

## The COMBINE Study Data Archive

The COMBINE Study: The CKD Optimal Management With Binders and Nicotinamide (COMBINE) Archive contains the Protocol, Manual of Procedures, Forms, Study Data, and Dataset Integrity Check.

In people with chronic kidney disease, kidneys struggle to get rid of enough phosphorus, so FGF23 levels increase in the blood to help get rid of extra phosphorus. Over time, with progressive loss of kidney function, both phosphorus and FGF23 can build up in the blood simultaneously. Researchers believe that too much phosphorus and FGF23 in the blood may lead to weak bones, increase the risk of heart problems, and accelerate progression of kidney disease. However, the best way to control phosphorus and FGF23 levels in the blood in patients with chronic kidney disease is not known. COMBINE is a study to determine new methods to lower serum phosphorus levels and levels of FGF23 in chronic kidney disease patients.

Archive files are organized into the following directories:

- Documentation
- Data
- Dataset Integrity Check (DSIC)

### **Documents**

The COMBINE Documents directory contains:

- All\_Forms.pdf – All Forms included in the study.
- Forms\_Variable\_Names.pdf – The forms updated to included the variable names of each variable in the forms.
- Manual\_of\_Procedures.pdf – Manual of procedures for the COMBINE study
- Protocol.pdf – Protocol for the COMBINE study

### **Data**

The COMBINE data directory contains the following datasets in SAS format (.sas7bdat). Each dataset corresponds to the form of the same name:

- death\_codes.sas7bdat
- fgf23\_plasma\_repos.sas7bdat
- form107.sas7bdat
- form115.sas7bdat
- form116.sas7bdat
- form121.sas7bdat

- form122.sas7bdat
- form123.sas7bdat
- form148.sas7bdat
- form149.sas7bdat
- form163.sas7bdat
- form203.sas7bdat
- form214.sas7bdat
- form215\_dtl.sas7bdat
- form215.sas7bdat
- form216.sas7bdat
- form248.sas7bdat
- form249.sas7bdat
- form250.sas7bdat
- form285\_dtl.sas7bdat
- form285.sas7bdat
- form289.sas7bdat
- form291.sas7bdat
- form300.sas7bdat
- form301.sas7bdat
- form329.sas7bdat
- form330.sas7bdat
- form331.sas7bdat
- form335.sas7bdat
- form362.sas7bdat
- form364.sas7bdat
- form380.sas7bdat
- form381.sas7bdat
- form384.sas7bdat
- form403.sas7bdat
- form475.sas7bdat
- form511.sas7bdat
- form512\_dtl.sas7bdat
- form512.sas7bdat
- form522.sas7bdat
- form531.sas7bdat
- form532.sas7bdat
- form540.sas7bdat
- form549.sas7bdat
- form550.sas7bdat
- form593.sas7bdat
- form612.sas7bdat
- form622.sas7bdat
- form632.sas7bdat

- form702.sas7bdat
- form703.sas7bdat
- form711.sas7bdat
- form712.sas7bdat
- form722.sas7bdat
- form723.sas7bdat
- hosp\_codes.sas7bdat
- hr24\_urine\_data\_2019.sas7bdat
- il6\_serum\_repos.sas7bdat
- pth\_data\_2019.sas7bdat
- rand.sas7bdat
- serum\_data\_2019.sas7bdat
- spot\_urine\_data\_2019.sas7bdat
- whole\_data\_2019.sas7bdat

## **DSIC**

The COMBINE Data Integrity Check (DSIC) directory contains:

- DSIC.pdf - A report of an examination of the analysis and form datasets (Ix paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the COMBINE data were compared to values recalculated from COMBINE archived datasets in the NIDDK repository.