

The START Study Data Archive

The Steroids in the Treatment of Biliary Atresia (START) archive contains the Documents, Forms, Study Data, and Dataset Integrity Check.

Archive files are organized into the following directories:

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

Documents

The START Documents directory contains:

- START protocol.pdf – The START Protocol
- MOO Folder – Folder containing the START Manual of Operations

Forms

The START Forms directory contains multiple versions of the forms provided by the study.

Data

The START Data directory contains the following files in SAS format (.sas7bdat):

- dosing_day_by_day.sas7bdat – The child univariate dataset from the publication
- start_final_dd2.sas7bdat – The demographics dataset
- study_medication_compliance.sas7bdat – The parent univariate dataset from the publication
- Codebooks Folder – Folder of the codebooks of the datasets above

DSIC

The START Dataset Integrity Check (DSIC) directory contains:

START_DSIC_Bezerra.doc – A report of an examination of the START datasets for completeness by statisticians and quality control specialists at the Repository. These datasets were used to replicate Table 1 from the paper “Use of Corticosteroids After Hepatopertoenterostomy for Bile Drainage in Infants With Biliary Atresia: The START Randomized Clinical Trial” by Bezerra et al. Published results from the START data were compared to values recalculated from START archived datasets in the NIDDK repository.