Predicting Response to Standardized Pediatric Colitis Therapy (PROTECT)

This multicenter open-label study was designed to evaluate the safety and efficacy of standardized initial therapy using either mesalamine or corticosteroids then mesalamine for the treatment of children and adolescents newly diagnosed with ulcerative colitis. The study investigated the hypothesis that response to the initial 4 weeks of therapy as well as specific clinical, genetic, and immune parameters determined during the initial course of therapy predicted severe disease as reflected by need for escalation of medical therapy or surgery.

Participants were assigned to one of two initial therapeutic plans (mesalamine only or prednisone/liquid equivalent prednisolone followed by mesalamine) depending upon initial disease severity determined by the validated multi-dimensional Pediatric Ulcerative Colitis Activity Index (PUCAI). Biospecimens were obtained at diagnosis, and subsequently following the initiation of therapy at weeks 4, 12, and 52 (blood and stool at weeks 4 and 12; blood, stool, and colonic tissue at week 52). Follow-up clinic visits were conducted for a minimum of 1 year to a maximum of 5 years depending on when the participant enrolled. Adherence to mesalamine dosing was monitored using a state of the art electronic Medication Event Monitoring System (MEMS®).

The PROTECT data archive contains related descriptive documentation, data collection forms, study data, and a dataset integrity check for this study.

Archive files are organized into the following directories:

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

Data

The Data directory contains the following files:

- ALF_NIDDK_FULL.CSV
- alf_niddk_full.sas7bdat
- AMT_NIDDK_FULL.CSV
- amt_niddk_full.sas7bdat
- ATF_NIDDK_FULL.CSV
- atf_niddk_full.sas7bdat
- ATZ_NIDDK_FULL.CSV
- atz_niddk_full.sas7bdat
- BDF_NIDDK_FULL.CSV
- bdf_niddk_full.sas7bdat
- CBH_NIDDK_FULL.CSV
- cbh_niddk_full.sas7bdat
- CDF_NIDDK_FULL.CSV
- cdf_niddk_full.sas7bdat
- CDZ_NIDDK_FULL.CSV

- cdz_niddk_full.sas7bdat
- CLF_NIDDK_FULL.CSV
- clf_niddk_full.sas7bdat
- COD_NIDDK_FULL.CSV
- cod_niddk_full.sas7bdat
- CSR_NIDDK_FULL.CSV
- csr_niddk_full.sas7bdat
- DED_NIDDK_FULL.CSV
- ded_niddk_full.sas7bdat
- EDZ_NIDDK_FULL.CSV
- edz_niddk_full.sas7bdat
- EEF_NIDDK_FULL.CSV
- eef_niddk_full.sas7bdat
- EFH_NIDDK_FULL.CSV
- efh_niddk_full.sas7bdat
- ERF_NIDDK_FULL.CSV
- erf_niddk_full.sas7bdat
- FDF_NIDDK_FULL.CSV
- fdf_niddk_full.sas7bdat
- HDF_NIDDK_FULL.CSV
- hdf_niddk_full.sas7bdat
- ICT_NIDDK_FULL.CSV
- ict_niddk_full.sas7bdat
- IMP_NIDDK_FULL.CSV
- imp_niddk_full.sas7bdat
- LLN_NIDDK_FULL.CSV
- lln_niddk_full.sas7bdat
- LLR_NIDDK_FULL.CSV
- llr_niddk_full.sas7bdat
- MEF_NIDDK_FULL.CSV
- mef_niddk_full.sas7bdat
- MES_NIDDK_FULL.CSV
- mes_niddk_full.sas7bdat
- PCF_NIDDK_FULL.CSV
- pcf_niddk_full.sas7bdat
- PUC_NIDDK_FULL.CSV
- puc_niddk_full.sas7bdat
- SAE_NIDDK_FULL.CSV
- sae_niddk_full.sas7bdat
- SBH_NIDDK_FULL.CSV
- sbh_niddk_full.sas7bdat
- SCF_NIDDK_FULL.CSV
- scf_niddk_full.sas7bdat
- SEF_NIDDK_FULL.CSV

- sef_niddk_full.sas7bdat
- SEG_NIDDK_FULL.CSV
- seg_niddk_full.sas7bdat
- SFF_NIDDK_FULL.CSV
- sff_niddk_full.sas7bdat
- SLR_NIDDK_FULL.CSV
- slr_niddk_full.sas7bdat
- SMF_NIDDK_FULL.CSV
- smf_niddk_full.sas7bdat
- STR_NIDDK_FULL.CSV
- str_niddk_full.sas7bdat
- STZ_NIDDK_FULL.CSV
- stz_niddk_full.sas7bdat
- SWF_NIDDK_FULL.CSV
- swf_niddk_full.sas7bdat

Data/Primary Manuscript Dataset

- PRIMARY_MANUSCRIPT_NIDDK_FULL.CSV
- primary_manuscript_niddk_full.sas7bdat

Documents

The PROTECT Documents directory contains:

- Manual of Procedures_MOP.pdf
- PROTECT variable formats.pdf
- PROTECT_Protocol.pdf

Documents/Primary Manuscript Documentation

- PROTECT Primary Manuscript (MS13) Dataset Documentation.pdf
- PROTECT Statistical Analysis Plan.pdf

DSIC

The PROTECT Dataset Integrity Check (DSIC) directory contains:

- PROTECT_DSIC.pdf

Forms

The PROTECT Forms directory contains:

- Annotated Forms 20210303.pdf
- Form Completion Guidelines (QxQs)_20210525.pdf