Official Title: An Indian Multicentric Open Label Prospective Phase IV Study to Evaluate Safety and Efficacy of Trastuzumab in Her2 Positive, Node Positive or High Risk Node Negative Breast Cancer as Part of a Treatment Regimen Consisting of Doxorubicin, Cyclophosphamide, With Either Docetaxel or Paclitaxel (AC-TH) or Docetaxel and Carboplatin (TCH)

NCT Number: NCT02419742

Document Date: SAP Version 2: 18-June-2021

STATISTICAL ANALYSIS PLAN

PROTOCOL TITLE	**:**	AN INDIAN MULTICENTRIC OPEN LABEL PROSPECTIVE PHASE IV STUDY TO EVALUATE SAFETY AND EFFICACY OF TRASTUZUMAB IN HER2 POSITIVE, NODE POSITIVE OR HIGH RISK NODE NEGATIVE BREAST CANCER AS PART OF A TREATMENT REGIMEN CONSISTING OF DOXORUBICIN, CYCLOPHOSPHAMIDE, WITH EITHER DOCETAXEL OR PACLITAXEL (AC→TH) OR DOCETAXEL AND CARBOPLATIN (TCH)
PROTOCOL NO.	**:**	ML28714
STUDY DRUG	**:**	Trastuzumab (Ro 45-2317)
VERSION NUMBER	**:**	Version 2.0
IND NUMBER	**:**	4517
EUDRACT Number	**:**	NA
SPONSOR	**:**	Roche Products (India) Pvt. Ltd.
PLAN PREPARED BY	**:**	[redacted] Dr. [redacted]
DATE FINAL	**:**	18 Jun 2021
DATE AMENDED	**:**	NA

Sponsor Signature

I hereby declare that I have reviewed the statistical analysis plan and agree to its form and content. In addition, I confirm that the outlined statistical analysis plan contains all relevant information for the data analysis to be performed in the Protocol No. - **ML28714** study by the Biostatistics Department.

Represented by:

_____ _____

Date

Represented by:

_____ _____

Date

Authorization Document

[redacted]	Biostatistician	[redacted]	18JUN2021
Reviewer	Designation	Signature	Date
[redacted]	Biostatistician	[redacted]	18JUN2021
Reviewer	Designation	Signature	Date
Dr. [redacted]	[redacted]	[redacted]	18JUN2021
Reviewer	Designation	Signature	Date
Dr. [redacted]	[redacted]	[redacted]	18JUN2021
Approver	Designation	Signature	Date

Revision History

Version No.	Version Date	Author	Description of Modifications from Previous Version
1.0	07 Jun 2016	[redacted]	-
2.0	18 Jun 2021	[redacted]	

STATISTICAL ANALYSIS PLAN AMENDMENT RATIONALE

TABLE OF CONTENT

1.0 BACKGROUND

Trastuzumab is produced by a genetically engineered Chinese hamster ovary (CHO) cell line grown in large scale, which secretes Trastuzumab into the culture medium. The antibody is then purified extensively using standard chromatographic and filtration methods.
The addition of trastuzumab to standard chemotherapy increases time to progressive disease or the length of progression-free survival (PFS), and improves survival when given with chemotherapy to women with HER2-positive BC. Clinical benefits are greatest in patients with tumors strongly overexpressing HER2, graded 3+ by IHC, and/or with HER2 gene amplification.
Previously many studies of Phase III were done using single-agent and in combination with standard chemotherapy, such as Herceptin Adjuvant (HERA, BO16348) trial, North Central Cancer Treatment Group trial (NCCTG) N9831 trial, National Surgical Adjuvant Breast and Bowel Project (NSABP) trial B-31, Breast Cancer International Research Group (BCIRG-006) study, Protocol Adjuvant dans le Cancer du Sein (PACS04) trial, Finland Herceptin (FinHer) trial etc.
It is estimated that over one million patients have been treated with trastuzumab IV as of October 2011 (Roche, Data on file).

2.0 STUDY DESIGN

This is a prospective, phase IV, multi-center, single arm, open-label, interventional study in patients with HER2-positive node positive or high risk node negative breast cancer. A total of approximately 109 patients will be enrolled at approximately 10 sites across India. Patients eligible as per the inclusion and exclusion criteria will be treated with either AC→TH or TCH treatment regimens.

The choice of the Trastuzumab treatment regimen (either AC→TH or TCH) will be based on investigators' discretion referring the local prescribing document of Trastuzumab.

AC→TH Regimen:

- Every 3 weeks for 4 cycles, patients in the AC→TH regimen will be receiving 60mg/m2 doxorubicin as a 5 to15 minute I.V. bolus injection followed by 600mg/m2 cyclophosphamide as a 5 to 60 minute I.V. bolus injection.
- On Day 1 of Cycle 5, 4-mg/kg Trastuzumab loading dose will be administered as a 90 minute I.V. infusion as a weekly regimen OR 8-mg/kg Trastuzumab loading dose will be administered as a 90-minute I.V. infusion as a 3 weekly regimen at Investigator's discretion.
- If weekly regimen of Trastuzumab is selected, on Day 8 of Cycle 5, 2 mg/kg Trastuzumab will be administered as a 30-minute I.V. infusion and 2mg/ kg every week as a weekly regimen will be given OR beginning on Day 1 of Cycle 6, Trastuzumab 6 mg/kg will be administered as a 30-minute I.V. infusion every 3 weeks as a 3 weekly regimen for four cycles.
- Docetaxel 100 mg/m2 or Paclitaxel 175 mg/m2 (at investigator's discretion) will be administered as a 1 hour I.V. infusion every 3 weeks for four cycles, beginning on Day 1 of Cycle 5 and continued for up to Cycle 8.
- Three weeks after the last treatment with docetaxel/paclitaxel (i.e., on Day 1 of Cycle 9), 6 mg/kg Trastuzumab will be administered as a 30-minute I.V. infusion every 3 weeks. Trastuzumab treatment will be continued up to cycle 22 (completing a total 52 week trastuzumab therapy).

TCH Regimen:

- Trastuzumab will be given intravenously at a dose of 4 mg/kg loading dose administered as a 90 minute I.V. infusion followed by 2 mg/kg administered as a 30 minute I.V. infusion weekly as a weekly regimen or 8-mg/kg Trastuzumab loading dose administered as a 90 minute I.V. infusion followed by 6 mg/kg administered as a 30 minute I.V. infusion 3 weekly as a 3 weekly regimen during chemotherapy from cycle 1 to 6 at Investigator's discretion.

- Every 3 weeks for six cycles, patients in the TCH regimen will be receiving 75 mg/m2 docetaxel as a 60-minute I.V. bolus injection followed by AUC 6 x (GFR + 25) carboplatin as a 30 to 60 minute I.V. bolus injection.
- After completion of chemotherapy, Trastuzumab will be administered at a dose of 6 mg/kg every 3 weeks up to cycle 18 (completing total 52 week trastuzumab therapy).

The patient will be followed up for duration of 12 months from the last dose of Trastuzumab. All adverse events occurring during treatment and this follow up period will be captured.

There are two types of medicinal products in this study investigational medicinal product and non-investigational medicine.

Investigational Medicinal Products

Test Product

Trastuzumab- Trastuzumab is a humanized IgG1 kappa monoclonal antibody that selectively binds with high affinity to the extracellular domain of the human epidermal growth factor receptor 2 protein (HER2).

Test drug administration: Trastuzumab will be administered as weekly or 3 weekly regimens at the investigator's discretion.

- **Weekly regimen:** Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes followed by subsequent dose of 2 mg/kg as an intravenous infusion over 30 minutes every week.
- **Three weekly regimens:** Initial dose of 8 mg/kg as an intravenous infusion over 90 minutes followed by subsequent dose of 6 mg/kg as an intravenous infusion over 30 minutes every three weeks.

Non-Investigational Medicinal Products

Anthracycline based therapy (AC→TH protocol)

Doxorubicin (60 mg/m2) and cyclophosphamide (600 mg/m2) every 3 weeks for 4 cycles, followed by docetaxel (100 mg/m2 every 3 weeks for 4 cycles) or paclitaxel (175 mg/m2 every 3 weeks for 4 cycles). Trastuzumab is started concurrently with docetaxel or paclitaxel and continued to complete 52 weeks therapy. Dose and frequency of administration of taxanes is at investigator's discretion.

Non-anthracycline based therapy (TCH protocol)

Docetaxel (75 mg/m2) and carboplatin (AUC, 6 mg/ml/min x (GFR + 25)) every 3 week for 6 cycles will be given along with adjuvant therapy of Trastuzumab to complete 52 weeks therapy.

All the chemotherapeutic agents will administered as per the local prescribing information.

2.1 Protocol Synopsis

The protocol number is ML28714 titled as "An Indian Multi-centric open label prospective Phase IV study to evaluate safety and efficacy of Trastuzumab in Her2 Positive, Node Positive or High Risk Node Negative Breast Cancer as part of a treatment regimen consisting of Doxorubicin, Cyclophosphamide, with either Docetaxel or Paclitaxel (AC→TH) or Docetaxel and Carboplatin (TCH)." and the Version is 1.0 amended on 29 July 2013.

2.2 Study Objectives and Endpoints

2.2.1 Study Objectives

2.2.1.1 Primary Objectives

The primary objective for this study is as follows:-

- To evaluate the safety of Trastuzumab for the treatment of HER2-positive node positive or high risk node negative breast cancer patients with regimen consisting of doxorubicin and cyclophosphamide followed by either paclitaxel or Docetaxel (AC→TH) or a regimen consisting of Docetaxel and carboplatin (TCH) in Indian population.

2.2.1.2 Secondary Objectives

The secondary objectives for this study are as follows:-

- To determine the disease free survival (DFS)
- To determine the overall survival (OS)

2.2.2 Study Outcome Measures

2.2.2.1 Efficacy Outcome Measures

The efficacy outcome measures for this study are as follows:

- Disease free survival rate (DFS) and Overall Survival rate (OS)

2.2.2.2 Safety Outcome Measures

The safety outcome measures for this study are as follows:

- All Adverse Event (AE) and Serious Adverse Event (SAE) as well as laboratory abnormalities will be recorded and graded according to the NCI-CTCAE version 4.0.
- Cardiac function will be evaluated by measuring LVEF by echocardiography. Symptomatic left ventricular dysfunction (congestive heart failure [CHF]) will be graded according to the New York Heart Association functional classification.
- AEs and SAEs related to Trastuzumab will be coded using the Medical Dictionary for Regulatory Activities (MedDRA), version 15.1 or greater.
- Patients will undergo a Safety Follow-up, 4 weeks after their last dose of study treatment.
- AEs and SAEs also will be summarized using number and percentage by System Organ Class and Preferred Term. Summaries will be presented for all adverse events and adverse events related to study drug.
- Adverse events will also be summarized by toxicity grade, outcome, seriousness and action taken to the study medication.

2.3 Determination of Sample Size

A total of approximately 109 subjects will be required to conduct a phase IV study to evaluate safety and efficacy of Trastuzumab in HER2 positive node positive or high risk node negative breast cancer by assuming level of significance 5%, incidence of adverse event 65.9%, precision 10% and dropout rate 20%.

Incidence of adverse event in AC→TH group with Grade 3 or 4 hematologic events such as neutropenia, leucopenia, febrile neutropenia, neutropenic infection, anemia, thrombocytopenia, leukemia were 71.5%, 60.3 %, 10.9%, 11.9%, 3.1%, 2.1% and 0.1% respectively. In TCH group incidence of adverse event with Grade 3 or 4 hematologic events such as neutropenia, leucopenia, febrile neutropenia, neutropenic infection, anemia, thrombocytopenia, leukemia were 65.9%, 48.2 %, 9.6 %, 11.2%, 5.8%, 6.1% and 0.1% respectively.

While considering the 71.5%, the highest incidence of adverse event in AC→TH group, sample of size 99 patients will be required. Similarly, by considering the highest incidence of adverse event 65.9% in TCH group, sample of size 109 patients will be required. Also considered the incidence of 68.7% (i.e. mean of 71.5% and 65.9%), 104 patients will be required. The above three calculations, assumed a 5% level of significance, 10% precision and 20% dropout rate. Considering all the above calculation, it is suggested that approximately 109 patients will be required for the proposed study.

2.4 Analysis Timing

The study is estimated to last approximately 4 years, based on an expected 18-month recruitment, 12 months of study treatment and 12 months of follow-up after the treatment.

End of study is defined as the last patient last visit in the follow-up period. The study will end when all patients have been followed for at least 12 months after their last study treatment, or if withdrawal from the study, lost to follow up or death. The final analysis of OS and DFS will be conducted and updated safety parameters will be summarized at this stage.

3.0 STUDY CONDUCT

This is a prospective, phase IV, multi-center, single arm, open-label, interventional study in patients with HER2-positive node positive or high risk node negative breast cancer. A total of approximately 109 patients will be enrolled at approximately 10 sites across India. Patients eligible as per the inclusion and exclusion criteria will be treated with either AC→TH or TCH treatment regimens.

The choice of the Trastuzumab treatment regimen (either AC→TH or TCH) will be based on investigators' discretion referring the local prescribing document of Trastuzumab.

Safety will be carefully evaluated, and the type of data collected and the frequency with which patients are monitored will ensure safety of the patients.

The study team will periodically review patient eligibility and CRF data to ensure that the study is compliant with Good Clinical Practice.

4.0 STATISTICAL METHODS

The demographic characteristics will be summarized for all the patients enrolled into the study. All baseline & demographic data and general medical history will be summarized at screening visit. Descriptive statistics such as number of non-missing observations (n), mean, median, Standard Deviation (SD), 1st Quartile (Q1), 3rd Quartile (Q3), minimum and maximum will be estimated for continuous variables (e.g. Age, Height, etc.) and frequency counts and percentages will be employed for categorical variables (e.g. Gender, Race, etc.). All statistical tests will be done at 5 % significance level and $p \leq 0.05$ indicates the significance. Two-sided 95% confidence interval (CI) will be constructed, wherever appropriate.

All baseline summaries and efficacy analyses will be based on the intent-to-treat (ITT) population. This will be defined as all enrolled patients. All safety summaries and analysis will be based on the safety population, defined as all enrolled patients who receive at least one dose of study medication.

Disease free survival (DFS) and Overall survival (OS) will be analyzed by the Kaplan-Meier (KM) approach. The median Disease free survival time and median overall survival time with 95% confidence interval will be estimated using Kaplan Meier method and KM plots will also be provided. Log rank test will be used to compare the median survival time between subjects with ECOG PS 0 and ECOG PS 1-2 at baseline for DFS and OS.
Efficacy variables will be summarized for the intent-to-treat (ITT) population.

4.1 Analysis Population

4.1.1 Intent–to-Treat (ITT) population

Intent-to-Treat (ITT) population is defined as all the patients who are enrolled in the study.

4.1.2 Safety population

Safety population will include all those patients who have received at least one dose of study medication.

4.2 Analysis of Study Conduct

This is a prospective, phase IV, multi-center, single arm, open-label, interventional study in patients with HER2-positive node positive or high risk node negative breast cancer. A total of approximately 109 patients will be enrolled at approximately 10 sites across India. Patients eligible as per the inclusion and exclusion criteria will be treated with either AC→TH or TCH treatment regimens.

The analysis for different parameters is described below:

4.2.1 Demographics and Baseline Characteristics

Subject demographics include Age, Sex and Race.

The demographic characteristics will be summarized for all the patients enrolled into the study. All baseline & demographic data and general medical history will be summarized at screening visit. Descriptive statistics such as number of non-missing observations (n), mean, median, Standard Deviation (SD), 1st Quartile (Q1), 3rd Quartile (Q3), minimum and maximum will be estimated for continuous variables (e.g. Age, Height etc.) and frequency counts and percentages will be employed for categorical variables (e.g. Gender, Race etc.). All statistical tests will be done at 5 % significance level and $p \leq 0.05$ indicates the significance. Two – sided 95% confidence interval (CI) will be constructed, wherever appropriate.

Medical/Surgical History includes clinically significant diseases, surgeries, cancer history, reproductive status, smoking, alcoholic and drug abuse history, prior cancer therapy, prior cancer surgery will be summarized by frequency counts and percentages.

All demography and baseline characteristics (collected at either the screening or baseline) will be summarized using the ITT population.

4.3 Efficacy and Safety Analyses

4.3.1 Efficacy Analyses

The efficacy outcomes include Disease free survival rate and Overall survival rate. DFS is defined as time from the date of first study treatment to the date of local, regional or distant recurrence, contra-lateral breast cancer or death due to any cause. OS is defined as time from the date of first study treatment until date of death, regardless of the cause of death.

The median Disease free survival time and median overall survival time with 95% confidence interval will be estimated using Kaplan Meier method and KM plots will also be provided. Log rank test will be used to compare the median survival time between subjects with ECOG PS 0 and ECOG PS 1-2 at baseline for DFS and OS.

4.3.2 Safety Analyses

Safety measurements include adverse events, laboratory tests (hematology and biochemistry), vital signs, electrocardiograms, physical examinations, and toxicity evaluations. Toxicities will be evaluated at each course of therapy using the NCICTCAE version 4.0 or a non-CTC grading scale for toxicities that are not covered by the NCI CTC.

Adverse Events (AEs) and Serious Adverse Events (SAEs) related to Trastuzumab will be summarized by using number and percentage (Incidence of AEs and SAEs). AEs and SAEs related to Trastuzumab will be coded using MedDRA, version 15.1 or greater. AEs and SAEs also will be summarized using number and percentage by System Organ Class and Preferred Term. Summaries will be presented for all adverse events and adverse events related to study drug. Adverse events will also be summarized by toxicity grade, outcome, seriousness and action taken to the study medication.

All the Laboratory evaluations (hematology & biochemistry) will be considered at baseline and completion/early termination visits. Descriptive statistics such as n, mean, median, standard deviation (SD), Q1, Q3, minimum (Min), and maximum (Max) will be provided for all. Change from Baseline will be calculated for all the available hematology and biochemistry parameters as specified in the eCRF pages. Mean change from baseline will be compared using paired t test or Wilcoxon signed-rank test based on normality assumption.

ECOG performance status will be collected at baseline and every 4 Cycles during treatment period. Counts and percentages will be reported in the results. Generalized Cochrane Q test will be used to compare the ECOG PS between baseline and follow-up visits. Patient data will be analyzed for evidence of cumulative toxicity with repeated courses of therapy.

Summary of ECG status will be evaluated at all visits. Counts and percentages will be reported in the results. HER-2 testing will be collected at Baseline/Screening. This will be summarized using number and percentage.

LVEF will be collected for every 3 months or and percentage change from baseline will be reported for every 3 months. Mean change from baseline will be compared using paired t test or Wilcoxon signed-rank test based on normality assumption. All statistical tests will be done at 5 % significance level and $p \leq 0.05$indicate the significance.

4.4 Missing Data

No statistical imputation method will be applied for any missing values.

4.5 Interim Analyses

An Interim Analysis was done for safety once all enrolled patients have received at least one dose of the IP.

4.6 Additional Analyses

If any additional statistical analyses required during the final analysis, appropriate methods will be used, and any changes, including the rationale for use, will be documented via Statistical Analysis Plan amendment. Any deviations from the planned analyses or prospective amendments to the statistical analysis plan will be documented in the Clinical Study Report (CSR).

4.7 Data Listings

All CRF data, as well as any outcomes derived from the data, will be summarised in detailed data listings. Patient data listings will be presented for all patients enrolled into the study.

4.8 Plots and Figures

The plots and graphs will be presented to illustrate the analysis of safety and efficacy.

- A K-M plot of survival probability versus time will be generated to see the overall survival profile of the patients in each regimen and for overall also.
- A K-M plot of DFS probability versus time will be generated to see the DFS profile of the patients in each regimen and for overall also.
- A multiple bar chart will be generated to understand the ECOG performance status at each visit.
- A graph of LVEF over a period of time for all patients (Including mean and median)

5.0 REFERENCES

1. ICH E3: Structure and content of Clinical Study Reports, November 1995, Committee for Proprietary Medicinal Products.
2. ICH E9: Statistical Principles for Clinical Trials, September 1998, Committee for Proprietary Medicinal Products.

APPENDIX 1 PROTOCOL SYNOPSIS

PROTOCOL SYNOPSIS	
TITLE:	**AN INDIAN MULTICENTRIC OPEN LABEL PROSPECTIVE PHASE IV STUDY TO EVALUATE SAFETY AND EFFICACY OF TRASTUZUMAB IN HER2 POSITIVE, NODE POSITIVE OR HIGH RISK NODE NEGATIVE BREAST CANCER AS PART OF A TREATMENT REGIMEN CONSISTING OF DOXORUBICIN, CYCLOPHOSPHAMIDE, WITH EITHER DOCETAXEL OR PACLITAXEL (AC→TH) OR DOCETAXEL AND CARBOPLATIN (TCH)**
PROTOCOL NUMBER:	ML28714
VERSION NUMBER:	1.0
EUDRACT NUMBER:	NA
IND NUMBER:	NA
TEST PRODUCT:	Trastuzumab
PHASE:	IV Post marketing study
INDICATION:	HER2 positive early breast cancer
SPONSOR:	Roche Products India Pvt. Ltd. The View, 2nd floor, 165, Dr Annie Besant Road, Worli, Mumbai-400018, India

APPENDIX 2 SCHEDULE OF ASSESSMENTS

Appendix 1- Schedule of Assessments (AC→TH protocol)

	Screening and baseline	Treatment Period (Cycle/Week)																						Unplanned Visit [a]	Completion/Early Termination Visit [b]	Follow-Up [c]
Week	–2 to –1	1	4	7	10	13	16	19	22	25	28	31	34	37	40	43	46	49	53	56	59	62	65			
Cycle		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
Informed consent	X																									
Inclusion & Exclusion Criteria	X																									
Demographic data	X																									
General medical history and baseline conditions	X																									
Vital signs [d]	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Weight	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Height	X																									
Physical examination [e]	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Hematology [f]	X																								x	
Histology	X																									

	Screening and baseline	Treatment Period (Cycle/Week)																						Unplanned Visit [a]	Completion/Early Termination Visit [b]	Follow-Up [c]
Week	–2 to –1	1	4	7	10	13	16	19	22	25	28	31	34	37	40	43	46	49	53	56	59	62	65			
Cycle		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
Radiography (mammogram)	X																								x	
CT/MRI	X																								x	
Biochemistry [g]	X																								x	
LVEF(measured by Echocardiography)	X					x				x				x				x				x			x	x
12 Lead ECG	X					x				x				x				x				x			x	x
HER2 testing	X																									
ECOG	X					x				x				x				x				x			x	x
Chemotherapy [h]		x	x	x	x	x	x	x	x																	
Trastuzumab administration [i]						x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Routine Breast Cancer follow up [j]	X									x								x							x	

	Screening and baseline	Treatment Period (Cycle/Week)																						Unplanned Visit [a]	Completion/Early Termination Visit [b]	Follow-Up [c]
Week	−2 to −1	1	4	7	10	13	16	19	22	25	28	31	34	37	40	43	46	49	53	56	59	62	65			
Cycle		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22			
Treatment compliance		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Concomitant medications	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Adverse events	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Survival																										x

eCRF = electronic Case Report Form.

Notes: All assessments should be performed within 3 days of the scheduled visit, unless otherwise specified. On treatment days, all assessments should be performed prior to dosing, unless otherwise specified.

[a] Visit not specified by the protocol.

[b] Patients who complete the study or discontinue from the study early will be asked to return to the clinic 4 weeks after the last dose of study drug for a follow-up visit.

[c] Follow-up information will be collected via telephone calls and/or clinic visits every 6 months until death, loss to follow-up, or study termination by the Sponsor.

[d] Respiratory rate, pulse rate, temperature, systolic and diastolic blood pressure, before and after trastuzumab infusion.

[e] Record abnormalities observed at baseline on the General Medical History and Baseline Conditions eCRF. New or worsening abnormalities should be recorded on the Adverse Event eCRF.

[f] Includes hemoglobin, hematocrit, platelet count, RBC count, WBC count, absolute differential count (neutrophils, eosinophils, lymphocytes, monocytes, basophils, other cells). Hematology assessment will also be performed during the study, if clinically indicated.

[g] Includes sodium, potassium, chloride, bicarbonate, fasting glucose, BUN or urea, creatinine, calcium, total and direct bilirubin, total protein, albumin, ALT, AST, alkaline phosphatase, phosphorus, magnesium, LDH, creatine phosphokinase, uric acid. Biochemistry assessment will also be performed during the study, if clinically indicated.

[h] Doxorubicin (60 mg/m^2) and cyclophosphamide (600 mg/m^2) every 3 weeks for 4 cycles (Cycles 1 to 4), followed by docetaxel (100 mg/m^2) or paclitaxel (175 mg/m^2 every 3 weeks for 4 cycles (Cycles 5 to 8).

[i] The selection of the dosage regimen from cycle 5 to 8 (weekly or 3 weekly) at investigators' discretion. After completion of chemotherapy, Trastuzumab will be administered every 3 weeks from cycle 9 to cycle 22 (so as to complete total of 52 week Trastuzumab therapy).

[j] History/physical examination, mammography and pelvic examination will be carried out during the routine breast cancer follow-up.

Appendix 2 - Schedule of Assessments (TCH protocol)

	Screening and baseline	Treatment Period (Cycle/Week)																	Unplanned Visit [a]	Completion/Early Termination Visit [b]	Follow-Up [c]
Week	–2 to –1	1	4	7	10	13	16	19	22	25	28	31	34	37	40	43	46	49	53			
Cycle		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18			
Informed consent	X																					
Inclusion & Exclusion Criteria	X																					
Demographic data	X																					
General medical history and baseline conditions	X																					
Vital signs [d]	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Weight	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Height	X																					
Physical examination [e]	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Hematology [f]	X																				x	
Histology	X																					

	Screening and baseline	Treatment Period (Cycle/Week)																		Unplanned Visit [a]	Completion/Early Termination Visit [b]	Follow-Up [c]
Week	−2 to −1	1	4	7	10	13	16	19	22	25	28	31	34	37	40	43	46	49	53			
Cycle		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18			
Radiography (mamogram)	X																				x	x
CT/MRI	X																				x	x
Biochemistry [g]	X																				x	
LVEF (measured by Echocardiography)	X					x				x				x				x			x	x
12 Lead ECG	X					x				x				x				x			x	x
HER2 testing	X																					
ECOG	X					x				x				x				x			x	x
Chemotherapy [h]		x	x	x	x	x	x															
Trastuzumab administration [i]		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			

	Screening and baseline	Treatment Period (Cycle/Week)																		Unplanned Visit [a]	Completion/Early Termination Visit [b]	Follow-Up [c]
Week	−2 to −1	1	4	7	10	13	16	19	22	25	28	31	34	37	40	43	46	49	53			
Cycle		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18			
Routine Breast Cancer follow up [j]	X									x								x			x	
Treatment compliance		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Concomitant medications	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Adverse events	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Survival																						x

eCRF = electronic Case Report Form.

Notes: All assessments should be performed within 3 days of the scheduled visit, unless otherwise specified. On treatment days, all assessments should be performed prior to dosing, unless otherwise specified.

[a] Visit not specified by the protocol.

[b] Patients who complete the study or discontinue from the study early will be asked to return to the clinic 4 weeks after the last dose of study drug for a follow-up visit.

[c] Follow-up information will be collected via telephone calls and/or clinic visits every 6 months until death, loss to follow-up, or study termination by the Sponsor.

[d] Respiratory rate, pulse rate, temperature, systolic and diastolic blood pressure, before and after trastuzumab infusion.

[e] Record abnormalities observed at baseline on the General Medical History and Baseline Conditions eCRF. New or worsening abnormalities should be recorded on the Adverse Event eCRF.

[f] Includes hemoglobin, hematocrit, platelet count, RBC count, WBC count, absolute differential count (neutrophils, eosinophils, lymphocytes, monocytes, basophils, other cells). Hematology assessment will also be performed during the study, if clinically indicated.

[g] Includes sodium, potassium, chloride, bicarbonate, fasting glucose, BUN or urea, creatinine, calcium, total and direct bilirubin, total protein, albumin, ALT, AST, alkaline phosphatase, phosphorus, magnesium, LDH, creatine phosphokinase, uric acid. Biochemistry assessment will also be performed during the study, if clinically indicated.

[h] Docetaxel (75 mg/m2) and carboplatin (AUC, 6 mg/ml/min x (GFR + 25)) every 3 week for 6 cycles.

[i] The selection of the dosage regimen from cycle 1 to 6 (weekly or 3 weekly) at investigators' discretion. After completion of chemotherapy, Trastuzumab will be administered every 3 weeks from cycle 7 to cycle 18 (so as to complete 52 week Trastuzumab therapy).

[j] History/physical examination, mammography and pelvic examination will be carried out during the routine breast cancer follow-up.

14.1 Demographics and Baseline Characteristics

14.1.1 Patient Disposition

Table 14.1.1.1 Summary of Inclusion/Exclusion Criteria- Enrolled Population (N=XXX)

Inclusion/Exclusion Criteria, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Number of Subjects Screened	XXX		
Number of Subjects Enrolled [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of Subjects Enrolled meeting all Inclusion Criteria	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of Subjects meeting at least one exclusion criteria	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source: Listing 16.2.3

Note: [1] Percentage will be calculated by taking respective column header count as denominator.

General Note:
- Subjects who are meeting inclusion and exclusion criteria will be considered for eligibility analysis.
- Subjects who are eligible will be considered to enroll into the study.

Table 14.1.1.2 Summary of Patient Disposition- Enrolled Population (N=XXX)

Patient Disposition, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Population			
ITT Population	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Safety Population	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Patients who completed the protocol			
Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Reason for discontinuation			
Adverse Event	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Disease progression	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Insufficient therapeutic response	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Lost to follow Up	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Withdrew Consent	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Investigator's decision	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Other	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.1, 16.2.2.1 and 16.2.2.2

Note:

[1] Percentages will be calculated using respective column header group count as denominator.

Table 14.1.1.3 Summary of Patient Disposition by Site- Enrolled Population (N=XXX)

Site, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Site 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Site 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Site 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Site 4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Site 5	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
……	**……**	**……**	**……**
Site n	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.1

Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.

Table 14.1.1.4 Summary of Subject Follow-up Rate at each Visit- Enrolled Population (N=XXX)

Visit, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Screening and Baseline	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 5	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 6	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
……	**……**	**……**	**……**

Source Data: Listing 16.2.1

Note:

[1] Percentages will be calculated using respective column header group count as denominator.

14.1.2 Demographic and Baseline Characteristics

Table 14.1.2.1 Summary of Patient Demographics at Screening- ITT Population (N=XXX)

Demographics	Statistics / Category, n(%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Age (years) [2]				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q3	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Sex				
	Male	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Female	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Race				
	Indian	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Others	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.4.1

Note:

[1]Percentages will be calculated using respective column header group count as denominator.

[2]If Date of Birth date is given then to calculate the Age by following formula: Age = {[Date of Informed Consent signed (Screening Date) – Date of Birth +1] /365.25

[3]If a particular parameter measurement is not captured, it will be displayed under 'Missing' category.

Table 14.1.2.2 Summary of Medical History at Screening- ITT Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
System Organ Class 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
……	……	……	……
System Organ Class 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
……	……	……	……

Source Data: Listing 16.2.4.2
Note:
[1]Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Medical Conditions will be coded using MedDRA version 21.1 or later

Table 14.1.2.3 Summary of Cancer History and Reproductive Status at Screening- ITT Population (N=XXX)

History	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cancer History				
Stage of Cancer(During Diagnosis)				
	Stage IA	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IB	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIA	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIB	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIIA	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIIB	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IV	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Current Stage of Cancer				
	Stage IA	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IB	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIA	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIB	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIIA	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IIIB	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Stage IV	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Reproductive Status				
Reproductive Status				
	Post-menopausal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Surgically Sterile	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Uses contraception	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Other	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Menopausal age (years)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q3	XX.X	XX.X	XX.X

	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
No. of Live Births				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q3	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.4.3, Listing 16.2.4.4

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2]If a particular parameter measurement is not captured, it will be displayed under ‘Missing’ category.

Table 14.1.2.4 Summary of Smoking, Alcoholic and Drug Abuse History at Screening- ITT Population (N=XXX)

History	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Smoking Status				
	Smoker	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Former Smoker	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Never Smoked	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If "Smoking status" is Smoker, Average no. of Cigarettes per day [3]				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q3	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Chew Tobacco				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If "Yes", Average quantity (g/day)[4]				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q3	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Alcoholic Status				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If "Yes",				
Alcohol Taken [5]				
	Occasional	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Light	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Moderate	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Heavy	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Drug Abuse Status				
	Positive	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Negative	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.4.5
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, it will be displayed under 'Missing' category.
[3] Percentages will be calculated using count "Smoker" of "Smoking status" as denominator.
[4] Percentages will be calculated using count "Yes" of "Chew Tobacco" as denominator.
[5] Percentages will be calculated using count "Yes" of "Alcoholic Status" as denominator.

Table 14.1.2.5 Summary of Prior Cancer Surgery at Screening- ITT Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
System Organ Class 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
……	……	……	……
System Organ Class 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
……	……	……	……

Source Data: Listing 16.2.7
Note:
[1]Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Prior Cancer Surgery will be coded using MedDRA version 21.1 or later.

Table 14.1.2.6 Summary of Histology and Mammogram at Screening- ITT Population (N=XXX)

History	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Histology				
Biopsy performed				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If "Yes" , Result Grade [2]				
	Grade 1 (low grade)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Grade 2(intermediate grade)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Grade 3 (high grade)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Mammogram				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Findings				
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.4.7, Listing 16.2.8.4
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using count "Yes" of "Biopsy performed" as denominator.

Table 14.1.2.7 Summary of Prior Medication at Screening- ITT Population (N=XXX)

Therapeutic Class, Generic name, n (%) [1],[2]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)	Count of Ongoing [3]
Therapeutic Class 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	
Generic Name 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Generic Name 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Generic Name 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	……	……	……	……

Source Data: Listing 16.4.6
Note:
[1] Percentages of Therapeutic class will be calculated from respective column header group count as denominator in percentage calculation.
[2] Percentages of Generic Name will be calculated from Respective Class counts.
[3] Percentages of Count of Ongoing will be calculated from respective generic name counts.

Table 14.1.2.8 Summary of Vital Signs at Screening- ITT Population (N=XXX)

Vital Signs [1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Respiratory Rate (breathes/min)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pulse Rate (Beats/min)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Blood Pressure (mmHg)				
Systolic	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Diastolic	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX

	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Temperature (°C)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Weight (kgs.)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Height (cms.)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.4.1

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, it will be displayed under ‘Missing’ category.

Table 14.1.2.9 Summary of Physical Examination at Screening- ITT Population (N=XXX)

System/Result/Significance [1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Heart				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Lungs				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Abdomen				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Neurological				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Head				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Ears, nose and throat				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Neck				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Extremities				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Lymph nodes				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Skin				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Musculoskeletal				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Others				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.4.2
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using count “Done” of “Body System” as denominator.

Table 14.1.2.10 Summary of Investigations done at Screening- ITT Population (N=XXX)

Investigations [1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
12 Lead Electrocardiogram				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
LVEF				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Value (%)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min:Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
HER2 Testing				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Method [2]				
	IHC	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	FISH	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

	Both	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If IHC [3]				
Observation	0	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	+1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	+2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	+3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If FISH [3]				
Observation	Positive	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Negative	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Brain CT/MRI				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Bone Scan				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Liver Imaging				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Clinical Significance [2]				
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.4.7, Listing 16.2.8.3, Listing 16.2.8.4
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages for clinical significance (CS/NCS) will be calculated using count "Done" of "Investigations" as denominator.
[3] Percentages for HER2 testing will be calculated using count "Done" as denominator.

Table 14.1.2.11 Summary of Routine Breast Cancer Follow Up at Screening- ITT Population (N=XXX)

Breast Cancer History[1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Familial History				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Physical Examination				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Presence of symptoms				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If Yes, then symptoms [2]				
	New lumps	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Bone pain	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Chest pain	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Dyspnea	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Abdominal pain	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Persistent headaches	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Others	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Mammography				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If Done, Results of Mammogram [3]				
	Normal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Abnormal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pelvic Examination				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If Done, Results of Pelvic Examination [4]				
	Normal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Abnormal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.4.3.1
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using count “Yes” of “Presence of symptoms” as denominator.
[3] Percentages will be calculated using count “Done” of “Mammography” as denominator.
[4] Percentages will be calculated using count “Done” of “Pelvic Examination” as denominator.

14.2 Efficacy Analysis

Table 14.2.1.1 Summary of Disease Free Survival at End of Study- ITT Population (N=XXX)

Visits	Category, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
End of Study				
	Disease Free Patients	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.6.1

Note:

[1] Percentage will be calculated taking "n" count as denominator.

[2] "n" denotes the number of subjects who would have completed "X visits" in study from the date of randomization

.

Table 14.2.1.2 Summary on Disease Progression by K-M Analysis- ITT Population (N=XXX)

Category, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Number (%) of Patients who achieved Disease Progression	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number (%) of censored Patients	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Median duration of Disease Progression (95 % CI) [2]	XX.X (XX.XX : XX.XX)	XX.X (XX.XX : XX.XX)	XX.X (XX.XX : XX.XX)

Source Data: Listing 16.2.6.1

Note:

[1] Percentage will be calculated taking respective column header group count as denominator.

[2] The median duration of Disease Progression will be estimated by Kaplan-Meier method and also 95 % confidence interval will be calculated for the median duration of Disease Progression.

General Note:

- Events: It will be the documented Disease Progression.
- Censoring: Subjects for whom disease progression is not observed during study period, drop outs and lost-to-follow up subjects will be censored at the time of last follow-up visit.

Table 14.2.1.3 Summary of Median Survival Time between ECOG sub-groups for Disease Free Survival- ITT Population (N=XXX)

Category, n (%)	Overall (N=XX)		Trastuzumab with AC→TH Regimen (n=XX)		Trastuzumab with TCH Regimen (n=XX)	
	ECOG PS 0	**ECOG PS 1-2**	**ECOG PS 0**	**ECOG PS 1-2**	**ECOG PS 0**	**ECOG PS 1-2**
Median duration of Overall Survival [1]	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
p-value (Using Log-rank Test)[2]	0.XXXX		0.XXXX		0.XXXX	

Source Data: Listing 16.2.6.1

Note:

[1] The median duration of overall survival will be estimated by Kaplan-Meier method.

[2] The Log-rank Test will be used to compare the median survival time between the subjects with ECOG PS 0 and ECOG PS 1-2 at Baseline.

General Note:

- Events will be the documented Disease Free.
- Censoring: Subjects without occurrence of death during study period, drop outs and lost-to-follow up subjects will be censored at the time of last follow-up visit.

Programming Note:

- The duration will be considered as difference between first drug administrations to date of documented death of any patient.

Table 14.2.1.4 Summary of Overall Survival at Each Visit - ITT Population (N=XXX)

Visits	Category, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
End of Study				
	Alive Patients	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.6.1

Note:

[1] "n" denotes the number of subjects who would have completed X months in study from the date of randomization

[2] Percentage will be calculated taking respective "n" count as denominator.

Table 14.2.1.5 Summary of Overall Survival by K-M Analysis-ITTPopulation (N=XXX)

Category, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Number (%) of Patients who died	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number (%) of censored Patients	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Median duration of Overall Survival (90 % CI) [2]	XX.X (XX.XX : XX.XX)	XX.X (XX.XX : XX.XX)	XX.X (XX.XX : XX.XX)

Source Data: Listing 16.2.1

Note:

[1] Percentage will be calculated taking respective column header group count as denominator.

[2] The median duration of overall survival will be estimated by Kaplan-Meier method and also 95% confidence interval will be calculated for the median duration of overall survival.

General Note:

- Events: It will be the documented Death.
- Censoring: Subjects who are alive during study period, drop outs and lost-to-follow up subjects will be censored at the time of last follow-up visit.

Programming Note:

- The duration will be considered as difference between first drug administrations to date of documented death of any patient.
- The probability of survival at any visit will be derived by the "OUTSURV =" option of PROC LIFETEST. The probability from Survival Distribution Function in dataset derived by "OUTSURV =" option will be represented at each specified time point.
- Same mock-up will be used to generate the table for Aggressive vs. Non-aggressive by specifying "Disease Status" as STRATA in PROC LIFETEST with change in table number and table title as:

Table 14.2.1.6 Summary of Overall Survival by K-M Analysis for Disease Status

Table 14.2.1.7 Summary of Median Survival Time between ECOG sub-groups for Overall Survival- ITT Population (N=XXX)

Category, n (%)	Overall (N=XX)		Trastuzumab with AC→TH Regimen (n=XX)		Trastuzumab with TCH Regimen (n=XX)	
	ECOG PS 0	ECOG PS 1-2	ECOG PS 0	ECOG PS 1-2	ECOG PS 0	ECOG PS 1-2
Median duration of Overall Survival [1]	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
p-value (Using Log-rank Test)[2]	0.XXXX		0.XXXX		0.XXXX	

Source Data: Listing 16.2.6.1

Note:

[1] The median duration of overall survival will be estimated by Kaplan-Meier method.

[2] The Log-rank Test will be used to compare the median survival time between the subjects with ECOG PS 0 and ECOG PS 1-2 at Baseline.

General Note:

- Events will be the documented death of the patient due to any cause.
- Censoring: Subjects without occurrence of death during study period, dropouts and lost-to-follow up subjects will be censored at the time of last follow-up visit.

Programming Note:

- The duration will be considered as difference between first drug administrations to date of documented death of any patient.

14.3 Safety Analysis

14.3.1 Adverse Events

Table 14.3.1.1 Overall Summary of Adverse Events- Safety Population (N=XXX)

Events	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total Number of AEs Reported	XX	XX	XX
Subjects Reporting Any AEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting 1 AE	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting >1 AE	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting No AEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of AEs with Intensity (NCI -CTCAE v4.0): [2]			
Grade 0	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 5			
Number of AEs with Relationship to study drug:[2]			
Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Not Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of AEs by Action taken:[2]			
Dose modification	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Stop Therapy	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Dose delay	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
No action	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Number of AEs by Event Outcome:[2]			
Resolved	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Resolved-with Sequelae	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Ongoing	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Unknown	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting AEs Leading to Discontinuation [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Serious AEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.7.1

Note:

[1] Percentage will be calculated by taking respective column header group count as denominator.

[2] Percentage will be calculated by taking count of 'Total Number of AEs Reported' in corresponding treatment group as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later.
- AEs: Adverse Events

Table 14.3.1.2 Overall Summary of Treatment Emergent Adverse Events -Safety Population (N=XXX)

Events	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total Number of TEAEs Reported	XX	XX	XX
Subjects Reporting Any TEAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting 1 TEAE	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting >1 TEAE	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting No TEAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of TEAEs with Intensity (NCI -CTCAE v4.0): [2]			
Grade 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 5			
Number of TEAEs with Relationship to study drug:[2]			
Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Not Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of TEAEs by Action taken:[2]			
No action taken	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Infusion Slow Down	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Infusion Interrupted	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Appropriate Medical Therapies Administered	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of TEAEs by Event Outcome:[2]			
Resolved No-Sequelae	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Resolved-with Sequelae	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Unresolved	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting TEAEs Leading to Withdraw [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Serious TEAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.7

Note:

[1] Percentage will be calculated by taking respective column header group count as denominator.

[2] Percentage will be calculated by taking count of 'Total Number of TEAEs Reported' in corresponding treatment group as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later.
- TEAEs: Treatment Emergent Adverse Events

Table 14.3.1.3 Overall Summary of Non-Treatment Emergent Adverse Events-Safety Population (N=XXX)

Events	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total Number of non-TEAEs Reported	XX	XX	XX
Subjects Reporting Any non-TEAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting 1 **non-TEAE**	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting >1 **non-TEAE**	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting No non-TEAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of non-TEAEs with Intensity (NCI -CTCAE v4.0): [2]			
Grade 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 5			
Number of non-TEAEs with Relationship to study drug:[2]			
Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Not Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of non-TEAEs by Action taken:[2]			
No action taken	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Infusion Slow Down	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Infusion Interrupted	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Appropriate Medical Therapies Administered	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of non-TEAEs by Event Outcome:[2]			
Resolved No-Sequelae	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Resolved-with Sequelae	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Unresolved	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting non-TEAEs Leading to Withdraw [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Serious non-TEAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.7

Note:

[1] Percentage will be calculated by taking respective column header group count as denominator.

[2] Percentage will be calculated by taking count of 'Total Number of non TEAEs Reported' in corresponding treatment group as denominator.

General Note:

- Non Treatment Emergent Adverse events will be coded using MedDRA version 22.1 or later.
- Non TEAEs: Non Treatment Emergent Adverse events

Table 14.3.1.4 Summary of Adverse Events (including subjects reporting SAEs) by MedDRA System Organ Class and Preferred Term-Safety Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total number of subjects with at least one Adverse Events(including subjects reporting SAEs)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Total number of Adverse Events	XX	XX	XX
System Organ Class 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……
System Organ Class 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……

Source Data: Listing 16.2.7

Note:

[1] Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later.
- All Adverse events are presented as: number of subjects (percent of subjects) [number of events].
- Subjects may have reported more than one event per system organ class or preferred term. Subjects will be only counted once for each system organ class or preferred term.

Table 14.3.1.5 Summary of Adverse Events (excluding subjects reporting SAEs) by MedDRA System Organ Class and Preferred Term-Safety Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total number of subjects with at least one Adverse Events(excluding subjects reporting SAEs)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Total number of Adverse Events	XX	XX	XX
System Organ Class 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……
System Organ Class 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……

Source Data: Listing 16.2.7
Note:
[1] Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later
- All Adverse events are presented as: number of subjects (percent of subjects) [number of events].
- Subjects may have reported more than one event per system organ class or preferred term. Subjects will be only counted once for each system organ class or preferred term.

Table 14.3.1.6 Summary of Adverse Events by MedDRA System Organ Class and Preferred Term by Intensity-Safety Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Intensity	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total number of subjects with at least one Adverse Events (Including subjects reporting SAEs)		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Total number of Adverse Events		XX	XX	XX
System Organ Class 1		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1		XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 3	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 4	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 5	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2		XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 3	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 4	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Grade 5	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……	……

Source Data: Listing 16.2.7.1
Note:
[1] Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later
- All Adverse events are presented as: number of subjects (percent of subjects) [number of events].

- Subjects may have reported more than one event per system organ class or preferred term. Subjects will be only counted once for each system organ class or preferred term.

Table 14.3.1.7 Summary of Adverse Events by MedDRA System Organ Class and Preferred Term by Action Taken-Safety Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Action Taken	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total number of subjects with at least one Adverse Events (including subjects with SAEs)		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Total number of Adverse Events		XX	XX	XX
System Organ Class 1		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1		XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Dose modification	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Stop Therapy	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Dose delay	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	No action	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2		XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Dose modification	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Stop Therapy	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Dose delay	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	No action	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……	……

Source Data: Listing 16.2.7.1
Note:
[1] Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later
- All Adverse events are presented as: number of subjects (percent of subjects) [number of events].
- Subjects may have reported more than one event per system organ class or preferred term. Subjects will be only counted once for each system organ class or preferred term.

Table 14.3.1.8 Summary of Adverse Events by MedDRA System Organ Class and Preferred Term by Event Outcome-Safety Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Event Outcome	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total number of subjects with at least one Adverse Events (including subjects reporting SAEs)		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Total number of Adverse Events		XX	XX	XX
System Organ Class 1		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1		XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Resolved	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Resolved-with Sequelae	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Ongoing	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Death	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Unknown	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2		XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Resolved	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Resolved-with Sequelae	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Ongoing	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Death	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
	Unknown	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……	……

Source Data: Listing 16.2.7.1
Note:
[1] Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Adverse events will be coded using MedDRA version 22.1 or later
- All Adverse events are presented as: number of subjects (percent of subjects) [number of events].

- Subjects may have reported more than one event per system organ class or preferred term. Subjects will be only counted once for each system organ class or preferred term.

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14.3.2 Serious Adverse Events

Table 14.3.2.1 Overall Summary of Serious Adverse Events -Safety Population (N=XXX)

Events	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total Number of SAEs Reported	XX	XX	XX
Subjects Reporting Any SAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting 1 SAE	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting >1 SAE	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting No SAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of SAEs with Intensity (NCI -CTCAE v4.0): [2]			
Grade 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Grade 5			
Number of SAEs with Relationship to study drug:[2]			
Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Not Related	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Number of SAEs by Action taken:[2]			
Dose modification	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Stop Therapy or discontinuation of treatment	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Dose delay	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
No action	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Number of SAEs by Event Outcome:[2]			
Resolved	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Resolved-with Sequelae	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Ongoing	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Unknown	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting SAEs Leading to Discontinuation [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Serious SAEs [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Subjects Reporting Death	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Source Data: Listing 16.2.7.1

Note:

[1] Percentage will be calculated by taking respective column header group count as denominator.

[2] Percentage will be calculated by taking count of 'Total Number of SAEs Reported' in corresponding treatment group as denominator.

General Note:

- Serious Adverse events will be coded using MedDRA version 22.1 or later.
- SAEs: Serious Adverse Events

Table 14.3.2.2 Summary of Serious Adverse Events by MedDRA System Organ Class and Preferred Term -Safety Population (N=XXX)

System Organ Class/Preferred Term, n (%) [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Total number of subjects with at least one serious adverse event	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Total number of serious adverse events	XX	XX	XX
System Organ Class 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……
System Organ Class 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Preferred Term 1	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
Preferred Term 2	XX (XX.X %) [XX]	XX (XX.X %) [XX]	XX (XX.X %) [XX]
……	……	……	……

Source Data: Listing 16.2.7.1
Note:
[1] Percentage will be calculated by taking respective column header group count as denominator.

General Note:

- Serious Adverse events will be coded using MedDRA version 22.1 or later
- All Serious Adverse events are presented as: number of subjects (percent of subjects) [number of events].
- Subjects might have reported more than one event per system organ class or preferred term. Subjects will be only counted once for each system organ class or preferred term.

14.3.3 Concomitant Medication

Table 14.3.3.1 Summary of Concomitant Medication Assessment -Safety Population (N=XXX)

Therapeutic Class, n (%) [1]	Generic name, n (%) [2]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)	Count of Ongoing [3]
Therapeutic Class 1		XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	
	Generic Name 1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Generic Name 2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Generic Name 3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	……	……	……	……	……

Source Data: Listing 16.4.6
Note:
[1] Percentages of Therapeutic class will be calculated from respective column header group count as denominator in percentage calculation.
[2] Percentages of Generic Name will be calculated from Respective Class counts.
[3] Percentages of Count of Ongoing will be calculated from respective generic name counts.

14.3.4 Vital Signs

Table 14.3.4.1 Summary of Weight at all visits -Safety Population (N=XXX)

Visits	Statistics	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle 1				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…

Source Data: Listing 16.4.1

Note:

[1] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for remaining available cycles.**

Table 14.3.4.2 Summary of Vital Signs at different Cycles before administration of Trastuzumab-Safety Population (N=XXX)

Vital Signs	Statistics	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle 1				
Respiratory Rate(Breaths/minute)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pulse rate (Beats/minute)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Blood Pressure(mm Hg)				
Systolic				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)

	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Diastolic				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Temperature (°C)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…

Source Data: Listing 16.4.1.1

Note:

[1] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for cycle1, cycle2, cycle3 and cycle4 for Trastuzumab with AC→TH Regimen.**

Table 14.3.4.3 Summary of Vital Signs at different Cycles (for Prior and Post Loading Dose) -Safety Population (N=XXX)

Vital Signs	Statistics	Overall (N=XX)		Trastuzumab with AC→TH Regimen (n=XX)		Trastuzumab with TCH Regimen (n=XX)	
		Prior Loading Dose	Post Loading Dose	Prior Loading Dose	Post Loading Dose	Prior Loading Dose	Post Loading Dose
Cycle X Respiratory Rate(Breaths/minute)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pulse rate (Beats/minute)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Blood Pressure(mmHg) Systolic							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX

	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Diastolic							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Temperature (°C)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…	…	…	…

Source Data: Listing 16.4.1.2

Note:

[1] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for cycle5 for Trastuzumab with AC→TH Regimen and for cycle1 for Trastuzumab with TCH Regimen.**

Table 14.3.4.4 Summary of Vital Signs at different Cycles (for Prior and Post Maintenance Dose) -Safety Population (N=XXX)

Vital Signs	Statistics	Overall (N=XX)		Trastuzumab with AC→TH Regimen (n=XX)		Trastuzumab with TCH Regimen (n=XX)	
		Prior Maintenance Dose	Post Maintenance Dose	Prior Maintenance Dose	Post Maintenance Dose	Prior Maintenance Dose	Post Maintenance Dose
Cycle X Weekly Basis Day 1 Respiratory Rate(Breaths/minute)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pulse rate (Beats/minute)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

Blood Pressure(mmHg)							
Systolic							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Diastolic							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Temperature (°C)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…	…	…	…

Source Data: Listing 16.4.1.2

Note:

[1] If a particular parameter measurement is not captured, will be displayed under ‘Missing’ category

Programming Note:

- **The same table will also include the analysis for Day 8 and Day 15 under weekly basis for each cycle and Day 1 under 3 weekly basis for each cycle.**
- **Also the same table will also include the analysis for Cycle5, Cycle6, Cycle7 and Cycle8 for Trastuzumab with AC→TH Regimen and for Cycle1, Cycle2, Cycle3, Cycle4, Cycle5 and Cycle6 for Trastuzumab with TCH Regimen.**

Table 14.3.4.5 Summary of Vital Signs at different Cycles (for Prior and Post Administration) -Safety Population (N=XXX)

Vital Signs	Statistics	Overall (N=XX)		Trastuzumab with AC→TH Regimen (n=XX)		Trastuzumab with TCH Regimen (n=XX)	
		Prior Administration	Post Administration	Prior Administration	Post Administration	Prior Administration	Post Administration
Cycle X Respiratory Rate(Breaths/minute)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pulse rate (Beats/minute)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Blood Pressure(mmHg) Systolic							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X

	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Diastolic							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Temperature (°C)							
	n	XX	XX	XX	XX	XX	XX
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…	…	…	…

Source Data: Listing 16.4.1.2

Note:

[1] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for Cycle9 to Cycle21 for Trastuzumab with AC→TH Regimen and for Cycle7 to Cycle18 for Trastuzumab with TCH Regimen.**

Table 14.3.4.6 Summary of Vital Signs at End of Study-Safety Population (N=XXX)

Vital Signs	Statistics	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Study Completion/Early Termination Visit				
Respiratory Rate(Breaths/minute)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pulse rate (Beats/minute)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Blood Pressure(mmHg) **Systolic**				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X

	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Diastolic				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Temperature (°C)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Weight (kgs.)				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [1]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…

Source Data: Listing 16.4.1.1

Note:

[1] If a particular parameter measurement is not captured, will be displayed under ‘Missing’ category

Programming Note:

- **The same table will also include the analysis for Follow-up Visit.**

14.3.5 Physical Examination

Table 14.3.5.1 Summary of Physical Examination at all visits-Safety Population (N=XXX)

Physical Examination [1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle 1				
Body System				
Heart				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If Done, Result[2]				
	Clinically Significant	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Clinically Significant	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Lungs				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If Done, Result[2]				
	Clinically Significant	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Clinically Significant	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
.....	.....	.....	.....	.....

Source Data: Listing 16.4.2
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using category "Yes" of "Physical examinations performed" as denominator.

Programming Note:
- **The same table will also include Body Systems-Abdomen, Neurological, Head, Ear, Nose and Throat, Neck, Extremities, Lymph nodes, Skin, Musculoskeletal and others.**
- **Also, the same table will also include the analysis for the remaining visits.**

14.3.6 Laboratory Assessments

Table 14.3.6.1 Summary of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.1 Summary of WBC Count of Hematology-Safety Population (N=XXX)

Visits/Statistics/Category, n (%) [1]	Baseline			Change from Baseline		
	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Done	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Baseline						
n	XX	XX	XX	-	-	-
Mean	XX.X	XX.X	XX.X	-	-	-
SD	XX.XX	XX.XX	XX.XX	-	-	-
Median	XX.X	XX.X	XX.X	-	-	-
Q1	XX.X	XX.X	XX.X	-	-	-
Q2	XX.X	XX.X	XX.X	-	-	-
Range(Min: Max)	XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	-	-	-
Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Significance [2]						
CS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
NCS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Done	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	X (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle1						
n	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Range(Min: Max)	XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
Missing [3]	X (XX.X%)	XX (XX.X %)	XX (XX.X %)	X (XX.X%)	XX (XX.X %)	XX (XX.X %)

p-value [4]	0.XXXX	0.XXXX	0.XXXX	-	-	-
Significance [2]						
CS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	X (XX.X %)	XX (XX.X %)	XX (XX.X %)
NCS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	X (XX.X %)	XX (XX.X %)	XX (XX.X %)
…	…	…	…	…	…	…

Source Data: Listing 16.2.8.1

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using "Done" count as denominator in each visit.
[3] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.
[4] The p-value will be calculated using paired t-test for comparing mean from baseline to all other visits for each regimen.

Programming Note:

- **The same table will also include the analysis for remaining visits.**
- **The same mock-up will be used to generate the table for Trastuzumab with AC→TH Regimen, with TCH Regimen and overall for all visits and change from baseline with change in table number and table title as:**

Table 14.3.6.1.2 Summary of RBC Count of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.3 Summary of Hemoglobin of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.4 Summary of Hematocrit of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.5 Summary of Platelet Count of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.6 Summary of Neutrophils of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.7 Summary of Eosinophils of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.8 Summary of Basophils of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.9 Summary of Monocytes of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.10Summary of Lymphocytes of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.11Summary of Other cells of Hematology-Safety Population (N=XXX)

Table 14.3.6.1.12 Shift table for Parameters of Hematology-Safety Population (N=XXX)

Parameters/Statistics/Category, n (%) [1]	Overall (N=XX)			Trastuzumab with AC→TH Regimen (n=XX)			Trastuzumab with TCH Regimen (n=XX)		
	Baseline	End of Study		Baseline	End of Study		Baseline	End of Study	
		CS	NCS		CS	NCS		CS	NCS
WBC Count									
CS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
NCS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
RBC Count									
CS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
NCS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
……	……	……	……	……	……	……	……	……	……

Source Data: Listing 16.2.8.1

Note:

[1] Percentage will be calculated by using CS and NCS count at Baseline as denominator.

Programming Note:

- The same shift table will include the analysis for other Hematology parameters: Hemoglobin, Hematocrit, Platelet Count, Neutrophils, Eosinophils, Basophils, Monocytes, Lymphocytes and other cells.

Table 14.3.6.2 Summary of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.1 Summary of Sodium of Biochemistry-Safety Population (N=XXX)

Visits/Statistics/Category, n (%) [1]	Baseline			Change from baseline		
	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Baseline						
n	XX	XX	XX	-	-	-
Mean	XX.X	XX.X	XX.X	-	-	-
SD	XX.XX	XX.XX	XX.XX	-	-	-
Median	XX.X	XX.X	XX.X	-	-	-
Q1	XX.X	XX.X	XX.X	-	-	-
Q2	XX.X	XX.X	XX.X	-	-	-
Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	-	-	-
Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Significance [2]						
CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle1						
n	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
p-value [4]	0.XXXX	0.XXXX	0.XXXX	-	-	-
Significance [2]						

CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)				
NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)				
…	…	…	…	…	…	…	

Source Data: Listing 16.2.8.1

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using "Done" count as denominator in each visit.
[3] If a particular parameter measurement is not captured, will be displayed under 'Missing' category
[4] The p-value will be calculated using paired t-test for comparing mean from baseline to all other visits for each regimen.

Programming Note:

- **The same table will also include the analysis for remaining visits.**
- **The same mock-up will be used to generate the table for Trastuzumab with AC→TH Regimen, with TCH Regimen and overall for all visits and change from baseline with change in table number and table title as:**

Table 14.3.6.2.2 Summary of Potassium of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.3 Summary of Calcium of Biochemistry -Safety Population (N=XXX)

Table 14.3.6.2.4 Summary of Chloride of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.5 Summary of Bicarbonate of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.6 Summary of Fasting Glucose of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.7 Summary of BUN/ Urea of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.8 Summary of Creatinine of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.9 Summary of Total Protein of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.10Summary of Albumin of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.11Summary of Phosphorus of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.12Summary of Magnesium of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.13Summary of Total Bilirubin of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.14Summary of Direct Bilirubin of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.15Summary of Alkaline Phosphatase of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.16Summary of Creatinine Phosphokinase of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.17Summary of ALT of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.18Summary of AST of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.19Summary of Uric Acid of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.20Summary of LDH of Biochemistry-Safety Population (N=XXX)

Table 14.3.6.2.21 Shift table for Parameters of Biochemistry-Safety Population (N=XXX)

Parameters/Statistics/Category, n (%) [1]	Overall (N=XX)			Trastuzumab with AC→TH Regimen (n=XX)			Trastuzumab with TCH Regimen (n=XX)		
	Baseline	End of Study		Baseline	End of Study		Baseline	End of Study	
		CS	NCS		CS	NCS		CS	NCS
Sodium									
CS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
NCS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
Potassium									
CS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
NCS	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)	XX(XX.X%)
……	……	……	……	……	……	……	……	……	……

Source Data: Listing 16.2.8.2

Note:

[1] Percentage will be calculated by using CS and NCS count at Baseline as denominator.

Programming Notes:

- The same shift table will include the analysis for other Hematology parameters: Calcium, Chloride, Bicarbonate, Fasting Glucose, BUN/ Urea, Creatinine, Total Protein, Albumin, Phosphorus, Magnesium, Total Bilirubin, Direct Bilirubin, Alkaline Phosphatase, Creatinine Phosphokinase, ALT, AST, Uric Acid and LDH.

Table 14.3.6.3 Summary of LVEF-Safety Population (N=XXX)

Visits/Statistics/Category, n (%) [1]	Baseline			Change from Baseline		
	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Done	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Baseline						
n	XX	XX	XX	-	-	-
Mean	XX.X	XX.X	XX.X	-	-	-
SD	XX.XX	XX.XX	XX.XX	-	-	-
Median	XX.X	XX.X	XX.X	-	-	-
Q1	XX.X	XX.X	XX.X	-	-	-
Q2	XX.X	XX.X	XX.X	-	-	-
Range(Min: Max)	XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	-	-	-
Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Significance [2]						
CS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
NCS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	-	-	-
Done	X (XX.X %)	XX (XX.X %)	XX (XX.X %)	X (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle5						
n	XX	XX	XX	XX	XX	XX
Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
SD	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX	XX.XX
Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q1	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Q2	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Range(Min: Max)	XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)	XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
Missing [3]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
p-value [4]	0.XXXX	0.XXXX	0.XXXX	-	-	-

Significance [2]						
CS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)			
NCS	X (XX.X %)	XX (XX.X %)	XX (XX.X %)			
…	…	…	…	…	…	…

Source Data: Listing 16.2.8.3

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using "Done" count as denominator in each visit.
[3] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.
[4] The p-value will be calculated using paired t-test for comparing mean from baseline to all other visits for each regimen.

Programming Note:

- **The same table will also include the analysis for the remaining available Visits.**

Table 14.3.6.4 Summary of 12 Lead Electrocardiogram-Safety Population (N=XXX)

LVEF Value [1]	Statistics/Category, n (%), [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle 5				
Significance				
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
.....	.....	.....	.....	.....

Source Data: Listing 16.2.8.3

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the remaining available Visits.**

Table 14.3.6.5 Summary of ECOG-Safety Population (N=XXX)

ECOG Score [1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle 5				
	0	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	1	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	3	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	4	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	5	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
.....	.....	.....	.....	.....

Source Data: Listing 16.2.8.3
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.

Programming Note:
- **The same table will also include the analysis for the remaining available Visits.**

Table 14.3.6.5.1 Summary of ECOG PS-Safety Population (N=XXX)

ECOG Score [1]	Statistics/Category, n (%)	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Baseline				
	0	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	1-2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Cycle 5				
	0	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	1-2	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
McNemar's Test [2]	p-value	0.XXXX	0.XXXX	0.XXXX
.....	.....	.....	.....	.....

Source Data: Listing 16.2.8.3
Note:
[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] The p-value will be calculated using McNemar's Test for comparing ECOG PS from baseline to all other visits for each regimen.

Programming Note:
- **The same table will also include the analysis for the remaining available Visits.**

Table 14.3.6.6 Summary of Routine Breast Cancer Follow Up-Safety Population (N=XXX)

Examination [1]	Statistics/Category, n (%), [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle 9				
Physical Examination				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Occurrence of any symptoms				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Any recurrence of prior symptoms				
	Yes	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
If Yes, Specify [2]				
	New Lumps	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Bone Pain	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Chest Pain	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Dyspnea	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Abdominal pain	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Persistent headaches	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Others	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Location of recurrence [2]				
	Local	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Regional	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Distant	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Contra-lateral breast cancer	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Mammography				

	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Results of Mammogram				
	Normal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Abnormal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Pelvic Examination				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Results of Pelvic Examination				
	Normal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Abnormal	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Brain CT/MRI				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Findings				
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Bone Scan				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Findings				
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Liver Imaging				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Findings				
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

.....	.....	.....	.....	.....

Source Data: Listing 16.4.3.1

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] Percentages will be calculated using "Yes" count of "Any recurrence of prior symptoms" as denominator.

Programming Note:

- **The same table will also include the analysis for the remaining available Visits.**

Table 14.3.6.7 Summary of CT/MRI and Mammogram at Study Completion and Follow-up-Safety Population (N=XXX)

Test	Statistics/Category, n (%), [1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)	Trastuzumab with TCH Regimen (n=XX)
Study Completion/ Early Termination				
CT/MRI				
Size of Lesion 1				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Size of Lesion 2				
	n	XX	XX	XX
	Mean	XX.X	XX.X	XX.X
	SD	XX.XX	XX.XX	XX.XX
	Median	XX.X	XX.X	XX.X
	Q1	XX.X	XX.X	XX.X
	Q2	XX.X	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Mammogram				
	Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	Not Done	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
Finding				
	CS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)
	NCS	XX (XX.X %)	XX (XX.X %)	XX (XX.X %)

.....	.....	.....	.....	.....

Source Data: Listing 16.2.8.4

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the Follow-up Visits.**

Table 14.3.7 Summary of Drug Administration-Safety Population (N=XXX)

Table 14.3.7.1 Summary of Drug Administration in AC→TH Regimen -Safety Population (N=XXX)

Table 14.3.7.1.1 Summary of Chemotherapy- Doxorubicin Administration in AC→TH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle 1			
Doxorubicin administered			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Dose of 60 mg/m² Doxorubicin administered			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Administration of Doxorubicin delayed			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
……	**……**	**……**	**……**

Source Data: Listing 16.4.5.1

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the cycle1, cycle2, cycle3 and cycle4.**

Table 14.3.7.1.2 Summary of Chemotherapy- Cyclophosphamide Administration-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle 1			
Cyclophosphamide administered			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Dose of 600 mg/m² Cyclophosphamide administered			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Administration of Cyclophosphamide delayed			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
.....	.....	.....	.....

Source Data: Listing 16.4.5.2

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the cycle1, cycle2, cycle3 and cycle4.**

Table 14.3.7.1.3 Summary of Chemotherapy- Docetaxel/ Paclitaxel Administration-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle X			
Drug administered to the patient			
	Docetaxel	XX (XX.X %)	XX (XX.X %)
	Paclitaxel	XX (XX.X %)	XX (XX.X %)
	None	XX (XX.X %)	XX (XX.X %)
Dose of 100 mg/m² Docetaxel administered on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Dose of 175 mg/m² Paclitaxel administered on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Administration for the above mentioned drug delayed			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Administration of Cyclophosphamide delayed			

	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
.....	.....	.....	.....

Source Data: Listing 16.4.5.3

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the cycle6, cycle7, and cycle8.**

Table 14.3.7.1.4 Summary of Trastuzumab Administration (weekly total dose=8 mg/kg) in AC→TH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle 5			
Schedule of Trastuzumab administration			
	Weekly	XX (XX.X %)	XX (XX.X %)
	3-Weekly	XX (XX.X %)	XX (XX.X %)
If Weekly, then [3]			
Total loading dose of 4 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)

Patients who were administered Trastuzumab (2 mg/kg) on Day 8			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Patients who were administered Trastuzumab (2 mg/kg) on Day 15			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)

Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
If 3-Weekly, then [4]			
Total loading dose of 8 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
…….	…….	…….	…….

Source Data: Listing 16.4.5.6a

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, will be displayed under ‘Missing’ category.
[3] Percentages will be calculated using “Weekly” count of “Schedule of Trastuzumab administration” as denominator.
[4] Percentages will be calculated using “3-Weekly” count of “Schedule of Trastuzumab administration” as denominator.

Table 14.3.7.1.5 Summary of Trastuzumab Administration (weekly total dose=6 mg/kg) in AC→TH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle X			
Schedule of Trastuzumab administration			
	Weekly	XX (XX.X %)	XX (XX.X %)
	3-Weekly	XX (XX.X %)	XX (XX.X %)
If Weekly, then [3]			
Total loading dose of 2 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)

Patients who were administered Trastuzumab (2 mg/kg) on Day 8			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Patients who were administered Trastuzumab (2 mg/kg) on Day 15			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)

Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
If 3-Weekly, then [4]			
Total loading dose of 6 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
…….	…….	…….	…….

Source Data: Listing 16.4.5.6b

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.
[3] Percentages will be calculated using "Weekly" count of "Schedule of Trastuzumab administration" as denominator.
[4] Percentages will be calculated using "3-Weekly" count of "Schedule of Trastuzumab administration" as denominator.

Programming Note:

- **The same table will also include the analysis for the cycle6, cycle7 and cycle8.**

Table 14.3.7.1.6 Summary of Trastuzumab Administration in AC→TH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle X			
Dose of 6 mg/kg Trastuzumab administered on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
…….	…….	…….	…….

Source Data: Listing 16.4.5.6c

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.

Programming Note:

- **The same table will also include the analysis for the cycle9, cycle10, cycle11, cycle12, cycle13, cycle14, cycle15, cycle16, cycle17, cycle18, cycle19, cycle20, cycle21, and cycle22.**

Table 14.3.7.2 Summary of Drug Administration in TCH Regimen-Safety Population (N=XXX)

Table 14.3.7.2.1 Summary of Chemotherapy- Docetaxel Administration in TCH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle X			
Docetaxel administered			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Dose of 75 mg/m² Docetaxel administered			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Administration of Docetaxel delayed			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
……	**……**	**……**	**……**

Source Data: Listing 16.4.5.4

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the cycle1, cycle2, cycle3, cycle4, cycle5 and cycle6.**

Table 14.3.7.2.2 Summary of Chemotherapy- Carboplatin Administration in TCH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle X			
Docetaxel administered on Day1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Total Dose of Carboplatin (mg)			
	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
GFR (ml/min)			
	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X

	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Administration of Carboplatin delayed			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
.....	.....	.....	.....

Source Data: Listing 16.4.5.5

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.

[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category

Programming Note:

- **The same table will also include the analysis for the cycle1, cycle2, cycle3, cycle4, cycle5 and cycle6.**

Table 14.3.7.2.3 Summary of Trastuzumab Administration (weekly-total dose=8mg/kg) in TCH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle X			
Schedule of Trastuzumab administration			
	Weekly	XX (XX.X %)	XX (XX.X %)
	3-Weekly	XX (XX.X %)	XX (XX.X %)
If Weekly, then [3]			
Total loading dose of 4 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)

Patient take Trastuzumab (2 mg/kg) on Day 8			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Patient take Trastuzumab (2 mg/kg) on Day 15			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX

	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
If 3-Weekly, then [4]			
Total loading dose of 8 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
…….	…….	…….	…….

Source Data: Listing 16.4.5.6a

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.
[3] Percentages will be calculated using "Weekly" count of "Schedule of Trastuzumab administration" as denominator.
[4] Percentages will be calculated using "3-Weekly" count of "Schedule of Trastuzumab administration" as denominator.

Table 14.3.7.2.4 Summary of Trastuzumab Administration (weekly-total dose=6mg/kg) in TCH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with TCH Regimen (n=XX)
Cycle X			
Schedule of Trastuzumab administration			
	Weekly	XX (XX.X %)	XX (XX.X %)
	3-Weekly	XX (XX.X %)	XX (XX.X %)
If Weekly, then [3]			
Total loading dose of 2 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)

Patient take Trastuzumab (2 mg/kg) on Day 8			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Patient take Trastuzumab (2 mg/kg) on Day 15			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX

	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
If 3-Weekly, then [4]			
Total loading dose of 6 mg/kg administered to the patient on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
…….	…….	…….	…….

Source Data: Listing 16.4.5.6b

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.
[3] Percentages will be calculated using "Weekly" count of "Schedule of Trastuzumab administration" as denominator.
[4] Percentages will be calculated using "3-Weekly" count of "Schedule of Trastuzumab administration" as denominator.

Programming Note:

- **The same table will also include the analysis for the cycle2, cycle3, cycle4, cycle5 and cycle6.**

Table 14.3.7.2.5 Summary of Trastuzumab Administration in TCH Regimen-Safety Population (N=XXX)

Administration	Statistics/Category, n (%)[1]	Overall (N=XX)	Trastuzumab with AC→TH Regimen (n=XX)
Cycle X			
Dose of 6 mg/kg Trastuzumab administered on Day 1			
	Yes	XX (XX.X %)	XX (XX.X %)
	No	XX (XX.X %)	XX (XX.X %)
Duration of Administration	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
Duration of Observation	n	XX	XX
	Mean	XX.X	XX.X
	SD	XX.XX	XX.XX
	Median	XX.X	XX.X
	Q1	XX.X	XX.X
	Q2	XX.X	XX.X
	Range(Min: Max)	(XX.X:XX.X)	(XX.X:XX.X)
	Missing [2]	XX (XX.X %)	XX (XX.X %)
…….	…….	…….	…….

Source Data: Listing 16.4.5.6c

Note:

[1] Percentages will be calculated using corresponding column header group count as denominator.
[2] If a particular parameter measurement is not captured, will be displayed under 'Missing' category.

Programming Note:

- **The same table will also include the analysis for the cycle7, cycle8, cycle9, cycle10, cycle11, cycle12, cycle13, cycle14, cycle15, cycle16, cycle17, and cycle18.**

Table 14.3.7.2.6a Summary of exposure to Doxorubicin and cyclophosphamide in patients treated with ACTH regimen-ITT Population(N=XXX)

Category, n (%)	No. of cycles received	Treated patients (%)
AC*		
	1(Cycle 1)	XX (XX.X %)
	2(Cycle 2)	XX (XX.X %)
	3(Cycle 3)	XX (XX.X %)
	4(Cycle 4)	XX (XX.X %)

Source Data: Listing 16.4.5.1 & Listing 16.4.5.2

Note:

[1] Percentages will be calculated by taking the subject in AC-TH regimen Count as denominator.

General Note:

* Subject in AC-TH Regimen recieved AC treatment between the Cycle 1 to Cycle 4.

Table 14.3.7.2.6b Summary of exposure to taxanes and trastuzumab in patients treated with AC-TH regimen(3-Weekly) (N=XXX)

Category, n (%)	No. of cycles received	Treated patients (%)
TH*		
	5(Cycle 5)	XX (XX.X %)
	6(Cycle 6)	XX (XX.X %)
	7(Cycle 7)	XX (XX.X %)
	8(Cycle 8)	XX (XX.X %)
	……	
	……	

Source Data: Listing 16.4.5.6.1 ,Listing 16.4.5.6.2 ,Listing 16.4.5.6.2a , Listing 16.4.5.6.3
[1] Percentages will be calculated by taking the subject in AC-TH regimen from ITT Population count as denominator.
General Note:
* Subject in AC-TH Regimen received study medication (TH) in 3-weekly basis between the Cycle 9 to Cycle 22 and some subjects takes study medication (TH) in 3-weekly basis between cycle 5 to cycle 8.

Programming Note: The same table will also include the analysis for the cycle9, cycle10, cycle11, cycle12, cycle13, cycle14, cycle15, cycle16, cycle17, cycle18, cycle19, cycle20, cycle21 and cycle22.

Table 14.3.7.2.6c: Summary of exposure to taxanes and trastuzumab in patients treated with AC-TH regimen(Weekly) (N=XXX)

Category, n (%)	No. of cycles received	Day of Receive	Treated patients (%)
TH*			
	Treatment Cycle 5	**Day-1**	XX (XX.X %)
	Treatment Cycle 5	**Day-8**	XX (XX.X %)
	Treatment Cycle 5	**Day-15**	XX (XX.X %)
	…….		XX (XX.X %)
	……..		
	……..		

Source Data: Listing 16.4.5.3 & Listing 16.4.5.6.1a
Note:
[1] Percentages will be calculated by taking the subject in AC-TH regimen from ITT Population count as denominator.
General Note:
* Subject in AC-TH Regimen received study medication (TH) in weekly basis between the Cycle 9 to Cycle 22.

Programming Note: The same table will also include the analysis for the cycle6, cycle7, cycle8.

1.2 Figures

14.2.1 Figures for Efficacy Analysis

Figure 14.2.1.1 K-M Plot for Disease Free Survival by Treatment-ITT Population (N=XXX)

K-M Plot	A step diagram of K-M analysis for AC→TH Regimen, TCH Regimen and Overall will be generated where X-axis will represent Time (Days) and Y-axis will represent Disease Free survival probability for AC→TH Regimen, TCH Regimen and Overall.

Source Data: Table 14.2.2.2

Figure 14.2.1.2 K-M Plot for Overall Survival by Regimen-ITT Population (N=XXX)

K-M Plot	A step diagram of K-M analysis for AC→TH Regimen, TCH Regimen and Overall will be generated where X-axis will represent Time (Days) and Y-axis will represent overall survival probability for AC→TH Regimen, TCH Regimen and Overall.

Source Data: Table 14.2.1.2

Source Data: Table 14.2.1.3

- Same analysis figure will be prepared for the Efficacy Population with an appropriate change in title:

Figure 14.2.1.3 K-M Plot for Overall Survival by Disease Status-ITT Population (N=XXX)

Figure 14.2.1.4 Line Diagram for LVEF over a period of time-Safety Population (N=XXX)

Line Diagram for Mean for both AC→TH Regimen, TCH Regimen and Overall	Two line diagram for LVEF will be generated where X-axis will represent Time (Days) and Y-axis will represent Mean for both AC→TH Regimen, TCH Regimen and Overall.

Source Data: Table 14.3.6.7

Figure 14.2.1.5 Multiple Bar Diagram for ECOG over a period of time-Safety Population (N=XXX)

Multiple Bar Diagram for ECOG for both AC→TH Regimen, TCH Regimen and Overall	Multiple Bar diagram for ECOG will be generated where X-axis will represent ECOG status at different Time (only Baseline and Study Completion Visit) and Y-axis will represent Count and Frequency for both AC→TH Regimen, TCH Regimen and Overall.

Source Data: Table 14.3.6.5

1.3 LISTINGS

16.2 Patient Data Listings

Listing 16.2.1 Listing of Patient Discontinuation-ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	The patient completed the protocol	If No, Date of last administration of study regimen	The primary reason for discontinuation	If other reason, specify
NN/XXX	NN/XXX	Yes/No	DDMMMYYYY	XXXX	XXXX
NN/XXX	NN/XXX	Yes/No	DDMMMYYYY	XXXX	XXXX
NN/XXX	NN/XXX	Yes/No	DDMMMYYYY	XXXX	XXXX
…	…	…	…	…	…

Listing 16.2.2.1 Listing of Protocol Deviation -ITT Population (N=XXX)

Site No./ Subject ID	Age/ Sex	Date	Reason of Deviation	Comments
NN/XXX	NN/XXX	DDMMMYYYY	XXXXXXX	XXX
NN/XXX	NN/XXX	DDMMMYYYY	XXXXXXX	XXX
NN/XXX	NN/XXX	DDMMMYYYY	XXXXXXX	XXX
…	…	…	…	…

Listing 16.2.2.2 Listing of Analysis Population Sets-ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	ITT Population	Safety Population
NN/XXX	NN/XXX	Yes/No	Yes/No
NN/XXX	NN/XXX	Yes/No	Yes/No
NN/XXX	NN/XXX	Yes/No	Yes/No
…	…	…	…

Listing 16.2.3 Listing of Patients who fail to meet Inclusion/Exclusion Criteria

Site No./ Subject ID	Age/Sex	Patient signed the Informed Consent	Date of Informed Consent	All Inclusion criteria met	If No, Inclusion Criteria Number(s)	Any Exclusion criteria met	If yes, Exclusion criteria number(s)
NN/XXX	NN/XXX	Yes/No	DDMMMYYYY	Yes/No/NA	NN	NN	NN
NN/XXX	NN/XXX	Yes/No	DDMMMYYYY	Yes/No/NA	NN	NN	NN
NN/XXX	NN/XXX	Yes/No	DDMMMYYYY	Yes/No/NA	NN	NN	NN
…	…	…	…	…	…	…	…

16.2.4 Listing of Demographics

Listing 16.2.4.1 Listing of Patient Demographics -ITT Population (N=XXX)

Site No./ Subject ID	Age	Sex	Date of Birth	Race	Treatment
NN/XXX	NN	Male/Female	DDMMMYYYY	XXX	XXX
NN/XXX	NN	Male/Female	DDMMMYYYY	XXX	XXX
NN/XXX	NN	Male/Female	DDMMMYYYY	XXX	XXX
…	…	…	…	…	…

Listing 16.2.4.2 Listing of Medical History at Screening -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Medical Conditions	Start date	Stop Date	Ongoing	Currently Being Treated
NN/XXX	NN/XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	Yes/No
NN/XXX	NN/XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	Yes/No
NN/XXX	NN/XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	Yes/No
…	…	…	…	…	…	…

Listing 16.2.4.3 Listing of Cancer History at Screening -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Primary Diagnosis	Date of Diagnosis	Method of Diagnosis	Stage of Cancer (during diagnosis)	Current stage of Cancer
NN/XXX	NN/XXX	XXX	DDMMMYYYY	XXX	XXX	Yes/No
NN/XXX	NN/XXX	XXX	DDMMMYYYY	XXX	XXX	Yes/No
NN/XXX	NN/XXX	XXX	DDMMMYYYY	XXX	XXX	Yes/No
…	…	…	…	…	…	…

Listing 16.2.4.4 Listing of Reproductive Status at Screening -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Reproductive Status	Menopausal age	No. of Live births	Breast Feeding History
NN/XXX	NN/XXX	XXX	NN	NN	XXX
NN/XXX	NN/XXX	XXX	NN	NN	XXX
NN/XXX	NN/XXX	XXX	NN	NN	XXX
…	…	…	…	…	…

Listing 16.2.4.5 Listing of Smoking, Alcoholic & Drug Abuse History at Screening -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Smoking Status	If Smoking Status is Smoker, Average no. of Cigarettes per day	Chew tobacco	If Yes, the average quantity	Alcoholic Status	If "Alcoholic Status" is Yes	Drug abuse Status Positive/Negative	If "drug abuse Status" is positive, specify
NN/XXX	NN/XXX	XXX	NN	Yes/No	NN	XXX	XXX	XXX	XXX
NN/XXX	NN/XXX	XXX	NN	Yes/No	NN	XXX	XXX	XXX	XXX
NN/XXX	NN/XXX	XXX	NN	Yes/No	NN	XXX	XXX	XXX	XXX
…	…	…	…	…	…	…	…	…	…

Listing 16.2.4.6 Listing of Prior Cancer Therapy & Prior Cancer Surgery at Screening -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Prior Cancer Therapy					Prior Cancer Surgery		
		Treatment agent	Start date	Stop Date	Reason for stopping	Therapy type	Site/ Organ System	Type of Procedure	Date of Surgery
NN/XXX	NN/XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY
NN/XXX	NN/XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY
NN/XXX	NN/XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	XXX	XXX	XXX	DDMMMYYYY
…	…	…	…	…	…	…	…	…	…

Listing 16.2.4.7 Listing of Histology and HER2 testing test at screening -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Histology					HER2 Testing			
		Biopsy Performed	Date of Biopsy	Biopsy Result	Grade	Not Done	Date of sample collection	Method Used	If IHC, observation	If FISH, observation
NN/XXX	NN/XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
NN/XXX	NN/XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
NN/XXX	NN/XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX
…	…	…	…	…	…	…	…	…	…	…

16.2.6 Listing for Efficacy

Listing 16.2.6.1 Listing of Survival Assessment -ITT Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visitname	Regimen	Survival Status	Specify the date for the selected status	If Died, cause of death	Recurrence of any prior symptoms	If "Yes", specify	Therapy / medication used	Any new therapy/ medication have been introduced	If "Yes", specify the details	Date of initiation	Has the follow up discontinued	If "Yes", specify the reason
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Yes/No	XXX	XXX	Yes/No	XXX	DDMMMYYYY	Yes/No	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Yes/No	XXX	XXX	Yes/No	XXX	DDMMMYYYY	Yes/No	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	Yes/No	XXX	XXX	Yes/No	XXX	DDMMMYYYY	Yes/No	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…	…	…

16.2.7 Listing for Adverse Event

Listing 16.2.7.1 Listing of Adverse Event -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visits	Regimen	Patient experienced any AE	SOC	Preferred Term	Event	Date of Onset	Date of Resolution	Ongoing	Grade of Severity	Causality	Action taken with study medication	Outcome	Has the patient taken any medication to treat the AE	Is the reported event serious
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	Yes/No	XXX	Yes/No	XXX	XXX	Yes/No	Yes/No
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	Yes/No	XXX	Yes/No	XXX	XXX	Yes/No	Yes/No
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	Yes/No	XXX	Yes/No	XXX	XXX	Yes/No	Yes/No
…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…

16.2.8 Lab Test Evaluations

Listing 16.2.8.1 Listing of Hematology -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Lab Test	Not Done	Values	Unit	Significance	If Clinically Significant, specify details
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	NN	CS/NCS	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	NN	CS/NCS	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	NN	CS/NCS	NN
…	…	…	…	…	…	…	…	…	…

Listing 16.2.8.2 Listing of Biochemistry -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Lab Test	Not Done	Values	Unit	Significance	If Clinically Significant, specify details
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	NN	CS/NCS	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	NN	CS/NCS	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	NN	CS/NCS	NN
…	…	…	…	…	…	…	…	…	…

Listing 16.2.8.3 Listing of 12 Lead ECG, LVEF and ECOG -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	12 Lead ECG				LVEF				ECOG Performance Status	
				Not Done	Date of assessment	Significance	If CS, please specify	Not Done	Date of assessment	Significance	If CS, please specify	Date of Assessment	ECOG Score
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	NN
…	…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.2.8.4 Listing of Mammogram and CT/MRI -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Mammogram			CT/MRI				
				Date when Mammography done	Findings CS/NCS	If CS, specify	Site of Lesion	Location	Method of Assessment	Date of Assessment	Size (mm)
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	NN
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	NN
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	XXX	DDMMMYYYY	XXX	XXX	XXX	DDMMMYYYY	NN
…	…	…	…	…	…	…	…	…	…	…	…

16.4 Individual subject data listings

Listing 16.4.1 Listing of Vital Signs -Safety Population (N=XXX)

Listing 16.4.1.1 Listing of Vital Signs -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Date of Examination	Respiratory Rate	Pulse Rate	Blood Pressure		Temperature	Weight	Height
							Systolic	Diastolic			
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	NN	NN	NN	NN	NN	NN	NN
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	NN	NN	NN	NN	NN	NN	NN
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	NN	NN	NN	NN	NN	NN	NN
…	…	…	…	…	…	…	…	…	…	…	…

Programming Note:

- **This listing will include the visit: Screening, Study Completion/ Withdrawal and Follow-up for both Regimen and Cycle1, Cycle2, Cycle3, Cycle4 for AC→TH Regimen.**

Listing 16.4.1.2 Listing of Vital Signs during different Loading, Maintenance and Administration Dose-Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Time of capturing Vital Signs	Not Done	Date of Examination	Respiratory Rate	Pulse Rate	Blood Pressure		Temperature	Weight
									Systolic	Diastolic		
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	NN	NN	NN	NN	NN	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	NN	NN	NN	NN	NN	NN
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	NN	NN	NN	NN	NN	NN
…	…	…	…	…	…	…	…	…	…	…	…	…

Programming Note:

- Time of capturing Vital Signs will be Prior/Post Loading Dose, Prior/Post Maintenance Dose(Day1), Prior/Post Maintenance Dose(Day8), Prior/Post Maintenance Dose(Day15), Prior/Post Maintenance Dose and Prior/Post Administration Dose at different visits for both regimen.

Listing 16.4.2 Listing of Physical Examination -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Not Done	Date of Examination	Body System/Site	Not Done	Significance	If Clinically Significant, specify details
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	NN	NN	CS/NCS	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	NN	NN	CS/NCS	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	DDMMMYYYY	NN	NN	CS/NCS	XXX
…	…	…	…	…	…	…	…	…	…

Listing 16.4.3.1 Listing of Routine Breast Cancer Follow Up -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Date of assessment	Familial History			Physical Examination							Mammography		
								If Done,									
					Any Familial History	If yes, please specify	Done/ Not Done	Occurrence of any new symptoms	If Yes, specify	Recurrence of prior symptoms	If yes, specify	Location of recurrence	Done/ Not Done	If not done, specify reason	Results of Mammogram	If Abnormal, specify
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.3.2 Listing of Other Investigations -Safety Population (N=XXX)

				Pelvic Examination				Brain CT/MRI			Bone Scan			Liver Imaging		
Site No./ Subject ID	**Age/Sex**	**Visit**	**Regimen**	**Done / Not Done**	**If not done, specify**	**Result of Pelvic Examination**	**If Abnormal, specify**	**Date of Assessment**	**Findings**	**If CS, specify**	**Date of Assessment**	**Findings**	**If CS, specify**	**Date of Assessment**	**Findings**	**If CS, specify**
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	XXX	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	XXX	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	XXX	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	XXX	XXX	DDMMMYYYY	XXX	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.4 Listing of Cycle Delay, Reminder and Treatment Compliance -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Cycle Delay		Reminder			Treatment Compliance
				Has the cycle delayed	If Yes, Specify Reason	Patient experienced any change in previous AE or new AE since last visit	Patient experienced any change in previous concomitant medications or new concomitant medications since last visit	Patient experienced any unplanned visit since last visit	Is the patient compliant to the protocol specific procedures
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	Yes/No	Yes/No	Yes/No	Yes/No
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	Yes/No	Yes/No	Yes/No	Yes/No
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	Yes/No	Yes/No	Yes/No	Yes/No
…	…	…	…	…	…	…	…	…	…

Listing 16.4.5 Listing of Study Drug Administration -Safety Population (N=XXX)

Listing 16.4.5.1 Listing of Chemotherapy- Doxorubicin Administration for AC→TH Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Has Doxorubicin administered to the patient	Was the dose of 60 mg/m² Doxorubicin administered to the patient	If No, please Specify	Date of Administration	Start time	Stop Time	Is the administration of Doxorubicin delayed	If Yes, specify
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.2 Listing of Chemotherapy- Cyclophosphamide Administration for AC→TH Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Has Cyclophosphamide administered to the patient	Was the dose of 600 mg/m² Cyclophosphamide administered to the patient	If No, please Specify	Date of Administration	Start time	Stop Time	Is the administration of Cyclophosphamide delayed	If Yes, specify
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.3 Listing of Chemotherapy- Docetaxel/ Paclitaxel Administration for AC→TH Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Drug administered to the patient	If "Docetaxel", was the dose of 100 mg/m² administered to the patient on Day 1	If "No", specify	If "Paclitaxel", was the dose of 175 mg/m² administered to the patient on Day 1	If No, Specify	Date of Administration	Start time	Stop Time	If none of the drug administered, please specify the reason
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	XXX
…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.4 Listing of Chemotherapy- Docetaxel Administration for TCH Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Has Docetaxel administered to the patient	Was the dose of 75 mg/m² Docetaxel administered to the patient	If No, please Specify	Date of Administration	Start time	Stop Time	Is the administration of Docetaxel delayed	If Yes, specify
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.5 Listing of Chemotherapy- Carboplatin Administration for TCH Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Has Carboplatin administered on Day 1	Total Dose of Carboplatin	GFR (ml/min)	If No, please Specify	Date of Administration	Start time	Stop Time	Is the administration of Carboplatin delayed	If Yes, specify
NN/XXX	NN/XXX	XXX	Yes/No	NN	NN	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	NN	NN	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
NN/XXX	NN/XXX	XXX	Yes/No	NN	NN	XXX	DDMMMYYYY	NN:NN	NN:NN	Yes/No	XXX
…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.6 Listing of Trastuzumab Administration for Both Regimen -Safety Population (N=XXX)

Listing 16.4.5.6.1 Listing of Trastuzumab Administration (8mg/kg /3-weekly) for Both Regimen-Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Schedule of Trastuzumab administration (Weekly/ 3-Weekly)	Was total loading dose of 8 mg/kg administered to the patient on Day 1	If No, please Specify	Date of Administration	Start time	Stop Time	Observation Start Time	Observation Stop Time	If any AE occurred, please
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.6.1a Listing of Trastuzumab Administration (8mg/kg weekly) for Both Regimen-Safety Population(N=XXX)

Site No./ Subject ID	**Age/Sex**	**Visit**	Regimen	Schedule of Trastuzumab administration(Weekly)	Day of Administration	Was total loading dose of 4 mg/kg/2 mg/kg /2 mg/kg administered to the patient on Day 1/8/15	**If No, please Specify**	**Date of Administration**	**Start time**	**Stop Time**	**Observation Start Time**	**Observation Stop Time**	**If any AE occurred, please**
NN/XXX	NN/XXX	XXX	XXX	XXX	NN	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	NN	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	NN	Yes/No NN	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.6.2 Listing of Trastuzumab Administration (6mg/kg /3-weekly) for Both Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Schedule of Trastuzumab administration (3-Weekly)	Was total loading dose of 6 mg/kg administered to the patient on Day 1	If No, please Specify	Date of Administration	Start time	Stop Time	Observation Start Time	Observation Stop Time	If any AE occurred, please
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.6.2a Listing of Trastuzumab Administration (6mg/kg weekly) for Both Regimen-Safety Population(N=XXX)

Site No./ Subject ID	**Age/Sex**	**Visit**	Regimen	Schedule of Trastuzumab administration(Weekly)	Was total loading dose of 6 mg/kg/2 mg/kg administered to the patient on Day 1/8/15	**If No, please Specify**	**Date of Administration**	Day of Administration	**Start time**	**Stop Time**	**Observation Start Time**	**Observation Stop Time**	**If any AE occurred, please**
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	XXX	Yes/No NN	XXX	DDMMMYYYY	NN	NN:NN	NN:NN	NN:NN	NN:NN	XXX
…	…	…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.5.6.3 Listing of Trastuzumab Administration (6mg/kg) for Both Regimen -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Visit	Regimen	Was total loading dose of 6 mg/kg administered to the patient on Day 1	If No, specify	Date of administration	Start Time	Stop Time	Observation Start Time	Observation Stop Time	If any AE occurred, please specify
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
NN/XXX	NN/XXX	XXX	XXX	Yes/No	XXX	DDMMMYYYY	NN:NN	NN:NN	NN:NN	NN:NN	XXX
…	…	…	…	…	…	…	…	…	…	…	…

Listing 16.4.6 Listing of Prior and Concomitant Medication -Safety Population (N=XXX)

Site No./ Subject ID	Age/Sex	Medication	Indication	Start Date	Stop Date	Ongoing	Daily Dose	Units	Route	Frequency
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	NN	XXX	XXX	NN
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	NN	XXX	XXX	NN
NN/XXX	NN/XXX	XXX	XXX	DDMMMYYYY	DDMMMYYYY	XXX	NN	XXX	XXX	NN
…	…	…	…	…	…	…	…	…	…	…