# 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](mailto:compliance@ki.se).

Send the final form together with the published article as attachment to [compliance@ki.se](mailto: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 |  |  |  |
| 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 |  |  |  |
| 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) |  | |