

Extension Study to Evaluate the Long-Term Safety and Durability of Effect of LUM001 in the Treatment of Cholestatic Liver Disease in Pediatric Subjects With Alagille Syndrome (IMAGINE-II) Study Data Archive

The IMAGINE-II study was a multicenter, extension study of LUM001 in children diagnosed with Alagille syndrome (ALGS) who had completed participation in a core LUM001 treatment protocol (ITCH study). The primary objective was to evaluate long-term safety and tolerability of LUM001. Efficacy was assessed by evaluating the effect of LUM001 on the biochemical markers and pruritus associated with ALGS.

Archive files are organized into the following directories:

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

Data

The IMAGINE-II Data directory contains the following datasets and files:

- IM2_ADaM_Archive_SAS_ADAM_datasets_Specs2_20221005.xlsx
- IM2_SDTM_Archival_SAS_SDTM_2datasets_Specs_20220908.xlsx

Data/IM2_SDTM_Archival_SAS_ADaM_datasets

- ADAE.CSV
- adae.sas7bdat
- ADCM.CSV
- adcm.sas7bdat
- ADEFF.CSV
- adefl.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/IM2_SDTM_Archival_SAS_SDTM_datasets

- AE.CSV
- ae.sas7bdat
- CM.CSV
- cm.sas7bdat
- CO.CSV
- co.sas7bdat
- DA.CSV
- da.sas7bdat
- DM.CSV
- dm.sas7bdat
- DS.CSV
- ds.sas7bdat
- DV.CSV
- dv.sas7bdat
- EC.CSV
- ec.sas7bdat
- EX.CSV
- ex.sas7bdat
- FA.CSV
- fa.sas7bdat
- IE.CSV
- ie.sas7bdat
- LB.CSV
- lb.sas7bdat
- MH.CSV
- mh.sas7bdat
- PC.CSV
- pc.sas7bdat
- PE.CSV
- pe.sas7bdat
- qs.csv
- qs.sas7bdat
- SE.CSV
- se.sas7bdat
- SUPPAE.CSV
- suppaе.sas7bdat
- SUPPCM.CSV
- suppcm.sas7bdat
- SUPPDM.CSV
- suppdm.sas7bdat
- SUPPDS.CSV
- suppds.sas7bdat
- SUPPDV.CSV
- suppdv.sas7bdat

- SUPPFA.CSV
- suppfa.sas7bdat
- SUPPLB.CSV
- supplb.sas7bdat
- SUPPQS.CSV
- suppqs.sas7bdat
- SV.CSV
- sv.sas7bdat
- VS.CSV
- vs.sas7bdat

Documents

The IMAGINE-II Documents directory contains:

- IMAGINE_II_MOO_Combined.pdf
- LUM001-305 Protocol Amendment 6.2 clean13May2019 final_signed.pdf

Documents/IM2 ADaM define codebook materials

- ADRG.pdf
- define.txt
- define.xml
- define2-0-0.txt
- define2-0-0.xsl
- pinnacle21-report-2020-12-18T09-49.xlsx
- pinnacle21-report-2020-12-18T09-54.xls

Documents/IM2 SDTM define codebook materials

- acrf.pdf
- cSDRG.pdf
- define.txt
- define.xml
- define2-0-0.txt
- define2-0-0.xsl
- pinnacle21-report-2020-12-17T20-38.xlsx
- pinnacle21-report-2020-12-17T20-42.xlsx

DSIC

The IMAGINE-II Dataset Integrity Check (DSIC) directory contains:

- IMAGINE-II_DSIC.pdf

Forms

The IMAGINE-II Forms directory contains:

- BlankCasebook_LUM001-305_v6.0_20181108.pdf
- CRF-Annotated_LUM001-305_6.0_20181112.pdf