

## **The STONE Study Data Archive**

The Study of Tamsulosin for Urolithiasis in the Emergency Department (STONE) archive contains the Documents, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

- Documents
- Forms
- Data
- Dataset Integrity Check (DSIC)

### **Documents**

The STONE Documents directory contains:

- Manual of Operations.pdf – Manual of Operations for the STONE study
- Protocol.pdf – Protocol for the STONE study
- Release Reference Dictionary – Database Reference document with specific information regarding the datasets included in the data package

### **Forms**

The STONE Forms directory contains the following forms:

- STONE Phase 1 CRFs.pdf – Case Report Forms from the first phase of STONE
- STONE Phase 2 CRFs.pdf – Case Report Forms from the second phase of STONE

### **Data**

The STONE Data directory contains the following files in SAS format (.sas7bdat):

- cl.sas7bdat – Phase 1 – Clinical Screening Form Dataset
- mc.sas7bdat – Phase 2 – Analysis Dataset Variables Dataset
- pilot.sas7bdat – Phase 1 – Analysis Dataset Variables
- scrn.sas7bdat – Phase 1 – Screening Log Dataset
- st01.sas7bdat – Phase 2 – Screening Log Dataset
- st02.sas7bdat – Phase 2 – Clinical Screening Form Dataset
- st03.sas7bdat – Phase 2 – Radiological Screening Form Dataset
- st10.sas7bdat – Phase 2 – Follow-up Form Dataset
- tfu.sas7bdat – Phase 1 – Follow-up Form Dataset

### **DSIC**

The STONE Dataset Integrity Check (DSIC) directory contains:

- DSIC.pdf – A report of an examination of the STONE datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 from the paper “Effect of Tamsulosin on Passage of Symptomatic Ureteral Stones: A

Randomized Clinical Trial” by Meltzer et al. Published results from the STONE data were compared to values recalculated from STONE archived datasets in the NIDDK repository.