The folder structure for all tests can be found at: P:\CTRU\Stats\Programming\SAS\Eudract\Validation

Scenario A: Each dataset contains only variables with the correct names, variable types, lengths and formats as specified in documentation.

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractGrps   * Variable name changed from idn to ifn * Deathae changed from numeric to character * Length of ID changed from 62 to 500 * Format added to death * Label added to patn | Error printed to log saying that cont1 and cont2 don’t match based off name, type, length, format label. | ✓ |  |
| 2 | EudractAE   * Variable name changed from patsn to patn * Asstype changed from numeric to character * Length of desc changed from 250 to 10 * Format added to term * Label added to occur | Error printed to log saying that cont3 and cont4 don’t match based off name, type, length, format label. | ✓ |  |
| 3 | EudractSAE   * Variable name changed from occur to occurrence * patsn changed from numeric to character * Length of SOC changed from 100 to 50 * Format added to SOC * Label added to AssType | Error printed to log saying that cont5 and cont6 don’t match based off name, type, length, format label. | ✓ |  |

Scenario B: For required fields in the Eudract system each dataset contains no missing data.

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractGrps   * Mandatory variables set to have at least one missing value. | Following errors in log  ERROR: variable IDN has missing values in the EudractGrps dataset  ERROR: variable ID has missing values in the EudractGrps dataset  ERROR: variable patn has missing values in the EudractGrps dataset  ERROR: variable patae has missing values in the EudractGrps dataset  ERROR: variable patsae has missing values in the EudractGrps dataset  ERROR: variable death has missing values in the EudractGrps dataset | ✓ |  |
| 2 | EudractAE   * Mandatory variables set to have at least one missing value. | Following errors in log  ERROR: variable IDN has missing values in the EudractAE dataset  ERROR: variable SOC has missing values in the EudractAE dataset  ERROR: variable term has missing values in the EudractAE dataset  ERROR: variable Asstype has missing values in the EudractAE dataset  ERROR: variable patsn has missing values in the EudractAE dataset  ERROR: variable occur has missing values in the EudractAE dataset | ✓ |  |
| 3 | EudractSAE   * Mandatory variables set to have at least one missing value | Following errors in log  ERROR: variable IDN has missing values in the EudractSAE dataset  ERROR: variable SOC has missing values in the EudractSAE dataset  ERROR: variable term has missing values in the EudractSAE dataset  ERROR: variable Asstype has missing values in the EudractSAE dataset  ERROR: variable patsn has missing values in the EudractSAE dataset  ERROR: variable occur has missing values in the EudractSAE dataset  ERROR: variable occurtrt has missing values in the EudractSAE dataset  ERROR: variable death has missing values in the EudractSAE dataset  ERROR: variable deathtrt has missing values in the EudractSAE dataset | ✓ |  |

Scenario C: Each SOC entry in the EudractAE and EudractSAE maps to a EUTTC number

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractAE   * Adding a typo to “Ear and labyrinth disorders” so it won’t match up properly. | The following error message will show, stating which SOC is wrong.  ERROR: Ear and labirinth disorders hasn't matched, check the format or input dataset | ✓ |  |
| 2 | EudractSAE   * Adding a typo to “Renal and urinary disorders” so it won’t match up properly. | The following error message will show, stating which SOC is wrong.  ERROR: Renel and urinary disorders hasn't matched, check the format or input dataset | ✓ |  |

Scenario D: A unique IDN is specified for each entry in the EudractGrps dataset

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractGrps   * Set both IDNs to equal 3 | The following error message will show to the log  ERROR: variable IDN in the EudractGrps dataset isn't unique | ✓ |  |

Scenario E: Check to see that the IDN terms defined in the EudractGrps are in both AE and SAE datasets.

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractAE   * Set all IDN that are 2 to missing * Set one IDN that is 1 to 3 | The following error messages will show to the log  ERROR: variable with IDN=2 is in the EudractGrps dataset but not in the EudractAE dataset  ERROR: variable with IDN=3 is in the EudractAE dataset but not defined in the EudractGrps dataset  ERROR: variable with IDN=. is in the EudractAE dataset but not defined in the EudractGrps dataset | ✓ |  |
| 2 | EudractSAE   * Set all IDN that are 2 to missing * Set one IDN that is 1 to 3 | The following error messages will show to the log  ERROR: variable with IDN=2 is in the EudractGrps dataset but not in the EudractSAE dataset  ERROR: variable with IDN=3 is in the EudractSAE dataset but not defined in the EudractGrps dataset  ERROR: variable with IDN=. is in the EudractSAE dataset but not defined in the EudractGrps dataset | ✓ |  |

Scenario F: Each unique event term in EudractAE and EudractSAE datasets has one entry for each of the groups defined in the EudractGrps dataset

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractAE   * Removed “Anorectal infection” from the second group. * Added “Capillary leak syndrome” to the second group | The following error messages will show to the log  ERROR: term= Anorectal infection in dataset=EudractAE has missing groups  ERROR: term=Capillary leak syndrome in dataset=EudractAE has duplicate entries | ✓ |  |
| 2 | EudractSAE   * Removed “Dysgeusia” from the first group. * Added “Hemorrhoids” to the first group | The following error messages will show to the log  ERROR: term= Dysgeusia in dataset=EudractSAE has missing groups  ERROR: term= Hemorrhoids in dataset=EudractSAE has duplicate entries | ✓ |  |

Scenario G: Each Asstype entry in the EudractAE and EudractSAE datasets is either 1 or 2

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractAE   * AssType of anorectal infection in the second group changed to 3. | The following error should be printed to the log  Asstype in dataset=EudractAE has entries that are not 1 or 2 | ✓ |  |
| 2 | EudractSAE   * AssType of Dysgeusia in the first group changed to -1. | The following error should be printed to the log  Asstype in dataset=EudractSAE has entries that are not 1 or 2 | ✓ |  |

Scenario H: No Errors are outputted if the AE dataset is empty.

| # | Test | Expected Result | OK?  ✓X | Problem |
| --- | --- | --- | --- | --- |
| 1 | EudractAE   * An empty data set is fed through the program. | The program should run without errors. | ✓ |  |