Project Title:

"SDTM Conversion and Standardisation of Hypertension Study Data – Valsartan-Hydrochlorothiazide."

Project Description:

As part of my SAS training, I worked on converting raw clinical trial data into CDISC SDTM-compliant datasets for a Phase II hypertension study involving adult subjects treated with CO-DIOVAN (Valsartan-Hydrochlorothiazide) across multiple sites in India.

The raw data included information on demographics, vital signs, exposure, adverse events, medical history, concomitant medications, trial design, and patient-reported assessments. Using SAS, I successfully created 14 SDTM domains—DM, EX, DS, MH, CM, SU, SC, VS, TA, TV, TI, AE, QS, SV, and SE.

Key activities undertaken during this project included:

- Created **unique subject identifiers, sequence numbers, and baseline flags** using **SAS DATA step**, with functions like **CATX, SUBSTR, INPUT/PUT** and **IF-THEN-ELSE** logic.
- Standardised variable names, formats, and units according to **CDISC SDTM guidelines**, using **PROC SQL, MERGE, and BY-group processing** for accurate alignment.
- Organised clinical measurements, exposure data, and visit information to maintain correct study timelines, applying **WHERE statements, conditional logic, and arrays**.
- Imported raw datasets using **LIBNAME, INFILE, and PROC IMPORT**, and exported the final SDTM datasets with **PROC EXPORT**.
- Automated repetitive tasks and ensured consistency across domains with **SAS macros**, improving efficiency and reliability.

This project strengthened my practical understanding of SDTM implementation and enhanced my SAS programming skills, giving me hands-on experience in clinical data standardisation and preparation for real-world clinical programming tasks.

LIST OF DATASETS:

SDTM Domain	Description / Key Variables
DM	Subject demographics (USUBJID, AGE, SEX)
EX	Study drug exposure (EXTRT, EXSTDTC)
DS	Subject disposition (DSTERM, DSDECOD)
MH	Medical history (MHTERM, MHDTC)
CM	Concomitant medications (CMTRT, CMSTDTC)
SU	Substance use (SUTRT, SUSTDTC)
SC	Subject characteristics (SCTEST, SCORRES)
VS	Vital signs (VSTEST, VSORRES)
TA	Trial arms (ARM, ARMCD)
TV	Trial visits (VISITNUM, TVSTDTC)
TI	Inclusion/Exclusion criteria (IETEST, IECAT)
AE	Adverse events (AETERM, AESEV)
QS	Questionnaires (QSTEST, QSORRES)
SV	Subject visit timings (VISIT, SVSTDTC)
SE	Subject evaluations (ELEMENT, SESTDTC)