IBCSG

DataFax #054 Plate #111

SAE Number (001, 002, 003, etc.) ☐☐☐

IBCSG Patient ID 5 4 ☐☐☐☐ **Center Code** ☐☐☐☐☐☐☐☐ **Ver. #** 1

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

Instructions: Submit SAE-B within 15 days of initial report and, if not resolved, revise for the definitive SAE outcome.

Follow-Up Report

	day	month	year
1. Date of onset	☐☐	☐☐	☐☐☐☐
2. Date of Follow-Up Report	☐☐	☐☐	☐☐☐☐

3. Treatments/procedures for SAE (please describe)

_____

_____

_____

Indicate Causality and Action Taken for each trial treatment if different from initial report:

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

Paclitaxel (ARM A) (If on ARM B, skip to page 2)

Causality Code ☐ Action Taken Code ☐ If "7 other", specify _____

If Action Taken is code 2 - 7, provide dates/dose as appropriate.

	day	month	year		
Date dose delayed	☐☐	☐☐	☐☐☐☐		
Date dose restarted	☐☐	☐☐	☐☐☐☐		
If reduced, date reduced and dose given	☐☐	☐☐	☐☐☐☐	reduced dose	☐☐☐ mg/m^2
Date treatment permanently discontinued	☐☐	☐☐	☐☐☐☐		

* 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.
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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Vinorelbine (ARM B)

Causality Code ☐ Action Taken Code ☐ If "7 other", specify ____________

If Action Taken is code 2 - 7, provide dates/dose as appropriate.

	day	month	year		
Date dose delayed	☐☐	☐☐	☐☐☐☐		
Date dose restarted	☐☐	☐☐	☐☐☐☐		
If reduced, date reduced and dose given	☐☐	☐☐	☐☐☐☐	reduced dose	☐☐☐ mg
Date treatment permanently discontinued	☐☐	☐☐	☐☐☐☐		

Cyclophosphamide (ARM B)

Causality Code ☐ Action Taken Code ☐ If "7 other", specify ____________

If Action Taken is code 2 - 7, provide dates/dose as appropriate.

	day	month	year		
Date dose delayed	☐☐	☐☐	☐☐☐☐		
Date dose restarted	☐☐	☐☐	☐☐☐☐		
If reduced, date reduced and dose given	☐☐	☐☐	☐☐☐☐	reduced dose	☐☐☐ mg
Date treatment permanently discontinued	☐☐	☐☐	☐☐☐☐		

Capecitabine (ARM B)

Causality Code ☐ Action Taken Code ☐ If "7 other", specify ____________

If Action Taken is code 2 - 7, provide dates/dose as appropriate.

	day	month	year		
Date dose delayed	☐☐	☐☐	☐☐☐☐		
Date dose restarted	☐☐	☐☐	☐☐☐☐		
If reduced, date reduced and dose given	☐☐	☐☐	☐☐☐☐	reduced dose	☐☐☐ mg
Date treatment permanently discontinued	☐☐	☐☐	☐☐☐☐		

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4. **Report all medications used to treat the SAE.**

SAE Treatment Codes	
1 - Anticoagulant	6 - Pain killers
2 - Antiemetic	7 - Antibiotics
3 - Opioids	8 - Growth factors
4 - i.v. fluids/electrolytes	9 - Other relevant drug
5 - Steroids	

SAE Treatment Codes	Agent Name (Trade Name of Medication)	Total Daily Dose of Agent		day	month	year	
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing
			Agent Start	☐☐	☐☐	☐☐☐☐	
☐	______	______	Agent End	☐☐	☐☐	☐☐☐☐	☐ Check box if continuing

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DataFax #054 Plate #114

SAE Number (001, 002, 003, etc.) ☐☐☐

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5. **Outcome** (select one)

	day	month	year	
☐ **Resolved**	☐☐	☐☐	☐☐☐☐	
☐ **Resolved with Sequelae**	☐☐	☐☐	☐☐☐☐	please specify ____________

____

☐ **Not resolved/ongoing** (Submit SAE-B Form every 15 days until resolved.)

☐ **Death** **Date of death** ☐☐ day ☐☐ month ☐☐☐☐ year

Primary cause of death (select only one)

- ☐ Progression of underlying breast cancer
- ☐ Second (non-breast) malignancy
- ☐ Myocardial infarction
- ☐ Thromboembolic event
- ☐ Cerebrovascular accident
- ☐ Other cause, specify ____________________
- ☐ Congestive heart failure
- ☐ Accident
- ☐ Sepsis / infection
- ☐ Suicide

Autopsy performed?

- ☐ No
- ☐ Yes. If **yes**, provide report.

____

Investigator/*MD Name* (please print)

Investigator email ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

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Form reviewed/approved/signed by Investigator/Designee

Date ☐☐ *day* ☐☐ *month* ☐☐☐☐ *year*