT DATA=ST11 OUT=ST11 NODUPKEY;
BY ID_NO;
```

```
RUN;
DATA ST11;
SET ST11;
*HIGHEST is code for highest position of a follow-up stone
(kidney is highest UVJ is lowest);
IF DKIDNEY=1 THEN HIGHEST=0;
ELSE IF DLRENPEL=1 THEN HIGHEST=1;
ELSE IF DLPROXUR=1 THEN HIGHEST=2;
ELSE IF DLMIDUR=1 THEN HIGHEST=3;
ELSE IF DLDISTUR=1 THEN HIGHEST=4;
ELSE IF DLUVJ=1 THEN HIGHEST=5;
*LOWEST is code for lowest position of a follow-up stone
(UVJ is lowest position and kidney highest position);
IF DLUVJ=1 THEN LOWEST=5;
ELSE IF DLDISTUR=1 THEN LOWEST=4;
ELSE IF DLMIDUR=1 THEN LOWEST=3;
ELSE IF DLPROXUR=1 THEN LOWEST=2;
ELSE IF DLRENPEL=1 THEN LOWEST=1;
ELSE IF DKIDNEY=1 THEN LOWEST=0;
RUN;

PROC SORT DATA=ST03 OUT=ST03 NODUPKEY;
BY ID_NO;
RUN;
DATA ST03;
SET ST03;
IF RCTSTONE NE 2 THEN SIDES = RSIDESYM;
ELSE DO;
IF RSIDESYM=1 AND RSIDELOC=1 THEN SIDES = 1;
IF RSIDESYM=2 AND RSIDELOC=2 THEN SIDES = 2;
IF RSIDESYM=1 AND RSIDELOC IN (2,3) THEN SIDES = 3;
IF RSIDESYM=2 AND RSIDELOC IN (1,3) THEN SIDES = 3;
END;
RUN;

DATA STONECT;
MERGE ST11 (IN=A) ST03 (IN=B);
BY ID_NO;
IF A;
ARRAY ARR1(*) RLRENPEL RLPROXUR RLMIDUR RLDISTUR RLUVJ
RLKIDNEY;
ARRAY ARR2(*) DLRENPEL DLPROXUR DLMIDUR DLDISTUR DLUVJ
DKIDNEY;
LENGTH LOC_ST03 LOC_ST11 $ 200;
DO I = 1 TO 6;
IF ARR1(I) = 1 THEN LOC_ST03 = CATX (' // ', LOC_ST03,
VLABEL(ARR1(I)));
IF ARR2(I) = 1 THEN LOC_ST11 = CATX(' // ', LOC_ST11,
VLABEL(ARR2(I)));
END;
*STATUS 1: No follow-up CT;
IF DCTPERF=0 THEN STATUS=1;
*STATUS 2: No stones on follow-up CT;
ELSE IF DCTPERF=1 AND DCTSTONE=0 THEN STATUS=2;
*STATUS 3: No stones on same side at screening vs. follow-
up;
ELSE IF DCTSTONE>0 AND RCTSTONE>0 AND ((DSIDESTN=1 AND
```

```
SIDES=2) OR (DSIDESTN=2 AND SIDES=1)) THEN STATUS=3
*STATUS 4: Single stone at screening and a single at
follow-up and follow-up, with the stone in same place or
lower;
ELSE IF RCTSTONE=1 AND DCTSTONE=1 AND HIGHEST>=RLOCASYM>1
THEN STATUS=4;
*STATUS 5: Single stone at screening and a single stone at
follow-up and follow-up stone is not in same place or
lower;
ELSE IF RCTSTONE=1 AND DCTSTONE=1 AND .<HIGHEST<RLOCASYM
AND RLOCASYM>1 THEN STATUS=5;
ELSE IF RCTSTONE=2 AND RLOCASYM>1 AND (RLKIDNEY=1 AND
SUM(RLRENPEL, RLPROXUR, RLMIDUR, RLDISTUR, RLUVJ)<1) THEN
DO;
*STATUS 6: Multiple stones at screening, symptomatic stone
in ureter and non-symptomatic stones in kidney; follow-up
stone(s) not higher than symptomatic stone;
      IF HIGHEST>=RLOCASYM THEN STATUS=6;
*STATUS 7: Multiple stones at screening, symptomatic stone
in ureter and non-symptomatic stones in kidney; follow-up
stone(s) higher than symptomatic stone and not in ureter;
      ELSE IF SUM(DLPROXUR, DLMIDUR, DLDISTUR, DLUVJ)<1
THEN STATUS=7;
*STATUS 8: Multiple stones at screening, symptomatic stone
in ureter and non-symptomatic stones in kidney; follow-up
stone(s) higher than symptomatic stone and in ureter;
      ELSE STATUS = 8;
END;
*STATUS 9: Multiple stones at screening;
IF RCTSTONE=2 AND STATUS=. THEN DO;
*STATUS 9.1;
IF (DSIDESTN=2 AND RSIDESYM=1) OR (DSIDESTN=1 AND
RSIDESYM=2) THEN STATUS = 9.1;
*STATUS 9.2;
ELSE IF RLOCASYM>1 AND ((DKIDNEY=1 AND RSIDESYM=DSIDESTN)
OR LOC_ST11='Kidney') THEN STATUS = 9.2;
ELSE STATUS = 9;
END;
*STATUS 10: Other, single stone at screening;
IF RCTSTONE=1 AND STATUS=. THEN STATUS=10;
IF STATUS=10 THEN DO;
*STATUS 10.1: Other, single stone at screening;
IF LOC_ST11='Kidney' THEN STATUS=10.1;
END;
*STATUS 11: Reports reviewed by Review Committee;
IF ID_NO IN ('1259', '3016', '2134') THEN STATUS = 11;
DROP I;
RUN;

DATA STONECT;
   SET STONECT;
     IF STATUS=. then delete;
       IF STATUS in (2,3,5,7,9.2,10.1) then CTPASS=1;
       IF STATUS in (4,6,8,9,10,11) then CTPASS=0;
CTSTATUS = PUT(STATUS, STATUSF.);
KEEP ID_NO CTPASS;
RUN;
```