

DATA REQUIREMENT

The input data must follow the SDTM format. The folder structure of the input data should follow the standard electronic data submission requirement. Please see the PKView installation instruction manual for data folder setup.

Required Domain	Required Variables	Comments
DM.xpt	USUBJID, ARM	ARM can be substituted by other variables, e.g.: ARMCD, ACTARM, SEX, RACE, ...
PC.xpt	USUBJID, VISIT, PCTESTCD, PCSTRESN, PCTPTNUM, PCSPEC, PCDTC	The following variables can be substituted: VISIT, PCTESTCD, PCTPTNUM
PP.xpt	USUBJID: VISIT, PPCAT, PPSTESN, PPTESTCD, PPSPEC	The following variables can be substituted: VISIT, PPCAT

Optional data domains:

1. SUPPDM.xpt
2. SC.xpt

Sample Data and Analysis Template

A test dataset and the corresponding analysis template are provided with the installation package. Once PKView is successfully installed and all required folder structures are created with proper user permission, please

1. Copy the data folder "Drug000" to under the folder C:\OCP\data\clinical
2. Copy the analysis template file "DRUG000 template.xml" to under the folder C:\OCP\iPortal\webroot\App_Data\userData\((USER NAME))\PkView. Replace (USER NAME) with the user login name on the computer.