Statistical report prepared by:

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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

* Summary recent and/or important amendments
* Sample size + objectives
* Summary interim or past analyses (conclusions, modifications to design or analysis plan) + results of former stage for multi-stage trials
* Description of trial-specific QC procedures + impact on trial and/or analysis

# Objectives of the present analysis and data selection for this report

* Nature & objectives of analysis
* IAR: questions IDMC is asked to answer
* HQ team remarks on study conduct and problems (data collection, data management)
* Cut-off date + data selection
* Nbr patients randomized vs planned; nbr events vs planned + impact on design

# Patient availability

## Accrual

* Recruitment rate (over time and by instit) +info on compliance to entry rate
* For IAR: graph actual & expected accrual over time
* Table with nbr patients by instit (name) in descending order of accrual  
  Intergroup trials:2-way table cross tabulating the primary group vs affiliation to EORTC
* For EUDRACT report make sure to include:
  + start and end date of recruitment
  + table with nbr of patients by country

## Follow-up

* FU duration by treatment arm and overall estimated by the inverse Kaplan-Meier method
* Kaplan-Meier figure by treatment arm

## Eligibility

* Table with eligibility status by treatment arm + listing ineligible patients
* Patients entered with a waiver on some eligibility criteria must be identified clearly

## Patient populations used in the analyses

* Table with nbr patients by treatment arm and in total in all “patient populations” including “intent-to-treat population” and “per protocol” population for analysis of efficacy endpoints, and “safety population” for reporting of safety endpoints

# Baseline characteristics

* Distribution of all baseline characteristics by treatment arm (organize by meaningful sections)
  + For EUDRACT reporting make sure to include a table by age, according to the following categories
    - Adolescents (12-17 years)
    - Adults (18-64 years)
    - From 65 to 84 years
    - 85 years and over
* Multi step studies: report baseline characteristics at each step
* Distribution of stratification factors (as declared at the time of randomization) + inconsistencies between the values declared during the randomization versus those updated later on (from baseline forms)

# Compliance to the protocol

## Central medical review of compliance to protocol

* Table by treatment arm: central assessment of “deviations from protocol treatment”

## Compliance to treatment allocation

* Table by treatment arm: treatment actually received vs randomized treatment (nbr patients who started allocated treatment, nbr patients who did not start allocated treatment + reasons, patients with no available info)

## Other compliance measures

* Description of other aspects of compliance to protocol (if relevant)

# Exposure to treatment

* Prior agreement with CRP on format and content strongly recommended
* Concise description of adherence to theoretical main treatment & reasons for non-adherence by treatment arm
* For each part of the treatment:
* summary of total duration of exposure to treatment
* nbr patients who did not receive full treatment + when & why treatment stopped
* summary table of total dose received
* tables of modifications of treatment

# Safety evaluations

## Adverse Events

* Prior agreement with CRP on format and content strongly recommended
* AEs grouped according to type of toxicity(hematology versus non- hematology and organ)
* Report worst grade of AE over a specified time period (or by different time periods). Frequency of nbr of patients & % with a given grade presented by treatment arm.
* If relationship is collected: tables of non hematological related AEs will be produced

## 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

# Reasons for stopping treatment

* Table with status of patients (on vs off treatment) with reasons for stopping treatment
* Listings on details collected in text fields

# Post-protocol therapy

* Table of additional treatment received for all patients who stopped protocol treatment and for whom follow-up information is available
* Listings on details collected in text fields

# Post-treatment evaluations (as appropriate: response to treatment, surgery and pathology)

* If response to treatment is an endpoint: table with response to treatment in patient population defined in the SAP/protocol for that endpoint; confidence intervals around the response rates and P-values
* If applicable, chapter on surgery: nbr patients, type of surgery, complications & outcome, nbr patients who didn’t have surgery but should have according to protocol + reasons for non compliance, histopathology result if available

# Disease status (includes tables of frequency of events, sequence of events)

* Frequency of events of interest (& combinations of events) by treatment arm in primary analysis set (separate tables for sensitivity analysis in alternative patient populations)
* Chapter on efficacy to be subdivided according to endpoint
* Composite endpoints: tabulate type of first event that was considered in the endpoint
* Cumulative incidence analyses: sequence of events + nbr patients in a table or flow chart

# Statistical inference on efficacy endpoints

* Primary/secondary/exploratory analysis to be clearly identified
* One section per endpoint + one subsection per analysis (primary analysis to be clearly identified)

# Compliance to Quality of Life *(if collected in the study)*

* 1st table: compliance by assessment time
* 2nd table: % of baseline forms & FU QOL forms by instit

# Summary of the results

* Written by statistician and CRP
* Short summary (1 page) of the main features & statistical conclusions: recruitment, compliance to protocol, exposure to treatment, safety results, efficacy results, conclusions (abstract format)

# CONSORT Flow Chart

* CONSORT Flow Chart to be prepared for FAR

Assessed for eligibility (n= )

Excluded (n= )

  Not meeting inclusion criteria(n= )

  Declined to participate (n= )

  Other reasons (n= )

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Stratum1/Arm 1 (n= )

 Received intervention (n= )

 Did not receive intervention (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Stratum 2/Arm 2 (n= )

 Received intervention (n= )

 Did not receive intervention (give reasons) (n= )

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

Stratification/ Arm

Analysis

Follow-Up

Registered/Randomised (n=)

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Enrollment