

Efficacy and Safety of the Intestinal Bile Acid Transport (IBAT) Inhibitor LUM001 in the Treatment of Pruritus in Alagille Syndrome Patients (ITCH) Study Data Archive

The ITCH study was a randomized, double-blind, placebo-controlled, parallel group, multi-center study in children with Alagille syndrome (ALGS). The study was designed to investigate the effects of LUM001 (Maralixibat), compared to placebo, on pruritus, serum bile acids, liver enzymes, and other biochemical markers associated with cholestatic liver disease, following daily dosing over a 13-week period.

Only baseline data are available in the data package. Archive files are organized into the following directories:

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

Data

The ITCH Data directory contains the following datasets:

Data/ADaM data

- ADAE.CSV
- adae.sas7bdat
- ADCM.CSV
- adcm.sas7bdat
- ADEFF.CSV
- adeff.sas7bdat
- ADEG.CSV
- adeg.sas7bdat
- ADEX.CSV
- adex.sas7bdat
- ADLB.CSV
- adlb.sas7bdat
- ADPC.CSV
- adpc.sas7bdat
- ADQS.CSV
- adqs.sas7bdat
- ADSL.CSV
- adsl.sas7bdat
- ADVS.CSV
- advs.sas7bdat

Data/ADaM data/Contents

- LUM001_301_ADaM_Specs_Archive_copy_20201027.xls

Data/SDTM data

- AE.CSV
- ae.sas7bdat
- CE.CSV
- ce.sas7bdat
- CM.CSV
- cm.sas7bdat
- CO.CSV
- co.sas7bdat
- DM.CSV
- dm.sas7bdat
- DS.CSV
- ds.sas7bdat
- DV.CSV
- dv.sas7bdat
- EG.CSV
- eg.sas7bdat
- EX.CSV
- ex.sas7bdat
- FA.CSV
- fa.sas7bdat
- LB.CSV
- lb.sas7bdat
- MH.CSV
- mh.sas7bdat
- PC.CSV
- pc.sas7bdat
- PE.CSV
- pe.sas7bdat
- QS.CSV
- qs.sas7bdat
- QS_RAW_DATA_ITCHRO.CSV
- qs_raw_data_itchro.sas7bdat
- RELREC.CSV
- relrec.sas7bdat
- SE.CSV
- se.sas7bdat
- SV.CSV
- sv.sas7bdat
- TA.CSV
- ta.sas7bdat

- TV.CSV
- tv.sas7bdat
- VS.CSV
- vs.sas7bdat

Data/SDTM data/Contents

- LUM001-301_SDTM_Specs_Archive_copy_20201027.xls

Documents

The ITCH Documents directory contains:

- ITCH MOO Complete.pdf
- Protocol LUM001-301 Amend 3_2015_02_11.pdf

DSIC

The ITCH Dataset Integrity Check (DSIC) directory contains:

- ITCH_DSIC.pdf

Forms

The ITCH Forms directory contains:

- CRF-Template_LUM001-301_v2.0_20150409.pdf