

## The EPISOD Study Data Archive

The EPISOD Archive contains the Protocol, Forms, Study data, published papers, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

### Documents

The EPISOD Documents directory contains:

- Baseline\_6month
  - EPISOD\_PROTOCOL\_V7 05.01.11 final.pdf – the protocol for EPISOD “Evaluating Predictors & Interventions in Sphincter of Oddi Dysfunction: The EPISOD Trial”.
  - EPISOD 2 Protocol Version 7 final.pdf – protocol for EPISOD2, “A Naturalistic Follow-Up Study”.
  - EPISOD Data Collection Schedule.pdf – the data collection schedule for all of the forms in both the EPISOD and EPISOD 2 trials.
  - ReadMeFile\_EPISOD\_Jan2015.pdf – data handling instructions from the EPISOD investigators.
- Long\_term\_Followup
  - EPISOD 3 Protocol 9-3-2014 Clean.pdf – Protocol provided with the follow-up data
  - EPISOD3 Data Collection Schedule.pdf – Data Collection Schedule provided with the follow-up data
  - ReadMeFile\_EPISOD5.pdf – Readme provided with the follow-up data
- EPISOD Publications.pdf – Publications

### Forms

The EPISOD Forms directory contains the following forms, all of which are annotated with the corresponding variables names for the data set of the same name as the form:

Baseline\_6month:

- Form00.pdf - Subject Enrollment Form
- Form01.pdf - Inclusion Exclusion Criteria
- Form02.pdf – Functional Biliary Disorders Module
- Form03.pdf – Medical History
- Form06.pdf – Vital Signs

- Form07.pdf – Complete Blood Count (Baseline)
- Form08.pdf – Liver/Pancreas Test (Baseline)
- Form09.pdf – HCG Blood Serum/H. Pylori Test
- Form10.pdf – Abdominal Imaging
- Form11.pdf – MINI International Neuropsychiatric Interview
- Form12.pdf – RAPID
- Form13.pdf – Becks Depression Inventory II
- Form14.pdf – HADS
- Form15.pdf – SF-36
- Form16.pdf – Functional Gastrointestinal Disorders – Rome III (Rome III Diagnostic Module)
- Form17.pdf – Sphincter of Oddi Manometry (unblinded)
- Form18.pdf – ERCP (unblinded)
- Form19.pdf – Trauma Scale
- Form20.pdf – Coping
- Form21.pdf – Baseline Resource Utilization Questionnaire
- Form25.pdf – Adverse Events
- Form26.pdf – Follow Up Resource Utilization Questionnaire
- Form27.pdf – Review for Re-intervention
- Form28.pdf – Liver/Pancreas Test (Follow Up)
- Form29.pdf – Complete Blood Count (Follow Up)
- Form30.pdf – Best Guess (Study Coordinator)
- Form31.pdf – Best Guess (Subject)
- Form32.pdf – Best Guess (Evaluating Physician)
- Form33.pdf – Unscheduled Clinic Assessment
- Form35.pdf – End of Study
- Form36.pdf – RAPID – Central Caller
- Form37.pdf – Subject Randomization (unblinded)
- Form39.pdf – RAPID START
- Form40.pdf – Post Procedure Labs
- Form41.pdf – Subject Treatment Form (unblinded)
- Form42.pdf – EPISOD2 Subject Treatment Form
- Form43.pdf – EPISOD2 Sphincter of Oddi Manometry (SOM)
- Form44.pdf – EPISOD2 ERCP
- Form45.pdf – Adverse Events (unblinded)
- Form46.pdf – Monthly Abdominal Pain Assessment

Long\_term\_Followup:

- form12.pdf – RAPID (Follow-up)
- form14.pdf – HADS (Follow-up)
- form15.pdf – SF-36 (Follow-up)
- form16.pdf – Functional Gastrointestinal Disorders – Rome III (Rome III Diagnostic Module)

(Follow-up)

- form50.pdf - Follow Up Resource Utilization Questionnaire (Follow-up)
- form51.pdf – Adverse Events (Follow-up)
- form52.pdf – End of Study (Follow-up)
- form53.pdf – Coping (Follow-up)
- form54.pdf – Patients’ Global Impression of Change (Follow-up)
- form55.pdf - Pain Questionnaire (Follow-up)

## **EPISOD Data**

The EPISOD data directory contains the following raw datasets in SAS format:

Baseline\_6month:

- codelist.sas7bdat – This dataset contains 486 observations, with each record representing a code list value. This dataset should be used in conjunction with datadictionary.sas7bdat.
- datadictionary.sas7bdat – This dataset contains 704 observations, with each record representing a field in a form dataset.
- derived.sas7bdat – This dataset contains 286 observations and contains the primary treatment and success variables for the subjects in both the EPISOD and EPISOD2 studies.
- form00.sas7bdat – This dataset contains 286 observations for Form00.
- form01.sas7bdat – This dataset contains 286 observations for Form01.
- form02.sas7bdat – This dataset contains 286 observations for Form02.
- form03.sas7bdat – This dataset contains 286 observations for Form03.
- Form06.sas7bdat – This dataset contains 354 observations for Form06.
- form07.sas7bdat – This dataset contains 282 observations for Form07.
- form08.sas7bdat – This dataset contains 285 observations for Form08.
- form09.sas7bdat – This dataset contains 254 observations for Form09.
- form10.sas7bdat – This dataset contains 285 observations for Form10.
- form11.sas7bdat – This dataset contains 286 observations for Form11.
- form12.sas7bdat – This dataset contains 813 observations for Form12.
- form13.sas7bdat – This dataset contains 1179 observations for Form13.
- form14.sas7bdat – This dataset contains 1243 observations for Form14.
- form15.sas7bdat – This dataset contains 1308 observations for Form15.
- form16.sas7bdat – This dataset contains 286 observations for Form16.
- form17.sas7bdat – This dataset contains 262 observations for Form17.

- form18.sas7bdat – This dataset contains 278 observations for Form18.
- form19.sas7bdat – This dataset contains 286 observations for Form19.
- form20.sas7bdat – This dataset contains 282 observations for Form20.
- form21.sas7bdat – This dataset contains 286 observations for Form21.
- form25.sas7bdat – This dataset contains 877 observations for Form25.
- form26.sas7bdat – This dataset contains 895 observations for Form26.
- form27.sas7bdat – This dataset contains 73 observations for Form27.
- form28.sas7bdat – This dataset contains 54 observations for Form28.
- form29.sas7bdat – This dataset contains 50 observations for Form29.
- form30.sas7bdat – This dataset contains 1282 observations for Form30.
- form31.sas7bdat – This dataset contains 1264 observations for Form31.
- form32.sas7bdat – This dataset contains 64 observations for Form32.
- form33.sas7bdat – This dataset contains 80 observations for Form33.
- form35.sas7bdat – This dataset contains 286 observations for Form35.
- form36.sas7bdat – This dataset contains 513 observations for Form36.
- form37.sas7bdat – This dataset contains 214 observations for Form37.
- form39.sas7bdat – This dataset contains 286 observations for Form39.
- form40.sas7bdat – This dataset contains 210 observations for Form40.
- form41.sas7bdat – This dataset contains 277 observations for Form41.
- form42.sas7bdat – This dataset contains 82 observations for Form42.
- form43.sas7bdat – This dataset contains 77 observations for Form43.
- form44.sas7bdat – This dataset contains 82 observations for Form44.
- form45.sas7bdat – This dataset contains 14 observations for Form45.

- form46.sas7bdat – This dataset contains 1947 observations for Form46.
- Addition.sas7bdat – This dataset contains 286 observations for variables calculated by the investigators that were not included in the derived dataset, but were used in the manuscript.

Long\_term\_Followup:

- codelist.sas7bdat – Code List (Follow-up)
- datadictionary.sas7bdat – Data Dictionary Dataset (Follow-up)
- derived.sas7bdat – Derived Analysis Data (Follow-up)
- form12\_followup.sas7bdat – RAPID (Follow-up)
- form14\_followup.sas7bdat – HADS (Follow-up)
- form15\_followup.sas7bdat – SF-36 (Follow-up)
- form16\_followup.sas7bdat - – Functional Gastrointestinal Disorders – Rome III (Rome III Diagnostic Module (Follow-up)
- form50\_followup.sas7bdat - Follow Up Resource Utilization Questionnaire (Follow-up)
- form51\_followup.sas7bdat – Adverse Events (Follow-up)
- form52\_followup.sas7bdat – End of Study (Follow-up)
- form53\_followup.sas7bdat – Coping (Follow-up)
- form54\_followup.sas7bdat – Patients’ Global Impression of Change (Follow-up)
- form55\_followup.sas7bdat - Pain Questionnaire (Follow-up)

## EPISOD\ Data\Contents

- Contents.pdf—Variable listing output from SAS Proc Contents procedure.

## EPISOD DSIC

The EPISOD Data Integrity Check (DSIC) directory contains:

- EPISOD\_DSIC.docx - A report of an examination of the EPISOD datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Tables x1-4 in the paper “Effect of Endoscopic Sphincterotomy for Suspected Sphincter of Oddi Dysfunction on Pain-Related Disability Following Cholecystectomy” published by Cotton PB, Durkalski V, Romagnuolo J, et al. in JAMA, May 28, 2014. Published results from the EPISOD data were compared to values recalculated from the EPISOD archived analysis datasets in the NIDDK repository.
- EPISOD\_Follow\_up\_DSIC.doc - A report of an examination of the EPISOD datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Tables 1 in the paper “Peter B. Cotton, MD, FRCS, FRCP, Qi Pauls, MS, Jamila Keith, BS, Andre Thornhill, MS, Douglas Drossman, MD, April Williams, BS, Valerie Durkalski-Mauldin, MPH PhD. "The EPISOD Study: long term outcomes". Gastrointestinal Endoscopy, Volume 87 , Issue 1 , 205 – 210. Published results from the EPISOD data were compared to values recalculated from the EPISOD archived analysis datasets in the NIDDK repository.