Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title ABBREVIATED FOLLOW-UP

This section should be completed ONLY if any systemic therapy (chemotherapy, hormonotherapy, gene-therapy or immunotherapy) has been given and documented for breast relapse and/or second primary malignancy.

PATIENT STATUS

Date of assessment : day / month / year

Are there any changes since previous assessment ? ☐0 No ☐1 Yes, *specify below*

- ☐1 Breast cancer relapse (Complete Forms B.C.R.1 and B.C.R.2)
- ☐2 Second primary malignancy (Complete form S.P.M.F.1)
- ☐3 Significant cardiac disease (Specify in form E.F.9) or if CHF then complete below CHF section
- ☐5 Death (Complete Death Report Form)
- ☐6 Lost to follow-up, Date of last contact: day / month / year
- ☐7 Other, specify: _____

CONGESTIVE HEART FAILURE

Did the patient experience congestive heart failure since last visit ?

☐0 No ☐1 Yes, *fill-in SAE form and complete below:*

Anthracycline / Anthracenedione

Did the patient receive anthracycline or anthracenedione since the end of chemotherapy visit ?

☐0 No ☐1 Yes, *specify below the cumulative dose since the end of chemotherapy visit:*

Product Name	Cumulative dose mg/m^2	Start date	Stop date
☐1 Doxorubicin	_____	day / month / year	day / month / year
☐2 Epirubicin	_____	day / month / year	day / month / year
☐3 Mitoxantrone	_____	day / month / year	day / month / year
☐4 Other specify: _____	_____	day / month / year	day / month / year

Radiotherapy

Did the patient receive radiotherapy after relapse to the mediastinum and/or left chest wall since the end of chemotherapy visit other than the adjuvant radiotherapy (if any)?

☐0 No ☐1 Yes

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title ADJUVANT RADIOTHERAPY

ADJUVANT RADIOTHERAPY

Did the patient receive radiation therapy?

☐ 0 No, *complete below.*

Please specify the main reason why the patient did not receive radiation therapy:(Select only one)

- ☐ 1 As per protocol (Mastectomy)
- ☐ 2 Investigator Decision
- ☐ 3 Patient Refusal
- ☐ 4 Other, specify _____

☐ 1 Yes, *complete below.*

Please specify the main reason why the patient received radiation therapy: (Select only one.)

- ☐ 1 As per protocol (Breast Conserving Surgery)
- ☐ 2 Institutional Guidelines (Post Mastectomy Radiotherapy)
- ☐ 3 Investigator Decision
- ☐ 4 Patient Request
- ☐ 5 Other, specify _____

If patient received radiation therapy, please complete below.

Site (description)	Left/Right	Estimated total dose (specify units) Dose	Units	Start Date	Stop Date	Stop Reason 1. As planned 2. Toxicity* 3. Other
Breast / Chest Wall 1.	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	
Boost 2. Breast	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	
Boost 3. Axillary Lymph node	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	
Axillary region 4.	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	
Supraclavicular region 5.	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	
Internal mammary chain 6.	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	
Other, specify:_____ 7.	☐ 1 Left ☐ 2 Right		☐ 3 cGy ☐ 1 Gy ☐ 2 rads	day month year	day month year	

*If toxicity, report on E.F.9

BASELINE

CONFIDENTIAL PATIENT DATA

INVESTIGATOR'S NAME: _____

INVESTIGATOR'S NO.: | | | | | | | |

~~BCIRG 005 (TAX GMA 301)~~

A MULTICENTER PHASE III RANDOMIZED TRIAL COMPARING DOCETAXEL IN COMBINATION WITH DOXORUBICIN AND CYCLOPHOSPHAMIDE (TAC) VERSUS DOXORUBICIN AND CYCLOPHOSPHAMIDE FOLLOWED BY DOCETAXEL (AC → T) AS ADJUVANT TREATMENT OF OPERABLE BREAST CANCER HER2NEU NEGATIVE PATIENTS WITH POSITIVE AXILLARY LYMPH ~~NODES.~~

PATIENT INITIALS: | | | | (First Mid Last)

PATIENT NUMBER: | | | | | | |

CRA BUSINESS CARD:

Protocol No BCIRG 005 TAX GMA 301	Investigator No	Patient Initials	Site No.	Patient No.	BASELINE REGISTRATION

PLEASE COMPLETE REGISTRATION FORM (Pages B/R.1 to B/R.6) AND FAX TO BCIRG AS PER "SECTION 5.8 - STUDY ENTRY REGISTRATION" SECTION OF THE PROTOCOL

BCIRG 005/ PATIENT REGISTRATION FORM AND BASELINE ASSESSMENT

Site Information:

Principal Investigator's Name / Institution (country): _____

Fax Number: [ ] country code [ ] area code [ ] fax number

Phone Number: [ ] country code [ ] area code [ ] phone number

Startup date of treatment planned: [ ] day [ ] month [ ] year

PATIENT DATE OF BIRTH /SEX/ INFORMED CONSENT

Patient Date of birth: [ ] day [ ] month [ ] year Sex: ☐ 1 Male* ☐ 2 Female

Date informed consent was obtained from patient: [ ] day [ ] month [ ] year

TUMOR SAMPLE SHIPMENT FOR HER2NEU

HER2Neu sample was sent to Central Lab?

☐ 0 No ☐ 1 Yes

If Yes, date specimen was sent: [ ] day [ ] month [ ] year

Date specimen was collected: [ ] day [ ] month [ ] year

Please specify sample number from originating site lab: No.: [ ]

CHILDBEARING POTENTIAL

Patient is of childbearing potential: ☐ 0 No ☐ 1 Yes

If YES, is adequate contraception being practiced? ☐ 0 No** ☐ 1 Yes

If YES, specify contraception method: _____

** Patient is NOT eligible if adequate contraception not implemented. Only non hormonal contraception is allowed. Hormonal contraception must be stopped before study entry and report on page E.F.3

PREGNANCY TEST (For patient of childbearing potential only)

☐ 1 Not Applicable To be performed within 7 days prior to registration.

Date of sample: [ ] day [ ] month [ ] year Results: ☐ 1 Positive* ☐ 2 Negative

PERFORMANCE STATUS

To be performed within 14 days prior to registration.

Date of assessment: [ ] day [ ] month [ ] year Performance Status (0 to 100, Karnofsky index): [ ] %

* Patient is NOT eligible.

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STAGING AT FIRST DIAGNOSIS AJCC Cancer Staging Manual, 5th Edition 1997

pT- Primary Tumor (Post surgical)

*pTX Primary tumor cannot be assessed

*pTO No evidence of primary tumor

*pTIS Carcinoma in situ: intraductal carcinoma, or lobular carcinoma in situ, or Paget disease of the nipple with no tumor

pT1 Tumor of 2 cm or less in its greatest dimension

pT2 Tumor more than 2 cm but not more than 5 cm in its greatest dimension

pT3 Tumor more than 5 cm in its greatest dimension

*pT4 Tumor of any size with direct extension to chest wall or skin

pN-Regional Lymph nodes (Post surgical)

*pNX Regional lymph nodes cannot be assessed

pNO No regional lymph nodes metastasis

pN1 Metastasis to movable ipsilateral axillary node(s)

*pN2 Metastasis to ipsilateral axillary node(s) that are fixed to one another or to other structures

*pN3 Metastasis to ipsilateral internal mammary lymph node(s)

M-Distant Metastases

*MX Presence of distant metastasis cannot be assessed

MO No distant metastasis

*M1 Distant metastasis (including metastasis to ipsilateral supraclavicular lymph nodes)

* Patient is NOT eligible.

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE REGISTRATION

BREAST CANCER SURGERY AND DIAGNOSIS

Primary tumor type: BREAST ☐ 1 Left ☐ 2 Right

SURGERY (check all that apply and specify dates)

	Date (day / month / year)
☐ 1 Lumpectomy	
☐ 2 Quadrantectomy/ Segmental	
☐ 3 Mastectomy	
☐ 4 Other, specify: _____	
☐ 4 Other, specify: _____	

HISTOPATHOLOGIC TYPE (check one)

☐ 1 Infiltrating Ductal Carcinoma
☐ 2 Infiltrating Lobular Carcinoma ☐ 3 Other, specify: _____

NUCLEAR GRADE (Refer to AJCC Cancer Staging Manual, 5th Edition, 1997)

☐ GX: Grade cannot be assessed
☐ G1: Well Differentiated
☐ G2: Moderately Differentiated
☐ G3: Poorly Differentiated
☐ G4: Undifferentiated

MARGINS IN THE DEFINITIVE SPECIMEN

Involved by the tumor or DCIS: ☐ 0 No ☐ 1 Yes *

AXILLARY LYMPH NODE DISSECTION

Axillary Node Dissection** ___ ___ ___ (day / month / year)

Number of resected axillary nodes (minimum of 6): ___

Number of positive axillary nodes (minimum of 1): ___

STAGING AT FIRST DIAGNOSIS Refer to the back of B/R.1 for a full description of each staging category.

pT ___ pN ___ M ___

Size: pT = ___ . ___ cm

* Patient is NOT eligible.

** Maximum of 60 days allowed from node dissection to registration.

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE REGISTRATION

HEMATOLOGY

To be performed within 14 days prior to registration.

Date of Sample: day / month / year

Test	Units		Value
	Recommended	Actual (Complete ONLY if differs from recommended)	
Hemoglobin	g/dl		
WBC	10^9/l		
Neutrophils (segs & bands)	10^9/l		
Platelets	10^9/l		

BLOOD CHEMISTRY

To be performed within 14 days prior to registration.

Date of sample: day / month / year

Laboratory Name: _____

Laboratory Address: _____

Test	Units		Value	Upper normal limit for the institution (same unit as value)
	Recommended	Actual (Complete ONLY if differs from recommended)		
Creatinine*	µmol/l			
Alkaline Phosphatase	IU/l			
ASAT (SGOT)	IU/l			
ALAT (SGPT)	IU/l			
Total Bilirubin	µmol/l			

*Complete Creatinine Clearance on page E.F.6 if the Serum Creatinine is ≥140 µmol/l (1.6 mg/dl).

HORMONAL RECEPTOR STATUS

Test	Estrogen receptors	Progesterone receptors
Biochemical method Date: day / month / year ☐ 1 Not Done	☐ 1 Positive ☐ 2 Negative ☐ 5 Not assessable/Not Done	☐ 1 Positive ☐ 2 Negative ☐ 5 Not assessable/Not Done
Immunohistochemistry Date: day / month / year ☐ 1 Not Done	☐ 1 Positive ☐ 2 Negative ☐ 5 Not assessable/Not Done	☐ 1 Positive ☐ 2 Negative ☐ 5 Not assessable/Not Done

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE REGISTRATION

PATIENT WORKUP

All tests must have been performed within 3 months prior to registration.

Type of Evaluation	Not Done	Date Assessed	Tumor Involvement	
			No	Yes*
1. Chest X-Ray (PA and lateral)**	☐ 0	day month year	☐ 0	☐ 1
2. Chest CT-Scan**	☐ 0	day month year	☐ 0	☐ 1
3. Chest MRI**	☐ 0	day month year	☐ 0	☐ 1
4. Abdominal Ultrasound***	☐ 0	day month year	☐ 0	☐ 1
5. Abdominal CT Scan***	☐ 0	day month year	☐ 0	☐ 1
6. Abdominal MRI***	☐ 0	day month year	☐ 0	☐ 1
7. Bone Scan (i.e. Scintingraphy)#	☐ 0	day month year	☐ 0	☐ 1
8. Bone X-Ray#	☐ 0	day month year	☐ 0	☐ 1
Contralateral Breast Imaging## ☐ 11 Not applicable due to prior procedure (Report on B.8 or E.F.7) Mammography ☐ 9 Left ☐ 10 Right	☐ 0	day month year	☐ 0	☐ 1
Ultrasound ☐ 15 Left ☐ 16 Right	☐ 0	day month year	☐ 0	☐ 1
12. Other, specify: _____	☐ 0	day month year	☐ 0	☐ 1
12. Other, specify: _____	☐ 0	day month year	☐ 0	☐ 1

* Patient is NOT eligible.
** Chest X-Ray or CT-Scan or MRI is MANDATORY.
*** Abdominal Ultrasound or MRI or CT Scan is MANDATORY.
# Bone Scan is MANDATORY. Positive Bone Scan should be confirmed by Bone X-Ray or CT-Scan or MRI to rule out metastatic hot spots on Bone Scan.
Contralateral Breast Imaging is MANDATORY.

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LEFT VENTRICULAR EJECTION FRACTION

To be performed within 3 months prior to registration.

Date of assessment: day / month / year

LVEF at rest	Value	Unit	Lower normal limit for the institution	Unit
☐ 1 Radionuclide angiocardiography (MUGA scan) ☐ 2 Echocardiography	.	%	.	%

ELECTROCARDIOGRAM

To be performed within 3 months prior to registration.

Date of assessment: day / month / year

☐ 1 Within normal Limits

☐ 3 Non-significant abnormalities

☐ 2 Significant abnormalities (If present, specify in B9)

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE REGISTRATION

OTHER CRITERIA

Please check the appropriate box for each question:

		No	Yes
1.	Patients will be accessible for treatment and follow-up. Patients registered for this trial must be treated and followed at participating centers which will include principal or co-investigator's sites.	☐ 0	☐ 1
2.	Prior or current systemic anticancer therapy for breast cancer (immunotherapy, genetherapy, hormonotherapy, chemotherapy).	☐ 0	☐ 1
3.	Prior anthracycline therapy, taxoids (paclitaxel, docetaxel ...) for any malignancy.	☐ 0	☐ 1
4.	Prior radiation therapy for breast cancer.	☐ 0	☐ 1
5.	Other serious illness or medical condition:		
	a) Congestive Heart Failure or unstable angina pectoris, previous history of myocardial effusion	☐ 0	☐ 1
	b) history of significant neurologic or psychiatric disorders including psychotic disorders, dementia or seizures that would prohibit the understanding and giving of informed consent	☐ 0	☐ 1
	c) active uncontrolled infection	☐ 0	☐ 1
	d) active peptic ulcer, unstable diabetes mellitus	☐ 0	☐ 1
6.	Current therapy with any hormonal agent such as raloxifene, tamoxifen, or other selective estrogen receptor modulators (SERMs), either for osteoporosis or prevention of breast cancer.	☐ 0	☐ 1
7.	Chronic treatment with corticosteroids unless initiated > 6 months prior to study entry and at low dose ($\leq$ 20 mg methylprednisolone or equivalent).	☐ 0	☐ 1
8.	Concurrent treatment with ovarian hormonal replacement therapy. Treatment must be stopped prior to randomization.	☐ 0	☐ 1
9.	Definite contraindications for the use of corticosteroids.	☐ 0	☐ 1
10.	Concurrent treatment with any other anti-cancer therapy or other experimental drugs. Participation in another clinical trial with any investigational not marketed drug within 30 days prior to study entry.	☐ 0	☐ 1
11.	Patient has pre-existing motor or sensory neurotoxicity of a severity $\geq$ grade 2 by NCI criteria.	☐ 0	☐ 1
12.	Patient is lactating.	☐ 0	☐ 1
13.	Past or current history of other neoplasm:	☐ 0	☐ 1

If "Yes", specify below (check all that apply) and complete form E.F.4

- ☐ Curatively treated non-melanoma skin cancer.
- ☐ In situ carcinoma of the cervix.
- ☐ Cancer curatively treated and with no evidence of disease for at least 10 years.
- ☐ Ipsilateral ductal carcinoma in situ (DCIS) of the breast.
- ☐ Lobular carcinoma of the breast (LCIS) (Ipsilateral or Contralateral)
- ☐ Other, specify: _____

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE

PHYSICAL EXAMINATION

To be performed within 14 days prior to registration.

Date of assessment: day / month / year

☐ 1 Normal ☐ 2 Abnormal, please specify in form B.9

WEIGHT, HEIGHT & BSA

Record the assessment closest to the first infusion.

Date of assessment: day / month / year

Weight	Height	BSA
☐ 1 lb ☐ 2 kg	☐ 1 in ☐ 2 cm	m^2

QUALITY OF LIFE QUESTIONNAIRE

☐ 0 Not Done To be completed within 14 days prior to registration.

Date of completion: day / month / year

EORTC QLQ-C30 (version 3.0)	☐ 0 No	☐ 1 Yes	☐ 2 Not available in patient's language
EORTC QLQ-BR23 (version 1.0)	☐ 0 No	☐ 1 Yes	☐ 2 Not available in patient's language
EURO QOL-5D	☐ 0 No	☐ 1 Yes	☐ 2 Not available in patient's language

MENOPAUSAL STATUS (To be completed within 3 months prior to treatment)

Date of last menses: day / month / year

Hormonal treatment replacement: ☐ 0 No ☐ 1 Yes Stop Date: day / month / year

If yes, report hormonal treatment on E.F.3

Bilateral ovariectomy: ☐ 0 No ☐ 1 Yes Date: day / month / year

Hysterectomy: ☐ 0 No ☐ 1 Yes Date: day / month / year

In case of hysterectomy without bilateral ovariectomy in patients ≤ 55 years old, FSH and LH values must be collected, within 3 months prior to registration, in order to determine menopausal status.

FSH/LH ☐ 1 Not Applicable

Laboratory Name: _____

Date of sample: day / month / year

Laboratory Address: _____

_____

Test	Units		Value	Postmenopausal Institution Limits (same as reported units)	
	Recommended	Actual (Complete ONLY if differs from recommended)		Lower	Upper
FSH	IU/l				
LH	IU/l				

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE

GENERAL MEDICAL/ SURGICAL HISTORY AND CONCOMITANT CONDITIONS, OTHER THAN CANCER

☐$_0$ Check if None

Please enter any significant and relevant medical/ surgical history and concomitant medical conditions of the patient other than cancer.

Cardiac history (e.g.: myocarditis, pericarditis...) and cardiac risk factors (eg: obesity, high blood pressure...) should be accurately documented.

Allergic history should be thoroughly documented (including allergy to polysorbate 80).

Any changes occurring during the study will be documented on the Clinical Adverse Experiences form.

Description	Date Ceased or indicate if ongoing (Ong)
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong
	day month year ☐$_1$ Ong

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	BASELINE

EXISTING SIGNS AND SYMPTOMS

☐$_0$ Check if none

Please describe below any signs and symptoms reported at study entry whether related to previous or ongoing therapies or diseases. Any relevant sign and symptom which occurred in the past two weeks should also be reported. During the study all ongoing signs and symptoms will be followed on the Clinical Adverse Experiences form, at the appropriate cycle.

Report all Relevant Medications on E.F.3

Signs and symptoms (Please report NCI term or the most appropriate medical term when NCI term is not available.)	**Grade #** (1-4)	**Indicate if Ongoing or Ceased** (or specify dates of infection)
Cardiac Ischemia / Infarction		☐$_1$ Ongoing ☐$_2$ Ceased
Cardiac Left Ventricular Function		☐$_1$ Ongoing ☐$_2$ Ceased
Cardiovascular/Arrhythmia - Other (specify: _____)		☐$_1$ Ongoing ☐$_2$ Ceased
Dry Skin		☐$_1$ Ongoing ☐$_2$ Ceased
Dyspnea		☐$_1$ Ongoing ☐$_2$ Ceased
Fatigue		☐$_1$ Ongoing ☐$_2$ Ceased
Irregular Menses		☐$_1$ Ongoing ☐$_2$ Ceased
Lymphatics		☐$_1$ Ongoing ☐$_2$ Ceased
Neuropathy-motor		☐$_1$ Ongoing ☐$_2$ Ceased
Neuropathy-sensory		☐$_1$ Ongoing ☐$_2$ Ceased
Pericardial Effusion / Pericarditis		☐$_1$ Ongoing ☐$_2$ Ceased
Peripheral Edema#		☐$_1$ Ongoing ☐$_2$ Ceased
Pleural Effusion		☐$_1$ Ongoing ☐$_2$ Ceased
Infection without neutropenia (specify site) _____		day month year ☐$_1$ Ongoing / day month year
		☐$_1$ Ongoing ☐$_2$ Ceased
		☐$_1$ Ongoing ☐$_2$ Ceased
		☐$_1$ Ongoing ☐$_2$ Ceased
		☐$_1$ Ongoing ☐$_2$ Ceased
		☐$_1$ Ongoing ☐$_2$ Ceased
		☐$_1$ Ongoing ☐$_2$ Ceased
		☐$_1$ Ongoing ☐$_2$ Ceased

If NCI version 2.0 grade is not applicable, code severity as: 1= Mild, 2= Moderate, 3= Severe, 4= Life threatening.

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title BREAST CANCER RELAPSE SECTION

BREAST CANCER RELAPSE

Date of relapse : day / month / year

Check all that apply:

☐ Local relapse

- ☐ 1 Scar
- ☐ 2 Ipsilateral breast
- ☐ 3 Ipsilateral anterior chest wall
- ☐ 4 Skin or soft tissue within the local area

Mandatory histopathologic or cytological proof obtained: ☐ 0 No ☐ 1 Yes Date : day / month / year

☐ Regional relapse

- ☐ 1 Ipsilateral axillary lymph node
- ☐ 2 Ipsilateral internal mammary lymph node
- ☐ 3 Ipsilateral infraclavicular lymph node
- ☐ 4 Skin or soft tissue within the regional area

Mandatory histopathologic or cytological proof obtained: ☐ 0 No ☐ 1 Yes Date : day / month / year

☐ Distant relapse

- ☐ 1 Ipsilateral supraclavicular lymph node
- ☐ 2 Contralateral breast cancer*
- ☐ 3 Solitary Bone Lesion
- ☐ 4 Multiple Bone Lesions
- ☐ 5 Solitary Liver Lesion*
- ☐ 6 Multiple Liver Lesions
- ☐ 7 Solitary Lung Lesion*
- ☐ 8 Multiple Lung Lesions
- ☐ 9 Central Nervous System
- ☐ 10 Skin, other than specific in local or regional relapse
- ☐ 11 Other distant nodes, specify: _____
- ☐ 12 Other, specify: _____

Histopathologic or cytological proof obtained: ☐ 0 No ☐ 1 Yes Date : day / month / year

* Histopathological or cytological proof is preferred. Specimen to be submitted to **BCIRG** as per protocol.

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title BREAST CANCER RELAPSE SECTION

ANTI-TUMOR THERAPY FOR BREAST CANCER RELAPSE

☐$_0$ Check if None — *Systemic anti-cancer therapy:*

Type of Therapy G : Gene therapy H : Hormonal I : Immunotherapy C : Chemotherapy O : Other	Trade Name (one drug per line)	Start Date	Stop Date
☐ G ☐ H ☐ I ☐ C ☐ O		day / month / year	day / month / year
☐ G ☐ H ☐ I ☐ C ☐ O		day / month / year	day / month / year

☐$_0$ Check if None — *Non-systemic anti-cancer therapy :*

Type of Therapy R : Radiotherapy S : Surgery	Site/Procedure for radiotherapy and surgery	Start Date	Stop Date
R ☐ S ☐		day / month / year	day / month / year
R ☐ S ☐		day / month / year	day / month / year

Protocol No BCIRG 005 TAX GMA 301	Investigator No	Patient Initials	Site No.	Patient No.	Visit Title CYCLE No

STUDY DRUG ADMINISTRATION FOR TAC AND AC ⟶ T ARMS

Setting	☐ 1 Out patient clinic		☐ 2 In patient clinic, fill in page C.10
Product name (check appropriate box(es))	☐ 2 Doxorubicin*	☐ 3 Cyclophosphamide*	☐ 1 Docetaxel*
Date of Administration	day ☐☐ month ☐☐ year ☐☐☐☐		day ☐☐ month ☐☐ year ☐☐☐☐
Route	i.v.	i.v.	i.v.
Intended dose (mg/m²)			
Total dose given (mg)			

For Cycle 1 DO NOT COMPLETE BELOW.

Doxorubicin Dose Reduced

☐ 0 No ☐ 1 Yes, specify reason :

Study drug related adverse experience(s), specify below:

- ☐ 1 Hematological toxicity (including infection or febrile neutropenia)
- ☐ 2 Non-Hematological toxicity
- ☐ 3 Both
- ☐ 4 Non-Study drug related adverse experience(s)
- ☐ 5 Other, Specify: _____

Cyclophosphamide Dose Reduced

☐ 0 No ☐ 1 Yes, specify reason :

Study drug related adverse experience(s), specify below:

- ☐ 1 Hematological toxicity (including infection or febrile neutropenia)
- ☐ 2 Non-Hematological toxicity
- ☐ 3 Both
- ☐ 4 Non-Study drug related adverse experience(s)
- ☐ 5 Other, Specify: _____

Docetaxel Dose Reduced

☐ 0 No ☐ 1 Yes, specify reason :

Study drug related adverse experience(s), specify below:

- ☐ 1 Hematological toxicity (including infection or febrile neutropenia)
- ☐ 2 Non-Hematological toxicity
- ☐ 3 Both
- ☐ 4 Non-Study drug related adverse experience(s)
- ☐ 5 Other, Specify: _____

Delay: ☐ 0 No ☐ 1 Yes, specify reason :

Study drug related adverse experience(s), specify below:

- ☐ 1 Hematological toxicity (including infection or febrile neutropenia)
- ☐ 2 Non-Hematological toxicity
- ☐ 3 Both
- ☐ 4 Non-Study drug related adverse experience(s)
- ☐ 5 Other, Specify: _____

* In case of interruption of drug administration, complete form E.F.1

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE N°

☐0 Not Done

HEMATOLOGY

Report all blood counts performed during the cycle (including day -1 or day 1 before chemotherapy infusion of the next cycle) and at 21 to 28 days after the last infusion of chemotherapy.

Test	Units Recommended	Date of Sample (day / month / year)	Actual units (Complete only if differs from recommended)	Value	Date of Sample (day / month / year)	Actual units (Complete only if differs from recommended)	Value	Date of Sample (day / month / year)	Actual units (Complete only if differs from recommended)	Value
Hemoglobin	g/dl									
WBC	10^9/l									
Neutrophils (seg & bands)	10^9/l									
Platelets	10^9/l									

Test	Units Recommended	Date of Sample (day / month / year)	Actual units (Complete only if differs from recommended)	Value	Date of Sample (day / month / year)	Actual units (Complete only if differs from recommended)	Value	Date of Sample (day / month / year)	Actual units (Complete only if differs from recommended)	Value
Hemoglobin	g/dl									
WBC	10^9/l									
Neutrophils (seg & bands)	10^9/l									
Platelets	10^9/l									

If repeated tests are performed, form E.F.5 should be used.

☐0 Not Done

BLOOD CHEMISTRY

To be performed at the end of cycle within 3 days prior to the next chemotherapy infusion and at 21 to 28 days after the last infusion of chemotherapy.

Date of sample: day / month / year

Laboratory Name: _____

Laboratory Address: _____

Test	Units Recommended	Units Actual (Complete ONLY if differs from recommended)	Value	Upper normal limit for the institution (same unit as value)
Creatinine	μ mol/l			
Alkaline Phosphatase	IU/l			
ASAT (SGOT)	IU/l			
ALAT (SGPT)	IU/l			
Total Bilirubin	μ mol/l			

If repeated tests and/or creatinine clearance are measured, form E.F.6 should be used.

ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE No

☐0 Check if none

CLINICAL ADVERSE EXPERIENCES

Clinical Adverse Experiences	Status of Adverse Experience 1: Ongoing without any change (Do not complete) 2: New or any change to ongoing adverse events (Complete all information)	Grade# (1-4)	Serious 0: No 1: Yes*	Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0: None 1: Discontinued** 2: Interrupted 3: Dose Reduced 4: Dose Frequency Changed 5: Dose Reduced and Dose Frequency Changed	Significant Consequences 0: None 1: Hospitalized* 2: Death***	Relation to Study Medication 0: None 1: Remote 2: Possible 3: Probable
Allergic Reaction / Hypersensitivity	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Alopecia	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Arthralgia	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Cardiac Ischemia / Infarction	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Cardiac Left Ventricular Function	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Cardiovascular / Arrhythmia - other specify _____	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Diarrhea	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Dyspnea	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Fatigue	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Injection Site Reaction	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Irregular Menses	1☐ 2☐			☐1 Ongoing ☐2 Ceased			

* All serious adverse experiences must be reported within 24 hours by phone or fax.
** Complete End of Chemotherapy Section.
*** Complete Death Report Form/ End of Chemotherapy and SAE form.
# If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening.
Adverse Experiences not listed should be reported on C.5 or E.F.8

ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE No

☐$_0$ Check if none

CLINICAL ADVERSE EXPERIENCES

Clinical Adverse Experiences	Status of Adverse Experience 1: Ongoing without any change (Do not complete) 2: New or any change to ongoing adverse events (Complete all information)	Grade# (1-4)	Serious 0: No 1: Yes*	Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0: None 1: Discontinued** 2: Interrupted 3: Dose Reduced 4: Dose Frequency Changed 5: Dose Reduced and Dose Frequency Changed	Significant Consequences 0: None 1: Hospitalized* 2: Death***	Relation to Study Medication 0: None 1: Remote 2: Possible 3: Probable
Myalgia	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Nail Changes	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Nausea	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Neuropathy-Motor	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Neuropathy-Sensory	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Pericardial Effusion / Pericarditis	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Peripheral Edema	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Pleural Effusion	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Rash/ Desquamation	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Stomatitis / Pharyngitis	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			
Vomiting	1☐ 2☐			☐$_1$ Ongoing ☐$_2$ Ceased			

* All serious adverse experiences must be reported within 24 hours by phone or fax.
** Complete End of Chemotherapy Section.
*** Complete Death Report Form/ End of Chemotherapy and SAE form.
# If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening.
Adverse Experiences not listed should be reported on C.5 or E.F.8

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE No

☐0 Check if none

CLINICAL ADVERSE EXPERIENCES

Clinical Adverse Experiences	Status of Adverse Experience 1: Ongoing without any change (Do not complete) 2: New or any change to ongoing adverse events (Complete all information)	Grade# (1-4)	Serious 0: No 1: Yes*	Indicate if Ongoing or Ceased prior to next cycle	Action Taken Study Medication 0: None 1: Discontinued** 2: Interrupted 3: Dose Reduced 4: Dose Frequency Changed 5: Dose Reduced and Dose Frequency Changed	Significant Consequences 0: None 1: Hospitalized* 2: Death***	Relation to Study Medication 0: None 1: Remote 2: Possible 3: Probable
Weight Gain	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
Weight Loss	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			
	1☐ 2☐			☐1 Ongoing ☐2 Ceased			

* All serious adverse experiences must be reported within 24 hours by phone or fax.
** Complete End of Chemotherapy Section.
*** Complete Death Report Form/ End of Chemotherapy and SAE form.

If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening.
Adverse Experiences not listed should be reported on C.5 or E.F.8

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE No

☐$_0$ Check if None

CLINICAL ADVERSE EXPERIENCES (continued)

Clinical Adverse Experiences	Status of Adverse Experience 1: Ongoing without any change *(Do not complete)* 2: New or any change to ongoing adverse events *(Complete all information)*	Grade (1-4)#	Serious * 0: No 1: Yes*	Date of Onset (for infection and fever)	Indicate if Ongoing or Ceased (provide date when applicable)	Action Taken Study Medication 0: None 1: Discontinued** 2: Interrupted 3: Dose Reduced[a] 4: Dose Frequency Changed 5: Dose Reduced and Dose Frequency Changed[a]	Significant Consequences 0: None 1: Hospitalized* 2: Death***	Relation to Study Medication 0: None 1: Remote 2: Possible 3: Probable
Febrile Neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 10^9/L)	1 ☐ 2 ☐	☐ 3 ☐ 4			☐$_1$ Ongoing ☐$_2$ Ceased			
Fever ≥ 38.5 °C				day month year ☐$_1$ Ongoing	day month year ☐$_1$ Ongoing			
Fever in the absence of neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 10^9/L)	1 ☐ 2 ☐			day month year ☐$_1$ Ongoing	day month year ☐$_1$ Ongoing			
Catheter-related Infection (specify site) _____	1 ☐ 2 ☐	☐ 3 ☐ 4		day month year ☐$_1$ Ongoing	day month year ☐$_1$ Ongoing			
Infection with unknown ANC (specify site) _____	1 ☐ 2 ☐			day month year ☐$_1$ Ongoing	day month year ☐$_1$ Ongoing			
Infection without neutropenia (where Neutropenia is defined as AGC/ANC <1.0 x 10^9/L) (specify site) _____	1 ☐ 2 ☐	☐ 3 ☐ 4		day month year ☐$_1$ Ongoing	day month year ☐$_1$ Ongoing			
Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (specify site) _____	1 ☐ 2 ☐			day month year ☐$_1$ Ongoing	day month year ☐$_1$ Ongoing			

If NCI CTC Version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening.

* All serious adverse experiences must be reported within 24 hours by phone or fax.

** Complete End of Chemotherapy Section.

*** Complete Death Report Form/ End of Chemotherapy and SAE form.

Additional Adverse Experiences should be reported on E.F.8

ORIGINAL - BCIRG YELLOW - BCIRG PINK - CRA CARDBOARD - For your records

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE Nº

☐0 Not done

PERFORMANCE STATUS & WEIGHT

To be performed prior to the next cycle (day -1 or day 1 before chemotherapy infusion of the next cycle) and at 21 to 28 days after the last infusion of chemotherapy.

Date of assessment: ☐☐ day ☐☐ month ☐☐☐☐ year

Performance Status (0 to 100, Karnofsky index): ☐☐☐ %

Weight: ☐☐☐.☐ ☐1 lb ☐2 kg

☐0 Not done

PHYSICAL EXAMINATION

To be performed prior to the next cycle (day -1 or day 1 of the next cycle) and at 21 to 28 days after the last infusion of chemotherapy.

Date of assessment: ☐☐ day ☐☐ month ☐☐☐☐ year

If there are any changes since the last visit, record these changes in the Clinical Adverse Experiences form whenever appropriate.

QUALITY OF LIFE QUESTIONNAIRE

To be completed : Day -1 to Day 1 for Cycle 4
Day -1 to Day 1 for Cycle 7 of the AC ⟶T arm
End of Chemotherapy for all arms

☐1 Not Applicable Date of completion: ☐☐ day ☐☐ month ☐☐☐☐ year

Quality of life questionnaire completed.

EORTC QLQ-C30 (version 3.0)	☐0	No	☐1	Yes	☐2	Not available in patient's language
EORTC QLQ-BR23 (version 1.0)	☐0	No	☐1	Yes	☐2	Not available in patient's language
EURO QOL-5D	☐0	No	☐1	Yes	☐2	Not available in patient's language

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE N°

SIGNIFICANT CONCOMITANT THERAPY OTHER THAN ANTI-TUMOR

(E.G. PRE-MEDICATION, ANTIBIOTICS, GROWTH FACTORS, TRANSFUSIONS, ANTIEMETICS…)

☐0 Check if None   If drug is PRN, the approximate Total Daily Dose must be recorded.

Product Name (1 product per line) (use capital letters) (Trade Name)	**Route** (I.V., SC, PO, etc...)	**Total average daily dose** specify units (mg, g, tab, etc...)		**Start date** or indicate if ongoing	**Stop date** or indicate if ongoing	**Indication for use** 1: Treatment of febrile neutropenia 2: Curative or symptomatic 3: Antiemetic prophylaxis 4: Taxotere steroid prophylaxis 5: Prophylaxis 6: Other
		Dose	**Units**			
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	

If required, use form E.F.3

Record use of Bisphosphonates, Chronic Steroids, Chemoprotective agents such as Cardioxane® and Ethyol® in this module, however, note use of these agents is NOT PERMITTED as per protocol.

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OUT-PATIENT CARE DURING CYCLE PERIOD

Since the last visit has the patient seen a physician or another healthcare professional or had any investigations as an out-patient (including emergency room visits)? ☐0 No ☐1 Yes, complete section below:

1. Emergency room (patient was not admitted subsequently). Indicate number of emergency room visits: ☐☐ ☐1 Not Applicable

2. Physician visits not mandated by study (indicate number of visits): ☐1 Not Applicable

☐1 General practitioner: ☐☐

☐2 Oncologist/ Internist: ☐☐

☐3 Other: ☐☐ Specify: _____

3. Other health professional visits (indicate number of visits): ☐1 Not Applicable

☐1 Nurse: ☐☐
(concomitant medication and care)

☐2 Physiotherapy: ☐☐

☐3 Rehabilitation: ☐☐

☐4 Other: ☐☐
(specify below):

_____

4. During this cycle period, have any major procedures or tests been performed?

☐0 No

☐1 Yes, please complete form E.F.7 or E.F.2 if applicable.

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE Nº

IN-PATIENT ADMISSION DURING CYCLE PERIOD

Since the last visit, has the patient been admitted for overnight stay to hospital (excluding emergency room visit)?

☐ 0 No ☐ 1 Yes, complete section below:

Admission/ Transfer* Date or Ongoing (day/month/year)	Discharge/ Transfer* Date or Ongoing (day/month/year)	Reason for admission	Unit (check one only)
☐ 1 Ongoing	☐ 1 Ongoing	☐ 1 Chemotherapy treatment ☐ 2 Tumor related Adverse Event** ☐ 3 Treatment related Adverse Event** ☐ 4 Other, specify**:	☐ 1 Surgery ☐ 2 Internal Medicine ☐ 3 ICU ☐ 4 Other, specify:
☐ 1 Ongoing	☐ 1 Ongoing	☐ 1 Chemotherapy treatment ☐ 2 Tumor related Adverse Event** ☐ 3 Treatment related Adverse Event** ☐ 4 Other, specify**:	☐ 1 Surgery ☐ 2 Internal Medicine ☐ 3 ICU ☐ 4 Other, specify:
☐ 1 Ongoing	☐ 1 Ongoing	☐ 1 Chemotherapy treatment ☐ 2 Tumor related Adverse Event** ☐ 3 Treatment related Adverse Event** ☐ 4 Other, specify**:	☐ 1 Surgery ☐ 2 Internal Medicine ☐ 3 ICU ☐ 4 Other, specify:

During those hospitalizations, have any major procedures been performed?

☐ 0 No

☐ 1 Yes, please fill-in form E.F.7or E.F.2 if applicable.

*When a patient is transferred from one unit to another one (e.g. from surgery to internal medicine).
**Complete an SAE form and fax it to the BCIRG Safety Manager.

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title DEATH REPORT FORM

DEATH REPORT FORM

Date of death : day / month / year

Was an autopsy performed? ☐0 No ☐1 Yes, *specify below and attach autopsy report*

Site of disease at autopsy (check all that apply):

- ☐1 Lungs
- ☐2 Liver
- ☐3 GI tract
- ☐4 Kidney
- ☐5 CNS
- ☐6 Local regional
- ☐7 Bone
- ☐8 No evidence of disease
- ☐9 Other, specify: _____

Cause of death (check the most probable cause):

- ☐ Toxicity due to study treatment. (Please specify in AE form).
  - ☐1 Septic
  - ☐2 Non septic
- ☐3 Toxicity due to anti-cancer treatment given after relapse or second primary malignancy.
- ☐4 Breast cancer
- ☐5 Malignant disease, other than breast cancer
- ☐6 Other, specify: _____

Investigator's signature : _____ Date : day / month / year

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title CYCLE

Please enter the appropriate information from the medication (Taxotere, Cyclophosphamide, Doxorubicin and Solvents - Chemotherapy only) vials used during the cycle.

Medication Name	# of Vials	Cycle Number	Lot or Batch Number	Expiry Date
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year
				day month year

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title END OF CHEMOTHERAPY

END OF CHEMOTHERAPY REASON

Specify primary reason for the patient's discontinuation from chemotherapy:

☐ 1 Received maximum number of cycles as per protocol*

☐ 2 Breast cancer relapse (Complete forms B.C.R.1 and B.C.R.2)

☐ 3 Second primary malignancy (Complete form S.P.M.F.1)

☐ 4 Adverse experience (Complete forms C.3, C.4, C.5 and C.6)

☐ 5 Consent withdrawn / refused further treatment, specify reason: _____

☐ 6 Death (Complete Death Report Form)

☐ 7 Patient required therapy and / or procedure not permitted

☐ 8 Other deviation from protocol, specify reason: _____

☐ 9 Lost to follow-up, date of last contact: ☐☐ day ☐☐ month ☐☐☐☐ year

☐ 10 Other, specify: _____

_____

*TAC arm: 6 cycles of TAC. AC → T arm: 4 cycles of AC followed by 4 cycles of T

CASE REPORT FORM REVIEW

I have reviewed all data contained in this case report form and verified that the contents are consistent with observations and source records. They accurately reflect the condition of the patient before study, during study and at the end of chemotherapy.

Investigator's signature: _____ Date: ☐☐ day ☐☐ month ☐☐☐☐ year

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM

BASELINE ☐ CYCLE No. ☐ F.U. No. ☐☐

ANTI-TUMOR THERAPY

☐$_0$ Check if None — *Systemic anti-cancer therapy :*

Type of Therapy G : Gene therapy H : Hormonal I : Immunotherapy C : Chemotherapy O : Other	Trade Name (one drug per line)	Start Date	Stop Date
☐ G ☐ H ☐ I ☐ C ☐ O		day month year	day month year
☐ G ☐ H ☐ I ☐ C ☐ O		day month year	day month year

☐$_0$ Check if None — *Non-systemic anti-cancer therapy :*

Type of Therapy R : Radiotherapy S : Surgery	Site/Procedure for radiotherapy and surgery	Start Date	Stop Date
R ☐ S ☐		day month year	day month year
R ☐ S ☐		day month year	day month year

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM CYCLE No.

RE-ADMINISTRATION OF STUDY DRUG THERAPY: TAC AND AC → T

Setting ☐ 1 Out patient clinic ☐ 2 In patient clinic, complete page C.10

Product name	Route	Total dose given (mg) after Interruption	Date of Administration
☐ 2 Doxorubicin	IV		day / month / year
☐ 3 Cyclophosphamide	IV		day / month / year
☐ 1 Docetaxel	IV		day / month / year

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM

BASELINE ☐ CYCLE No. ☐ F.U. No. ☐☐ ABB. FU No. ☐☐

☐0 Not Done ELECTROCARDIOGRAM

Date of assessment: ☐☐ day ☐☐ month ☐☐☐☐ year

☐1 Within normal limits ☐3 Non-Significant abnormalities

☐2 Significant abnormalities. If abnormalities are present, please specify in form B.9, C.4, C.5 or E.F.9.

☐0 Not Done LEFT VENTRICULAR EJECTION FRACTION

Date of assessment: ☐☐ day ☐☐ month ☐☐☐☐ year

LVEF at rest	Value	Unit	Lower normal limit for the institution	Unit
☐1 Radionuclide angiocardiography (MUGA scan) ☐2 Echocardiography	☐☐☐.☐	%	☐☐☐.☐	%

Date of assessment: ☐☐ day ☐☐ month ☐☐☐☐ year

LVEF at rest	Value	Unit	Lower normal limit for the institution	Unit
☐1 Radionuclide angiocardiography (MUGA scan) ☐2 Echocardiography	☐☐☐.☐	%	☐☐☐.☐	%

Date of assessment: ☐☐ day ☐☐ month ☐☐☐☐ year

LVEF at rest	Value	Unit	Lower normal limit for the institution	Unit
☐1 Radionuclide angiocardiography (MUGA scan) ☐2 Echocardiography	☐☐☐.☐	%	☐☐☐.☐	%

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM

BASELINE ☐ CYCLE No. ☐ F.U. No. ☐☐ ABB. FU No. ☐☐

SIGNIFICANT CONCOMITANT THERAPY OTHER THAN ANTI-TUMOR

If drug is PRN, the approximate Total Daily Dose must be recorded.

Product Name (1 product per line) (use capital letters) (Trade Name)	**Route** (I.V., SC, PO, etc...)	**Total average daily dose** specify units (mg, g, tab, etc...)		**Start date** or indicate if ongoing	**Stop date** or indicate if ongoing	**Indication for use** 1: Treatment of febrile neutropenia 2: Curative or symptomatic 3: Antiemetic prophylaxis 4: Taxotere steroid prophylaxis 5: Prophylaxis 6: Other
		Dose	**Units**			
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	
				day month year ☐1 Ongoing	day month year ☐1 Ongoing	

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM BASELINE

PAST OR CURRENT HISTORY OF NEOPLASM

Diagnosis

Anatomic site of primary tumor type	Histological type	Date of Diagnosis
_____	_____	day / month / year
_____	_____	day / month / year

Has there been any evidence of disease in the last 10 years? ☐$_0$ No ☐$_1$ Yes* ☐$_2$ N.A. (Diagnosis within 10 years)

* Patient is not eligible.

ANTI-TUMOR THERAPY FOR NEOPLASM

☐$_0$ Check if None

Systemic anti-cancer therapy :

Type of Therapy G : Gene therapy H : Hormonal I : Immunotherapy C : Chemotherapy O : Other	Trade Name (one drug per line)	Start Date	Stop Date
☐ G ☐ H ☐ I ☐ C ☐ O	_____ _____ _____	day / month / year	day / month / year
☐ G ☐ H ☐ I ☐ C ☐ O	_____ _____ _____	day / month / year	day / month / year

☐$_0$ Check if None

Non-systemic anti-cancer therapy :

Type of Therapy R : Radiotherapy S : Surgery	Site/Procedure for radiotherapy and surgery	Start Date	Stop Date
R ☐ S ☐		day / month / year	day / month / year
R ☐ S ☐		day / month / year	day / month / year

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM

BASELINE ☐ CYCLE No. F.U. No. ABB.F.U. No.

HEMATOLOGY

Test	Units Recommended	Date of Sample (day month year)		Date of Sample (day month year)		Date of Sample (day month year)	
		Actual units (Complete only if differs from recommended)	Value	Actual units (Complete only if differs from recommended)	Value	Actual units (Complete only if differs from recommended)	Value
Hemoglobin	g/dl						
WBC	$10^9/l$						
Neutrophils (seg & bands)	$10^9/l$						
Platelets	$10^9/l$						
Test	**Units** Recommended	**Date of Sample** (day month year)		**Date of Sample** (day month year)		**Date of Sample** (day month year)	
		Actual units (Complete only if differs from recommended)	Value	Actual units (Complete only if differs from recommended)	Value	Actual units (Complete only if differs from recommended)	Value
Hemoglobin	g/dl						
WBC	$10^9/l$						
Neutrophils (seg & bands)	$10^9/l$						
Platelets	$10^9/l$						
Test	**Units** Recommended	**Date of Sample** (day month year)		**Date of Sample** (day month year)		**Date of Sample** (day month year)	
		Actual units (Complete only if differs from recommended)	Value	Actual units (Complete only if differs from recommended)	Value	Actual units (Complete only if differs from recommended)	Value
Hemoglobin	g/dl						
WBC	$10^9/l$						
Neutrophils (seg & bands)	$10^9/l$						
Platelets	$10^9/l$						

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM

BASELINE ☐ CYCLE No. ☐☐ F.U. No. ☐☐ ABB.F.U. No. ☐☐

☐0 Not Done

BLOOD CHEMISTRY

Date of sample: ☐☐ day ☐☐ month ☐☐☐☐ year

Laboratory Name: _____

Laboratory Address: _____

Test	Units		Value	Upper normal limit for the institution (same unit as value)
	Recommended	Actual (Complete ONLY if differs from recommended)		
Creatinine	μ mol/l			
Alkaline Phosphatase	IU/l			
ASAT (SGOT)	IU/l			
ALAT (SGPT)	IU/l			
Total Bilirubin	μ mol/l			

Date of sample: ☐☐ day ☐☐ month ☐☐☐☐ year

Laboratory Name: _____

Laboratory Address: _____

Test	Units		Value	Upper normal limit for the institution (same unit as value)
	Recommended	Actual (Complete ONLY if differs from recommended)		
Creatinine	μ mol/l			
Alkaline Phosphatase	IU/l			
ASAT (SGOT)	IU/l			
ALAT (SGPT)	IU/l			
Total Bilirubin	μ mol/l			

☐0 Not Done

CREATININE CLEARANCE

To be completed only if Serum Creatinine is > 140 μmol/l (1.6mg/dl).

Date of sample: ☐☐ day ☐☐ month ☐☐☐☐ year

Test	Units Recommended	Value
☐ Calculated (Using Cockroft-Gault formula)	ml/min	
☐ Measured	ml/min	

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OTHER PROCEDURES

Please note any additional assessment whether related to tumor or not e.g.: imaging, cultures, etc.

a: **Procedure** (enter the appropriate number) 1= Cultures 2= Imaging 3= Puncture/ Drainage 4= Biopsy 5= Surgery 6= Test 7= Other, specify procedure b: **Description**	**Date assessed**	**Comments** (if applicable)
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	
a b	day month year	

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM CYCLE Nº

CLINICAL ADVERSE EXPERIENCES (CYCLES)

Clinical Adverse Experiences	Status of Adverse Experience 1: Ongoing without any change *(Do not complete)* 2: New or any change to ongoing adverse events *(Complete all information)*	Grade# (1-4)	Serious* 0: No 1: Yes*	Date of Onset (for infection and fever)	Date Ceased (for infection only) Indicate if Ongoing or Ceased (for other AEs)	Action Taken Study Medication 0: None 1: Discontinued** 2: Interrupted 3: Dose Reduced 4: Dose FrequencyChanged 5: Dose Reduced and Dose Frequency Changed	Significant Consequences 0: None 1: Hospitalized* 2: Death***	Relation to Study Medication 0: None 1: Remote 2: Possible 3: Probable
Fever (in the absence of neutropenia, where neutropenia is defined as AGC< 1.0X10⁹L)	1 ☐ 2 ☐			day month year ☐1 Ongoing	day month year ☐1 Ongoing			
Catheter-related Infection (specify site) _____	1 ☐ 2 ☐			day month year ☐1 Ongoing	day month year ☐1 Ongoing			
Infection with unknown ANC (specify site) _____	1 ☐ 2 ☐	☐3 ☐4		day month year ☐1 Ongoing	day month year ☐1 Ongoing			
Infection without neutropenia**** (specify site) _____	1 ☐ 2 ☐			day month year ☐1 Ongoing	day month year ☐1 Ongoing			
Infection (documented clinically or microbiologically) with grade 3 or 4 neutropenia (specify site) _____	1 ☐ 2 ☐	☐3 ☐4		day month year ☐1 Ongoing	day month year ☐1 Ongoing			
	1 ☐ 2 ☐				☐1 Ongoing ☐2 Ceased			
	1 ☐ 2 ☐				☐1 Ongoing ☐2 Ceased			
	1 ☐ 2 ☐				☐1 Ongoing ☐2 Ceased			
	1 ☐ 2 ☐				☐1 Ongoing ☐2 Ceased			
	1 ☐ 2 ☐				☐1 Ongoing ☐2 Ceased			

* All serious adverse experiences must be reported within 24 hours by phone or fax.
** Complete End of Chemotherapy Section. # If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe,4=Life Threatening.
*** Complete Death Report Form/ End of Chemotherapy and SAE form.
****Where Neutropenia is defined as AGC/ANC < 1.0 X 10^9 / L

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM F.U. No. ABB.F.U. No.

CLINICAL ADVERSE EXPERIENCES (FOLLOW-UP)

To be completed only for:
-Ongoing clinical Adverse events possibly or probably related to study drug at time of end of chemotherapy.
-Relevant non cancer related signs and symptoms occurring after completion of chemotherapy.
(i.e. congestive heart failure ***, toxicities related to Tamoxifen and/ or radiation therapy...).

Clinical Adverse Experiences	Status of Adverse Experience 1: Ongoing without any change *(Do not complete)* 2: New or any change to ongoing adverse events *(Complete all information)* 3: No longer followed due to new chemotherapy regimen started.	Grade# (1-4)	Serious 0: No 1: Yes*	Date of Onset (day/month/year) Ong=Ongoing	Date Ceased (day/month/year) Ong=Ongoing	Significant Consequences 0: None 1: Hospitalized* 2: Death**	Most Likely Cause 1: Study chemotherapy 2: Tamoxifen as per protocol 3: Radiotherapy as per protocol 4: Tumor 5: Other
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		
	1 ☐ 2 ☐ 3 ☐			day month year ☐ 1 Ong	day month year ☐ 1 Ong		

If NCI version 2.0 grade is not applicable, code severity as: 1=Mild, 2=Moderate, 3=Severe, 4=Life Threatening.

* All serious adverse experiences must be reported within 24 hours by phone or fax. *** Report Details in E.F.10

** Complete Death Report Form and SAE form.

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Breast Cancer International Research Group

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM F.U. No.

To be completed if the patient develops CHF at any time after the End of Chemotherapy visit and inserted into the corresponding Follow-Up.
All CHF must be reported on a Serious Adverse Event Report Form.

CONGESTIVE HEART FAILURE

Anthracycline / Anthracenedione

Did the patient receive anthracycline or anthracenedione since the end of chemotherapy visit ?

☐ 0 No ☐ 1 Yes, *specify below the cumulative dose since the end of chemotherapy visit:*

Product Name	Cumulative dose mg/m²	Start date	Stop date
☐ 1 Doxorubicin		day month year	day month year
☐ 2 Epirubicin		day month year	day month year
☐ 3 Mitoxantrone		day month year	day month year
☐ 4 Other specify: _____		day month year	day month year
☐ 4 Other specify: _____		day month year	day month year

Radiotherapy

Did the patient receive radiotherapy to the mediastinum and/or left chest wall since the end of chemotherapy visit other than the adjuvant radiotherapy (if any)?

☐ 0 No ☐ 1 Yes

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title EXTRA FORM

BASELINE ☐ CYCLE No. ☐ F.U. No. ☐☐

PATIENT IMAGING

Refer to pages B/R.4 or F.U.3 for appropriate terminology.

Type of evaluation	Date Assessed	Tumor Involvement	
		No	Yes*
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1
	day / month / year	☐0	☐1

Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	Visit Title SECOND PRIMARY MALIGNANCY SECTION

SECOND PRIMARY MALIGNANCY

Date of occurrence : day / month / year

Diagnosis :

- ☐ Primary breast cancer *
  - ☐ 1 Left ☐ 2 Right
- ☐ 3 Endometrium cancer
- ☐ 4 Ovarian cancer
- ☐ 5 Leukemia
- ☐ 6 Other cancer, specify : _____
- ☐ 7 Non-melanoma skin cancer
- ☐ 8 Carcinoma in situ of the cervix

Histopathologic proof obtained : ☐ 0 No ☐ 1 Yes, specify type : _____

Date of histopathology : day / month / year

Send Block to BCIRG.

* If Ipsilateral to the primary tumor and same histology, please fill in only the breast cancer relapse form.

ANTI-TUMOR THERAPY FOR SECOND PRIMARY MALIGNANCY

☐ 0 Check if None — *Systemic anti-cancer therapy :*

Type of Therapy G : Gene therapy H : Hormonal I : Immunotherapy C : Chemotherapy O : Other	Trade Name (one drug per line)	Start Date	Stop Date
☐ G ☐ H ☐ I ☐ C ☐ O		day / month / year	day / month / year
☐ G ☐ H ☐ I ☐ C ☐ O		day / month / year	day / month / year

☐ 0 Check if None — *Non-systemic anti-cancer therapy :*

Type of Therapy R : Radiotherapy S : Surgery	Site/Procedure for radiotherapy and surgery	Start Date	Stop Date
R ☐ S ☐		day / month / year	day / month / year
R ☐ S ☐		day / month / year	day / month / year

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	FOLLOW-UP SUMMARY

PHYSICAL EXAMINATION AND PATIENT STATUS

To be performed as per protocol follow-up flowchart (see CRF guidelines).

To be completed yearly and sent to CIRG Edmonton Office suite 1100, 9925-109th Street Edmonton, Alberta, CANADA T5K 2J8

Date of follow-up visit: ___ day ___ month ___ year ☐ Not Done Follow-up number ___

Are there any changes since previous assessment? ☐0 No ☐1 Yes, specify below:

☐1 Breast cancer relapse (Complete forms B.C.R.1 and B.C.R.2)

☐2 Second primary malignancy (Complete form S.P.M.F.1)

☐5 Death (Complete death report form)

☐6 Lost to follow-up. Date of last contact: ___ day ___ month ___ year

☐7 Other, specify:___________________________

Date of follow-up visit: ___ day ___ month ___ year ☐ Not Done Follow-up number ___

Are there any changes since previous assessment? ☐0 No ☐1 Yes, specify below:

☐1 Breast cancer relapse (Complete forms B.C.R.1 and B.C.R.2)

☐2 Second primary malignancy (Complete form S.P.M.F.1)

☐5 Death (Complete death report form)

☐6 Lost to follow-up. Date of last contact: ___ day ___ month ___ year

☐7 Other, specify:___________________________

Date of follow-up visit: ___ day ___ month ___ year ☐ Not Done Follow-up number ___

Are there any changes since previous assessment? ☐0 No ☐1 Yes, specify below:

☐1 Breast cancer relapse (Complete forms B.C.R.1 and B.C.R.2)

☐2 Second primary malignancy (Complete form S.P.M.F.1)

☐5 Death (Complete death report form)

☐6 Lost to follow-up. Date of last contact: ___ day ___ month ___ year

☐7 Other, specify:___________________________

Date of follow-up visit: ___ day ___ month ___ year ☐ Not Done Follow-up number ___

Are there any changes since previous assessment? ☐0 No ☐1 Yes, specify below:

☐1 Breast cancer relapse (Complete forms B.C.R.1 and B.C.R.2)

☐2 Second primary malignancy (Complete form S.P.M.F.1)

☐5 Death (Complete death report form)

☐6 Lost to follow-up. Date of last contact: ___ day ___ month ___ year

☐7 Other, specify:___________________________

Ongoing Adverse events possibly or probably related to study drug, toxicities related to hormonotherapy or radiotherapy have to be followed and recorded on extra form EF9

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Protocol No BCIRG 005 TAX GMA 301	Investigator No.	Patient Initials	Site No.	Patient No.	FOLLOW-UP NUMBER

HORMONOTHERAPY AS PER PROTOCOL

☐0 Not Done (at the investigator's discretion or if patient has previously stopped treatment).
☐1 Not Applicable (Progesterone and Estrogen receptors negative)

Product Name (1 product per line) (use capital letters)	Start date or indicate if ongoing	Stop date or indicate if ongoing	Early Discontinuation of Hormonotherapy*
TAMOXIFEN	day month year ☐1 Ongoing	day month year ☐1 Ongoing	☐1 BCR ☐2 SPM ☐3 AE ☐4 other _____
_____	day month year ☐1 Ongoing	day month year ☐1 Ongoing	☐1 BCR ☐2 SPM ☐3 AE ☐4 other _____

* BCR = Breast Cancer Relapse (Complete forms BCR1 and BCR2), SPM = Second Primary Malignancy (complete form SPMF1), AE = Adverse Events (specify in form EF9)

FOLLOW-UP PATIENT IMAGING

☐0 Not Done

Type of evaluation	Not Done	Date Assessed	Tumor Involvement No	Tumor Involvement Yes*
Left Breast Imaging [c] ☐9 Mammography ☐15 Ultrasound ☐ MRI ☐13 Not applicable due to prior procedure (Report on E.F.7)	☐0	day month year	☐0	☐1
Right Breast Imaging [c] ☐10 Mammography ☐16 Ultrasound ☐ MRI ☐14 Not applicable due to prior procedure (Report on E.F.7)	☐0	day month year	☐0	☐1
12. Other, specify: _____	☐0	day month year	☐0	☐1
12. Other, specify: _____	☐0	day month year	☐0	☐1
12. Other, specify: _____	☐0	day month year	☐0	☐1

c: Once a year for 10 years.

* If tumor involvement complete Breast Cancer Relapse Section or Second Primary Malignancy Section.

CASE REPORT FORM REVIEW

I have reviewed all data contained in this follow-up section and verified that the contents are consistent with observations and source records. They accurately reflect the condition of the patient during follow-up.

Investigator's signature: _____ Date: day month year

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