IBCSG

DataFax #054 Plate #108

SAE Number (001, 002, 003, etc.) ☐☐☐

IBCSG Patient ID 54☐☐☐☐ **Center Code** ☐☐☐☐☐☐☐☐ **Ver. #** 1

Patient Birth Year ☐☐☐☐ Country _____

SERIOUS ADVERSE EVENT FORM (Form 54-SAE-A)

Instructions: Submit 54-SAE-A form within 24 hours of awareness from the time Informed Consent has been signed, until 28 days after treatment stops. Cases of second (non-breast) malignancy and congenital anomalies must always be reported, even after 28 days of treatment stop. **Submit 54-SAE-B** within 15 days of initial report and/or for definitive SAE outcome.

SERIOUS ADVERSE EVENT ONSET

	day	month	year
1. **Date of onset**	☐☐	☐☐	☐☐☐☐
2. **Date Investigator became aware of SAE**	☐☐	☐☐	☐☐☐☐

3. **Serious Adverse Event**
   a. Main Event _____
   b. CTCAE* Grade for *Main* Event ☐
   c. Brief Description (development, signs and symptoms): _____

4. **Reason for seriousness:** (select one only)
   - ☐ Fatal (any cause). If **fatal**, submit SAE-B Form with SAE-A Form.
   - ☐ Life-threatening
   - ☐ Requires or prolongs inpatient hospitalization (except elective surgery or progression of disease)
   - ☐ Results in persistent or significant disability/incapacity
   - ☐ Congenital anomaly or birth defect (including neonatal deaths)
   - ☐ Second (non-breast) malignancy
   - ☐ Relevant medical event
   - ☐ Pregnancy/Lactation
   - ☐ Other, specify _____

5. In the Investigator's opinion, the *Main* Event was most likely due to:

_____

_____

_____

* CTCAE - Common Terminology Criteria for Adverse Events, v4, National Cancer Institute.

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6. **Protocol therapy at time of SAE**

a. **Trial phase (select one)**

☐ On trial treatment or within (≤) 28 days after stopping all trial treatment - complete Q6b or Q6c

☐ More than (>) 28 days after all trial treatment discontinuation - go to Q7

☐ Never started any trial treatment - go to Q7

Note: Report all SAEs beyond 28 days that are considered at least possibly related to previous trial treatment. Cases of second (non-breast) malignancies and congenital anomalies must always be reported.

b. **Trial treatment - ARM A (If on ARM B, skip to Q6c)**

Paclitaxel 90 mg/m^2, days 1, 8, 15 every 4 weeks.

Start Date (day ☐☐ month ☐☐ year ☐☐☐☐) Date of last administration before SAE (day ☐☐ month ☐☐ year ☐☐☐☐) Causality Code ☐ Action Taken Code ☐ If "7, Other" specify _____

If Action Taken Code 4 or 5, reduced dose ☐☐☐ mg/m^2

c. **Trial treatment - ARM B**

Vinorelbine 40 mg, days 1, 3, 5 each week

Start Date (day ☐☐ month ☐☐ year ☐☐☐☐) Date of last administration before SAE (day ☐☐ month ☐☐ year ☐☐☐☐) Causality Code ☐ Action Taken Code ☐ If "7, Other" specify _____

If Action Taken Code 4 or 5, reduced dose ☐☐☐ mg

Cyclophosphamide 50mg daily

Start Date (day ☐☐ month ☐☐ year ☐☐☐☐) Date of last administration before SAE (day ☐☐ month ☐☐ year ☐☐☐☐) Causality Code ☐ Action Taken Code ☐ If "7, Other" specify _____

If Action Taken Code 4 or 5, reduced dose ☐☐☐ mg

Capecitabine 500mg three times daily

Start Date (day ☐☐ month ☐☐ year ☐☐☐☐) Date of last administration before SAE (day ☐☐ month ☐☐ year ☐☐☐☐) Causality Code ☐ Action Taken Code ☐ If "7, Other" specify _____

If Action Taken Code 4 or 5, reduced dose ☐☐☐ mg

Causality Codes*
1 - Suspected
2 - Not suspected

Action Taken Codes
1 - None
2 - Dose delayed
3 - Dose delayed, restarted at same dose
4 - Dose delayed, restarted at reduced dose
5 - Dose reduced
6 - Permanently discontinued
7 - Other, specify

* Suspected:
Definite: The adverse event is *clearly related* to the study treatment.
Probable: The adverse event is *likely related* to the study treatment.
Possible: The adverse event *may be related* to the study treatment.

Not suspected:
Unlikely: The adverse event is *doubtfully related* to the study treatment.
Unrelated: The adverse event is *clearly NOT related* to the study treatment.

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Plate #110

SAE Number (001, 002, 003, etc.) ☐☐☐

IBCSG Patient ID 5 4 ☐☐☐☐

Center Code ☐☐☐☐☐☐☐☐ **Ver. #** 1

7. **Relevant tests/Laboratory data**

Relevant tests/Laboratory data	Results	Date Performed: day	month	year

8. **Significant Medical History, Concomitant Diseases and/or Relevant Medical Conditions**

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Investigator/*MD Name* *(please print)*

Investigator e-mail ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

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Form reviewed/approved/signed by Investigator/Designee Date ☐☐ ☐☐ ☐☐☐☐ *day month year*