PROTOCOL A5991093

NON-INTERVENTIONAL DRUG STUDY

A PROSPECTIVE NON-INTERVENTIONAL STUDY OF CHINA EARLY INVASIVE BREAST CANCER PATIENTS RECEIVING ADJUVANT THERAPY WITH AROMASIN®

STATISTICAL ANALYSIS PLAN
(SAP)

Version: 1.2

Author: PPD , CRDC, PPD , China

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[redacted]

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1. AMENDMENTS FROM PREVIOUS VERSION(S)

Version 1.2 is amended from version 1.1 based on protocol amendment 3 dated 20 Mar 2015. Please see the below table for the detailed amendments from previous versions.

Revision History

Version	Date	Author(s)	Summary of Changes/Comments
1.0	Jul 8, 2011	PPD	Original SAP
1.1	Nov 5, 2013	PPD	Update citation of protocol amendment 1 to protocol amendment 2; Details: Section 2 Add targeted data cut-off date for final analysis. Section 3 V1.0: "The first is to occur when approximately 50% of subjects completed their 1st year of follow up. The second is to occur when approximately 50% of subjects completed the study drug treatment or withdrawal from the study." V1.1: "The first interim analysis data cut-off date is Dec 31, 2013. The second interim analysis data cut-off date is Dec 31, 2015." Section 5.3 Revised definition of the safety analysis set from "all enrolled patients" to "all enrolled patients who take at least one dose of the study drug" Section 8.1.3 Add method of Hall and Wellner. Section 8.2.1 Add method of Brookmeyer and Crowley. Delete duplicated sentence. Section 8.2.2 Delete "history of disease" as it duplicates medical history. Section 10.2 Add programming details for calculating confidence intervals for median time to event.
1.2	Jun 21, 2015	PPD	Update citation of protocol amendment 2 to amendment 3; Details: Section 3 Updated time for interim analyses. V1.1: "The second interim analysis data cut-off date is Dec 31, 2015." V1.2: "The second interim analysis is to occur when the study enrolled 550 subjects." Section 8.2.2 Common Technology Criteria for Adverse Events Version 4.0 was changed to 3.0 to be consistent with the protocol amendment 3. Appendix 1.3 Derivation of HER2 status changed. V1.1:" HER2 status positive or negative is defined below:

[redacted]

Version	Date	Author(s)	Summary of Changes/Comments
			• HER2 positive if HER2 IHC status = 3+, HER2 FISH status = positive or HER2 CISH status = positive or HER2 mutation = positive. • HER2 positive if HER2 IHC status = 2+ or unknown or undone, HER2 FISH status = positive or HER2 CISH status = positive or HER2 mutation = positive. • HER2 negative if HER2 IHC status = 2+ or unknown or undone, HER2 FISH status = negative or HER2 CISH status = negative or HER2 mutation = negative. • HER2 negative if HER2 IHC status = 0 or 1+, HER2 FISH status = negative or HER2 CISH status = negative or HER2 mutation = negative." V1.2: "HER2 status positive or negative is defined below, note that the results from HER2 FISH, CISH and mutation should be the same. • If HER2 FISH status = positive or HER2 CISH status = positive or HER2 mutation = positive, then HER2 is positive. • If HER2 FISH status = negative or HER2 CISH status = negative or HER2 mutation = negative, then HER2 is negative. • If HER2 FISH, HER2 CISH and HER2 mutation are all undone or unknown, then • If HER2 IHC status = 3+, HER2 is positive. • If HER2 IHC status = 0 or 1+, HER2 is negative. • If HER2 IHC status = 2+ or unknown or undone, HER2 is unknown." Appendix 2.2: sample SAS code added. Appendix 2.3 and 2.4 was added for programming cox model for HER2 Status and programming Cox model for multiple factors with stepwise selection.

[redacted]

2. INTRODUCTION

Note: in this document any text copied directly from the protocol is ***italicised***.

Aromasin® (Exemestane) is an irreversible, steroidal aromatase inhibitor, structurally related to the natural substrate androstenedione. In post-menopausal women, oestrogens are produced primarily from the conversion of androgens into oestrogens through the aromatase enzyme in peripheral tissues. Oestrogen deprivation through aromatase inhibition is an effective and selective treatment for hormone dependent breast cancer in postmenopausal women. In the year 2002, Aromasin® (Exemestane) was approved in China for the treatment of advanced breast cancer in women with natural or induced postmenopausal status whose disease has progressed following tamoxifen therapy.

Aromasin® (Exemestane) was approved in China for adjuvant treatment of postmenopausal women with estrogen receptor (ER) positive early invasive breast cancer who have received 2-3 years of tamoxifen & are switched to Aromasin® for completion of a total of 5 consecutive years of adjuvant hormonal therapy by State Food and Drug Administration (CFDA) with clinical trial waive in May. 2008. The approval was granted in view of the significant efficacy and tolerant safety from the Intergroup Exemestane Study (IES), which was a phase III randomized controlled trial conducted primarily in Caucasian patients. While Aromasin® has been used in China for adjuvant therapy of breast cancer since then, there is currently lack of systematic collection and analysis for the efficacy and safety data of Aromasin® adjuvant setting in Chinese population. The Aromasin® Non-Interventional Study is being proposed to collect data systematically and to assess the efficacy and safety of Aromasin® adjuvant setting in Chinese population. Generation of such information is expected to provide evidence for Chinese physicians to manage clinical practice of Aromasin® adjuvant setting. The safety document will be used in this study is the Aromasin® Local Product Document approved by CFDA.

2.1. Study Design

This is a multicenter, non-interventional, and prospective clinical study. The study will collect and analyze the efficacy and safety data from consecutive 550 eligible patients from study beginning to Dec. 31, 2016. If the 550 patient's recruitment has completed before Dec.31, 2016, the recruiting will stop.

2.2. Study Objectives

To generate the efficacy and safety data from patients with early invasive breast cancer treated with Aromasin® in the adjuvant setting in China.

Primary objective: *Efficacy of the treatment with Aromasin® in postmenopausal women with estrogen receptor positive early invasive breast cancer who have received adjuvant Tamoxifen therapy for up to 2-3 years.*

Secondary objective: *Safety of the treatment with Aromasin® in women with postmenopausal estrogen receptor positive early invasive breast cancer who have received adjuvant Tamoxifen therapy for up to 2-3 years.*

3. INTERIM ANALYSES, FINAL ANALYSES AND UNBLINDING

Up to 2 early analyses of the data will be performed. The first interim analysis data cut-off date is Dec 31, 2013. The second interim analysis is to occur when the study enrolled 550 subjects. The final analysis will be done at the end of treatment.

4. HYPOTHESES AND DECISION RULES

4.1. Statistical Hypotheses

This study is non-comparative and no inferential statistical analyses are planned. Analyses will consist of descriptive statistics and corresponding 95% 2-sided confidence intervals when appropriate.

4.2. Statistical Decision Rules

There are no statistical decision rules.

5. ANALYSIS SETS

5.1. Full Analysis Set

The Full Analysis Set (FAS) will be defined as all patients who receive at least one dose of Aromasin® during the observation period. All efficacy analyses will be performed using the FAS.

5.2. 'PER PROTOCOL' Analysis Set

Not applicable.

5.3. Safety Analysis Set

The safety population will be defined as all enrolled patients who take at least one dose of the study drug; all summaries of safety will be reported within the safety.

5.4. Other Analysis Sets

Not applicable.

5.5. Treatment Misallocations

Not applicable.

5.6. Protocol Deviations

Not applicable.

[redacted]

6. ENDPOINTS AND COVARIATES

6.1. Primary Efficacy Endpoint

The primary efficacy endpoint is time-to-recurrence, where recurrence is defined as the earliest occurrence of any of the following:

- Locoregional/distant recurrence of the primary breast cancer.
- Appearance of 2nd primary or contralateral breast cancer.
- Death due to any cause.

Locoregional recurrence is defined as any recurrence in the ipsilateral breast, chest wall or axillary lymph nodes.

6.2. SECONDARY EFFICACY Endpoints

Locoregional/distant recurrence, appearance of 2nd primary or contralateral breast cancer, and death will also be summarized as follows:

- Time to each event.
- The proportion of subjects experiencing each event.
- The incidence rate (per annum) is defined as a ratio of the number of events and the total exposure time (in years) to Aromasin® therapy.

6.3. Safety Endpoints

Safety endpoints include:

- Adverse events of particular interest are as follows:
    - Gynaecological: Bleeding ,discharge, uterine dilatation and curettage;
    - Cardiac: myocardial infarction, hypertension;
    - Venous thromboembolic events;
    - Musculoskeletal: Joint stiffness, arthralgia, muscle cramps, fractures;
    - Menopausal symptoms: Hot flushes, anxiety, depression, headaches.
- Changes in laboratory parameters, including lipids.
- Changes in bone mineral density.
- Vital signs.

[redacted]

- Reasons for discontinuation of Aromasin® therapy.
- Duration of Aromasin® therapy.

6.4. Other Endpoints

Not applicable.

6.5. PK Endpoints

Not applicable.

6.6. PD Endpoints

Not applicable.

6.7. Outcomes Research (OR) Endpoints

None.

6.8. Covariates

The following subgroup is of interest:

- HER2 status (binary: positive, negative).

7. HANDLING OF MISSING VALUES

Censoring for time-to-recurrence is defined in Section 8.2. Subjects with missing value for a given efficacy variable will not contribute to the analysis of that variable.

8. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

8.1. Statistical Methods

8.1.1. Analyses for Continuous Data

Continuous variables will be presented using summary statistics: number of observations, arithmetic mean, standard deviation, standard error, minimum, maximum, and median values. Additional 2-sided 95% confidence intervals based on Student's t-distribution will also be presented where specified.

8.1.2. Analyses for Categorical Data

For dichotomous variables (proportions, incidences and HER2 status), the number and percent of subjects will be presented. A two-sided 95% confidence interval (Wilson score interval) will be presented for the percent.

8.1.3. Time to Event Data

Time-to-recurrence will be summarized using the Kaplan-Meier (KM) estimates of the survival function and presented graphically. KM plots will display months as the unit of time (365.25/12 days per month). If estimable, the median time to event (based on the KM

[redacted]

estimate) and its associated 2-sided 95% confidence interval (method of Brookmeyer and Crowley 1982) will also be presented. 95% confidence bands for the survival distribution (method of Hall and Wellner, 1980) will be computed. In addition, a Cox regression model will also be fit for the purpose of comparing subgroup of HER2 status level, and hazard ratio estimated along with corresponding 2-sided 95% confidence interval.

8.2. Statistical Analyses

8.2.1. Efficacy Analyses

All summaries of efficacy parameters will be reported within the FAS population. Analyses will be primarily descriptive in nature, and therefore no statistical sample size estimation was performed.

Primary analysis

The primary analysis is time-to-recurrence, where recurrence is defined as the earliest occurrence any of the following:

- Locoregional/distant recurrence of the primary breast cancer.
- Appearance of 2nd primary or contralateral breast cancer.
- Death due to any cause.

Time-to-recurrence is calculated as the time from date of enrollment to first objective documentation of the recurrence defined above. In the analysis of time to recurrence, subjects lost to follow-up and subjects who are still being followed at the time of analysis with no documented event will be censored at the last date the subject was known to be event-free. The Kaplan Meier non-parametric estimate will be used to summarize the survival distribution and median for time-to-event. 95% confidence interval for median time to event (method of Brookmeyer and Crowley 1982) and 95% confidence bands for the survival distribution (method of Hall and Wellner, 1980) will be computed.

Secondary analyses

Locoregional/distant recurrence, appearance of 2nd primary or contralateral breast cancer, and death will also be summarized as follows:

- Time to each event will be summarized similarly as the primary analyses for time-to-recurrence (See Section 8.1.3).
- Summary statistics for the proportion of subjects experiencing each event.
- Summary statistics for the incidence rate (per annum), defined as a ratio of the number of events and the total exposure time (in years) to Aromasin® therapy.

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8.2.2. Safety Analyses

All summaries will use the safety analysis set.

Adverse events which will be graded according to grades of severity specified in the Common Technology Criteria for Adverse Events Version 3.0 (CTCAE v3.0). Pfizer data standards (PDS) will be used to summarize all safety data.

Patient baseline characteristics (demography, breast cancer history, medical history, primary diagnosis, lab data, treatment history related to primary diagnosis, history of hormonal therapy received before Aromasin, location of primary diagnosis, histopathological classification and grade, TNM stage) will also be summarized according to PDS. Vital signs, ECOG status, laboratory data and physical examination will be summarized by visit using observed data as well as each patient's last available value.

[redacted]

9. REFERENCES

1. Brookmeyer R, Crowley JJ. A confidence interval for the median survival time. Biometrics 1982; 38:29-41.

2. Hall, W. J. and Wellner, J. A. (1980), "Confidence Bands for a Survival Curve for Censored Data," *Biometrika 69*.

[redacted]

10. APPENDICES

Appendix 1. DATA DERIVATION DETAILS

Appendix 1.1. Derivation of Local, Distant and Locoregional

Cancer Event Assessment Case Report Form

Protocol ID: A5991093

Non Interventional Study - Exemestane

Visit: End of Study

CENTER ☐☐☐☐ SUBJECT ID ☐☐☐☐☐☐☐☐

DATE OF VISIT ☐☐ - ☐☐☐ - ☐☐☐☐
dd MMM yyyy

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CANCER EVENT ASSESSMENT: (Page 1 of 2)

☐ **(1) NOT DONE**

Date of test
(dd-MMM-yyyy): ___ - ___ - ___

Status (Check (X) ONE only):
☐ (1) No Recurrent Disease
☐ (1) Recurrent Disease

Disease Site
(Check (X) ONE only): ☐ (1) Brain ☐ (12) Breast ☐ (17) Lung
☐ (8) Bone ☐ (24) Lymph node ☐ (28) Liver
☐ (999) Other
If Disease Site Other, specify: ____________

Confirmed Method
(Check (X) ONE only): ☐ (1) Conventional CT scan ☐ (4) MRI ☐ (40) Mammogram
☐ (999) Other
If Confirmed Method other, specify: ____________

Disease Site
(Check (X) ONE only): ☐ (1) Brain ☐ (12) Breast ☐ (17) Lung
☐ (8) Bone ☐ (24) Lymph node ☐ (28) Liver
☐ (999) Other
If Disease Site Other, specify: ____________

Confirmed Method
(Check (X) ONE only): ☐ (1) Conventional CT scan ☐ (4) MRI ☐ (40) Mammogram
☐ (999) Other
If Confirmed Method other, specify: ____________

Disease Site
(Check (X) ONE only): ☐ (1) Brain ☐ (12) Breast ☐ (17) Lung
☐ (8) Bone ☐ (24) Lymph node ☐ (28) Liver
☐ (999) Other
If Disease Site Other, specify: ____________

Confirmed Method
(Check (X) ONE only): ☐ (1) Conventional CT scan ☐ (4) MRI ☐ (40) Mammogram
☐ (999) Other
If Confirmed Method other, specify: ____________

Disease Site
(Check (X) ONE only): ☐ (1) Brain ☐ (12) Breast ☐ (17) Lung
☐ (8) Bone ☐ (24) Lymph node ☐ (28) Liver
☐ (999) Other
If Disease Site Other, specify: ____________

Confirmed Method
(Check (X) ONE only): ☐ (1) Conventional CT scan ☐ (4) MRI ☐ (40) Mammogram
☐ (999) Other
If Confirmed Method other, specify: ____________

Continue to next page

[redacted]

The following types of cancer recurrence will be derived from the Cancer Event Assessment CRF:

- Local: "Recurrent Disease" is checked on the CRF and “Disease Site” is marked "Breast".
- Distant: "Recurrent Disease" is checked on the CRF and “Disease Site” is marked something other than breast (brain, lung, bone, lymph node, liver, other).
- Time to Locoregional recurrence: Time from inclusion into the study to the date of the first documentation of locoregional recurrence. Specifically, time to Locoregional recurrence is (date of inclusion into the study) – (first date of documented locoregional recurrence) +1.

Locoregional recurrence is defined as any recurrence in the ipsilateral breast, chest wall or axillary lymph nodes.

[redacted]

Appendix 1.2. Derivation of Appearance of 2^{nd} Primary or Contralateral Breast Cancer

Protocol ID: A5991093

CENTER ☐☐☐☐ SUBJECT ID ☐☐☐☐☐☐☐☐ [redacted]

Non Interventional Study - Exemestane

DATE OF VISIT ☐☐ (dd) ☐☐☐ (MMM) ☐☐☐☐ (yyyy)

Visit: End of Study

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CANCER EVENT ASSESSMENT: (Page 2 of 2)

SECOND PRIMARY MALIGNANCY OF BREAST CANCER

☐ (1) Second Primary Malignancy of Breast Cancer Date (dd-MMM-yyyy): __ - ___ - ____

Histological Classification:
- ☐ (2) Ductal Carcinoma
- ☐ (3) Lobular Carcinoma
- ☐ (4) Papillary Carcinoma
- ☐ (5) Medullary Carcinoma
- ☐ (6) Mucinous ("colloid") Carcinoma
- ☐ (999) Other Specify: ______

SECOND PRIMARY MALIGNANCY OTHER THAN BREAST CANCER

☐ (1) Second Primary Malignancy other than Breast Cancer Date (dd-MMM-yyyy): __ - ___ - ____

Diagnosis: ______

Histological Classification:
Specify: ______

☐ (1) Second Primary Malignancy other than Breast Cancer Date (dd-MMM-yyyy): __ - ___ - ____

Diagnosis: ______

Histological Classification:
Specify: ______

☐ (1) Second Primary Malignancy other than Breast Cancer Date (dd-MMM-yyyy): __ - ___ - ____

Diagnosis: ______

Histological Classification:
Specify: ______

☐ (1) Second Primary Malignancy other than Breast Cancer Date (dd-MMM-yyyy): __ - ___ - ____

Diagnosis: ______

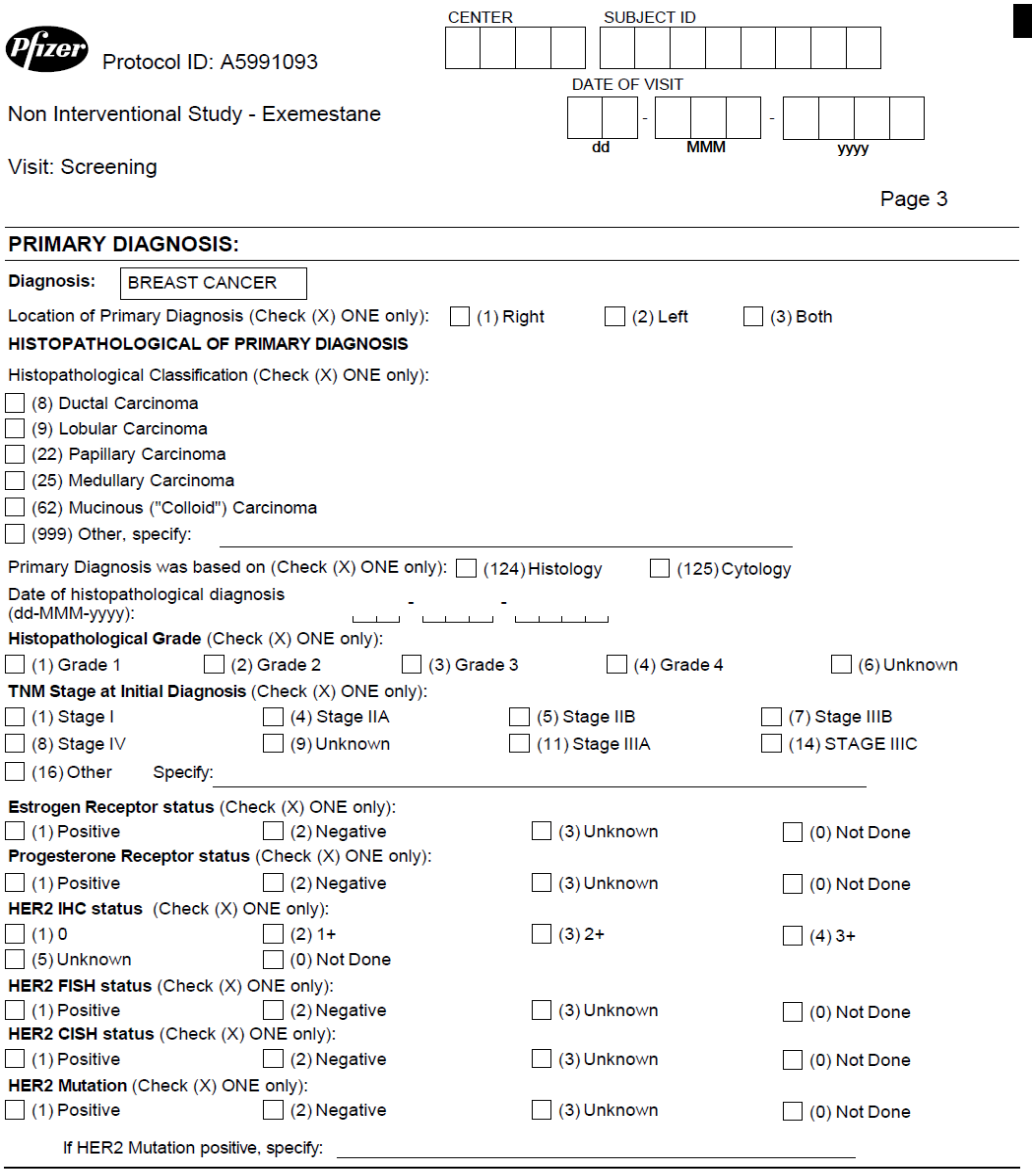
Histological Classification:
Specify: ______

- Appearance of 2^{nd} primary or contralateral breast cancer: When "Second Primary malignancy of breast cancer" is checked on the CRF. This represents either ipsilateral or contralateral breast cancer recurrence. When "Second Primary malignancy other than breast cancer" is checked, a disease site other than breast **will not** be considered recurrent disease.

- Time to appearance of 2^{nd} primary or contralateral breast cancer: Time from inclusion into the study to the date of the first documentation appearance of 2^{nd} primary malignancy of breast cancer or contralateral breast cancer. Specifically, time to appearance of 2^{nd} primary or contralateral breast cancer is (date of inclusion into the study) – (first date of documented appearance of 2^{nd} primary or contralateral breast cancer) +1.

[redacted]

Appendix 1.3. Derivation of HER2 Status



CENTER SUBJECT ID

Protocol ID: A5991093

DATE OF VISIT

dd - MMM - yyyy

Non Interventional Study - Exemestane

Visit: Screening

Page 3

PRIMARY DIAGNOSIS:

Diagnosis: BREAST CANCER

Location of Primary Diagnosis (Check (X) ONE only): ☐ (1) Right ☐ (2) Left ☐ (3) Both

HISTOPATHOLOGICAL OF PRIMARY DIAGNOSIS

Histopathological Classification (Check (X) ONE only):

☐ (8) Ductal Carcinoma
☐ (9) Lobular Carcinoma
☐ (22) Papillary Carcinoma
☐ (25) Medullary Carcinoma
☐ (62) Mucinous ("Colloid") Carcinoma
☐ (999) Other, specify: _____

Primary Diagnosis was based on (Check (X) ONE only): ☐ (124) Histology ☐ (125) Cytology

Date of histopathological diagnosis (dd-MMM-yyyy): __ - ___ - ____

Histopathological Grade (Check (X) ONE only):

☐ (1) Grade 1 ☐ (2) Grade 2 ☐ (3) Grade 3 ☐ (4) Grade 4 ☐ (6) Unknown

TNM Stage at Initial Diagnosis (Check (X) ONE only):

☐ (1) Stage I ☐ (4) Stage IIA ☐ (5) Stage IIB ☐ (7) Stage IIIB
☐ (8) Stage IV ☐ (9) Unknown ☐ (11) Stage IIIA ☐ (14) STAGE IIIC
☐ (16) Other Specify: _____

Estrogen Receptor status (Check (X) ONE only):

☐ (1) Positive ☐ (2) Negative ☐ (3) Unknown ☐ (0) Not Done

Progesterone Receptor status (Check (X) ONE only):

☐ (1) Positive ☐ (2) Negative ☐ (3) Unknown ☐ (0) Not Done

HER2 IHC status (Check (X) ONE only):

☐ (1) 0 ☐ (2) 1+ ☐ (3) 2+ ☐ (4) 3+
☐ (5) Unknown ☐ (0) Not Done

HER2 FISH status (Check (X) ONE only):

☐ (1) Positive ☐ (2) Negative ☐ (3) Unknown ☐ (0) Not Done

HER2 CISH status (Check (X) ONE only):

☐ (1) Positive ☐ (2) Negative ☐ (3) Unknown ☐ (0) Not Done

HER2 Mutation (Check (X) ONE only):

☐ (1) Positive ☐ (2) Negative ☐ (3) Unknown ☐ (0) Not Done

If HER2 Mutation positive, specify: _____

HER2 status positive or negative is defined below, note that the results from HER2 FISH, CISH and mutation should be the same.

- If HER2 FISH status = positive or HER2 CISH status = positive or HER2 mutation = positive, then HER2 is positive.
- If HER2 FISH status = negative or HER2 CISH status = negative or HER2 mutation = negative, then HER2 is negative.

[redacted]

- If HER2 FISH, HER2 CISH and HER2 mutation are all undone or unknown, then
  - If HER2 IHC status = 3+, HER2 is positive.
  - If HER2 IHC status = 0 or 1+, HER2 is negative.
  - If HER2 IHC status = 2+ or unknown or undone, HER2 is unknown.

[redacted]

Appendix 2. SAS PROGRAMMING DETAILS

Appendix 2.1. Programming Confidence Bands for KM Survival Curve

- Use of PROC LIFETEST;
- Create an OUTPUT dataset containing the survival estimates;
- Use CONFBAND = HW to produce confidence bands for the method of Hall and Wellner in the PROC LIFETEST statement.

Appendix 2.2. Programming Confidence Intervals for KM Median Time to Event

- Use of PROC LIFETEST;
- Use CONFTYPE=LINEAR to produce confidence intervals for the method of Brookmeyer and Crowley in the PROC LIFETEST statement;

Sample SAS code:

```
proc lifetest data=mydata outsurv=estimates confband=HW conftype=linear
timelist=182;
      time Days*Status(0);
run;
```

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