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The future of cancer therapy

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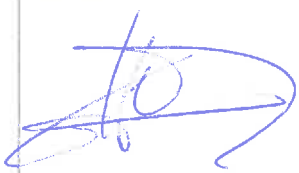
Statistical Analysis Reports of Phase I Trials

ST-006-WIN-01

Version 3

ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

Author: *Head of Statistics Department* Laurence Collette	Signature: 	Date: *(ex:10-Feb-2017)* 25.06.12
Approved and authorized by *Head of Statistics Department* Laurence Collette	Signature: 	Date: *(ex:10-Feb-2017)* 25.06.12

1 PURPOSE

To describe the contents of the statistical analysis reports for phase I clinical trials.

2 INSTRUCTION

2.1 Before starting the analysis report

Make sure that the study analysis plan is absolutely clear in respect of the following points:

- The dose limiting toxicities (DLTs), with special attention to the relationship to the drugs.
- The period of assessment of the DLTs (e.g. cycle 1, or cycle 2, or cycles 1 and 2).
- The population evaluable for the assessment of the DLTs and maximum tolerated doses (MTDs) are ineligible patients included? Do the patients need to have received a minimum amount of treatment, of a specific drug in the combination?) and the corresponding rules for replacing patients.
- All other populations that are needed to report the results.
- Clearly decide on the analysis populations that must be used for the presentation of each section of the report (e.g. baseline - all patients, treatment exposure - evaluable population).

If not sufficiently detailed in protocol and/or Statistical Analysis Plan (SAP), please refer to ST-005-SOP and discuss these points with the Clinical Research Physician (CRP).

2.2 Standard table of contents of Analysis Reports

The analysis report is to be structured according to the form ST-006-AF-03.

	Chapter	**Population used***
1	Summary of the trial	Enrolled
2	Statistical considerations and study history *(includes trial design with dose levels, definition of DLT, definition of patient populations, replacement rules, history of past amendments)*	-
3	Patient availability (recruitment, eligibility, patient populations used in the analysis)	Enrolled
4	Number of patients per dose level (with identification of patients who were replaced)	Enrolled
5	Baseline characteristics	Safety
6	Exposure to treatment (also includes reasons to stop treatment)	Evaluable (and safety to display cycle 1 in case evaluation starts after cycle 1)
7	Safety evaluations	Evaluable
8	Identification of DLT and MTD	Evaluable
9	Activity of the treatment	All treated patients with measurable disease
10	Summary of the results	-

*** The "populations to use" indicated in the present WIN are recommendations, and are superseded by other choices made in the SAP or decided with the CRP. (Please refer to section 2.4.2.5)**
Supplementary chapters or sections within chapters may be added as necessary.

2.3 Automatic reporting

A SAS program has been developed to automatically insert SAS output at pre-specified locations in the report. These locations are identified by bookmarks. Standard bookmarks have been inserted in the template report form ST-006-AF-05 and can be modified/extended as necessary. For more information, see the EORTC SAS Macro Guide.

2.4 Patient selection

All patients are accounted for in the reports except those who never signed an informed consent or who withdrew consent and asked that none of their data are used. Such patients, if any have been identified, are reported separately in the publication and in all reports: the total number of such patients and the fact that they are excluded are mentioned at the beginning of the report, no other data are reported.

The patient population (subset) used must be clearly stated at the beginning of each chapter.

2.4.1 General guidelines for data display

- Frequency tables are tabulated for all categorical variables, by level of the variable.
- Whenever categories prompt for a specification, a listing details for the patients fulfilling the condition the patient id, institution, (eligibility) treatment, value of the item and text field contents.
- Time delays are calculated as delays in days between the past event and the date of entry (date of entry – date of past event + 1), and expressed in a suitable time unit. They are usually presented using median and range, and/or categorized into appropriate intervals.
- Continuous variables such as laboratory data, for which a grading system exists and is specified in the protocol are recoded into categories. Whenever no specific grading system exists, the laboratory data are categorized in function of the normal range as below the lower normal limit, within the normal range, above the upper normal limit. For laboratory data, the nadir may also be displayed. The nadir in a given cycle is the lowest laboratory value in that cycle; the overall nadir for a patient is the lowest laboratory value among all cycles.
- Other continuous variables (eg. Age, doses …) are presented using median and range (minimum, maximum). If appropriate, the data may additionally be presented in categories (eg. Age may be grouped in decades in addition to the median and range being reported).
- **Dose intensity:** The dose intensity of a drug is calculated on actual treatment duration (in appropriate units of time, weeks, cycles, or days) and actual treatment dose received (total dose received expressed in appropriate units (kg, m^2.).
- Whenever the treatment is given in cycles and the last planned day of treatment is not the last day of the cycle, the total duration of the treatment must account for this by adding the appropriate number of days to complete the last cycle (e.g. if treatment is given on days 1-5 of a 21-day cycle, the total treatment duration in days is [date of last injection]-[date of first injection]+1+(21-5)).

- The dose intensity (expressed in units of dose / unit of time) (e.g. mg/m² x week) is the ratio of the total dose received to the total treatment duration, for example, for a dose in mg/m² and a duration in weeks

$$DI_{observed}\ (mg/m^2 \times week) = \frac{Total\ dose\ (mg/m^2)}{Actual\ total\ treatment\ duration\ (weeks)}$$

- The relative dose intensity is calculated as the ratio of the dose intensity as calculated above to the dose intensity indicated in the protocol, expressed in percent (%). Note that to obtain a correct ratio, the theoretical dose intensity must be expressed in the same units of dose and time as those used for the actual dose intensity. For example

$$DI_{protocol}\ (mg/m^2 \times week) = \frac{Dose\ \ per\ cycle\ (mg/m^2)}{Theoretical\ duration\ of\ \ one\ cycle\ (weeks)}$$

- The relative dose intensity is usually presented using median and ranges, accompanied or not by a distribution into categories (e.g. ≤70%, >70-90%, >90-110%, >110-120%, >120%).

2.5 Contents of the chapters

The populations used to display the various tables and analyses should be clear from the SAP/protocol.
The "populations to use" indicated in the present WIN are recommended, but are superseded by other choices made in the SAP or decided with the CRP.
The contents and format of the report is discussed and agreed with the CRP before the first draft is prepared. The medically relevant information must be clear from the report.

2.5.1 Summary of the trial

This chapter is a one-page summary of the study.

2.5.2 Statistical considerations and study history

This chapter consists of an introduction followed by several sections that are copied from the study protocol and clarified as necessary.
The **introduction** presents the overall study objectives and general design of the study
Example :
"This is an open label, non-randomized, multi-center, phase I dose escalation trial of lonafarnib (SCH66336) in combination with herceptin and paclitaxel in breast cancer patients conducted in three study centers.
The primary objective of the trial is to assess the toxicity profile, measured using Common Toxicity Criteria (CTC version 2.0), to determine the maximum tolerated dose (MTD) and dose limiting toxicity (DLT) of this combination and to establish a recommended dose for phase II of lonafarnib when given in combination with herceptin and paclitaxel in c-erbB2 positive patients with breast cancer.
Patients evaluable for the study endpoint, with advanced-stage refractory or relased breast cancer amenable to treament with paclitaxel and herceptin will be enrolled to receive the combined treatment. The dose of paclitaxel and herceptin are maintained throughout the various dose levels of lonafarnib, except the first dose level for which for safety reasons, it has been decided to use 135 mg/m² of paclitaxel.

The number of dose-levels is not fixed in advanced. However, the first dose levels were decided upfront but the exploration of intermediate dose levels was envisaged once the MTD had been reached. Dose levels were allocated according to a modified Fibonacci schedule. The dose levels are allocated according to a 3+3 scheme design (3 patients/dose level, up to 6 in case of a DLT) (see section xxx for the definition of DLT and MTD and section yyy for the dose escalation rules)."

2.5.2.1 Main eligibility criteria

These can be copied from the protocol.

2.5.2.2 Treatment schedule

Explains how the treatment is delivered and details the dose levels planned by the protocol (even if not visited in practice).

2.5.2.3 DLT and MTD

Includes definitions of DLT and of the MTD and on which time period these are assessed.

2.5.2.4 Statistcal design (dose escalation rules)

Explains the statistical design used (3+3, CRM) and how the decision to escalate the dose for the next patient is made.

2.5.2.5 Study populations

This section defines all populations used in the report.
These include:

- The **evaluable patient population.** This is the subset of patients that was used to decide on the dose escalations. **The replacement rules must also be defined.**
- The **enrolled population** is defined as **"a**ll enrolled patients, whether treated or not" .
- The **safety population** is defined, generally as "all patients who received at least one dose of one of the drugs in the treatment combination during cycle 1".

2.5.2.5.1 Structure of the statistical analysis report

This section summarizes for the reader the population that is used in each of the following chapters. It is extremely important to agree on the SAP with the CRP before starting the report. In case of disagreement, the Head of Statistics Department (or author of the WIN) must be consulted and will take the final decision.

2.5.2.6 History of amendments

This section summarizes the important amendments to the trial and explains how they affect the statistical design and/or analysis.

2.5.3 Patient availability

Tables are **displayed by dose level**.

2.5.3.1 Accrual

This chapter informs on the recruitment by dose level by center and over time. At minimum it contains a statement about start date and end date of recruitment, total number of patients enrolled, number of sites and, number of dose levels visited, and a table of recruitment by center by dose level.

2.5.3.2 Eligibility

This information is summarized in a table eligibility status by dose level supplemented by a listing of ineligible patients (with institution number, seqid, date of entry, dose level, and details of the reasons of ineligibility).
Patients who have been entered in the study with a waiver on eligibility criteria (ref. CM-010-WIN-01, Management of Eligibility Compliance) must be identified clearly in the table and are considered as eligible when defining the populations used in the analysis.

2.5.3.3 Patient populations used in the analysis

This section shows in a table, the total number of patients included in each of the patient populations. The patients excluded from each population are identified in a second column and the reasons for exclusion are detailed in a listing.
Patients who require specific attention (for example a patient who would have started the cycle used for assessing the DLTs but would not have received the drug of interest) must also be listed here, with the justification for their inclusion/exclusion from the evaluable patient population.

2.5.4 Number of patients by dose level

A table must show the total number of patients included at each dose levels (rows=dose levels, total number is showed in column 1). Patients that were replaced must be identified in a second column. The reasons why the patients were replaced is detailed in a listing/text below the table.
The effective replacement of patients should have followed the protocol specifications for replacement of patients. If this is not the case, deviations must be explained.

2.5.5 Baseline characteristics

This chapter describes all the baseline characteristics for all patients who started the treatment (safety population) or for the population specified in the SAP/protocol.
The most important baseline factors (specified by the CRP) are presented in by-patient listing. The listing identifies the patient id and dose level.
All baseline characteristics are then summarized in tabular format, by dose-level (= column).
Such tables are organized in meaningful sections, for example:

- Demographics: age, sex (if applicable)
- Medical history: Concomitant illnesses, relevant previous illnesses, previous treatments for protocol disease, if appropriate
- Disease characteristics: TNM or other relevant classification, baseline measurements
- Baseline values of other known prognostic factors such as markers used as stratification factors.
- Baseline hematology
- Baseline biochemistry

- Baseline signs and symptoms

Listings that provide details on specific items are provided below the table. Such listings always provide both the dose level and the patient id.
It is common that the same information is available from the randomization questions and from the eligibility checklist. As the information from the randomization is not validated by the Data Managers it should not be used to replace missing information from the eligibility checklist.

2.5.6 Exposure to treatment

This chapter describes the adherence to the theoretical main protocol treatment and the reasons for non-adherence by treatment arm, as well as the reasons why the treatment was stopped.
It should be organized to be concise, yet meaningful way, to enable the easy identification of the cycle(s) used for the assessment of the DLT. This chapter is typically reported on the evaluable.
In general the report of the exposure to treatment is heavily driven by the information that was collected on the case report form and by medical considerations. **It is strongly suggested to agree on the contents and format of this chapter with the CRP before drafting the report.**

2.5.6.1 Number of cycles

This table displays the number of patients by total number of cycles by dose level as well as the median and range of total number of cycles received.

2.5.6.2 Reasons for treatment discontinuation

This shows in a listing, by dose level, by patient, the institution number, number of cycles received, date of first and of last treatment administration and detailed reason for treatment discontinuation.

2.5.6.3 Schedule modifications

Schedule modifications (dose delays, dose reductions) are presented for each drug separately.
If the total number of patients in the study is ≤30, the information in this chapter is displayed in the form of listings. These listings indicate the dose level, the patient id, the cycle number, the type and reason for dose modification, the type and reason for dose delay. Only cycles with modifications are listed.

e.g.

Dose level	Patient id	Cycle	Drug X dose modification	Reason Drug X dose modification	Drug X schedule modification	Reason Drug X schedule modification
Dose level 1	1	2			Definitively stopped	Hemat. tox.: grade III neutropenia
Dose level 2	9	3			Delayed >=48 hrs	Hemat. tox.: ANC grade 2
	9	13	.		Interrupted >=48 hrs	n-hemat. tox.: decreased LVEF
	9	14	Escalation	n drug related: 4 mg/kg mistake by error		
	9	21			Interrupted >=48 hrs	n-hemat. tox.: decreased LVEF
	9	25	Escalation	n drug related: dose 300 mg as loading dose after interruption		

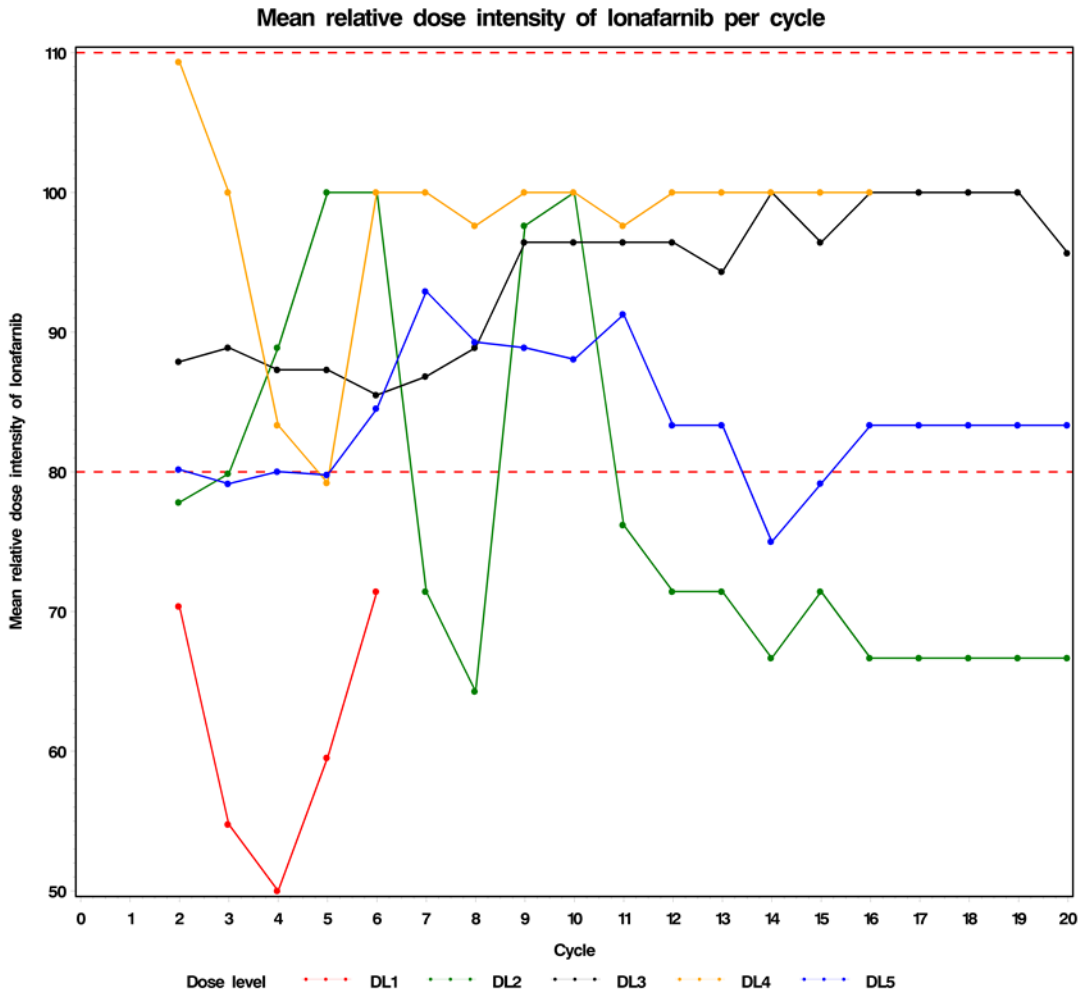
Dose level	Patient id	Cycle	Drug X dose modification	Reason Drug X dose modification	Drug X schedule modification	Reason Drug X schedule modification
	9	37	Reduction of >=10%	n-hemat. tox.: decreased LVEF	Interrupted >=48 hrs	n-hemat. tox.: decreased LVEF
Dose level 3	10	8	Reduction of >=10%	Admin. reason: Holiday	Interrupted >=48 hrs	Admin. reason: Holiday

If the total number of patients is ≥ 50, a tabular report of the frequency of dose modifications and reasons for each modification by dose level, supplemented by listings detailing the reasons is considered. This format is similar to the format used when reporting phase II trials.
If the total number of patients is between 31 and 49, the CRP recommends the preferred format for the presentation of this information.

2.5.6.4 Relative dose intensity (RDI)

The definition of dose intensity and relative dose intensity (adapted to the calculation performed for the specific trial based on the protocol) is given in the chapter, in order for the reader to fully appreciate what it represents.
The median and range of the RDI for each drug is tabulated by dose level. Additionally, the frequency of patients with RDI <70%, in 70%-<90%, 90%-<110%, ≥110% is also displayed.
Graphics may be provided to supplement the information. For example, a graphical display of the relative dose intensity of the drug of interest by cycle, may be of interest. The graphic may display the RDI by patient by cycle, or the average RDI of patients in same dose levels by cycle. Such graphics help assess if the RDI evolved over cycles.

e.g.



Scatter plots of RDI in cycle 2 vs cycle 1 may also be helpful, especially when the test drug is added only from cycle 2, or if toxicity is expected to occur only after some time on treatment.

2.5.7 Safety evaluations

This chapter is essential to the phase I reports and enables the reader to readily follow the DLTs during the evaluation period as well as to gather a full picture of the toxicity profile for each dose level.

It should be organized to be concise, yet meaningful way, to enable the easy identification of the cycle(s) used for the assessment of the DLT. This chapter is typically reported on the evaluable population.

It is strongly suggested to agree on the contents and format of this chapter with the CRP before drafting the report.

2.5.7.1 Toxicity

In all reports, the toxicities are grouped logically according to the type of adverse event: hematological adverse event (WBC, neutrophils, platelets, hemoglobin), non hematological adverse event and by organ class (gastro-intestinal, genito-urinary, skin, neurological, pulmonary). Of note, febrile neutropenia is a hematological adverse event.

To prepare these tables, one first reclassifies the "other adverse events" (from the non preprinted items) inside the appropriate organ class. In displaying the tables, listings are provided to describe all the adverse events that are either of particular interest to the medical reader, or for which a specification ("text field") was collected on the case report form.

2.5.7.1.1 Hematological adverse event and biochemistry

Hematology and biochemistry are presented separately.
The variables are listed in tables with rows being the adverse event per patient per dose level and columns showing the cycles (baseline, cycle 1, .., cycle k) and the entries being the adverse event grades. It is useful to identify the cycle that was used to assess the DLTs using shaded area or other marks.
The format of the hematology table would look like the following table. If some patients received many cycles, the table may be truncated to show only the first *x* cycles. This decision is made with the CRP who will recommend on the appropriate number *x* of cycles.

Dose level	Pat. id	Adverse event	Baseline	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18	C19	C20
Dose level1	1	ANC	0	0	3	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		HB	1	1	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		WBC	0	1	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	2	ANC	0	4	1	3	2	2	3	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		HB	0	1	1	1	1	0	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		WBC	0	2	1	2	2	2	2	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	4	ANC	0	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

And similar for the biochemistry

Dose level	Pat. id	Adverse event	Baseline	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14	C15	C16	C17	C18	C19	C20
Dose level 1	1	ALP	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		ALT	1	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		AST	1	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		BILI	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		CREAT	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		GGT	1	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
	2	ALP	1	1	1	0	0	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		ALT	0	0	1	0	0	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		AST	0	0	0	0	0	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.
		BILI	0	0	0	0	0	0	0	.	.	.	.	.	.	.	.	.	.	.	.	.	.

Whenever many patients were entered in the study a tabular presentation may be envisaged, after discussion with the CRP.

2.5.7.1.2 Non hematological adverse event

Non hematological adverse event is presented in tables.
Separate tables are prepared

- for the treatment period used to assess the DLT and
- for the worst grade reported over all cycles.

Should there be a loading cycle (one or several cycles without the experimental drug, before the DLT assessment period) then there should be three sets of tables:

- one set for the adverse event during the first cycles without the experimental drug

- one for the adverse event during DLT assessment period (first cycle(s) with the experimental drug) and
- one set for the worst adverse event over all cycles with the experimental drug

The full set of tables is duplicated (presents once the adverse event irrespective of relationship to treatment and once only the adverse event that is (at least possibly) related to the treatment).
The tables present the frequency of patients with each adverse event (in rows) by dose level (in marked columns), as:

	Dose level 1 (N=4)				Dose level 2 (N=4)				Dose level 3 (N=3)				Dose level 4 (N=3)				Dose level 5 (N=8)				Total (N=22)			
CTC Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Allergy	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	.	.	1	.	.
Edema	.	1	.	.	1	.	.	.	.	.	.	.	.	1	.	.	.	.	.	.	1	2	.	.
Hypotension	1	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.	1	.	.	.
Fatigue	1	.	.	.	3	1	.	.	.	1	.	.	2	.	.	.	3	2	.	.	9	4	.	.

Supplementary listings are added below the table, to detail the "other adverse event" and those for which further specification was collected.
The listings show per dose level, per patient, per cycle, per adverse event, the description of the event, the grade, the relationship to the study drug, the seriousness, the resolution, the date of onset and the date of resolution. There is no need to duplicate the listing after the tables showing the related adverse event, provided the related adverse events are clearly identified in the first listing.

2.5.7.2 Serious Adverse Events

This section contains the **standard tables provided by the Pharmacovigilance Unit.**
Further descriptions of the serious advserse events and toxic deaths events are added by the CRP.
The format of the presentation is the same as that used in the Development Safety Update Report which is, for example:

2.5.7.2.1 Study safety overview per treatment arm

Trt	SAE	SAR	SUSAR	Deaths	Toxic Deaths
Arm 1: Doxorubicin	139	78	5	12	5
Arm 2: Doxorubicin + Ifosf.	354	312	4	5	2
Grand Total	493	390	9	17	7

2.5.7.2.2 SUSARs by SOC and PT

Case ID	Trt	SOC	PT
62012-270-2	Arm 1: Doxorubicin	Gastrointestinal disorders	Intestinal perforation
62012-6-3	Arm 1: Doxorubicin	Gastrointestinal disorders	Steatorrhoea

2.5.7.2.3 Toxic deaths by SOC and PT

Case ID	Trt	SOC	PT
62012-105-1	Arm 1: Doxorubicin	Respiratory, thoracic and mediastinal disorders	Respiratory failure
62012-143-1	Arm 1: Doxorubicin	Infections and infestations	Pneumonia

2.5.7.2.4 Line Listings of Serious Adverse Reactions (SAR)

Provided in a pdf table that is placed in appendix and referred to in this chapter

2.5.7.2.5 Cumulative Summary Tabulation of Serious Adverse Events (SAE)

PRIMARY SOC	PT	Arm 1: Doxorubicin	Arm 2: Doxorubicin + Ifosf.	Grand Total
Blood and lymphatic system disorders	Anaemia	3	23	26
	Febrile bone marrow aplasia		5	5
	Febrile neutropenia	19	87	106
	Leukopenia		4	4
	Neutropenia	6	35	41
	Pancytopenia		7	7
	Thrombocytopenia		27	27
Blood and lymphatic system disorders Total		28	188	216
Cardiac disorders	Cardiac arrest	1	1	2
	Cardiac failure		1	1
	Congestive cardiomyopathy	1		1
	Tachycardia		1	1

2.5.7.2.6 Cumulative Summary Tabulations of Serious Adverse Reactions (SAR)

PRIMARY SOC	PT	Arm 1: Doxorubicin	Arm 2: Doxorubicin + Ifosf.	Grand Total
Blood and lymphatic system disorders	Anaemia	2	22	24
	Febrile bone marrow aplasia		5	5
	Febrile neutropenia	19	87	106
	Leukopenia		4	4
	Neutropenia	6	34	40
	Pancytopenia		7	7
	Thrombocytopenia		27	27
Blood and lymphatic system disorders Total		27	186	213

2.5.8 Identification of the DLTs and MTD

This short chapter summarizes in a tabular listing all DLTs that were observed in the study.
The table shows the dose level (with details of dosing of the drug(s)), patient number and description of the DLT as in the example below

Dose level	Patient number	DLT
Dose Level 5: lonafarnib: 300 mg/day, paclitaxel: 175mg/m²/cy, herceptin: 2mg/kg/wk 8 patients	18	Allergic reaction Gr. 3 (likely related)
	21	Laboratory value GGT Gr. 3

The listing is followed by a short summary of the conclusions that were derived regarding the MTD and the recommended dose.
Example:
"→ *As two DLTs were observed at dose level 5, the Maximum Tolerated Dose (MTD) and recommended dose for Phase II is Dose level 4: lonafarnib: 250 mg/day, paclitaxel: 175mg/m²/cycle, and herceptin: 4mg loading dose 2mg/kg/week thereafter*."

2.5.9 Activity of the treatment

2.5.9.1 Response to treatment

Response is not the primary endpoint of phase I trials but is commonly collected in such trials, for early signs of activity may be relevant to the decision to conduct further tests with the drug (-combination).
Response to treatment is presented in a table of best response by dose level and in a listing detailing for all patients in the study: dose level, patient id, number of cycles, best response, reason for non-evaluability if not evaluable for response, eligibility and duration of response (if response was observed), as in the following table

Dose level	Patient id	Hospital number	Total number of cycles	Best overall response	If not evaluable, specify	Was this patient eligible to enter the trial ?	Duration of response (days)
Dose level 1	1	301		Stable disease		yes	.
	2	301		not evaluable	End evaluation not done	yes	.
	3	301		not evaluable	Only one course taken	no	.
	4	301		Progressive disease		yes	.
	5	301	5	Partial response		yes	164
Dose level 2	6	301		Stable disease		yes	.

2.5.9.2 Progression and survival

If the date of progression and the survival data were collected, the time to progression and the survival duration, survival status and cause of death may be added to the listing of response data or presented in a separate listing. Kaplan-Meier curves (showing censoring ticks) may also be presented provided the cohort contains ≥10 patients.

2.5.10 Summary of the results

This chapter gives a short summary of the main features and conclusions of a trial.

2.5.11 EudraCT reporting

Since July 21, 2014, it is mandatory for sponsors to post results of clinical trials with a European Clinical trials Database (EudraCT) identifier in the database managed by the European Medicines Agency (EMA).

Most of the information required to complete the EudraCT website is readily available from

- The protocol "summary" section
- The accrual tables
- The section in the FAR of efficacy results (and quality of life);
- For Adverse event reporting on EudraCT website, an xml file should be uploaded. This is derived from the adverse events analysis in the FAR and the Serious Adverse Events recorded by the pharmacovigilance unit (PVU). The macro program %AE_table2 creates and excel file containing all information requested by EudraCT and a converter from xlsx to xml is available from the EORTC intranet.

3 ASSOCIATED DOCUMENTS

Document title	Reference (file name or path)
Analysis report template	ST-006-AF-03

4 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.00	Initial release	Laurence Collette	25 Feb 2011
1.00	No change	Laurence Collette	25 Feb 2014
2	Short Study Report for Health Authorities optional for Interventional Clinical Trials that ended on or after 21 July 2014 (EudraCT) + Minor edits	Laurence Collette	19 Jan 2015
3	No more reference to TSRs . Instructions for automatic reporting = clarifications concerning EudraCT reporting	Laurence Collette	03 Jul 2018