Pharmaceutical Supplemental Form

Instructions: *The TCGA treatment forms (Pharmaceutical and Radiation) act as supplemental forms to the Follow-up form and are due at the time the Follow-up form is submitted to the BCR. However, if the patient has completed treatment or if the patient is deceased, these forms can be submitted to the BCR at the time the Enrollment form is submitted.*

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By *(Interviewer Name on OpenClinica)*: _____Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	Please note that the time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box. *Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection).* *Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.*

Treatment Information

#	Data Element	Entry Alternatives	Working Instructions
2	Was Patient Treated on a Clinical Trial?	☐ Yes ☐ No	Indicate whether the patient was treated as part of a clinical trial (research study). 2503808
3	Drug Name (Brand or Generic)	_____	Provide the name of the individual pharmaceutical agent (drug) used to treat the patient. A separate form should be used for each drug. 2975232 *If patient is treated on a clinical trial and the drug name is unknown due to a blinded study or proprietary information, please leave this field blank and answer the next question regarding drug classification.*
4	Clinical Trial Drug Classification	_____	If the drug name is not available due to blinded clinical drug trial, indicate the drug classification or category associated with the specific therapeutic agent. 3378323
5	Pharmaceutical Type	☐ Chemotherapy ☐ Hormone Therapy ☐ Immunotherapy ☐ Targeted Molecular Therapy ☐ Ancillary ☐ Vaccine	Indicate the pharmaceutical type (classification) for the drug being given. 2793530
Date of Therapy Start			
6	Month of Therapy Start	☐ 01 ☐ 04 ☐ 07 ☐ 10	Provide the month that pharmaceutical therapy was started.

Pharmaceutical Supplemental Form

#	Data Element	Entry Alternatives	Working Instructions
		☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	3103072
7	Day of Therapy Start	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	Provide the day that pharmaceutical therapy was started. 3103070
8	Year of Therapy Start	_____	Provide the year that pharmaceutical therapy was started. 3103074
9	Number of Days from Date of Initial Pathologic Diagnosis to Date of Therapy Start	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of start of pharmaceutical therapy. 3392465 *Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.*
10	Therapy Ongoing	☐ Yes ☐ No	Indicate whether pharmaceutical therapy is ongoing. 3103479 *If therapy ongoing, date of therapy end should not be completed.*
Date of Therapy End			
11	Month of Therapy End	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month that pharmaceutical therapy was completed/ ended. 3103080
12	Day of Therapy End	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	Provide the day that pharmaceutical therapy was completed/ ended. 3103078
13	Year of Therapy End	_____	Provide the year that pharmaceutical therapy was completed/ ended. 31030782
14	Number of Days from Date of Initial Pathologic Diagnosis to Date of Therapy End	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of end of pharmaceutical therapy. 3392470 *Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.*
15	Measure of Best Response of Treatment	☐ Complete Response ☐ Partial Response ☐ Stable Disease ☐ Progressive Disease ☐ Not Applicable (Therapy Ongoing) ☐ Unknown	Indicate the patient's outcome (response) at the end of this treatment regimen. 2857291

_____ _____ ___ ___/ ___ ___/ ___ ___ ___ ___

Principal Investigator or Designee Signature | Print Name | Date