

## **Symptoms of Lower Urinary Tract Dysfunction Phenotyping Study (LURN)**

The purpose of the LURN study was to develop a framework for identifying and defining the subtypes of lower urinary tract symptoms (LUTS); create new questionnaires in order to improve the measurement of patient experiences of LUTS; and generate and share data, tools, and biological specimens with clinical and research communities, in an effort to advance the understanding of LUTS and improve patients' lives.

Archive files are organized into the following directories:

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

### **Data**

The LURN Data directory contains the following files and datasets. Each dataset corresponds to the form of the same name.

#### Data\AnalysisFiles

- descriptive.sas7bdat (Analysis SAS Dataset)
- Cameron\_2018\_JUrol\_ObsDescriptive.pdf (Primary Outcome Publication)
- LURN\_Descriptive\_Analyses.sas (Analysis SAS Program)
- LURN\_Descriptive\_Data.sas (Descriptive SAS Program)

#### Data\Phenotyping

- auditorysensitivity.sas7bdat
- baselineassessment.sas7bdat
- blfuitmedication.sas7bdat
- blfuitsurghist.sas7bdat
- blfuurineculture.sas7bdat
- bllutsfamhx.sas7bdat
- casus.sas7bdat
- controlassessment.sas7bdat
- controleligiconsent.sas7bdat
- controlgroup.sas7bdat
- enrollmentassessment.sas7bdat
- followupassessment.sas7bdat
- formats.sas7bcat
- Formats.txt
- iciqbladderdiary.sas7bdat
- interimassessment.sas7bdat
- lutstool.sas7bdat

- mast.sas7bdat
- mastprocedure.sas7bdat
- neuroeligiconsent.sas7bdat
- niprocedure.sas7bdat
- niselfreport.sas7bdat
- patientqsnlfollowup.sas7bdat
- patientqsnlinitial.sas7bdat
- patientvisits.sas7bdat
- pro\_scores\_all\_visits.sas7bdat
- studytermination.sas7bdat
- suicidality.sas7bdat

Data\Phenotyping\BiomarkerPilot

- normalizedplasma.sas7bdat
- normalizedurine.sas7bdat
- rawplasma.sas7bdat
- rawurine.sas7bdat

Data\Phenotyping\OrganBasedPilot

- organ\_based\_pilot.sas7bdat

Data\Protocol 1 Interview Transcripts\1A Clinician Interviews

- CL2000\_02272014.pdf
- CL2001\_04172014.pdf
- CL2002\_04182014.pdf
- CL2003\_050314.pdf
- CL2004\_050614.pdf
- CL2005\_050614.pdf
- CL2007\_05272014.pdf
- CL2008\_05272014.pdf
- CL2009\_05272014.pdf
- CL2010\_08062014.pdf
- CL2011\_08202014.pdf
- CL7001\_05142014.pdf
- CL7002\_07012014.pdf
- CL7003\_05072014.pdf
- CL7004\_05192014.pdf
- CL7005\_05202014.pdf
- CL7006\_06042014.pdf
- CL7007\_08052014.pdf
- CL7008\_08072014.pdf
- QL7009\_08222014.pdf

- QL7010\_08222014.pdf

Data\Protocol 1 Interview Transcripts\1B Qualitative Interviews

- QL1000\_07172014.pdf
- QL1001\_07162014.pdf
- QL1002\_07162014.pdf
- QL1003\_07302014.pdf
- QL1004\_07312014.pdf
- QL1005\_07312014.pdf
- QL1006\_08012014.pdf
- QL1009\_08012014.pdf
- QL1010\_08052014.pdf
- QL1011\_08062014.pdf
- QL1012\_08042014.pdf
- QL1013\_08062014.pdf
- QL1014\_07302014.pdf
- QL1015\_08062014.pdf
- QL1016\_08082014.pdf
- QL1017\_08142014.pdf
- QL1018\_08122014.pdf
- QL1019\_09102014.pdf
- QL1020\_09052014.pdf
- QL1022\_09172014.pdf
- QL1023\_09102014.pdf
- QL2001\_06162014.pdf
- QL2002\_06172014.pdf
- QL2003\_06192014.pdf
- QL2004\_06182014.pdf
- QL2006\_06202014.pdf
- QL2007\_06232014.pdf
- QL2008\_06272014.pdf
- QL2009\_06202014.pdf
- QL2010\_06242014.pdf
- QL2011\_06252014.pdf
- QL2012\_06262014.pdf
- QL2013\_06302014.pdf
- QL2014\_06242014.pdf
- QL2015\_06242014.pdf
- QL2016\_06252014.pdf
- QL2017\_06242014.pdf
- QL2018\_06242014.pdf
- QL2019\_06242014.pdf
- QL2020\_06242014.pdf

- QL2021\_06262014.pdf
- QL2022\_06262014.pdf
- QL2023\_06262014.pdf
- QL2024\_06252014.pdf
- QL2025\_07012014.pdf
- QL2026\_07102014.pdf
- QL2027\_07112014.pdf
- QL2028\_07152014.pdf
- QL2029\_07162014.pdf
- QL2030\_07252014.pdf
- QL3000\_07012014.pdf
- QL3002\_07022014.pdf
- QL3003\_07082014.pdf
- QL3004\_07082014.pdf
- QL3005\_07082014.pdf
- QL3006\_07312014.pdf
- QL3007\_07302014.pdf
- QL3008\_07182014.pdf
- QL3009\_07162014.pdf
- QL3011\_07232014.pdf
- QL3013\_08052014.pdf
- QL3014\_07252014.pdf
- QL3015\_07162014.pdf
- QL3018\_07232014.pdf
- QL3021\_07282014.pdf
- QL3022\_07252014.pdf
- QL3023\_07162014.pdf
- QL3024\_08072014.pdf
- QL3025\_07242014.pdf
- QL3026\_07252014.pdf
- QL3028\_07242014.pdf
- QL3029\_07232014.pdf
- QL3031\_07252014.pdf
- QL3032\_07252014.pdf
- QL3034\_07302014.pdf
- QL3035\_07242014.pdf
- QL3036\_07302014.pdf
- QL3037\_07282014.pdf
- QL3038\_07302014.pdf
- QL3041\_08062014.pdf
- QL3042\_08062014.pdf
- QL7000\_07092014.pdf
- QL7001\_07092014.pdf
- QL7002\_07092014.pdf

- QL7003\_07142014.pdf
- QL7004\_07182014.pdf
- QL7005\_07292014.pdf
- QL7006\_08012014.pdf

Data\Protocol 1 Interview Transcripts\1D Cognitive Interviews

- CG1017\_documents.pdf
- CG1018\_documents.pdf
- CG1019\_documents.pdf
- CG3000\_documents.pdf
- CG3001\_documents.pdf
- CG3002\_documents.pdf
- CG3003\_documents.pdf
- CG3004\_documents.pdf
- CG3006\_documents.pdf
- CG3007\_documents.pdf
- CG3015\_documents.pdf
- CG3017\_documents.pdf
- CG3021\_documents.pdf
- CG3022\_documents.pdf
- CG3023\_documents.pdf
- CG3042\_documents.pdf
- CG7000\_documents.pdf
- CG7001\_documents.pdf
- CG7002\_documents.pdf
- CG7003\_documents.pdf
- CG7004\_documents.pdf
- CG7005\_documents.pdf
- CG7006\_documents.pdf

Data\Recall

- baselineassessment.sas7bdat
- bladderdiarycangrow.sas7bdat
- bladderdiary.sas7bdat
- bladderdiarytracker.sas7bdat
- facilities.sas7bdat
- formats.sas7bcat
- Formats.txt
- patientscreening.sas7bdat
- patients.sas7bdat
- patientvisits.sas7bdat
- questionnaires.sas7bdat
- recall24hour.sas7bdat

- recall30day.sas7bdat
- recall3day.sas7bdat
- recall7day.sas7bdat
- rptcompletenessbysection.sas7bdat
- rptcompleteness.sas7bdat
- scscreening.sas7bdat
- terminationform.sas7bdat
- training24hour.sas7bdat
- training7day.sas7bdat

## **Documents**

The LURN Documents directory contains the following files.

- LURN SI-10 and SI-29 User's Manual - v1.2 - version date 26 May 2022.pdf

### Documents\Phenotyping

- LURN\_datadictionary 20190312.xlsx

### Documents\Phenotyping\Biomarker Pilot Supplemental Documentation

- SSM-020 - Rev 3 - Data Standardization and File Specification Technical.pdf
- SSM-071 - Rev 0 - SOMAscan Data Standardization - Short Note.pdf

### Documents\Phenotyping\MOO

- LURN Neuroimaging & Sensory Testing MOO V4.0.pdf
- Organ Based Pilot MOO.pdf
- Phenotyping Study MOO V4.0\_Final.pdf

### Documents\Phenotyping\Protocol

- LURN Phenotyping Protocol V8.0 060316 CLEAN.pdf

### Documents\Protocol 1

- LURN Protocol 1- Qualitative Item Generation and Review\_v 6.0.pdf
- LURN SRM Protocol 2\_V1 with appendices.pdf
- Protocol 1 MOO v 5.0 081315.pdf
- Protocol\_2\_MOO.pdf

### Documents\Recall

- LURN SRM Protocol 2\_V1 with appendices.pdf
- Protocol\_2\_MOO.pdf
- RECALL\_datadictionary 20190312\_means\_frequencies.xlsx

## **DSIC**

The LURN Dataset Integrity Check (DSIC) directory contains:

- LURN\_DSIC.doc - A report of an examination of the analysis and form datasets (Cameron paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the LURN data were compared to values recalculated from LURN archived analysis datasets in the NIDDK Central Repository.

## **Forms**

The LURN Forms directory contains the following files.

### **Forms\Phenotyping CRFs**

- AuditorySensitivity.pdf
- Baseline Assessment.pdf
- Biospecimen Collection\_Baseline.pdf
- Biospecimen Collection Follow Up 12 Month.pdf
- Biospecimen Collection Follow Up 3 Month.pdf
- Biospecimen Labels.pdf
- Biospecimen PlaceholderQuestionnaire.pdf
- Control Assessment.pdf
- Control Eligibility and Consent.pdf
- ControlGroup.pdf
- Enrollment Assessment.pdf
- Follow-up Assessment.pdf
- ICIQ Bladder Diary CanGrow.pdf
- ICIQ Bladder Diary.pdf
- Interim Assessment.pdf
- LUTS Tool - 1 Month recall.pdf
- MAST Procedure.pdf
- Neuroimaging Eligibility and Consent.pdf
- Neuroimaging Procedure.pdf
- Neuroimaging Self-Report Questionnaires.pdf
- Patient Questionnaire - Follow Up 12 month.pdf
- Patient Questionnaire - Follow Up 3 Month.pdf
- Patient Questionnaire - Initial.pdf
- Study Termination.pdf
- Suicidality Question Review.pdf

### **Forms\Phenotyping CRFs\Organ-Based CRFs**

- Pilot General Deviations.pdf
- Pilot LURN UDS Survey.pdf
- Pilot SAE CRF.pdf

- Pilot Screening CRF.pdf
- Pilot Telephone Screening CRF.pdf

#### Forms\Protocol 1 Interview Scripts

- Clinician interview form\_021714.pdf
- LURN Cognitive Interview Questionnaire .pdf
- LURN Protocol 1- Cognitive Interview.pdf
- LURN Protocol 1- Qualitative Interview.pdf

#### Forms\Recall CRFs

- CASUS.pdf
- LURN SI 10\_final with instruction and scoring - 12 May 2021.pdf
- LURN SI-29 questionnaire check boxes final\_7 22 19.pdf
- LURN SI 29 v1.1 04.18.2021\_MT 04.26.2021.pdf
- Questionnaire\_ 24-Hour Recall.pdf
- Questionnaire\_ 30-Day\_Final Recall.pdf
- Questionnaire\_ 3-Day Recall.pdf
- Questionnaire\_ 7-Day Recall.pdf
- Questionnaire\_ Baseline Assessment.pdf
- Questionnaire\_ BD Can Grow Questionnaire.pdf
- Questionnaire\_ Bladder Diary.pdf
- Questionnaire\_ Bladder Diary Tracker.pdf
- Questionnaire\_ Patient Screening.pdf
- Questionnaire\_ SAE.pdf
- Questionnaire\_ SC Screening.pdf
- Questionnaire\_ Termination Form.pdf