**FDA JUMPSTART SCRIPTS**

**TESTING USING FDA DATA AND LILLY’S STUDY DATA**

**PROGRAM NAME**: ae\_meddra\_w\_flag\_generation\_v1.sas (MedDRA at a Glance)

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**SAS VERSION**: 9.2 (Lilly SDD version 3.5)

**DESCRIPTION**: The program was tested in Lilly’s SDD using FDA-provided data and also Lilly’s study datasets.

**TESTING STEPS**

1. All the necessary files are stored into the SDD’s folder structure.
2. The following parameters were defined according to the right locations:

* Studypath: location of the drug study datasets.
* Utilpath: location of external SAS programs.
* Meddrapath: location of mdhier\_x\_y sas file
* DMEpath: location of dme sas file
* Outpath: location of the output.
* In SDD environment:

1. the %include statement should be outside of macro **%*params***;
2. use slash ‘/’ instead of ‘\’ for the path directory.
3. Create sas file mdhier\_x\_y using Meddra dictionary.

Variable PRIMARY\_SOC\_FG is needed for the dataset, please update the Spec.

1. Create DME file using mdhier\_x\_y dataset.

Variables VER(=”x.y”) and DME(=’Y’) are needed for DME , please update the Spec.

1. Run the program.
2. Warning from log:

%include "&saspath.\ae\_meddra\_output.sas";

SYMBOLGEN: Macro variable SASPATH resolves to \\Client\U$\Data\aJumpStart

WARNING: The quoted string currently being processed has become more than 262 characters long.

1. Error report is generated as under:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***MedDRA at a Glance Error Summary*** | |  |  |  |  |  | |
|  |  |  |  |  |  |  | |
| NDA/BLA: xxx |  |  |  |  |  |  | |
| Study: fdadata |  |  |  |  |  |  | |
| Analysis run date: 2016-03-07 8:16:46 PM | |  |  |  |  |  | |
|  |  |  |  |  |  |  | |
| There were zero adverse events with matching MedDRA descriptions.  ---------------------------------------------------------------------------------------------------------------------- | | | | | | | |
|  | | | | | | | |

**ADDITIONAL WORK PERFORMED**: The program was tested in SAS PC and still have the same warning/error message, output.

**SUGGESTION:** The output MedDRA at a Glance Error Summary.xls is created and no output for MedDRA at a Glance Analysis Panel.xls. The result is strange, there should have some AE records matched with MEDDRA data.