# Template for reporting of results in EudraCT

We at Compliance and Data Office are offering help in reporting results from your clinical trial in EudraCT. To make this process easier for us and for you, we would like to ask you to fill out this form. All the fields below are mandatory fields in EudraCT.

If you have any questions, please reach out to us at compliance@ki.se.

Send the final form together with the published article as attachment to compliance@ki.se.

## Trial Information

### Sponsor details

|  |  |
| --- | --- |
| EudraCT number |  |
| Full title of the trial |  |
| Responsible researcher (point of contact)* Name
* Email address
 |  |

### Paediatric regulatory details

|  |  |  |
| --- | --- | --- |
| Is trial part of an agreed paediatric investigation plan (PIP) | [ ] Yes | [ ] No |
| * If yes, enter EMA paediatric investigation plan (EMEA PIP code)
 |  |
| Does article 45 of Regulation (EC) No 1901/2006 apply to this trial?  | [ ] Yes | [ ] No |
| Does article 46 of Regulation (EC) No 1901/2006 apply to this trial? | [ ] Yes | [ ] No |

### Results analysis stage

|  |  |
| --- | --- |
| Date of interim/final analysis (dd/mm/yy):  |  |
| Is this the analysis of the primary completion data? | [ ] Yes | [ ] No |
| Primary completion date (dd/mm/yy):*(The primary completion date is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary end point.)* |  |
| Global end of trial date reached?*(The global end of trial date is when the last subject in the trial was examined or received an intervention globally.)* | [ ] Yes  | [ ] No |
| Date (dd/mm/yy):  |
| Was the trial ended prematurely? | [ ] Yes | [ ] No |

### General information about the trial

|  |  |
| --- | --- |
| Actual start date of recruitment (dd/mm/yy): |  |
| Long term follow-up planned? | [ ] Yes | [ ] No |
| * If yes, enter rationale (Select main reason(s) for long-term follow up)
 | [ ] Safety[ ] Efficacy[ ] Ethical reason[ ] Regulatory reason[ ] Scientific research |
| Long term follow-up duration (number of months/years) |  |
| Independent data monitoring committee (IDMC) involvement? | [ ] Yes | [ ] No |

### Population of trial subjects

|  |
| --- |
| **Subject number per country** |
| **Country** | **Actual number of subjects enrolled** |
| 1. Sweden
 |  |
| **Age group breakdown for trial** |
| **Age range** | **Actual number of subjects enrolled** |
| In utero |  |
| Preterm newborn infants (gestational age < 37 wks) |  |
| Newborns (0-27 days) |  |
| Infants and toddlers (28 days-23 months) |  |
| Children (2-11 years) |  |
| Adolescents (12-17 years) |  |
| Adults (18-64 years) |  |
| From 65-84 years |  |
| 85 years and over |  |

## Subject Disposition

### Period details

|  |  |
| --- | --- |
| Allocation method (choose one) | [ ] Randomized – controlled[ ] Non-randomized – controlled [ ] Not applicable |
| Blinding used (choose one) | [ ] Double blind [ ] Single blind [ ] Not blinded |
| * If blinded, choose roles that were blinded
 | [ ] Subject[ ] Investigator[ ] Monitor[ ] Data analyst[ ] Carer[ ] Assessor |

### Arm Information

|  |  |
| --- | --- |
| Total number of study arms |  |

#### Arm 1:

|  |  |
| --- | --- |
| Arm Title |  |
| Arm type (choose one)  | [ ] Experimentell[ ] Active comparator[ ] Placebo[ ] No intervention[ ] Other |
| Number of subjects started: |  |
| Number of subjects completed: |  |
| **Subject non-completion reason** |
| Reason | Number of subjects |
| 1. [ ] Adverse event, non-fatal
2. [ ] Adverse event, serious fatal
3. [ ] Consent withdrawn by subject
4. [ ] Lack of efficacy
5. [ ] Lost to follow-up
6. [ ] Physician decision
7. [ ] Pregnancy
8. [ ] Protocol deviation
9. [ ] Transferred to another arm/group
10. [ ] Other (please specify)
 |  |
| **Subject joining reason** |
| Number of subjects |  |
| Reason | [ ] Late recruitment[ ] Transferred from another arm/group[ ] Other (please specify) |

#### Arm 2 (only fill in if a 2nd arm was used in the study):

|  |  |
| --- | --- |
| Arm Title |  |
| Arm type (choose one)  | [ ] Experimentell[ ] Active comparator[ ] Placebo[ ] No intervention[ ] Other |
| Number of subjects started: |  |
| Number of subjects completed: |  |
| **Subject non-completion reason** |
| Reason | Number of subjects |
| 1. [ ] Adverse event, non-fatal
2. [ ] Adverse event, serious fatal
3. [ ] Consent withdrawn by subject
4. [ ] Lack of efficacy
5. [ ] Lost to follow-up
6. [ ] Physician decision
7. [ ] Pregnancy
8. [ ] Protocol deviation
9. [ ] Transferred to another arm/group
10. [ ] Other (please specify)
 |  |
| **Subject joining reason** |
| Number of subjects |  |
| Reason | [ ] Late recruitment[ ] Transferred from another arm/group[ ] Other (please specify) |

#### Arm 3 (only fill in if a 3rd arm was used in the study):

|  |  |
| --- | --- |
| Arm Title |  |
| Arm type (choose one)  | [ ] Experimentell[ ] Active comparator[ ] Placebo[ ] No intervention[ ] Other |
| Number of subjects started: |  |
| Number of subjects completed: |  |
| **Subject non-completion reason** |
| Reason | Number of subjects |
| 1. [ ] Adverse event, non-fatal
2. [ ] Adverse event, serious fatal
3. [ ] Consent withdrawn by subject
4. [ ] Lack of efficacy
5. [ ] Lost to follow-up
6. [ ] Physician decision
7. [ ] Pregnancy
8. [ ] Protocol deviation
9. [ ] Transferred to another arm/group

j) [ ] Other (please specify) |  |
| **Subject joining reason** |
| Number of subjects |  |
| Reason | [ ] Late recruitment[ ] Transferred from another arm/group[ ] Other (please specify) |

## Baseline Characteristics

|  |  |  |
| --- | --- | --- |
| Age and gender are always included as baseline characteristics. Are there other study specific baseline characteristics you would like to report? | [ ] Yes | [ ] No |
| * If yes, which baseline characteristics
* Where in your published article can these be found? (e.g. Table 1, column X, row Y)
 |  |

## End point definition

Please describe the primary end points that answer the main objective. Please also provide information on where in your published article these results can be found (e.g. Table X, column Y, row Z).

#### End point 1:

|  |  |
| --- | --- |
| End point title |  |
| End point type | [ ] Primary[ ] Secondary[ ] Other pre-specified[ ] Post-hoc |
| Data can be found here: *(Numerical raw data e.g. mean ± SD, median and IQR/ min-max range)* | Table | Row | Column |
|  |  |  |
| **Statistical Analysis** |
| Statistical Analysis Title: (e.g. “Difference in XXX”) |  |
| Comparison groups (which arms should be compared) |  |
| Analysis specification | [ ] Pre-specified | [ ] Post-hoc |
| Analysis type | [ ] Non-inferiority[ ] Equivalence[ ] Superiority[ ] Other (specify) |
| Statistical analysis method:  | [ ] ANCOVA[ ] ANOVA[ ] Chi-squared[ ] Chi-squared, corrected[ ] Cochran-Mantel-Haenszel[ ] Fisher exact[ ] Kruskal-wallis[ ] Logrank[ ] Mantel-Haenszel[ ] Mcnemar[ ] Mixed models analysis[ ] Regression, Cox[ ] Regression, Linear[ ] Regression, Logistic[ ] Sign test[ ] t-test, 1-sided[ ] t-test, 2-sided[ ] Wilcoxon (Mann-Whitney)[ ] Other (please specify) |

#### End point 2 (Optional):

|  |  |
| --- | --- |
| End point title |  |
| End point type | [ ] Primary[ ] Secondary[ ] Other pre-specified[ ] Post-hoc |
| Data can be found here: *(Numerical raw data e.g. mean ± SD, median and IQR/ min-max range)* | Table | Row | Column |
|  |  |  |
| **Statistical Analysis** |
| Statistical Analysis Title: (e.g. “Difference in XXX”) |  |
| Comparison groups (which arms should be compared) |  |
| Analysis specification | [ ] Pre-specified | [ ] Post-hoc |
| Analysis type | [ ] Non-inferiority[ ] Equivalence[ ] Superiority[ ] Other (specify) |
| Statistical analysis method:  | [ ] ANCOVA[ ] ANOVA[ ] Chi-squared[ ] Chi-squared, corrected[ ] Cochran-Mantel-Haenszel[ ] Fisher exact[ ] Kruskal-wallis[ ] Logrank[ ] Mantel-Haenszel[ ] Mcnemar[ ] Mixed models analysis[ ] Regression, Cox[ ] Regression, Linear[ ] Regression, Logistic[ ] Sign test[ ] t-test, 1-sided[ ] t-test, 2-sided[ ] Wilcoxon (Mann-Whitney)[ ] Other (please specify) |

#### End point 3 (Optional):

|  |  |
| --- | --- |
| End point title |  |
| End point type | [ ] Primary[ ] Secondary[ ] Other pre-specified[ ] Post-hoc |
| Data can be found here: *(Numerical raw data e.g. mean ± SD, median and IQR/ min-max range)* | Table | Row | Column |
|  |  |  |
| **Statistical Analysis** |
| Statistical Analysis Title: (e.g. “Difference in XXX”) |  |
| Comparison groups (which arms should be compared) |  |
| Analysis specification | [ ] Pre-specified | [ ] Post-hoc |
| Analysis type | [ ] Non-inferiority[ ] Equivalence[ ] Superiority[ ] Other (specify) |
| Statistical analysis method:  | [ ] ANCOVA[ ] ANOVA[ ] Chi-squared[ ] Chi-squared, corrected[ ] Cochran-Mantel-Haenszel[ ] Fisher exact[ ] Kruskal-wallis[ ] Logrank[ ] Mantel-Haenszel[ ] Mcnemar[ ] Mixed models analysis[ ] Regression, Cox[ ] Regression, Linear[ ] Regression, Logistic[ ] Sign test[ ] t-test, 1-sided[ ] t-test, 2-sided[ ] Wilcoxon (Mann-Whitney)[ ] Other (please specify) |

## Adverse events

### Overview

|  |  |
| --- | --- |
| Timeframe for adverse event reporting (Enter the time point(s) or time period for adverse events assessment) |  |
| Assessment type | [ ] Systematic | [ ] Non-systematic |
| Adverse events dictionary name | [ ] MedDRA[ ] SNOMED CT[ ] Other (specify):  |
| Dictionary version |  |

### Adverse event reporting

#### Summary

|  |  |  |
| --- | --- | --- |
| How do you wish to report adverse events? | [ ] Per arm  | [ ] For all study subjects |
| Number of subjects affected by serious adverse events |  |
| Number of subjects affected by non-serious adverse events |  |
| Total number of deaths (all causes) |  |
| Total number of deaths resulting from adverse events |  |

#### Serious adverse event details and values (Only needed if serious adverse events were reported)

|  |  |  |  |
| --- | --- | --- | --- |
| System organ class | Number of subjects | Event Term (i.e. headache, nausea etc) | Occurrences  |
| 1. [ ]  Blood and lymphatic system disorders
2. [ ]  Cardiac disorders
3. [ ]  Congenital, familial and genetic disorders
4. [ ]  Ear and labyrinth disorder
5. [ ]  Endocrine disorders
6. [ ]  Eye disorders
7. [ ] Gastrointestinal disorders
8. [ ] General disorders and administration site conditions
9. [ ] Hepatobiliary disorders
10. [ ] Immune system disorders
11. [ ] Infections and infestations
12. [ ] Injury, poisoning and procedural complications
13. [ ] Investigations
14. [ ] Metabolism and nutrition disorders
15. [ ] Musculoskeletal and connective tissue disorders
16. [ ] Neoplasms benign, malignant and unspecified (incl. cysts and polyps)
17. [ ] Nervous system disorders
18. [ ] Pregnancy, puerperium and perinatal conditions
19. [ ] Product issues
20. [ ] Psychiatric disorders
21. [ ] Renal and urinary disorders
22. [ ] Reproductive system and breast disorders
23. [ ] Respiratory, thoracic and mediastinal disorders
24. [ ] Skin and subcutaneous tissue disorders
25. [ ] Social circumstances
26. [ ] Surgical and medical procedures
27. [ ] Vascular disorders
 | 1.
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13.
 |
| Assessment type | [ ] Systematic | [ ] Non-systematic |  |

#### Non-serious adverse event details and values (Only needed if non-serious adverse events were reported)

|  |  |  |  |
| --- | --- | --- | --- |
| System organ class | Number of subjects | Event Term (i.e. headache, nausea etc) | Occurrences  |
| 1. [ ]  Blood and lymphatic system disorders
2. [ ]  Cardiac disorders
3. [ ]  Congenital, familial and genetic disorders
4. [ ]  Ear and labyrinth disorder
5. [ ]  Endocrine disorders
6. [ ]  Eye disorders
7. [ ] Gastrointestinal disorders
8. [ ] General disorders and administration site conditions
9. [ ] Hepatobiliary disorders
10. [ ] Immune system disorders
11. [ ] Infections and infestations
12. [ ] Injury, poisoning and procedural complications
13. [ ] Investigations
14. [ ] Metabolism and nutrition disorders
15. [ ] Musculoskeletal and connective tissue disorders
16. [ ] Neoplasms benign, malignant and unspecified (incl. cysts and polyps)
17. [ ] Nervous system disorders
18. [ ] Pregnancy, puerperium and perinatal conditions
19. [ ] Product issues
20. [ ] Psychiatric disorders
21. [ ] Renal and urinary disorders
22. [ ] Reproductive system and breast disorders
23. [ ] Respiratory, thoracic and mediastinal disorders
24. [ ] Skin and subcutaneous tissue disorders
25. [ ] Social circumstances
26. [ ] Surgical and medical procedures
27. [ ] Vascular disorders
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 |
| Assessment type | [ ] Systematic | [ ] Non-systematic |  |

## More information

|  |  |  |
| --- | --- | --- |
| Were there any global substantial amendments to the protocol? | [ ] Yes | [ ] No |
| * If yes, please provide Amendment date
* If yes, please provide Amendment description
 |  |
| Were there any global interruptions to the trial? | [ ] Yes | [ ] No |
| * If yes, please provide Interruption date
* If yes, please provide Interruption description
* If yes, please provide Restart date (if applicable)
 |  |