Statistical report prepared by:

[Name and title of trial statistician]

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With the collaboration of:

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* *The contents of this report are confidential* -

*Study Title: Write your title in this box. You can change the font and the size if needed.*

**EORTC protocol [number]**

(EudraCT Number [number])

STUDY COORDINATOR(S):

[Name1, Institution, City, Country – Group]

[Nam2, Institution, City, Country – Group]

COORDINATING GROUP: EORTC [group]

Final/interim analysis report – v. X

Date of the report: DD MM YYYY

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# Summary of the trial

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **COORDINATING GROUP**  **COOPERATING GROUP(S)** | | **DATE OF PRC APPROVAL**  **DATE OF DATABASE LOCK** | | **LAST VERSION OF PROTOCOL** |
| Title of study |  | | | |
| Phase | 1  2  1-2  2-3  3 4 | | | |
| Study center(s) |  | | | |
| Publication |  | | | |
| Study period | From:  To: | | Phase of development | |
| Objectives | Primary objectives:  Secondary objectives | | | |
| Methodology |  | | | |
| Number of patients | Planned:  Analyzed: | | | |
| Diagnosis and main criteria for inclusion |  | | | |
| Investigational product, dose and mode of administration |  | | | |
| Duration of treatment |  | | | |
| Criteria for evaluation | Primary endpoint(s):  Secondary endpoints(s): | | | |
| Statistical methods | Stratification factors: | | | |

# Statistical considerations and study history

*Study objectives and general design*

## Main eligibility criteria

## Treatment schedule

* *How treatment is delivered + dose levels planned by protocol*

## DLT and MTD

* *Definition of DLT and MTD and time period on which they are assessed*

## Statistical design (dose escalation rules)

* Statistical design + how decision escalation dose for next patient is made

## Study populations

* Include evaluable patient/enrolled/safety population
* Replacement rules to be defined

## Structure of the statistical analysis report

* Summary of population used (agreement with CRP on SAP necessary prior to drafting report)

## History of the amendments

* Summary of important amendments + impact on statistical design and/or analysis

# Patient availability

## Accrual

* *Recruitment by dose level by center and over time (Minimum: start/end recruitment date, enrollment, nbr sites, nbr dose levels visited, table of recruitment by center by dose level)*
* For EUDRACT report make sure to include:
  + start and end date of recruitment
  + table with nbr of patients by country

## Eligibility

* *Table with summary of eligibility status by dose level + listing ineligible patients*
* *Patients entered with a waiver on eligibility criteria must be clearly identified*

## Patient populations used in the analyses

* *Table: nbr patients included in each patient population + 2nd column for patients excluded & list reasons for exclusion*
* *Listing patients who require specific attention + justification for inclusion/exclusion*

# Number of patients by dose level

* Table: nbr of patients included at each dose level + 2nd column for patients replaced & list reasons for replacement
* Deviations to protocol specifications for replacement to be explained

# Baseline characteristics

* *Description of all baseline characteristics for safety population (or population specified in SAP/protocol)*
  + For EUDRACT reporting make sure to include a table by age, according to the following categories
    - Children (2-11 years)
    - Adolescents (12-17 years)
    - Adults (18-64 years)
    - From 65 to 84 years
    - 85 years and over
* *By-patient listing for selected baseline characteristics*
* *Table (by section) with summary of all baseline characteristics by dose level (column)*
* *Details on specific items (+ dose level & patient id) to be listed below the table*

# Exposure to treatment

* *Prior agreement with CRP on format and content strongly recommended*
* *Adherence to theoretical main protocol treatment and reasons for non-adherence by treatment arm and reasons why treatment was stopped. Report on the evaluable.*

## Number of cycles

* Table with nbr of patients by nbr of cycles by dose level + median/range of nbr of cycles received

## Reasons for treatment discontinuation

* Listing by dose level by patient: instit nbr, nbr cycles received, date first & last treatment administration + reason for treatment discontinuation

## Schedule modifications

* Each drug to be presented separately
* Format : ≤30 patients: listing; ≥ 50 patients: table; 31 to 49 patients: CRP to choose

## Relative Dose Intensity (RDI)

* Definition of Dose Intensity and RDI
* Table with median and range RDI for each drug by dose level + frequency of patients with RDI
* Graphics may be provided to supplement information

# Safety evaluations

## Toxicity

* Table with toxicities grouped according to type of AE

### Hematological adverse event and biochemistry

* Hematology and biochemistry to be presented separately (rows: AEs per patient per dose level; columns: cycles)

### Non hematological adverse event

* 2 tables: treatment period for DLT assessment + worst grade reported over all cycles
* In case of loading cycle, add one table: AE during the first cycles without the experimental drug
* Tables with frequency of patients with each AE (rows) by dose level (columns)
* Other AEs to be listed below tables

## Serious Adverse Events

* *Standard tables provided by PV Unit*
* *Further descriptions of SAEs and toxic deaths events added by CRP*
* *Same format as the one used in the Development Safety Update Report*

# Identification of the DLTs and MTD

* *Summary of all DLTs (tabular listing: dose level, patient nbr, description of DLT)*
* *Summary of conclusions regarding the MTD and recommended dose*

# Treatment activity

* *Report on all activity endpoint (short or long term) collected with special emphasis on primary activity endpoint (if there is one)*
* *Divide in several sections according to endpoint*

## Response to treatment

* Table with best response by dose level
* Listing with dose level, patient id, nbr cycles, best response, reason for non-evaluability, eligibility and duration of response

## Progression and survival

* Listing with time to progression, survival duration, survival status, cause of death

# Summary of the results

* *Written by statistician & CRP*
* *Short summary of main features (recruitment, safety, activity) + statistical and medical conclusions*