# Eudract data requirements SAEs/AEs

**General:**

There is a large section to describe the AE timeframe for reporting and also the assessment type. Here would be the place to describe how often AEs are collected and whether for example only ARs are collected.

There is a need to report the number of ‘Occurrences’ for each AE, I think here would be the place to define how this field been calculated.

You can give a percentage for which only AEs with an incidence rate greater than have been reported. Incidence in >5% of patients is the highest cut off rate you are able to specify

**Safety summary statistics by arm:**

Number of patients that safety information is reported – number in safety population

Number of patients reporting at least 1 adverse event.

Number of patients reporting at least 1 serious adverse event

Number of deaths – This would be the deaths while on treatment

Number of deaths due to treatment – this is optional but would be the number of SARs with death as outcome.

**SAEs:**

Coding to CTCAE/Medra preffered term is required. Summaries are produced for each unique SAE coding term and are split by arm.

For each arm:

Number of patients experiencing event

Number of occurrences (total number of reported SAEs)

Number of occurrences (SARs)

Number of deaths

Number of SARs/SUSARs resulting in death

**Adverse Events:**

Coding to CTCAE/Medra preferred term is required. Summaries are produced for each unique AE coding term and are split by arm.

For each arm:

Number of patients experiencing event

Number of Occurrences – I think this would change slightly depending on

# Adverse event reporting groups

**Dataset name: EudractGrps**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bold=required field | **idn** | **id** | desc | **patn** | **patae** | **patsae** | **death** | deathae |
| Description | Identification number for arm | Text identification for arm | Description of arm – this can be blank for | Number of patients in arm that safety information reported – i.e the number in the safety population | Number of patients reporting at least 1 adverse event in arm | Number of patients experiencing at least 1 serious adverse event | Number of deaths in arm | Number of drug-related deaths |
| Variable attributes | numeric | Text (length=62) | Text (length=999) | numeric | numeric | numeric | numeric | numeric |

**Example dataset**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| idn | id | desc | patn | patae | patsae | Death | Deathae |
| 1 | Arm A | A combination of all drugs in Arm A | 100 | 78 | 50 | 10 | 6 |
| 2 | Arm B | A combination of all drugs in Arm B | 99 | 88 | 44 | 20 | 10 |

Example SAS code to produce the above dataset

**data** EudractGrps;

attrib id length=$**62** desc length=$**999**;

infile datalines delimiter='\*';

input idn id $ desc $ patn patae patsae Death Deathae;

datalines;

1\*Arm A\*A combination of all drugs in Arm A\*100\*78\*50\*10\*6

2\*Arm B\*A combination of all drugs in Arm B\*99\*88\*44\*20\*10

;

**run**;

# Serious Adverse Events

A derived dataset from final analysis – Each SAE should have the same number of rows as the number of groups (make numbers 0 if didn’t occur in arm)

**Dataset name: EudractSAE**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bold=required field | **idn** | **SOC** | **term** | desc | **Asstype** | **patsn** | **occur** | **Occurtrt** | **death** | **deathtrt** |  |  |
| Description | Identification number for arm – this needs to match adverse event reporting groups dataset above | Meddra system organ class for SAE | SAE term | Additional description | Assessment type  1 for Systematic  2 for Non-Systematic | Number of patients experiencing event | Number of occurrences of event | Number of occurrences caused by treatment | Number of deaths for event | Number of deaths due to treatment |  | The number at risk is merged in the program to be the number of patients exposed for each arm and is equivalent to the safety population |
| Variable attributes | numeric | Text  (Length=100) | Text (length=100) | Text (length=250) | numeric | numeric | numeric | numeric | numeric | numeric |  |  |

# Adverse Events

A derived dataset from final analysis – Each AE term should have the same number of rows as the number of groups (make numbers 0 if didn’t occur in arm)

**Dataset name: EudractAE**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bold=required field | **idn** | **SOC** | **term** | desc | **Asstype** | **patsn** | **occur** |  |  |
| Description | Identification number for arm – this needs to match adverse event reporting groups dataset above | Meddra system organ class for AE | AE term | Additional description | Assessment type  1 for Systematic  2 for Non-Systematic | Number of patients experiencing event | Number of occurrences of event |  | The number at risk is merged in the program to be the number of patients exposed for each arm and is equivalent to the safety population |
| Variable attributes | numeric | Text (length=100) | Text (length=100) | Text (length=250) | numeric | numeric | numeric |  |  |

If AEs are not reported an empty dataset still needs to be created for the programs to work:

**data** EudractAE;

length soc $**100** term $**100** desc $**250**;

call missing(idn,soc,term,desc,Asstype,patsn,occur);

if \_N\_ = **0** then output;

stop;

**run**;

# XML\_Input\_checker program

From three datasets produced (**EudractGrps EudractAE, EudractSAE**) for a given trial the following checks are made to ensure that the XML creator SAS program will run correctly:

If any of the following conditions are violated an error is produced:

* Each dataset contains only variables with the correct names, variable types, lengths, formats and no labels as specified above
* For required fields in the Eudract system each dataset contains no missing data
* Each SOC entry in the **EudractAE** and **EudractSAE** maps to a EUTTC number
* A unique IDN is specified for each entry in the **EudractGrps** dataset
* Each unique event term in **EudractAE** and **EudractSAE** datasets has one entry for each of the groups defined in the **EudractGrps** dataset
* Each Asstype entry in the **EudractAE** and **EudractSAE** datasets is either 1 or 2.