FA

Radiation Therapy Oncology Group
Phase III Study of HER2 Overexpressing Esophageal Adenocarcinoma
FACT-E Cover Sheet

RTOG Study No.1010 Case #

PLACE LABEL HERE

Institution Name Institution No.

Patient Initials RTOG Patient ID

AMENDED DATA ☐ YES

INSTRUCTIONS: This page must be completed by the medical staff(nurse, data manager, physician, etc.) Questionnaires for all time points are required even if submission time points deviate from the specified intervals. Only patient death or documented patient refusal will be an acceptable reason for omission of the QOL questionnaires. **However, this page must be completed and submitted for every time point on the calendar regardless of whether the QOL questionnaire was completed. Every effort possible should be made to collect the data on time**.

1 ☐ **TIME POINT**(1)
- 1 Pretreatment
  Treatment Start date _____-_____-_____(2)
- 2 6-8 weeks post chemo/RT (prior to surgical resection)
- 3 1 year from start of treatment
- 4 2 years from start of treatment

2 ☐ **WAS PATIENT QUESTIONNAIRE COMPLETED?**(3)
- 1 No
- 2 Yes

2A **DATE PATIENT QUESTIONNAIRE COMPLETED**(4)
_____-_____-_____

3 ☐ **REASON QUESTIONNAIRE WAS NOT COMPLETED**(5)
- 0 Not applicable, questionnaire was completed
- 1 Patient refused due to illness
- 2 Patient refused for other reason, specify_____(6)
- 3 Patient unable to be contacted
- 4 Institutional error
- 5 Tool not available in patient's language
- 6 Other reason, specify _____(7)
- 9 Unknown

4 ☐ **SPECIFY METHOD OF COMPLETION**(8)
- 0 Not applicable (not completed)
- 1 At appointment
- 2 By mail
- 3 By telephone
- 9 Unknown

5 ☐ **DID THE PATIENT REQUIRE ANY ASSISTANCE IN COMPLETING THE QUESTIONNAIRE?**(9)
- 0 Not applicable (not completed)
- 1 No
- 2 Yes
- 9 Unknown if assistance given

6 ☐ **SPECIFY THE PERSON WHO ASSISTED THE PATIENT**(10)
- 0 Not applicable (not completed, no assistance)
- 1 Staff member
- 2 Family
- 3 Other, specify _____(11)
- 9 Unknown

7 ☐ **EXTENT OF THE ASSISTANCE**(12)
- 0 Not applicable (not completed, no assistance)
- 1 Read items to patient
- 2 Interpreted items for patient
- 3 Marked items per patient's response
- 4 Combination of above, specify _____(13)
- 5 Other, specify _____(14)
- 9 Unknown

_____ Signature of person completing this form(15)

_____-_____-_____ Date form completed(16)

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FACT-E (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

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	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

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	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
HN1	I am able to eat the foods that I like	0	1	2	3	4
HN2	My mouth is dry	0	1	2	3	4
HN3	I have trouble breathing	0	1	2	3	4
HN4	My voice has its usual quality and strength	0	1	2	3	4
HN5	I am able to eat as much food as I want	0	1	2	3	4
HN 10	I am able to communicate with others	0	1	2	3	4
HN7	I can swallow naturally and easily	0	1	2	3	4
E1	I have difficulty swallowing solid foods	0	1	2	3	4
E2	I have difficulty swallowing soft or mashed foods	0	1	2	3	4
E3	I have difficulty swallowing liquids	0	1	2	3	4
E4	I have pain in my chest when I swallow	0	1	2	3	4
E5	I choke when I swallow	0	1	2	3	4
E6	I am able to enjoy meals with family or friends	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
E7	I wake at night because of coughing	0	1	2	3	4
ACT 11	I have pain in my stomach area	0	1	2	3	4
C2	I am losing weight	0	1	2	3	4

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